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# Patent Litigation 2023

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**Contributing Editor**

Andreas von Falck  
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# Chambers

Global Practice Guides

# Patent Litigation

Contributing Editor

Andreas von Falck

**Hogan Lovells International LLP**

2023

# Chambers Global Practice Guides

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# INTRODUCTION

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## Patent Litigation Around the World

When looking back on 2022 from a European patent perspective, perhaps what will stick out most prominently is the decision of the European Patent Office (EPO) to make the video hearings introduced during the COVID-19 pandemic the new default format for opposition proceedings. Labelled by the EPO as “progress”, many say that it deprives litigants of the right to face the panel adjudicating their cases live and in person. Leaving that aside, 2022 has also been a return to normal in most other respects. With COVID-19 largely behind them, litigants seem to have truly enjoyed the return to pre-pandemic circumstances and the year was as busy as it gets with large, pan-European and global litigation, again, largely driven by the desire to increase revenue streams from licensing. It does not take much imagination to predict a continuing stream of patent litigation from patentees large and small.

In 2022, this [overview](#) predicted that it was unlikely for individual patentees to start patent litigation against competitors in the field of COVID-19 treatments while the pandemic was still ongoing and the discussion about a possible global IP waiver based on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) had not been concluded. With the pandemic largely behind us and a (limited) TRIPS waiver agreed in 2022, the door was opened to litigation between the leading mRNA companies. Curevac, Moderna, and Biontech/Pfizer are up against each other but, for the time being, seem to be seeking only patent damages, not injunctive relief. This is one to watch with mRNA technology promising to be useful also in the treatment of other diseases.

Finally, 2023 will now likely also see the EU’s Unified Patent Court (UPC) finally opening its doors to patentees seeking to enforce their European patents (insofar as they have not been opted out of the system) in the new single court. Currently, the sunrise period during which patentees will have the chance to opt their patents out of the UPC is scheduled to start on 1 March 2023 and the court to open its doors on 1 June 2023.

As in previous years, the present overview seeks to identify the themes that will be keeping litigants particularly busy during the next 12 months and casts an eye on upcoming important decisions as well as political developments.

## Europe

### *The UK*

UK patent courts had another busy year in 2022, with more than a fair share of FRAND licensing and innovator/generic pharma disputes being heard. Judgments are currently anticipated from hearings on FRAND determinations for both Apple/Optis and Lenovo/InterDigital, and the courts continue to be willing to assist patentees in seeking global rate-setting determinations.

Whilst “trends” may be an over simplification, it appears that the appetite for granting preliminary injunctions in pharma cases continues to wither but so too does the appetite for granting Arrow declarations (declarations that the “infringing act” was obvious at the priority date of the relevant patent application family) for use elsewhere. Equally, patentees continue to do well in cases involving telecoms patents.

This year may see development of the law by the UK Supreme Court in two areas: sufficiency (both plausibility and undue burden, *Akebia v*

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FibroGen, UKSC 2021/0209) and AI inventions (Thaler v The Comptroller-General of Patents, Designs and Trade Marks, UKSC 2021/0201).

## *The Netherlands*

The Dutch courts dealt with a substantial number of cross-border injunction claims in 2022 and are expected to continue to do so in 2023. Cross-border injunction claims can be based on patent infringement as well as on “facilitation” or “inducement” of patent infringement, which is deemed to be an unlawful act. On 1 March 2022, the Court of Appeal of The Hague held that a Dutch warehousing and distribution entity of the Chinese company LONGi infringed a patent of Hanwha relating to solar technology. The Court of Appeal granted a cross-border preliminary patent infringement injunction, even though the European patent at issue was not in force in the Netherlands. The injunction covered Belgium, Bulgaria, Germany, France, Hungary, Liechtenstein, Austria, Portugal, Spain, the United Kingdom and Switzerland. In another case, the Court of Appeal of The Hague upheld a decision to grant a cross-border preliminary injunction claim by Novartis to enjoin Pharmathen from marketing generic octreotide acetate in Austria, Belgium, France, Germany, Italy, Liechtenstein, the Netherlands, Portugal, Spain, Switzerland, Turkey and the United Kingdom. The cross-border injunction, however, did not cover Greece, as a Greek court had previously rejected a preliminary injunction claim and Greek law does not allow the same preliminary injunction to be claimed twice.

The Dutch courts also dealt with the question of whether an injunction can be issued prior to the grant of the patent. The Provisions Judge of the District Court of The Hague decided that this is not the case and that, instead, the patentee is, under some circumstances, entitled to reason-

able compensation for the period prior to the grant of the patent. This decision was upheld by the Court of Appeal. The courts are however willing to hear a preliminary injunction claim on the basis of a patent application provided that the claimed preliminary injunction relates to the period after grant of the patent.

The Dutch courts also continued to hear FRAND disputes in 2022. In a decision published early in the year, the District Court of The Hague used its discretionary powers to order confidential disclosure of licence and settlement agreements by both the Standard Essential Patent (SEP) holder and the implementer. According to the Court, the principles of truth finding and efficient dispute resolution provide the Court with the possibility to order such disclosure, even when it is not yet certain that the Court’s decision will ultimately turn on the FRAND aspects of the case. The Court considered that a proper FRAND assessment can only take place after disclosure of the licences and settlements concluded by the SEP holder. The Court took into account that the disclosure may cover licences that the SEP holder concluded with licensees that are difficult to compare with the implementer in this particular case, but according to the Court these licences do not necessarily lack overall relevance. The Court considered that the licences and settlements concluded by the implementer are of equal importance, as they can be used to gain a better understanding of whether the SEP holder’s licence offer and the implementer’s counter offer are FRAND. Since this disclosure decision, the District Court has granted further disclosure orders in other FRAND disputes.

## *Spain*

In 2022, the Spanish Supreme Court and the Court of Appeals of Barcelona have rendered a number of relevant decisions in the field of dam-

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ages in patent litigation, which continued to be a hot topic in Spain last year. Those decisions will give important guidance to lower courts following the provisions of the new Patents Act.

The Supreme Court clarified in a judgment of 31 March 2022 that the basis for the assessment of damages must be established by the court in the judgment confirming the infringement of the patent. In its decision, the Court reminded the parties that this is a question that cannot be deferred to the subsequent enforcement proceedings, the purpose of which should be limited to an “automatic” assessment of the amount to be paid by the infringer following the criteria established in the judgment. Whilst a practice already followed by some courts before its enactment, it was not until the new Patents Act was passed that the principle of deferring the calculation of damages to the enforcement phase of the proceedings (once the validity of the patent and its infringement have been confirmed) was formally established. This judgment will provide clarity and consistency to the parties and the lower courts which have been following different paths since the new law – and accompanying regime – came into force.

The Court of Appeals of Barcelona addressed a question to which the damages regime established in the new Patents Act gave rise – ie, whether there is a limitation in the number of years in relation to which the patentee can claim past damages. Under the former Patents Act – and other IP laws – the patentee could go back a maximum of five years from the date of filing of the infringement claim. In its judgment of 30 March 2022, the Court confirmed that, contrary to the relevant provisions in other IP laws – trade marks, for instance – in which there is a time limitation to claim damages for a maximum of five years prior to the filing of the complaint, such

limitation no longer exists in the current Patents Act. As long as the infringement acts are continued, the plaintiff is entitled to seek compensation for damages for the whole period in which the infringing acts took place, even if those acts began more than five years before bringing legal action.

In another matter, the Barcelona Court confirmed the optional nature of the suspension of several national proceedings regarding the same patents. The underlying context was the coexistence of proceedings involving an infringement action and a declaratory action for a finding of non-infringement. In an order dated 15 February 2022, the Court revoked the first instance decision ordering the (partial) suspension of the infringement proceedings until a judgment was issued in the non-infringement case. According to the Court, staying the proceedings is not mandatory but optional. The Court of Appeals also disagreed with the first instance court’s criterion in respect of the declaration of a partial stay (ie, only in connection with one of the patents allegedly infringed): a suspension cannot ever be partial, it must be ordered in relation to the proceedings as a whole.

In the field of technology and telecommunications, we will likely see the first decisions in FRAND/SEP cases launched in 2022 coming at the end of 2023 – or the beginning of 2024. These are expected to shed some light on a number of very relevant questions that have already been dealt with by other European courts following the CJEU leading decision in the Huawei v ZTE case.

With the MWC (a mobile communications trade show) around the corner, the Barcelona courts are getting ready for a waiver of applications for preliminary injunctions and published, weeks

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ago, jointly with the EU Trade Mark Courts based in Alicante, their annual protocol on the handling of ex parte requests and other urgent matters before and during the MWC. New case law on protective actions is also expected.

On the pharmaceutical patent side, several cases involving supplementary protection certificates (SPCs) were decided upon last year, with the expectation that new proceedings are brought taking into account, amongst other things, the potential disputes that may arise in connection with the application and interpretation of the provisions of the so-called SPC manufacturing waiver, which has already established itself as an interesting topic for discussion in the field.

Finally, on the legislative front, the reform of the Patents Act should, finally, be passed in 2023. Amongst other amendments under discussion, it sets out the possibility that the courts may stay national infringement proceedings if the validity of the patent at stake is being discussed before the European or the Spanish Patent Office, which has already been the position followed – if certain requirements were met – by the Court of Appeals of Barcelona but not by other relevant courts or tribunals in Spain.

## *France*

In France, as regards cross-border jurisdiction of French courts, contrasting with the French approach so far, the French Supreme Court decided that where there is evidence of an offer in France of an allegedly infringing product supplied from the UK and South Africa and possibly exported from France to customers in Germany, a patentee having a European patent designating France may initiate infringement proceedings before French courts for the French, German and English part of that European patent. Based on EU and French law, it is also possible to name

the French, UK and South African companies participating in the manufacture as defendants based on the supply and offer of the allegedly infringing goods. Consequently, the French court then has to apply French, German and English law, respectively, on the infringement analysis regarding the different parts of the European patent. (Cass. Com., 29 June 2022, S.A. Hutchinson v Tyron Runflat Ltd, case G 21-11.085). An interesting development at a time where there will be more forum shopping in Europe with the coming into operation of the UPC.

In the pharmaceutical sector, the Paris Court of appeal appears to have softened its position regarding the validity of SPCs. The Court recognised the validity of an SPC covering a monoclonal antibody which was not specifically characterised in the basic patent (and was covered by a subsequent patent). It notably held that the discovery of the antibody did not involve an independent inventive step with respect to the basic patent. This seems to mark a shift from the Court's previous case law which invalidated several SPCs in comparable circumstances. The shift seems in line with the latest case law of the Court of Justice of the European Union (CJEU) on these issues.

On the telecoms side, it remains to be seen if the French courts will ultimately go as far as setting global FRAND rates after the Paris Judicial Court ruled twice that it has jurisdiction to hear claims brought by a phone maker against both an SEP holder and the European Telecommunications Standards Institute (ETSI) to set such rate.

Paris also awaits the official going into operation of the UPC, a new kind of European patent court with the main seat of the central division located in Paris.

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## *Germany*

Following the 2021 German patent reform, which took effect from May 2022, the German Federal Patent Court has started to produce preliminary opinions on patent validity within six months from filing. These preliminary opinions have already assisted litigants and courts in assessing patent validity when deciding on requests from defendants to stay the infringement case in the civil courts pending resolution of co-pending nullity actions against the patent in dispute.

Equally, the patent reform has introduced the power for a patent court to refuse an injunction where the grant of an injunction appears “disproportionate”. The Munich Court has made it clear (decision of 5 August 2022 – 21 O 8879/21) that the mere fact that a patentee is a non-practising entity is not enough to refuse injunctive relief. Equally, that same court has ruled that in FRAND cases, where the FRAND defence has remained unsuccessful, there is no room for the application of the disproportionality defence. Along the same lines, the Dusseldorf Court (7 July 2022 – 4c O 18/21) held, in a case involving a potentially life-saving medication, that the defendant who fails to request a compulsory licence in time cannot resort to a proportionality defence. Moreover, the defendant must have shown a clear commitment to patient interests in order to qualify for a disproportionality defence which includes a serious attempt to obtain a contractual licence from the patentee.

Finally, the German courts have been reconsidering the criteria under which they grant preliminary injunctions in patent matters following the decision by the European Court of Justice (ECJ) in *Phoenix Contact v Harting* (28 April 2022, C-44/21). The ECJ ruled that a German practice to require a demonstration by the patentee of validity of the patent in suit was not in

line with the Enforcement Directive if it required that the patent had previously survived a contested validity attack. The reaction by the German courts to this decision has, at best, been lukewarm. German courts will still usually require demonstration of validity of a patent “beyond reasonable doubt”. The standard is, however, lower in cases involving generics of approved innovator medicaments.

On the FRAND side, while there have been a number of decisions, eight years into *Huawei v ZTE*, the precise criteria under which a patentee must offer a licence to the implementer and the specific duties that the implementer has to comply with in order to avoid an injunction are still being assessed differently by the courts in Mannheim, Dusseldorf and Munich. Critical questions continue to involve the assessment of the implementer’s willingness to enter into a FRAND agreement, the need to “actually” negotiate rather than insisting on one’s original offer, the timing of the respective offers, and the order in which the FRANDness of the offers is assessed, among others. It appears that only the *Bundesgerichtshof*, the highest German court will be able to streamline the application of FRAND principles in Germany if and when the next opportunity arises.

## *Italy*

In Italy, 2022 was a big year for patent litigation, especially in the life sciences industry.

During the summer, the government led by Mario Draghi proposed to abolish the Italian “patent linkage” provisions established in 2012 by the Balduzzi Decree. In the end, however, Law No 118/2022 fully confirmed the previous rules and provided some welcome clarifications. Under the new provisions, manufacturers of generic and biosimilar drugs are allowed to request mar-



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keting authorisations and reimbursement price decisions from the Italian Medicines Agency while the originators' patents are still in force. However, the National Health Service will not reimburse generic or biosimilar products until the patents or SPCs on the active ingredient have expired. As a result, the "patent linkage" rules will continue to play an essential role in administrative and civil cases between originator and generic companies in Italy.

Furthermore, the Courts of Turin and Naples applied the proportionality principle to preliminary injunctions in patent cases for the first time. Both decisions concerned patents on medical devices (an aortic valve and related components) held by Edwards Lifesciences. The Courts found that two of the plaintiffs' patents were valid and infringed, thus issuing injunction and seizure orders against the infringing devices. However, both Courts carved out from the injunction the ongoing supply of the infringing medical devices to some health facilities. The Court of Turin also prevented the seizure of the infringing devices that had been recently supplied to two other hospitals in Northern Italy. In doing so, the judges stressed the need to safeguard "the public interest related to the activity of health care facilities" and relied on Article 124(6) of the Italian IP Code, according to which "the judicial authority must take into account the necessary proportion between the seriousness of the infringements and the sanctions, as well as the interests of third parties". These cases are noteworthy because, until recently, it was questioned whether Article 124(6) could afford flexibility in the scope of injunctive relief (Court of Turin, 16 June 2021, Edwards Lifesciences Corp. et al. v Meril GmbH et al.; Court of Naples, 11 May 2022, Edwards Lifesciences Corp. et al. v Sintec S.r.l.).

Finally, the Court of Milan commented once again on the infringement of second medical use patents in "skinny labelling" cases – ie, where the leaflet of the allegedly infringing product does not include the patented indication (Court of Milan, 9 January 2022, Novartis Pharma AG et al. v Medac Pharma S.r.l.). Although the defendant had specifically removed the indication covered by the patent from the leaflet, the Court of Milan found that the patent was *prima facie* infringed. It noted that the generic manufacturer had won public tenders for the supply of the drug which did not specify any use limitations and that the patent holder did not receive any requests for additional supply to cover the patented use in relation to those tenders. Therefore the Court issued a preliminary injunction against the generic manufacturer.

## Eurasian Economic Union (EAEU)

The Eurasian Economic Union's (EAEU) single pharmaceutical market is developing rapidly. For innovators it means a need to monitor more closely the Unified EAEU Register of drugs and the national registers of the EAEU member states (Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia). To date, the search through the Unified EAEU Register of drugs does not provide sufficient information on activities of generic producers. Hence, only careful checking of national registers (often combined with inquiries to the local healthcare authorities) may help to identify in which member state bioequivalence studies and marketing authorisation registration applications for generic products have been initiated (which can be further used as a basis for simplified marketing authorisation generic approval for other EAEU member states).

Pharma patent disputes in the EAEU member states have largely been considered by the courts in a balanced manner despite the neg-

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active forecast that, as a reaction to sanctions in response to Russian attack on Ukraine, the courts would not grant claims of right holders originating from the countries introducing sanctions. This forecast has not materialised and the only matter where a Russian judge tried to restrict procedural rights of the claimant originating from an “unfriendly” country was criticised and overturned by the Russian IP Court. In a nutshell, international businesses have continued to enforce patent rights in the EAEU states including Russia and have had success with both injunction and damages recovery claims. More than before there have been attempts to challenge patent term extensions (PTEs) and the increase of such cases resulted – eg, in Russia – in a shift of competence over PTE challenges from the Russian IP Court to the Chamber for Patent Disputes under Rospatent. Simultaneously, the Eurasian Patent Office has introduced a pharma patents register where Russian, Kazakh, Belarus, Tajik, Azerbaijanian, Kyrgyz, Turkmen and Armenian pharma patents may be included. This register currently serves as an optional tool for assessing the patentability of new patent applications by the national patent and trade mark office. However, there is a hope that this register may be used for patent linkage purposes going forward.

Compulsory licences remain a matter requiring monitoring in EAEU countries. Since the majority of compulsory licences in the region are more likely to arise from generic producers obtaining a dependent patent, it has become evident that constant monitoring of patent applications in the EAEU countries is a must, as such a precaution may substantially help in shielding originators from potential compulsory licence claims (eg, by proceeding with a patent invalidity claim as soon as the relevant patent application is granted). It remains important to extend monitoring to

both national and Eurasian patents and in cases when monitoring has not been done before to extend a check for valid patents to the entire region. The latter is important as, in the past, the generic producers have based their compulsory licence court claims on patents which have been obtained earlier and have been unused by the generic producers for some time. Some of such dependent patents have been successfully invalidated due to non-compliance with patentability criteria.

In the EAEU countries there is an ongoing discussion about the need for compulsory licensing for software products and Belarus has just introduced relevant law provisions for this. While in the life sciences sector this may be relevant for producers of medical devices, the real benefit of such compulsory licences is fairly limited: even if the compulsory licence is granted for the initial version of software, it does not appear very helpful in view of the relatively short life cycle of software and the need to have physical access to updates which is not provided by the mechanism of compulsory licensing.

## Asia

### *Japan*

In Japan, a number of amendments to the Patent Act came into effect in 2022 following the passing by the National Diet (Japan’s legislature) of the relevant bill in May 2021. Many of the changes are practical in nature: given the impact of the COVID-19 pandemic in Japan, relevant amendments now set out rules governing online hearings, for example. Another amendment relieves the need for a patentee to seek its licensee’s consent to abandon or correct a patent; the prior requirement had occasionally been burdensome, for instance where a patentee sought to amend its patent as a defensive measure in an invalidation action and there were

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multiple existing (unregistered) licensees from which written consent was needed.

A further amendment has created a system by which a party to a litigation may request the court to seek amicus briefs from third parties. The first official use of this system was on 30 September 2022 (case No 2022 (ne) 10046 between Dwan-go Co., Ltd (appellant) and FC2, Inc. (appellee) and Homepage System, Inc. (appellee)), with the First Division of the IP High Court seeking written opinions from the general public. To the extent such written opinions are submitted by the parties as evidence, those documents become subject to inspection and copying (under Article 91 of the Code of Civil Procedure). The IP High Court provided guidelines in English in respect of its call for opinions, and permitted submissions in Japanese or English. The period for the call for opinions was from 30 September 2022 to 30 November 2022, which spanned the IP High Court's relocation and integration within Japan's new Business Court, which opened in October 2022. The Business Court incorporates the IP High Court and aspects of the Tokyo District Court (such as the IP Division) and is intended to be a one-stop court covering IP, corporate, bankruptcy and related business cases.

Other developments in 2022 include Japanese companies arguably continuing to become more assertive and initiating patent litigation, particularly in the technology field and including between domestic companies. More disputes may arise in this sector in the coming year or so, potentially in respect of 5G and other standards, the internet of things and connected devices, especially in respect of connectivity in the automotive sector.

In a related context, as reported last year, the Competition Enhancement Office and the Intel-

lectual Property Policy Office of the Japanese Ministry of Economy, Trade and Industry (METI) hosted a study group on the "Licensing Environment of Standard Essential Patents" in 2021. This reviewed the international standard essential patent (SEP) licensing negotiation landscape and discussed various measures to improve the licensing environment of SEPs in Japan. In March 2022, METI followed up by publishing the non-binding "Good Faith Negotiations Guidelines for Standard Essential Patent Licences", setting out expectations and a process by which SEP holders and implementers should negotiate; in June 2022, the Japan Patent Office (JPO) subsequently revised its "Guide to Licensing Negotiations involving Standard Essential Patents" that refers to METI's new guidelines and provides useful information on current, key and practical topics from a global perspective.

In July 2022, the IP High Court held for the first time that a Japanese patent can be enforced against acts of infringement that are partially committed outside the territory of Japan (case No 2018 (ne) 10077; the parties are identical to those in the case that led to the call for amicus briefs). The issue related to an online computer program hosted on servers in the USA but provided to Japan-based users. Having set out a four-part test to assess the circumstances and co-defendants' activities, the IP High Court held that the co-defendants' acts could be regarded as having been "substantially and wholly" conducted in Japan.

In the life sciences field, originator versus generics cases continue. Interestingly, a number of generic companies recently appear to have benefitted from Japan's non-statutory "patent linkage" system and the regulator's apparent readiness to grant generic marketing authorisation in certain cases (for instance, where a patent

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has been held invalid by the JPO but not all avenues of appeal have yet been exhausted and the decision finalised). If the grants of such generic marketing authorisations are found to have been premature (in the sense of a first instance patent invalidation decision being overturned on appeal, for example), there may be important changes to the regulator's practice in the future in favour of originators and patentees.

Finally, a number of biologics and biosimilar patent cases continue to be the subject of dispute resolution in Japan, somewhat mirroring cases in the USA and Europe. It is still unclear whether the Japanese courts will take similar positions in respect of issues already litigated elsewhere, but it is expected that the number of such biologics patent cases will increase, and it will be important to monitor Japan-specific developments in due course.

## *China*

In 2021, China amended its Patent Examination Guidelines, officially confirming that post-filing experimental data to fulfil the inventiveness and sufficient disclosure requirements under the Patent Law shall be considered by examiners, provided that the technical effect intended to be shown with such data can be obtained from the initial patent application. Before the amendment, there were several judicial cases, including one from the Supreme People's Court (SPC), relieving the previously strict rule on the admissibility of post-filing data. In line with such a trend, the official amendment of the Guidelines signals a more reasonable standard for patent owners, in particular in the pharmaceutical and chemical fields, to defend the validity of their patents with subsequent data. The practical standards are also becoming closer to the general practice elsewhere, allowing patent owners to have more consistent expectations regarding their ability to

obtain patents, or defend patents in validity challenges as they enforce patents in China.

With the amended Patent Law and the subsequent implementation rules issued in 2021, a number of patent linkage actions have been filed with the Beijing Intellectual Property Court and the China Intellectual Property Office (CNIPA), the two exclusive forums to hear such cases and determine whether a generic drug in an application falls under an eligible patent already registered with the Patent Registration Platform of Listed Drugs, upon which the drug authority may decide to hold the marketing approval of the generic drug. While there is no decided case yet, the initial numbers of cases filed suggests that the new administrative dispute resolution mechanism provided by the CNIPA may be preferred over the courts, possibly because of the expectation of higher efficiency.

There are, so far, still no official implementation rules on patent term extension, another new system brought in by the amended Patent Law. On 31 October 2022, yet another new list of proposed amendments was published which suggests China is getting closer to a final version.

## *Hong Kong*

Hong Kong's new patent system allowing original grant patents (OGPs) started in December 2019 and provides a direct route for seeking 20-year patent protection. As at 31 August 2022, around 600 applications for OGP had been filed at Hong Kong's Intellectual Property Department (IPD) and around 30 OGP had been granted, some in less than 18 months of filing. In a policy address in October 2022, the Hong Kong government announced it would enhance the substantive examination capability of patent examiners under the OGP patent system and develop a talent pool, with a view to acquiring

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institutional autonomy in conducting substantive patent examination by 2030.

A pilot scheme announced by the IPD in November 2021 enables an OGP applicant to request the deferral of the formality examination for a period of up to 12 months from the filing or priority date. The effect of this scheme has some similarities to a US provisional patent application and allows an applicant to establish an early filing date without having to file claim(s), giving applicants more time to assess the patentability and commercial potential of their invention. Such requests are granted at the Registrar's sole discretion and must satisfy certain requirements. If a request is granted, the processing of the OGP application will be suspended during the deferred period.

The alternative route for obtaining a 20-year Hong Kong invention patent, which requires a patentee to obtain a UK, European (UK) or Chinese patent ("designated patents") and then re-register the designated patent at the IPD without needing any local substantive examination, continues to operate in parallel with the OGP system, so patent applicants can choose between the OGP system or the re-registration route. In the 12 month period to the end of August 2022, over 20,000 applications were filed to re-register designated patents and around 11,800 patents were granted using the re-registration route. The IPD wants there to be possible advantages in terms of speed in using the OGP route. For example, if an applicant agrees not to request any amendments and requests early publication of the application, if the application progresses smoothly, the entire process to grant may be completed in around 12–18 months.

The Hong Kong High Court IP specialist list was set up in 2019, with a small number of design-

nated judges who can hear patent and other IP cases. The intention of the IP specialist list is to have more judge-led case management, to improve the level of judicial expertise for dealing with IP cases and to increase efficiency in – and therefore speed up – IP litigation. New procedural court rules for IP cases are currently being discussed and these are expected to be introduced soon.

China's 14th five-year plan (2021–2025) affirms the Chinese government's support for the future development of Hong Kong in a wide spectrum of areas, including developing Hong Kong into a regional IP trading centre and an international innovation and technology hub. The plan also supports Hong Kong developing as a centre for international legal and dispute resolution services in the Asia-Pacific region. The Hong Kong government wants to leverage Hong Kong's advantages in international financial, legal and dispute resolution services within China's Greater Bay Area (GBA), which covers Hong Kong and Macao, as well as nine major cities in mainland China including Guangzhou and Shenzhen, the home of many Chinese technology companies. Progress has recently been made in introducing a comprehensive framework for the reciprocal recognition and enforcement of judgments in civil and commercial matters between Hong Kong and mainland China. Although patent infringement and validity judgments are not covered by this arrangement, once the arrangement has been implemented future judgments in disputes, such as those for breach of contract will be covered (with some limited exceptions), allowing both monetary and non-monetary judgments from Hong Kong courts in many types of technology-related contractual disputes to be registered and enforced by mainland Chinese courts.

# INTRODUCTION

Contributed by: Andreas von Falck, Hogan Lovells International LLP

## The USA

### *Notable 2022 decisions*

The Federal Circuit in *CalTech v Broadcom* reset its precedent regarding estoppel for patent challengers in United States Patent and Trademark Office (USPTO) post-grant proceedings, such as inter partes reviews (IPRs). The ruling overruled *Shaw Industries v Automated Creel Systems*, which held that challenged patent claims and invalidity grounds in an IPR final written decision could not be later re-raised by the patent challenger in a district court litigation. The *CalTech* decision broadened the scope of the estoppel rule to sweep in “not just... claims and grounds asserted in the petition and instituted for consideration by the board, but... all claims and grounds not in the IPR but which reasonably could have been included in the petition.” It is a favourable decision for patent owners and will require alleged infringers to think more carefully about if and how they might choose to attack patent(s) asserted against them in an IPR.

One of the more notable decisions of 2022 was a decision by the US Supreme Court not to review a case. The patent community was closely monitoring *American Axle v Neapco*, as it potentially weighed on the often-scrutinised patent eligibility jurisprudence. The *American Axle* case evenly split the full Federal Circuit 6-6 on a question about subject matter eligibility. Such a close call invited the US Supreme Court to revisit its 2014 *Alice* decision and further clarify the doctrine. In June 2022, however, the Supreme Court declined the petition for review, effectively leaving clarification in the hands of the US legislature for the time being.

### *Inter partes review discretionary institution – “FinTiv” Considerations*

In recent years, the number of discretionary denials of IPR petitions based on so-called

*FinTiv* factors sky-rocketed. The *FinTiv* factors allow the USPTO’s Patent Trial and Appeal Board (PTAB) to deny petitions based on the status of co-pending district court litigations. In June 2022, USPTO Director Kathi Vidal issued new guidance on the factors. Most critically, the guidance essentially prohibited the board from denying a petition under *FinTiv* if the petitioners rely on a stipulation, commonly referred to as a *Sotera* stipulation, not to pursue invalidity arguments in district court that were raised or could have reasonably been raised in the petition if instituted. The guidance also directed the board to consider the median time to trial for the district rather than relying on a scheduling order setting a trial date. Additionally, the guidance directed the board not to invoke its discretion with petitions that present “compelling evidence” of unpatentability. The number of discretionary denials dropped dramatically in the second half of 2022, a trend that is likely to continue in 2023.

### *Western District of Texas patent docket shake-up*

Texas has long been viewed as a plaintiff-friendly state for patent litigation. The Eastern District of Texas first gained notoriety, but the Western District has experienced an explosion of patent cases in recent years. In fact, at one point in early 2022, the Western District accounted for more than one quarter of all patent litigation in the United States. Those cases were largely diverted to a single judge: Judge Alan Albright, who had gained popularity with patent plaintiffs that could effectively guarantee assignment to his courtroom under local filing rules. At the peak, Judge Albright was assigned to 23% of all patent lawsuits nationwide (for context, there are over 600 district court judges in the United States that can handle patent cases). In July 2022, the Chief Judge of the Western District



# INTRODUCTION

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of Texas issued a new policy in that district that all patent cases were to be randomly assigned to one of the twelve judges sitting in the district, taking away the ability of patent plaintiffs to guarantee assignment to Judge Albright. In the weeks immediately following the policy change in the Western District of Texas, there was a slowdown in patent filings, perhaps as plaintiffs reassessed their strategies. But overall, for the latter half of 2022, the data shows only a marginal slowdown of patent litigation in the Western District, as opposed to a dramatic drop-off some may have expected. There remains significant interest and scrutiny in perceived inequitable distribution of patent cases in the United States, including by Supreme Court justices and federal lawmakers, so it will be something to continue monitoring in 2023.

## *What to watch in 2023*

The US Supreme Court has already agreed to hear one patent case in 2023: Amgen Inc. v Sanofi. The Supreme Court will review the “enablement” requirement, a statutory patentability requirement that may not receive as much attention in litigation as subject matter eligibility, anticipation (novelty), and obviousness. The question posed to the court is whether a patent specification need only teach a skilled artisan how to “make and use” the invention, or whether the specification needs to enable skilled artisans to “reach the full scope of the invention.” The immediate repercussions of a decision may be seen most in life sciences and biopharma litigation.

A petition for review of the aforementioned CalTech case is currently pending at the US Supreme Court. The scope of petitioner estoppel may remain in flux until the Supreme Court weighs in.

# INTRODUCTION

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Hogan Lovells International LLP offers clients a full range of legal services. In a fast-changing and interconnected world, the firm provides fresh thinking combined with proven experience. Located in the world's key hubs, Hogan Lovells advises on a range of intellectual property matters as well as litigation, M&A, corporate, and capital markets transactions. Its experience in cross-border and emerging economies gives the firm the necessary market perspective to be a global partner to its clients. With more than 45 offices worldwide, the firm's practice groups co-operate closely with each other, providing clients the full resources of a global firm

from a single, local point of contact.

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## Trends and Developments

### Contributed by:

Ben Miller, Stephen Rohl, Katie Pryor and Jenny Wong  
Maddocks see p.25



### Patent Litigation

In November 2022, the Federal Court of Australia revoked its COVID-19 “Special Measures” practice notes, bringing an end to various necessities and conveniences arising from the pandemic, such as the acceptance of unsworn/unaffirmed affidavits. In-person hearings have returned as the norm but remote access to hearings remains common, enabling litigation teams, clients and interested observers to view proceedings from the office and around the globe.

A number of significant patent decisions were handed down in 2022. Some provided welcome guidance, such as the first decision on the experimental purposes infringement exemption and much-needed certainty by the Full Federal Court on patent term extensions. On the other hand, the High Court’s split decision on computer-implemented inventions will only fuel debate in years to come.

While the Patent Office has been largely operating under the heightened standards of the “Raising the Bar” regime for years now, only a few of these patents have made it to the courts to date. It remains to be seen how the law will evolve in light of recent developments overseas.

### *First judicial guidance on the “experimental purposes” infringement exemption*

Section 119C of the Patents Act provides a defence against infringement for acts done for experimental purposes relating to the subject matter of the invention. Jusand Nominees Pty

Ltd v Rattlejack Innovations Pty Ltd [2022] FCA 540 affords the first substantive judicial consideration of the provision since its introduction in 2012.

One of the respondents asserted that the supply of its device for use in underground mining was covered by Section 119C. Justice Rofe accepted that “experimental purposes” ought not be confined to laboratory work. Her Honour considered the expression to connote at least some application of scientific method to the discovery of new information, the testing of a hypothesis, the existence of a protocol or methodology documentation of some kind setting out the purpose of the experiment and the variables to be measured or observed, and the recording and reporting of results or observations.

Justice Rofe found that early field tests of the device fell within Section 119C. These tests involved a limited number of prototypes and were conducted for the purposes of determining whether the prototypes worked and, when they failed, for testing redesigned prototypes. Reports were also prepared on the failed tests, which included speculation as to the cause of the failures and what changes were required.

However, her Honour considered that the supply of 200 production model devices which were put to use for 12 months of purported testing in mining operations did not fall within the exemption. Her Honour held that the supply was nothing

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more than use in the ordinary course of mine operations. Importantly:

- the supplier had no input into any trial design for the devices, including what parameters to measure, where and how the trial was to be conducted, and what constituted success;
- testing was only conducted at some sites at which the devices were deployed;
- there was no scientific method associated with the trial or documentation recording it;
- the Partnering Agreement between the supplier and the recipient was silent as to any experimental use or trial; and
- the devices were supplied at a commercial price (ie, not discounted) that included a sales margin.

These findings are in line with the Explanatory Memorandum to the “Raising the Bar” Bill. While the Bill recognised the practical reality that research is frequently undertaken for mixed purposes, and so it is not fatal if there is some commercial purpose to the experiments, the commercial purpose cannot be the main purpose. Section 119C may, therefore, encompass research with a view to ultimately commercialising the end-products of the experimentation, including research partially funded by a commercial partner, but the relevant acts must be undertaken for the predominant purpose of gaining new knowledge, or testing a principle or supposition about the invention.

Jusand appealed the decision to the Full Court, which was heard in November 2022, with judgment reserved. The views of the Full Court will be heard in 2023.

### *Indemnity costs*

The usual order as to costs “as between party and party” only compensates the success-

ful party for those costs “that have been fairly and reasonably incurred” in Australian litigation. Indemnity costs, on the other hand, are intended to compensate a successful party fully for costs incurred, and thus represent a significant increase in compensation.

Indemnity costs are not punitive. The circumstances which have warranted indemnity costs include where the moving party should have known it had no chance of success, or persisted in what should have been seen to be a hopeless case, or unreasonably rejected an offer or compromise. In assessing unreasonableness, the court will, without the benefit of hindsight, have regard to the extent of the compromise offered and the losing party’s prospects of success, assessed at the time the offer was rejected.

In *Vector Corrosion Technologies Limited v E-Chem Technologies Ltd* [2022] FCA 519, the respondents (represented by Maddocks) sought indemnity costs. Justice Jagot considered Vector’s case to be weak but nonetheless arguable, and thus declined to award indemnity costs for the whole of the infringement/revocation proceeding, despite the fact that only four weeks before trial Vector consented to orders that the infringement proceeding be dismissed, the asserted claims of the patents be revoked and that it pay the respondents’ costs. However, her Honour concluded that indemnity costs should be awarded because of Vector’s unreasonable rejection of a “Calderbank” offer and an offer of compromise made by the respondents on 24 June 2019.

Justice Jagot considered a number of factors to indicate that Vector had acted unreasonably in not accepting the offers, including:

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- the offer letter clearly identified the respondents' position on invalidity, including on Vector's amendments to the claims;
- Vector rejected the offers four days after they were made on the basis that it could not assess the merits of the respondents' invalidity arguments and that the patent was entitled to the presumption of validity;
- Mr Whitmore, the President of Vector, was a person skilled in the art and "a sophisticated businessperson with a clear understanding of how patent rights can operate to Vector's advantage";
- it could be inferred that Mr Whitmore must always have known that the asserted claims were of seriously questionable validity;
- the doubtful validity of the claims asserted by Vector was reinforced by the fact that Vector's attempt to obtain equivalent amendments in Vector's European patent had previously been rejected;
- Vector must be taken to have known from all the circumstances that the attempt to amend the claims to capture the respondents' process involved, at best, a significant stretch of the terms of the specification; and
- the offers involved a real compromise by the respondents of value to Vector, in that Vector would pay no costs to the respondents and its amended claims would remain unchallenged.

Parties to litigation considering to make an offer to resolve a dispute should ensure that the offer represents a genuine compromise so that, in circumstances where the offer is unreasonably rejected, the court is more likely to award indemnity costs. In this case, a "walk away" offer was held to pass the test.

## Life Sciences

### *Pharmaceutical patent settlements – seeking authorisation from the regulator*

In 2022, the Australian Competition and Consumer Commission (ACCC) considered, for the first time, an application for authorisation of a patent settlement and licensing agreement.

Part IV of the Competition and Consumer Act 2010 (Cth) (CCA) contains prohibitions against substantially lessening competition and engaging in cartel conduct. Breach of these provisions can attract both civil and criminal penalties. Section 51(3) of the CCA previously provided a broad exemption to these prohibitions for certain conduct related to intellectual property rights. The repeal of Section 51(3) in 2019 thus opened parties to patent settlement and licensing arrangements to the risk of contravening these prohibitions.

One way this risk may be managed is to apply to the ACCC for authorisation. This is a public process, with the application published on the ACCC's website and the public invited to comment on the potential competitive effects of, and the public benefits and detriments that may result from, the conduct that is proposed to be authorised. The ACCC considers both the likely future with the proposed conduct (the factual) and the likely future in which that conduct does not occur (the counterfactual).

In November 2020, Juno Pharmaceuticals Pty Ltd and Natco Pharma Ltd commenced proceedings against Celgene Corporation, seeking to revoke certain of Celgene's patents relating to lenalidomide (REVLIMID) and pomalidomide (POMALYST). Celgene's compound patent for lenalidomide was due to expire on 23 July 2022, and various method of treatment patents were

due to expire in 2023 and 2027. Celgene cross-claimed for infringement.

The parties subsequently entered into a settlement agreement to resolve the litigation, whereby Juno and Natco were granted a non-exclusive licence to launch their generic lenalidomide and pomalidomide products before the latest expiry date of Celgene's patents. In December 2021, the parties applied for authorisation of aspects of the agreement.

In a draft determination issued in March 2022, the ACCC denied the application. The ACCC commented that it had received submissions on a confidential basis from the parties on the potential counterfactual scenarios but no evidence to substantiate those submissions. The ACCC stated that this approach had compromised the ACCC's ability to test the parties' submissions, which in turn influenced the ACCC's conclusions in assessing the application under the public benefit test. The parties were given time to respond to the draft determination.

The parties could perhaps be forgiven for limiting the amount of confidential information provided to the ACCC in their application for authorisation. There is a strong argument that a non-exclusive licence agreement to allow a competitor to market a generic brand before patent expiry necessarily increases competition, and necessarily benefits the public. The first generic listing triggers a 25% statutory reduction to the reimbursed price for all brands of a given medicine, and further reductions begin to apply under the price disclosure regime. Once the first generic brand has been listed, the prospects of the originator restraining additional generic brands also reduce, given the change to the status quo.

In July 2022, the parties withdrew the application before the ACCC's final determination was due to be made. The litigation was subsequently discontinued in September 2022. As at December 2022, REVLIMID remained the only lenalidomide brand listed on the PBS, but two additional pomalidomide brands were recently listed, including Juno's product. It can be inferred that the parties reached alternative settlement terms.

It remains to be seen whether the ACCC will take a heightened interest in patent settlement agreements following this experience, as has been the case in other jurisdictions and as recommended by the Productivity Commission in 2016. Given that settlement provides generic companies with a means to enter the market earlier than otherwise and at reduced risk, and the inherent increase in competition by having a second player in the market, parties should not lightly be deterred from reaching appropriate settlement arrangements.

### *Patent term extensions update – first in best dressed*

The patent term extension (PTE) regime in Australia recognises the length of time that is lost to patentees in the process of obtaining marketing approval for a new drug, during which time the drug cannot be commercialised. PTEs continue to be a contentious issue in Australian litigation.

Two recent decisions of the Full Court of the Federal Court of Australia (comprising the same panel of judges) have made abundantly clear that a PTE application may only be based on the first goods included on the ARTG which are disclosed and claimed in the patent. This is the case regardless of:

- whether the goods are sponsored by the patentee or another person;



- whether the patent discloses and claims multiple pharmaceutical substances and different products containing, or consisting of, the substances are included on the ARTG at different times; and
- how the products are included on the ARTG (registered, listed, listed for export-only, etc).

In *Ono Pharmaceuticals Co Ltd v Commissioner of Patents (Ono)*, the claims of Ono's patent encompassed not only the anti-PD-1 antibody in its product, OPDIVO, but also that in a competitor's product, KEYTRUDA. The Commissioner refused Ono's application, stating that it should not have been based on OPDIVO but rather KEYTRUDA, which was the first to be included in the ARTG. On appeal to a single judge ([2021] FCA 643), Justice Beach overturned the Commissioner's decision, finding that it would be "manifestly unreasonable" for a patentee to be denied the compensation offered by the PTE regime due to another party obtaining earlier marketing approval for a different product.

The Full Court ([2022] FCAFC 39) overturned Justice Beach's decision and refused the PTE. Their Honours accepted the compensatory objective of the PTE regime but this did not mean that the regime "should be construed to achieve what might be described as a commercial outcome for the patentee". Indeed, if so, a patentee could license a third party to exploit the patent and obtain ARTG registration in the third party's name, and only later seek regulatory approval in its own name so as to obtain the maximum term extension.

In *Merck Sharp & Dohme Corp v Sandoz Pty Ltd (Merck v Sandoz)*, the claims of Merck's patent encompassed two of its products on the ARTG, one comprising sitagliptin and the other comprising both sitagliptin and metformin. Merck

relied on the latter to obtain the term extension. At first instance ([2021] FCA 947), Justice Jagot considered that a patentee ought not be allowed to extend its monopoly simply because a second pharmaceutical substance is later included on the ARTG. As Merck's ARTG listing of sitagliptin alone occurred first and less than five years after the date of the patent, there could be no extension of term.

The Full Court ([2022] FCAFC 40) confirmed the primary judge's finding, noting that if the position were otherwise, a patentee could obtain an extended monopoly for one drug based not on a delay in its regulatory approval but a delay in relation to a different drug.

### *Looking forward*

Following *Ono*, patentees will need to keep an eye out for the potential for earlier inclusion of competitor products on the ARTG and consider their filing and prosecution strategies accordingly. While this is unlikely to be an issue for small molecules, broad claims regarding biologics may capture a competitor's structurally different product.

Following *Merck v Sandoz*, patentees will need to consider their current portfolios and future patenting strategy for patents encompassing multiple pharmaceutical substances. Patentees will need to consider limiting the claims of individual divisional applications to each of the substances on which a PTE may be based.

The decisions provide welcome clarity in this highly contentious space and curtail increasingly common PTE strategies. They have confirmed, and are likely to continue to confirm, the invalidity of several PTEs granted based on second generation or combination products and thus

bring forward entry opportunities in Australia for generics and biosimilar developers.

## TMT

### *AI inventors – not in Australia*

Dr Thaler’s multi-jurisdictional campaign has posed the question: can an artificial intelligence (AI) system be an “inventor”? This year, the Australian courts said “no”.

The dispute concerned a Device for the Autonomous Bootstrapping of Unified Sentience (DABUS), which was named as the inventor in a patent application filed by Dr Thaler.

Section 15(1) of the Patents Act states that a patent for an invention may only be granted to a person who:

- is the inventor; or
- would, on the grant of a patent for the invention, be entitled to have the patent assigned to the person; or
- derives title to the invention from the inventor or a person mentioned in the second bullet point above; or
- is the legal representative of a deceased person mentioned in one of the three bullet points above.

As was reported in the 2022 [Australian Trends & Developments](#) chapter in this guide, the Deputy Commissioner of Patents issued a direction to Dr Thaler to identify the inventor, stating that an inventor must be a natural person. The rationale was that Section 15(1) of the Patents Act is “not capable of sensible operation in the situation where an inventor would be an artificial intelligence machine as it is not possible to identify a person who could be granted a patent”. As the alleged deficiency was not capable of being cor-

rected, the patent application lapsed. Dr Thaler sought judicial review of the decision.

Justice Beach set aside the Commissioner’s decision and remitted the matter for determination, including on the basis that: (i) nothing in the Patents Act precludes the possibility of a patent grant for an invention with no human inventor; and (ii) the Commissioner interpreted the statute incorrectly by unnecessarily reading limitations and qualifications into the definition of “inventor”.

On appeal, the Full Court of the Federal Court of Australia considered the history of, and policy behind, the Patents Act, citing a number of provisions which were predicated on the inventor being a natural person. The Full Court said that there was no indication of legislative intent for the role of the inventor to change in the context of the current provisions.

The Full Court held that identification of the inventor within Section 15(1) is of “central relevance” to the operation of the Patents Act and is closely related to questions of validity. For example, allegations that a patent was obtained by fraud, false suggestion or misrepresentation call into question whether the inventor has made representations as to the nature of the invention.

The Full Court considered the construction of Section 15 as referring to a natural person to be consistent with the established rules of statutory construction and developments in case law. The appeal was allowed.

Dr Thaler sought special leave to appeal to the High Court of Australia, which was dismissed on the basis that the case was not an appropriate vehicle to consider the questions of principle raised by the applicant.

Although a future challenge remains possible, the outcome of these proceedings brings Australia into line, for now, with other jurisdictions (including Europe, the UK and the USA), where the patent offices and courts have consistently determined that their respective legislation does not recognise an AI machine as an inventor; rather, an inventor must be a natural person.

### *Computer-implemented inventions*

As was reported in the 2022 Australian Trends & Developments chapter in this guide, the Full Court of the Federal Court of Australia in *Commissioner of Patents v Aristocrat Technologies Australia* [2021] FCAFC 202 clarified that electronic gaming machines (EGMs) and the like are subject to the same patent eligibility criteria as other computer-implemented inventions.

Subsequently, Aristocrat sought and obtained special leave to appeal to the High Court of Australia. While the full bench normally consists of seven members, one judge became ill before the hearing, leading to the possibility of a 3:3 split decision. In these circumstances, the outcome of the decision below stands (in the present case, the Full Court's finding that Aristocrat's patents lack patentable subject matter).

That possibility became a reality ([2022] HCA 29), with Kiefel CJ, Gageler and Keane JJ (Kiefel et al) delivering one judgment and Gordon, Edelman and Steward JJ (Gordon et al) delivering a separate judgment.

At the heart of the issue was that the invention, as claimed, was not simply to a novel feature game but to an EGM comprising physical parts (including a display, a game controller comprising a processor, and a game play mechanism comprising a plurality of buttons) and the operation of which involves the novel feature game.

Kiefel et al would have dismissed the appeal, finding that the claimed invention, as a matter of substance, was to a new feature game that was itself inherently unpatentable. Their Honours considered that the invention did not produce some adaptation or alteration of, or addition to, technology otherwise well-known in the common general knowledge. Thus, the alleged invention rose no higher than the implementation of a new idea using old technology, which "is simply not patentable subject matter". Kiefel et al did, however, remark that a claimed invention for patentable subject matter does not become unpatentable because it is operated by generic computer technology.

Gordon et al would have allowed the appeal. Their Honours considered that the question of patentable subject matter "should not be deconstructed to require, separately from the general principles of patentability, consideration of whether the subject matter is 'computer implemented'". Their Honours accepted that implementation of a scheme or idea on a computer must do more than merely manipulate the abstract idea; rather, it must create an artificial state of affairs and a useful result. In finding that the claimed invention did so, Gordon et al had regard to the Commissioner's acceptance that if the claim had involved a mechanical gaming machine (using cogs, reels and motors) then it would have been patentable subject matter, and considered that a different conclusion should not be reached simply because these mechanical parts are replaced by complex software and hardware that generate digital images.

Aside from the rejection of the Full Court's proposed two-step approach by both Kiefel et al and Gordon et al, the only other certainty from the High Court's judgment is that the split decision will give rise to further debate in the years to come.

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**Maddocks** has extensive experience in strategic patent advice, freedom to operate advice and patent litigation across a number of sectors, including life sciences, pharmaceuticals and biotech, industrial manufacturing and engineering, mining, food technologies, TMT, consumer goods and gaming and leisure. The firm combines its IP expertise with market-leading healthcare and TMT practices in Australia to realise opportunities for its clients in pharmaceuticals and biologics, digital health, rapid diagnostics, personalised medicine and clinical

genomics. With offices in Sydney, Melbourne and Canberra, many of **Maddocks'** patent litigation team are dual-qualified with degrees in a number of scientific and technical disciplines. The partners and senior lawyers have strong track records of success in some of the leading recent cases in Australia before the Federal Court and High Court of Australia, including regarding biosimilars, pharmaceuticals, chemistry, biotechnology, second medical uses and medical devices.

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# AUSTRALIA TRENDS AND DEVELOPMENTS

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# Maddocks

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

The protection of rights relating to inventions in Brazil shall be assured by means of the issuance of patents for inventions (new technologies) and utility models (a new shape or arrangement in practical use objects). Patent rights, as well as other IP assets, are guaranteed by the Federal Constitution and governed by the Brazilian Industrial Property Law (Law No 9,279/96 or LPI), in accordance with applicable international treaties.

#### Invention Patents

A product or a process can be patentable as a patent for invention if (Article 8, LPI):

- it meets the requirements of novelty and inventive step; and
- it is susceptible to industrial application.

An invention patent has a protection term of 20 years from the date of filing.

#### Utility Models

An object of practical use, or a part of such an object, will be patentable as a utility model if:

- it is susceptible to industrial application;
- it presents a new shape or arrangement; and
- it involves an inventive act resulting in a functional improvement in its use or manufacture.

A utility model has a protection term of 15 years from the date of filing.

#### Ineligible Patent Subject Matter

Articles 10 and 18 of the LPI determine that the following shall not be patentable as invention or utility model:

- discoveries, scientific theories and mathematical methods;
- purely abstract concepts;
- schemes, plans, principles or methods of a commercial, accounting, financial, educational, or advertising nature;
- literary, architectural, artistic and scientific works or any aesthetic creation;
- computer programs per se;
- presentations of information;
- rules for games;
- techniques and methods for operations or surgery or therapeutic or diagnostic methods, for use on the human or animal body;
- all or part of natural living beings and biological materials found in nature, or isolated therefrom, including the genome or germ plasm of any natural living being and the natural biological process;
- anything contrary to morality, decency or public safety, order and public health;
- substances, materials, compounds, elements or products of any kind, including the modification of their respective physical-chemical properties and the respective processes for obtaining or modifying them, when they result from the transformation of the atomic nucleus; and
- living beings, whole or in part, except for transgenic micro-organisms meeting the three requirements of patentability – novelty, inventive step and industrial application – provided for in Article 8 and which are not mere discoveries.

For the purposes of the LPI, transgenic micro-organisms are organisms, except for plants or animals, whole or part, that due to direct human intervention in their genetic composition, express a characteristic that cannot be normally achieved by the species under natural conditions.

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## 1.2 Grant Procedure

Anyone seeking protection for an invention in Brazil shall apply to the Brazilian Patent and Trade Mark Office (BRPTO). The proceeding is governed by the LPI and the BRPTO's guidelines.

An invention shall be patentable if it meets the requirements of novelty, inventive step and industrial application. On the other hand, an object of practical use, or part thereof, shall be patentable as a utility model if it is intended for industrial use, presents a new shape or arrangement, and involves an inventive step, resulting in functional improvement in its use or manufacture.

## 1.3 Timeline for Grant Procedure

### Length of Grant Procedure

Currently, it takes six years on average to have a patent issued by the BRPTO. However, the length of the procedure may vary considerably according to the field of the invention. Fast-track procedures are available in several situations, including specific Patent Prosecution Highway programmes with the USPTO, JPO and other foreign patent offices.

Moreover, the average length of grant procedure has diminished since 2019, when the BRPTO established a programme to fight the backlog.

This programme foresees several actions to expedite granting procedures, including a special procedure by which the applicant can benefit from BRPTO patent searches already carried out by foreign patent offices, eliminating the need for a new search by the BRPTO. As over 80% of all patent applications filed in Brazil belong to foreign applicants that have already had their applications examined abroad, this new pro-

cedure is expected to considerably reduce the examination delay in Brazil.

According to the BRPTO, there were 149,912 patent applications filed until 2016 which benefited from the programme to fight the backlog pending examination in August 2019. By November 2022, this backlog has been reduced to 14,917 patent applications. Of the remaining patent applications, 6,550 are from the chemical field, the one with the greatest number of applications pending examination. Due to the success of the programme, the BRPTO has already started the examination of patent applications filed since 2017 in specific technical areas.

### Representation

The patent application may be filed by the inventor or the right-holder (Article 216, LPI). As per Article 217, a person domiciled abroad is required to have a duly qualified attorney domiciled in Brazil with powers to represent such a person or entity administratively and judicially – including the right to receive summons.

### Fees

Usually, the following official fees are due (bearing in mind an exchange rate of approximately USD1 = BRL5.30).

Approximately USD33 when the patent application is filed before the BRPTO (for a patent for an invention or for a utility model).

Approximately USD111 for a patent for the request for examination of an application for a patent (for a patent for an invention containing up to ten claims).

Approximately USD72 for a patent for a utility model.

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For annuities within the ordinary term, the fees are as follows.

- For a patent for an invention:
  - (a) pending application – approximately USD56;
  - (b) granted patent – depending on the age of the patent, between approximately USD147 and USD378.
- For a utility model:
  - (a) pending application – approximately USD38;
  - (b) granted patent, third to sixth year – depending on the age of the patent, between approximately USD76 and USD228.

## 1.4 Term of Each Intellectual Property Right

Patents are granted for 20 years as from the filing date and utility models are granted for 15 years as from the filing date, according to Article 40 of the LPI.

It is important to note that the automatic minimum ten-year term counted from the date of the grant, which used to protect applicants from the excessive delay caused by the BRPTO, is no longer applicable in Brazil. Such provision expressed by means of the sole paragraph of Article 40 was deemed unconstitutional by the Supreme Court in 2021.

As a reaction to the removal of the automatic minimum ten-year term safeguard, a number of owners of Brazilian patents have initiated lawsuits seeking compensation for term unjustifiably lost due to the PTO's delay. There is still no official stance of the Brazilian judiciary in regard to the admissibility of PTA lawsuits. Currently, there are a couple of complaints regarding the constitutionality of PTA suits which were brought

to the Supreme Court and are still pending decisions on the merits. A conclusive answer to these complaints should provide a clear stance either encouraging or dissuading those who wish to adjust the terms of their patents.

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

A patent shall afford its owner the following principal rights.

- Preventing others from producing, using, offering for sale, or importing for such purposes, without their consent, a product that is the subject matter of a patent or the process or product directly obtained by a patented process, as well as their respective equivalent product or process.
- Preventing third parties from contributing to anyone in carrying out the acts mentioned above.
- Licensing the right of use of the patent by third parties and transferring the ownership of the patent.
- Being indemnified for unauthorised exploitation of the subject matter of their patent, including exploitation that occurs between the date of publication of the application and the date of issue of the patent.
- Being indemnified for the damages in respect to acts that infringe industrial property rights directly, by equivalence and/or by contribution.

In return, the patent owner's obligation is to pay the annual patent fees and use the patent in a lawful manner within Brazil.

Although it is rare, some of the patentee's rights can be mitigated and additional obligations can be created, such as occurs by means of the compulsory licence (which, so far, only hap-

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pened once, since the enacting of the current statute, in 1996).

Preliminary injunctions are available to patent owners in Brazil for immediately ceasing infringement acts (paragraph 1, Article 209, LPI). Such a remedy needs to be requested from the courts, which will grant it upon assessing the existence of prima facie evidence of infringement and risk of irreparable harm.

Patent owners are not obliged to provide public information, such as patent listings or use codes, in relation to certain products or processes in Brazil. Even though it is not mandatory, public information may be available in relation to products or processes comprised of self-declared standard-essential patents (SEPs) for certain standards within the telecommunications sector. If applicable, such information will probably be available before standard-setting or standard-developing organisations (SDO), such as the Brazilian Association for Technical Standards.

## 1.6 Further Protection After Lapse of the Maximum Term

There is no further protection available. Once the patent is expired, the subject matter enters the public domain.

## 1.7 Third-Party Rights to Participate in Grant Proceedings

Third parties may oppose the granting of a patent by submitting relevant documents and information that would render the invention not patentable. This can be done:

- between the publication of the application and the end of the examination by the Patent Examiner (Article 31, LPI);
- within a period of 60 days after publication of any administrative appeal filed by the appli-

cant from a first instance decision by the Patent Examiner (Article 231, LPI); and

- in an administrative nullity proceeding, to be filed within six months counted from the grant of the patent (Article 51, LPI).

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

According to Article 212 of the LPI, any decision rendered by the BRPTO can be challenged through an administrative appeal. If the patent examiner issues a decision rejecting the patent application, it is possible to present an administrative appeal to the President of the BRPTO within a period of 60 days after the publication of the decision. If such appeal is not successful, the applicant may challenge that final decision of the BRPTO before the federal courts.

Moreover, the Brazilian legal system also permits any decision of the public administration to be discussed before the courts within a period of five years (Article 1, Decree No 20,910/1932 and Article 54, LPI). This is because administrative decisions (eg, rulings rendered by the BRPTO) are subject to judicial review. In this sense, a lawsuit against a decision rendered by the BRPTO can be filed during the pendency of the administrative proceeding, even when an administrative appeal is still pending a decision.

## 1.9 Consequences of Failure to Pay Annual Fees

According to Article 84 of the LPI, the applicant and patent owner shall be required to pay annual fees as from the beginning of the third year after the date of filing for the patent. The payment of the annual fee shall be made within the first three months of each annual period, but it may also be made, in an extraordinary term, within the following six months on payment of an additional fee.

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In the case of a failure to pay the annual fee, the application will be deemed extinct or, if already granted, the patent will be extinguished (Article 86, LPI). It is important to note that in one way or another the patent applicant/holder shall be previously notified by the BRPTO.

Regarding the measures available to remedy such consequences, note that the patent application and the patent may be restored at the request of the applicant or patent owner within three months after notification of the lapse of the patent. To obtain a patent restoration, the owner must pay a restoration fee (approximately USD83) as well as any previous fees due. If this procedure is not followed the application will not be valid.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

After being granted, the patentability of one or more claims can be reviewed by the BRPTO.

Post-grant review proceeding begins with the filing of a petition within six months after the grant of the patent. It can be instituted ex officio by the BRPTO or requested by a third party (Article 51, LPI). The BRPTO will issue a new opinion regarding the patentability of the patent and will notify the patentee and the applicant to reply within a joint 60-day term (Article 53, LPI). Then the review will be decided by the President of the BRPTO, finishing the administrative instance (Article 54, LPI). The patent does not have its effects suspended during the proceedings, meaning that the rights derived from the patent are enforceable while the post-grant review procedure is pending.

In a post-grant review, a patent can be voided on the following grounds:

- the absence of any of the statutory requirements;
- the insufficiency of the written description;
- unsupported claims;
- the extent of the scope of the application as originally filed; and
- the absence of any of the essential formalities for issuance were omitted during prosecution.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

Patent infringement in Brazil can be tackled by means of a civil and/or a criminal action.

As in Germany and many other countries, Brazil adopts a bifurcated system so that nullity and infringement are ruled on by different jurisdictions. Patent infringement actions, civil or criminal, are within the statutory authority of state courts.

In general, these lawsuits must be filed before the court of the place where the defendant has their main business or where the infringement happened, provided that other civil procedure rules are observed.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

The main remedies available for third parties to remove the effects of intellectual property rights are post-grant review proceedings, nullity lawsuits and compulsory licences. In addition, the nullity of a patent can also be argued as a means of defence in the dockets of an infringement lawsuit (paragraph 1, Article 56, LPI).



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## Nullity Lawsuit

The annulment of a patent can also be sought before the Federal Trial Courts (under the same grounds as a post-grant review – see **1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights**) and the BRPTO's participation is mandatory (Articles 56 and 57, LPI). The judicial nullity action can be filed at any time during the term of a patent by the BRPTO or any legitimately interested party.

After the filing of the lawsuit, the BRPTO is summoned to answer the initial complaint and can either maintain its opinion on the validity of the patent claims or review its opinion by agreeing with the nullity.

### *Nullity argument in infringement lawsuit dockets*

Paragraph 1, Article 56 of the LPI states that the nullity of a patent can be argued at any time as a matter of defence in an infringement lawsuit. The eventual removal of the effects of the patent rights ordered by a state judge in an infringement lawsuit are restricted to the parties involved in the infringement proceeding (inter partes effects). Although Brazilian courts are not unanimous regarding the acceptance of nullity as a means of defence in infringement lawsuits, there is no binding precedent on this issue. In this sense, case law remains inconclusive – the Superior Court of Justice, for instance, has issued rulings both for and against this possibility. That said, it is still a mechanism available to (temporarily) remove the effects of patent rights.

## Compulsory Licences

Compulsory licence is a mechanism which allows the use of patent rights without the consent of their owner. It is governed by Articles 68–74 of the LPI.

A patentee will be subject to having their patent licensed compulsorily if they exercise the rights resulting therefrom in an abusive manner or by means of abuse of economic power that is proven under the terms of the law by an administrative or court decision. The following situations may also result in a compulsory licence:

- non-exploitation of the subject matter of the patent in Brazil, unless local manufacture of the product is proven to not be economically feasible;
- commercialisation that does not meet the market's demand;
- when the use of a patent depends on licensing another patent, the subject matter of the dependent patent characterises substantial progress from the prior art and no agreement is reached between patent holder and licensee; and
- national emergency and protection of public interest.

Conversely, no compulsory licence shall be granted when the patent owner is able to demonstrate that:

- the lack of use of the invention in Brazil occurred for legitimate reasons;
- there have been serious and effective efforts to prepare for use; or
- the lack of manufacture or commercialisation occurred due to a legal obstacle.

## 2.3 Courts With Jurisdiction Bifurcated System

Brazil adopts a bifurcated patent litigation system. Patent infringement lawsuits fall within state jurisdiction, while nullity actions must be heard by federal courts (due to the mandatory presence of the BRPTO). Both the state and federal courts have trial and appellate levels.

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There are 27 state courts in Brazil (one for each of the 26 states and another for the Federal District) and the State Court of São Paulo is responsible for most of the complex infringement and contractual litigations involving patents. The Federal Court of Appeals for the 2nd Circuit, located in Rio de Janeiro, is the most relevant of the five federal courts in terms of patent litigations involving the BRPTO.

The Superior Court of Justice (STJ) has nationwide jurisdiction and hears challenges addressing violation of the federal laws (eg, the LPI) from the State Court of Appeals and the Federal Court of Appeals.

The Supreme Court of Justice (STF) is the highest court in Brazil and has jurisdiction over patent cases where they concern constitutional matters.

Therefore, the courts with jurisdiction over patent litigation are:

- at first level, the trial court (state or federal);
- at second level, the Court of Appeals (state or federal); and
- at the highest levels, the Superior Court of Justice (STJ) and the Supreme Court of Justice (STF).

## Specialised IP Courts

Although it is not a rule across the country, the courts that hear most patent cases do so using judges/panels specialised in IP to preside over IP cases.

The Federal Court of Appeals for the 2nd Circuit (TRF2) has two specialised panels with three appellate judges, each of which presides over IP cases. At the federal lower courts, four

courts are responsible solely for IP and pension law cases.

Regarding specialisation within the state courts, the Sao Paulo State Court of Appeals has one of the most technical bodies of experts in IP matters, counting eight specialised business courts at the trial level (two in the central region and six in other administrative regions) and two business courts of appeals. On the other hand, the State Court of Appeals of Rio de Janeiro has just started the process of having a chamber specialised in IP. The Court has nominated the first three appellate judges to take part in the specialised chamber amongst the 180 appellate judges acting at the Court. At the trial level, IP cases are heard by seven courts specialised in business matters.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

Although the Brazilian Civil Procedure Code (Law No 13,105/2015) encourages parties to settle, and provides that judges, attorneys and other stakeholders shall stimulate ADR proceedings, there is no specialised body in ADR for IP matters within the courts.

The most prominent and the only specialised chamber for dispute resolution in Brazil regarding IP matters (including domain name conflicts), named CSD-PI, is managed by the Brazilian Association of Intellectual Property (ABPI) – the Brazilian branch of AIPPI.

## 2.5 Prerequisites to Filing a Lawsuit

Patent infringement lawsuits in Brazil can be filed in compliance with the Brazilian Civil Procedure Code and there are no prerequisites (eg, previous negotiations between the parties) to filing a patent lawsuit. However, warning letters are usually issued by right-holders and are impor-

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tant to define the date on which the offender was informed of the violation for indemnification purposes in a future lawsuit.

## 2.6 Legal Representation

Parties in intellectual property matters must be represented by a lawyer. The parties cannot act as plaintiffs or defendants before Brazilian courts without a lawyer.

Foreign companies can sue in Brazil with or without headquarters in the country as long as they are represented by a Brazilian attorney with powers to do so.

## 2.7 Interim Injunctions

Interim injunctions are available. An interim injunction may be granted by the judge when there is prima facie evidence of infringement and risk of irreparable harm (Article 300, Brazilian Civil Procedure Code and paragraph 1, Article 209, LPI).

The judge must also weigh up the hardship caused by the decision granting the injunction, as opposed to the hardship caused by not granting it. The plaintiff may be required to provide a bond or a fiduciary guarantee if the judge deems it necessary.

If an interim injunction is eventually revoked, the plaintiff will be liable for damages possibly supported by the defendant due to the injunction (item III, Article 302, Brazilian Civil Procedure Code). The damages shall be sought in a separate lawsuit filed by the defendant.

## 2.8 Protection for Potential Opponents

A potential defendant may appeal against an interim injunction. It is also possible to require a bond to be posted by the patent owner; how-

ever, it is up to the judge to determine whether the party should submit a bond and its value.

Additionally, according to the Brazilian Civil Procedure Code, the party that requests the injunction is responsible for any injury that the enforcement of the injunction causes the other party.

Alternative steps that may be taken by the potential opponent are to:

- file a non-infringement declaratory action, aimed at obtaining a court decision attesting that there is no infringement; or
- file a separate patent annulment lawsuit before the federal courts, aimed at obtaining a court decision attesting that the patent is null or suspending the effects of the patent at least between the involved parties.

## 2.9 Special Limitation Provisions

According to Article 225 of the LPI, proceedings for damages suffered due to the violation of industrial property rights may not be brought before the courts after five years, while the usual deadline for a legal action on the terms of the Brazilian Civil Code is ten years.

Actions against the BRPTO in general need to be filed within five years as set forth by Article 1 of Decree 20,910/32.

## 2.10 Mechanisms to Obtain Evidence and Information

The Brazilian Civil Procedure Code provides for an early production of evidence procedure, by which the interested party can ask the court to determine the search and seizure of relevant documents as well as the infringing products. Such proceedings may also be used to seek a technical opinion from the court-appointed expert to prove the infringement, or even to

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hear witnesses. The pieces of evidence collected under this proceeding may be used in future lawsuits, if convenient.

During the course of an infringement lawsuit, besides the evidence brought by the parties, the judge shall appoint a court expert to work with the technical assistants named by the parties in order to produce an unbiased technical opinion to provide the judge with the technical grounds for deciding the case.

There are no discovery proceedings in Brazil.

## 2.11 Initial Pleading Standards

There are no special provisions for lawsuits in intellectual property proceedings. The same pleading standards as in other civil litigation apply.

Concerning infringement lawsuits and bearing in mind that a request for an *ex parte* preliminary injunction is sought, it is essential that the plaintiff presents robust evidence of infringement. In this sense, technical and legal opinions from the most prominent Brazilian and international experts are key.

## 2.12 Representative or Collective Action

The Brazilian legal system permits class actions for patent proceedings in certain situations. If damage is caused to the public as a whole or to the honour or dignity of a racial, ethnic or religious group, a civil action may be filed by public prosecutors or by any public group that is affected (Law No 7,347/85). The decision in this civil action will bind everyone, unless the decision is to dismiss the action on grounds of lack of proof, in which case anyone can file an individual complaint. In the last 20 years, there have been several important civil actions filed by ABPI (the Brazilian Association of Intellectual

Property) and ABAPI (the Brazilian Association of Intellectual Property Attorneys) regarding the interpretation of several aspects of IP Law and also challenging acts of the BRPTO.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

Article 45 of the LPI establishes that a person who in good faith benefited from the patent within Brazil, prior to the filing or priority date of a patent application, shall be entitled to continue receiving such benefits under the same form and conditions, without incurring liability. Thus, the owner of the patent cannot prohibit the use of the patent by a third party acting in good faith.

In addition, Article 43 of the LPI establishes certain acts and circumstances that the patent owner cannot oppose.

- Acts carried out privately and with no commercial purpose by unauthorised third parties, provided that these acts do not prejudice the economic interests of the patent owner.
- Acts carried out by unauthorised third parties for experimental purposes, if related to studies or scientific or technological research.
- The preparation of a medicine in accordance with a medical prescription in individual cases, and carried out by a qualified professional, or the medicine thus prepared.
- A product manufactured in accordance with a process or product patent that has been placed on the internal market directly by the patent holder or with his or her consent.
- Other persons who, in the case of patents related to living matter, use the patented product, without economic purpose, as an initial source of variation or propagation to obtain other products.
- Other persons who, in case of patents related to living matter, use, place in circulation, or

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market a patented product that has been lawfully placed on the market by the owner of the patent or their licensee, provided that the patented product is not used for commercial multiplication or propagation of the living matter concerned.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

The plaintiff can be the owner of the intellectual property or the licensee when the patent licence agreement expressly foresees it and if the agreement is recorded by the BRPTO. In such cases, the defendant is the alleged infringer.

### 3.2 Direct and Indirect Infringement

Direct infringement occurs when all the elements of a patent claim granted by the BRPTO are violated and an indirect infringement occurs when, although not all the elements of the claims of the patent are literally infringed, the offender uses equivalent means to the subject matter of the patent.

Although Article 186 of the LPI sets forth that a crime against a patent of invention is committed even if the violation does not affect all the claims of the patent or if it is restricted to the use of “means equivalent” to the subject matter of the patent, the statute does not define what such means would be. In this sense, the parties shall rely on case law and the work of legal scholars to prove the (non)violation by equivalence.

### 3.3 Process Patents

According to Article 42 of the LPI, a patent confers on its owner the right to prevent third parties from manufacturing, using, offering for sale, selling, or importing for such purposes a process or

product directly obtained by a patented process or from contributing to the practice of these acts by other parties, without their consent. Therefore, a process patent infringement occurs when a third party uses means or processes that are the subject matter of a patent of invention, without the authorisation of the patentee.

In a process patent infringement lawsuit, the burden of proof can be shifted by the trial judge to the accused party, which will be required to prove that the process used to obtain a certain product owned or held by them is different from that protected by the patent (paragraph 2, Article 42, LPI and paragraph 1, Article 373, Brazilian Civil Procedure Code).

### 3.4 Scope of Protection for an Intellectual Property Right

The scope of protection of a patent is determined by the claims as granted by the BRPTO, and it is interpreted in accordance with the state of the art at the date of filing, and with the history of the prosecution of the application.

### 3.5 Defences Against Infringement

Apart from the non-infringement of the patent, other usual defences against patent infringement include:

- prior use;
- experimental use;
- nullity of the patent; and
- abuse of dominant position/failure in the obligation to offer fair, reasonable and non-discriminatory (FRAND) licensing opportunities related to SEPs and patent exhaustion.

### 3.6 Role of Experts

As prescribed by Article 156 of the Civil Procedure Code, judges shall be assisted by experts

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whenever the facts depend on technical or scientific knowledge.

Experts can be appointed by the court or be appointed consensually by the parties. It is also possible that more than one unbiased expert is appointed specially when the patent in question involves multiple fields of knowledge.

The court expert will be required to provide the judge with a full report with their opinion on any questions raised by the parties (and allowed by the judge), as well as on questions possibly raised by the judge. After the judge nominates the court expert the parties shall indicate their own technical assistants, who will co-operate with the court expert.

Although judges are not obliged to follow an expert's opinions when ruling on cases, courts tend to rely on technical opinions, which play an important role in patent infringement actions.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

In Brazil, there is no separate phase or procedure to construe the claims. Instead, it is up to the court and the court-appointed expert to determine which is reasonably within the scope of the patent protection.

As set forth by Article 41 of the LPI, the scope of the protection conferred by the patent shall be determined by the content of the claims and will be construed based on the specifications and drawings.

In Brazil, claims must be worded using the connective "characterised by". All features following "characterised by" are within the patent scope. When there is any doubt on the meaning of a word used after the expression "characterised

by", the judge and/or the court-appointed expert must use the description of the patent to properly interpret the scope of the patent.

### 3.8 Procedure for Third-Party Opinions

Depending on the relevance, specificity, or wider social repercussions of a case, third parties can be heard as amici curiae in patent lawsuits. Such participation can be requested by both plaintiff and defendant, as well as by the person or entity seeking to be heard. Judges have also the power to nominate amici curiae ex officio (Article 138, Brazilian Civil Procedure Code). As a rule, amici curiae cannot appeal.

Third-party opinions can also be provided by independent experts or consultants directly to one of the parties, who will be able to file such opinions as documentary evidence, without the need of direct participation by the third party in the dispute.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

A patent may be invalidated if granted contrary to any of the provisions of the LPI, particularly if it lacks novelty, inventive step, or industrial application or does not disclose the full contents of the invention.

There are two possible ways of obtaining the declaration of nullity of a patent (see 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights and 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property):



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- by way of a post-grant review request before the BRPTO, to be filed within six months of the issuance of the patent; and
- by way of a judicial nullity action before the federal courts, to be filed at any time during the life term of the patent.

## 4.2 Partial Revocation/Cancellation

Partial revocation or cancellation is possible. According to Article 47 of the LPI, the nullity of a patent may apply to all the patent claims or to part of the claims. However, in case of a partial nullity it is necessary that the remaining claims constitute patentable subject matter themselves.

## 4.3 Amendments in Revocation/Cancellation Proceedings

Amendment is possible in revocation or cancellation proceedings, but it is unusual. According to Article 32 of the LPI, the amendments may be proposed by the applicant until the time of the request for examination of the patent application. Amendments to broaden the scope of the claims are not allowed.

## 4.4 Revocation/Cancellation and Infringement

Revocation or cancellation and infringement cases are not heard together due to the bifurcated nature of the Brazilian system (see 2.3 Courts With Jurisdiction).

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

The LPI lays out certain special procedural provisions for lawsuits in patent proceedings.

According to paragraph 2, Article 56, the judge may grant an injunction suspending the effects

of the patent if appropriate procedural requirements are met upon registration. The injunction request can be filed at any time during the litigation and it is usually decided within a short term due to its urgent nature. The injunction decision rarely requires fact witnesses; however, expert reports are commonly provided by the interested party. The decision on the injunction request is rendered by the trial judge and can be challenged through an interlocutory appeal to the Court of Appeals.

According to Article 57, annulment lawsuits shall be tried by the Brazilian Federal courts and the BRPTO is a mandatory defendant, together with the patent owner, even though it is authorised to agree with the plaintiff's claims and request that the patent be declared invalid by the judge.

According to paragraph 1, Article 57, there is a longer term (60 days, instead of the standard 15-day term) for the patent owner to submit its reply to an annulment lawsuit.

According to Article 210, the amount of damages shall be defined at a later stage (liquidation of damages phase) based on the most beneficial of the following criteria at the plaintiff's discretion:

- revenue lost by the plaintiff due to the infringement;
- revenue obtained by the defendant due to the infringement; or
- amount of a hypothetical licence agreement between the plaintiff and the defendant for the regular use of the infringed patent.

The plaintiff's choice shall be made by the beginning of the liquidation of damages phase, which is expected to last around two years after the final decision on the merits becomes *res judicata*. The liquidation of damages usually requires

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an accounting expert to assist the judge to determine the amount of damages.

## 5.2 Decision-Makers

Patent cases are heard by trial state judges or trial federal judges before the courts of first instance. Each trial court usually has one presiding judge and one auxiliary judge, and both have powers to rule over a patent case depending on the local court rules.

Due to the fact that judges, as a rule, tend to not have a technical background or IP expertise, court-appointed experts are required to provide an impartial and precise technical report. The technical report is evaluated by the trial judge, who can agree with it or not. The decisions issued by the trial judges may be challenged before state or federal courts of appeals and the superior courts, including the Supreme Court.

At the Court of Appeals the panels are comprised by at least three appellate judges who render a single opinion.

The parties shall have no influence on trial judges, state and federal courts or the superior courts. The Brazilian Civil Procedure Code provides that if the party has any personal connection with the judge, the judge must be replaced.

Regarding the nomination of judges in Brazil, it is important to note that judges at the trial level are individuals who have been approved in a public examination and can develop in their career to become appellate judges. 20% of the appellate judges shall be chosen from a three-name list formed by attorneys-at-law and public prosecutors. The President of the Republic is responsible for choosing the Justices of the Superior Court of Justice (from a three-name list provided by the Superior Court itself) and of the Supreme

Court (if approved by the Federal Senate). Justices are not required to be career judges.

## 5.3 Settling the Case

The parties may reach an agreement to settle the case at any time during the lawsuit. The negotiations can be conducted before the courts or between the parties directly. Furthermore, according to the Brazilian Civil Procedure Code, after the plaintiff files the complaint, and unless the plaintiff expressly states that there is no interest in a possible conciliation, the defendant will be summoned to appear in a preliminary conciliation hearing/conference, when the judge will try to settle the case. Conciliation hearings can be scheduled at any time by the judge *ex officio* or upon a request by the parties if a settlement agreement is feasible.

## 5.4 Other Court Proceedings

Both infringement and nullity lawsuits can be heard in parallel. Although it is not automatic or even mandatory, infringement proceedings can be stayed pending resolution of a validity or invalidity lawsuit before the federal court.

A request for a stay can be made by the parties or ordered *ex officio* by the judge. Such a decision can be challenged by means of an interlocutory appeal to the Court of Appeals. Anti-suit injunctions are not usual in Brazil and foreign anti-suit injunction decisions hardly have an influence on proceedings in Brazil, considering that Brazilian courts tend to be more open to arguments invoking the constitutional right of access to the courts and to obtain an effective legal remedy.

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## 6. Remedies

### 6.1 Remedies for the Patentee

The main remedies available for the patentee in infringement lawsuits are search and seizure orders, restraining orders and other kinds of injunctions, plus damages. In Brazil, judges can only order remedies based upon the request of the interested party. The remedies are usually enforced through sanctions, particularly fines, against non-compliant defendants.

Periodic deposits by the defendant to a bank account managed by the courts can be ordered as a form of provisional damages to assure that the execution of final damages will be successful when the litigation is over. The defendant can also be required to post a bond, which shall be updated on a regular basis.

### 6.2 Rights of Prevailing Defendants

The prevailing defendant is usually entitled to have court fees and other expenses incurred during the case reimbursed, including the court-appointed expert's fees.

### 6.3 Types of Remedies

All remedies admissible by law are available for all kinds of intellectual property rights, regardless of type.

### 6.4 Injunctions Pending Appeal

If a patent is found valid and infringed at first instance, as a rule the injunction granted is immediately enforceable and the appeal by the infringer does not automatically stay the injunction granted by the first instance.

However, staying effects can be requested from the appellate court so that the injunction will be enforced only after the appeal is tried.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

There are no special provisions concerning the appellate procedure for intellectual property right proceedings. All appeals follow the same path and procedure provided by the Civil Procedure Code.

### 7.2 Type of Review

The appeal implies a full review of the facts of the case.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

In Brazil, lawsuits are usually preceded by warning letters. A party may also take various steps to build a strong case, such as hiring an independent expert, commissioning a technical report confirming the validity of the patent and the infringement perpetrated by the opposite party or obtaining an infringement report by a court-appointed expert within an early production of evidence procedure. All these costs are paid by the interested party and are not recovered in a lawsuit, with the exception of the ones related to the early production of evidence procedure, which can be reimbursed in a regular infringement lawsuit (if the plaintiff is the winning party).

### 8.2 Calculation of Court Fees

Costs are calculated by each court, taking into consideration procedural expenses and other mandatory fees, which also vary by type of action (eg, a nullity lawsuit or an infringement lawsuit). Court fees, even though they might be different in each state, are usually low, and seldom exceed USD2,000. Fees for the court-appointed expert are usually around USD25,000.

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## 8.3 Responsibility for Paying the Costs of Litigation

Regarding court fees and expenses for patent litigation in Brazil, the losing party is responsible for reimbursing the winner for all the disbursed expenses incurred in the course of the lawsuit by the winning party, as well as for paying an additional amount as attorneys' fees for the attorneys of the winning party. In the case of a mixed result (ie, if both parties win in different and equally relevant aspects of the dispute), such litigation costs (with the exception of the attorneys' fees) shall be divided between them. If the losing party wins in a less relevant aspect, it shall still be responsible for all the court fees and expenses.

In Brazil, contractual attorneys' fees are not reimbursed by the losing party.

If the plaintiff is a foreign plaintiff, they may be ordered to post a bond in Brazilian currency before the court to secure the payment of judicial expenses. This bond is usually set in the amount of 20% of the value given to the lawsuit. However, if the plaintiff is successful, this bond is returned and duly adjusted according to the official inflation rates in Brazil.

According to item I, paragraph 1, Article 83 of the Brazilian Civil Procedure Code, the bond shall not be required when there is a waiver provided by any agreement or international treaty to which Brazil is signatory.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

Alternative dispute resolution (ADR) is not commonly used to settle patent cases or even intellectual property cases.

Mediation is only now slowly starting to become more popular in several areas of law in Brazil. Since Brazilian law is based on civil law, legal professionals have lacked a statutory basis for mediation, despite the obvious fact that mediation may be solely based on contract law. A Mediation Act was passed as Law No 13,140 of 26 June 2015. Nevertheless, in practical terms, mediation is still not being used to solve patent disputes.

Arbitration is also not commonly used in patent disputes, despite the significant adoption of arbitration in other areas of law in Brazil. Brazil's Arbitration Act was enacted through Law No 9,307 of 23 September 1996, and the past two decades have seen a significant increase in the use of mediation in Brazil.

The Brazilian Civil Procedure Code establishes a mandatory conciliation pre-dispute phase before the defendant has even presented their defence.

### Domain Name Disputes

ADR is commonly used for domain name disputes, as Brazil has an administrative domain name resolution system (commonly known by its acronym in Portuguese, SACI) that is based on ICANN's Uniform Domain-Name Dispute-Resolution Policy (UDRP) but incorporates several other causes for action, and a complaint under SACI may be based not only on trade mark rights (as is the case with the UDRP), but also on other intellectual property rights.

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## Litigation

As for the use of ADR in litigation, one must differentiate between invalidity and infringement lawsuits. Invalidity lawsuits must be filed before the federal courts, where ADR is not allowed because the BRPTO understands that only a court of law may decide on the validity of rights. Infringement lawsuits must be filed before the state courts and are disputes between private parties that may be negotiated freely.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

According to Articles 58–60 of the LPI, a patent application or a patent may be assigned in whole or in part.

Regarding patents, the BRPTO will make the following recordals (entries to the patents database):

- assignment, mentioning the complete qualification of the assignee;
- any limitation or onus applied to the application or patent; and
- changes of name, headquarters or address of the applicant or patentee.

The recordals will produce effects regarding third parties as from the date of their publication in the Official Gazette.

It is important to note that the assignment between a foreign company and a Brazilian company, when onerous, must be recorded by the BRPTO to obtain the corresponding certificate, otherwise the Central Bank of Brazil will

not authorise the payment of royalties of remittances abroad.

For assignment recordals, the following documents are required by the BRPTO.

- A transfer petition, completed with the data of the assignee.
- Proof of payment of the governmental fee.
- The assignment document, which should contain:
  - (a) the complete qualification of the assignor and the assignee;
  - (b) the powers of representation of the signatories of the assignment document and their signatures (the representatives' signatures need to be notarised by the Notary Public and the signature of the Notary Public then needs to be legalised by apostille or by the Brazilian Consulate); and
  - (c) the application number or the number of the patent and the date on which the assignment document was signed.
- The Power of Attorney of the assignee.
- A sworn translation into Portuguese of documents that were created in a foreign language.

### 10.2 Procedure for Assigning an Intellectual Property Right

Once the BRPTO has reviewed the relevant documents in accordance with the requirements discussed in **10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights**, providing that they are all in order, the notice of assignment is published on the Official Gazette and the certificate of assignment is then issued.

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## 10.3 Requirements or Restrictions to License an Intellectual Property Right Licence Recordal

It is important to mention that in Brazil a patent owner or applicant may execute an exclusive or non-exclusive licensing contract for exploitation with a third party. To be enforceable against third parties the licence agreement must be recorded at the BRPTO.

The recordal of a patent licence agreement by the BRPTO is mandatory for the following purposes:

- to obtain presumption of knowledge of the contract by third parties (Article 62, LPI);
- to authorise, when the agreement expressly allows it, the licensee to act by themselves before Brazilian courts in defence of the licensed patent; and
- to allow royalty payments to be deductible for withholding income tax purposes.

As of 1 January 2023, as a result of the liberalisation of foreign exchange controls in Brazil (a part of the country's effort to be accepted as a full member of the OECD), the recordal of the licence agreement with the BRPTO is no longer required for the remittance of royalties abroad to be allowed.

Note that, in general, freedom to contract prevails, but the BRPTO may provide some limitations as follows.

- The BRPTO only authorises the tax-deductibility of royalty payments for a granted patent, not for pending applications.
- There are limits for the tax deductions of the remittance of payments among companies that have a controlling shareholder relationship; in that case, besides taking into

consideration the usual rates of the market, the deductibility ceilings established by Ordinance of Treasury Ministry 436/1958 (between 1% and 5% of the net sales made by the licensee) should be observed.

- Usually, a patent licence agreement will be in force in accordance with the periods of validity of the licensed patents (20 years as from the filing date of the patent application).

Regarding improvements, the LPI determines that an improvement made to a licensed patent shall belong to the party who made it and the other contracting party shall be afforded a preferential right to acquire a licence.

### Documentation Requirements

For the licence recordal, the licence agreement notarised and legalised (by apostille or with the Brazilian Consulate) must be submitted to the BRPTO, along with other forms. The licence agreement must comply with some bureaucratic requirements as well.

### Compulsory Licensing

Finally, it is important to mention that patents may be subject to compulsory licences. Article 68 of the LPI determines that the patent owner shall be subject to compulsory licensing of their patent if they exercise their rights in the patent in an abusive manner, or if they use it to abuse economic power according to the law in force, under the terms of an administrative or judicial decision.

The following may also be grounds for a compulsory licensing request.

- Failure to exploit the subject matter of the patent within Brazilian territory or failure to manufacture or complete manufacturing of the product, or failure to fully use a patented



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process, except in case of economic non-viability, in which case imports shall be admitted.

- Commercialisation that does not satisfy market demand.

This compulsory licence may be requested only by a party possessing a legitimate interest and having the technical and economic ability to effectively use the subject matter of the patent predominantly for the purposes of the internal market, in which case the exception above, to do with economic non-viability, shall not apply.

## 10.4 Procedure for Licensing an Intellectual Property Right

After execution by the parties and two witnesses, the notarised and legalised or apostilled licensed agreement must be submitted to the BRPTO for recordal purposes. Such Office conducts a review of the agreement terms and, upon acceptance, issues a certificate of recordal to the licensee, enabling the licensee to pay royalties (if this is the case). Subsequently, a very short extract with basic information about the contract is published in the BRPTO's Official Gazette but the contract itself remains confidential and, as a general rule, the BRPTO does not furnish copies to third parties.

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Kasznar Leonardos provides tailored solutions to the most complex IP issues, both nationally and internationally, with a deep understanding of different cultures and business industries. Specialised in the management of intellectual assets, the multidisciplinary team has 21 partners and over 260 associates and employees, including skilled attorneys and technical experts from several fields, with correspondents in every state of Brazil and a broad international network. It acts as legal adviser on contractual matters, as an industrial property agent with the

Brazilian Patent and Trade Mark Office (BRPTO), and its lawyers, arbitrators and mediators act in litigation and extrajudicial dispute resolution. The firm's main areas of practice are patent, trade mark, trade dress, unfair competition, industrial designs, regulatory law, life sciences, digital law, marketing and entertainment law, sports law, biodiversity, copyright, technology transfer, geographical indication, trade secrets, franchising and licensing, fashion law, licence compliance and anti-piracy.

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

In Canada, patents protect inventions as set out in the Patent Act. Canada also has industrial designs which are analogous to design patents in the USA for the protection of aesthetic features as set out in the Industrial Design Act. For inventions and know-how that are kept confidential, trade secret protection may be available.

### 1.2 Grant Procedure

To obtain a patent, a patent application is filed, reviewed by the Canadian Intellectual Property Office, and if substantive and formality requirements are met, granted. A patent application must contain a description of the invention and its utility along with any figures, and claims setting out the scope of the claimed invention. After the application is filed along with identification of the applicant and inventors and the required fees, substantive examination must be requested within four years of the filing date. An examiner at the Patent Office may raise objections such as to the novelty and inventiveness of the claimed invention. If all objections are overcome, the application is allowed, and upon paying an issue fee, granted. Procedures of the Patent Co-operation Treaty (PCT) may be used to enter national phase in Canada.

Industrial designs follow a similar process but the applications only require figures showing the appearance of the claimed design and a brief description. Procedures of the Hague Agreement may be used to enter national phase in Canada.

Trade secrets do not have an application/registration process but arise under the common law if information has commercial value due to

its confidential nature. A trade secret may be maintained indefinitely if it is kept confidential including using physical, technological and legal means. Trade secret protection may be lost if the information becomes known.

### 1.3 Timeline for Grant Procedure

For patents, it typically takes two to three years from requesting examination for a patent application to be allowed by the Patent Office. Requesting examination may be deferred by up to four years from the filing date. Examination may be expedited upon request by paying a fee or under certain conditions, such as under the patent prosecution highway where similar claims have already been allowed in another jurisdiction. If the patent examiner issues multiple office actions or a final rejection is appealed, the process may take significantly longer. Retaining a Canadian patent agent is recommended although not required if:

- the inventor(s) is the applicant;
- for the formality of filing a patent application; and
- for paying annual maintenance fees.

The minimum government fees for filing, requesting examination and paying the final fee is currently about CAD1,600 although discounts may be available for small entities and if the Canadian Patent Office was the International Search Authority (ISA) for the PCT application. Legal/agent fees, annual maintenance fees, late fees and formality fees will be extra.

### 1.4 Term of Each Intellectual Property Right

In Canada, patents have a term of 20 years from the filing date or international filing date for applications that entered national phase.



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## Certificate of Supplementary Protection

For patents pertaining to a medicinal ingredient or a combination of medicinal ingredients approved for sale in Canada, a patentee may obtain a Certificate of Supplementary Protection (CSP) which can provide for up to two years of additional patent protection where there are delays in the regulatory approval for a drug.

## Patent Term Adjustment

Canada does not have patent term adjustment for prosecution delays but it has committed to implementing a form of term adjustment by 2025 for applications filed on or after 1 December 2020 under the Canada-United States-Mexico Agreement (CUSMA).

## Industrial Designs

The term for industrial designs is the later of 10 years from the date of registration or 15 years from the filing date.

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

The owner of a patent must pay annual maintenance fees for the life of the patent to maintain the rights.

There is no marking requirement in Canada.

For pharmaceutical patents, patents may be listed on the Patent Register maintained by Health Canada for approved pharmaceutical medicines which are used for Canada's patent/drug linkage system. In addition, there are certain pricing reporting requirements for patented medicines under jurisdiction of the Patented Medicines Prices Review Board.

It is possible for the government or a third party to bring an application before the Commissioner of Patents to seek a remedy, including licens-

ing at a determined royalty rate, if there has been an abuse of exclusive patents rights such as not meeting demand on reasonable terms. Such applications are exceedingly rare.

## 1.6 Further Protection After Lapse of the Maximum Term

After 20 years from the filing date, patent rights expire except if the owner has obtained a CSP which may provide up to two years of additional protection (see 1.4 Term of Each Intellectual Property Right).

## 1.7 Third-Party Rights to Participate in Grant Proceedings

There are two ways that a third party may interact with the grant process of a patent.

- Prior to or during examination before the Patent Office, a third party may submit prior art or a protest to the Patent Office. The materials submitted are provided to the examiner reviewing the application and the examiner may disregard or incorporate the protest into an objection. The patent applicant may then address the examiner's objection as they would in the normal course. Once a third party submits the protest, they have no further role in the process, except by filing a further protest.
- After a patent has been granted, a third party may request re-examination of the patent by making a request based on printed publications, including prior art patents. A re-examination board will decide if there is a substantial new question of patentability, and if so, notify the patentee and allow the patentee to respond including by proposing amendments to the patent. The re-examination board may cancel any claims, confirm its patentability or incorporate any amendments. Re-examina-

tion of a patent subject to litigation does not typically stay the litigation.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

If a patent examiner issues a final action rejecting a patent application, the applicant may pursue the application before the Patent Appeal Board, which considers the arguments of the applicant, including at an oral hearing. The Patent Appeal Board may uphold the rejection, allow the patent application, or incorporate any necessary amendments proposed by the applicant. An applicant that is unsuccessful at the Patent Appeal Board may further appeal the rejection of the patent application to the Federal Court.

## 1.9 Consequences of Failure to Pay Annual Fees

Annual maintenance fees are required by each anniversary of the filing date starting from the second anniversary. These maintenance fees may be paid by the agent handling the patent/application or by a third party such as an annuity service. Failure to pay a maintenance will result in a notice from the Patent Office fixing a deadline for paying both the missed fee and a late fee penalty of CAD150 at the later of six months after the deadline or two months after the notice. If the maintenance fee is not paid within this late fee period, the patent/application may be reinstated within one year of the due date by requesting reinstatement with a reinstatement fee and persuading the Patent Office that due care was taken to pay the fee in a timely way. Certain third-party rights may be available during the period the patent was considered abandoned prior to reinstatement.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

After a patent has been granted, there are limited procedures available to make amendments.

### Corrections

Obvious corrections in the specification or drawings may be made with the Patent Office within 12 months of the issuance of the patent. Similarly, errors made by the Patent Office may be corrected upon request during this 12-month period.

### Re-examination

A patentee may request re-examination of its own patent using the same procedure available to third parties by submitting a request for re-examination based on prior art printed documents. The re-examination board may permit amendments to address any substantial new question of patentability identified by the board. Conversely, the re-examination board may cancel claims and not accept the amendments proposed by the patentee.

### Disclaimer

A patentee may file a disclaimer along with a fee where, by “mistake, accident or inadvertence”, the patent is considered too broad. The patentee may disclaim parts of the patent including by providing amended claims. Note that if the disclaimer is later found improper, then the pre-disclaimed claims may also be found invalid based on the admission by the patentee that the claims are too broad.

### Re-issue

A patentee may request re-issue of a patent where, due to mistake, accident or inadvertence, the patent claims more or less than the patentee had a right to claim. This request may be made within four years of the grant of the patent.

Corrections or amendments to the inventors or applicants may be made post-grant by way of application to the Federal Court.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

In Canada, the most common proceeding to assert patent rights is a patent infringement action initiated in the Federal Court, which has jurisdiction over patent matters pursuant to the Patent Act and the Federal Courts Act.

The superior courts of each province or territory also have concurrent jurisdiction over patent matters, with the exception of in rem impeachment or invalidity of a patent pursuant to Section 60 of the Patent Act, which is exclusively within the jurisdiction of the Federal Court.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

The validity of a patent can be challenged either as a defence to patent infringement or as an action or counterclaim to impeach the patent. A declaration of non-infringement of a patent may also be sought as an action on its own, or as a defence to an action for patent infringement.

When invalidity is pleaded either as an action or counterclaim to impeach the patent in the Federal Court, which has exclusive jurisdiction to invalidate a patent pursuant to Section 60 of the Patent Act, a successful decision renders the patent invalid in rem. If the validity of the patent is challenged in provincial or territorial court or only as a defence (as opposed to a counterclaim) in the Federal Court, the decision only applies in personam.

### 2.3 Courts With Jurisdiction

Any patent infringement action or impeachment action may be brought before the Federal Court for adjudication. The Federal Court has jurisdiction across Canada and is the venue for the vast majority of patent infringement actions. Decisions of the Federal Court can be appealed as of right to the Federal Court of Appeal, which has jurisdiction pursuant to the Federal Courts Act to hear appeals from the Federal Court and certain tribunals.

Patent infringement matters can also be commenced in the superior courts of a province or territory, particularly where the alleged infringement is restricted to one province. There is generally a right of appeal to the Court of Appeal of that province or territory.

From the Federal Court of Appeal or a provincial or territorial Court of Appeal, an appeal can be taken to the Supreme Court of Canada, but only with leave.

### 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

There are no specialised bodies or organisations for the resolution of patent infringement disputes in Canada. However, the Federal Court being the venue for the vast majority of patent infringement actions has developed significant expertise in adjudicating patent disputes. Several presiding judges of the Federal Court previously practised as patent litigators before being appointed to the Court.

### 2.5 Prerequisites to Filing a Lawsuit

There are no prerequisites to filing a patent infringement lawsuit in Canada. A warning or demand letter requesting that the alleged infringer cease and desist is not mandatory before asserting a patent in court proceedings,

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although a demand letter may be considered when assessing pre-judgment interest if successful.

To bring an action to impeach a patent pursuant to Section 60 of the Patent Act, a plaintiff must first establish that it is an “interested person”. This is commonly met when the plaintiff is able to establish that it is a competitor or dealing in similar products or processes to those disclosed in the patent. Similarly, when a statement of claim is filed to impeach a patent pursuant to Section 60 of the Patent Act, security for costs must be filed at the time of issuance of the claim. The purpose of the security for costs is to deter frivolous or unfounded attacks on a patent.

## 2.6 Legal Representation

A person is generally entitled to represent themselves in any matter before the Federal Court, as well as in any intellectual property proceeding before a provincial or territorial superior court. However, the courts recognise that patent infringement cases are inherently complex and, in some circumstances, have required unsophisticated self-represented patentees to obtain legal representation for their cases to proceed.

Corporations, partnerships or other unincorporated parties must be represented by a lawyer unless leave of the court is obtained.

## 2.7 Interim Injunctions

Interim injunctions are available in certain circumstances, even *ex parte*, for a period not exceeding 14 days, after which an interlocutory injunction will be required. To obtain an interim injunction, the court must be satisfied that the matter is urgent, and the three-part test of *American Cyanamid Co. v Ethicon Ltd.*, [1975] AC 396 (UKHL) is satisfied, namely the applicant must show:

- a serious question to be tried;
- that it will suffer irreparable harm if the relief is not granted; and
- that the balance of convenience lies in its favour.

For an interlocutory injunction, the same three-part test from *American Cyanamid* must be satisfied.

Interim and interlocutory injunctions have historically been difficult to obtain in the Federal Court of Canada in patent disputes. The Court has been hesitant to find irreparable harm where a party can be fully compensated through a damages award.

## 2.8 Protection for Potential Opponents

Security for costs can be sought by any party to an action, including a party that brings a counterclaim or third-party claim, pursuant to Rule 415 of the Federal Courts Rules. The Rules provide for certain circumstances when security for costs is more frequently sought, including for (i) a plaintiff resident outside of Canada; or (ii) when a plaintiff is a corporation, unincorporated or a nominal plaintiff and there is reason to believe that the plaintiff would have insufficient assets in Canada available to pay the costs of the defendant if so ordered to do so.

The entitlement to security for costs is not automatic and resides within the discretion of the Federal Court. The burden rests with the party seeking security to prove that the other party falls within one of the scenarios prescribed by Rule 416.

## 2.9 Special Limitation Provisions

To recover monetary remedies, an infringement action must be brought within six years of the act of infringement, pursuant to Section 55.01 of the

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Patent Act. For ongoing infringement, the practical implication of this limitation period is that recovery for acts of infringement that occurred before the six-year period will be barred.

## 2.10 Mechanisms to Obtain Evidence and Information

The discovery process in an action for patent infringement or impeachment is the mechanism by which a party can obtain relevant information and evidence from the other party or a third party.

For documentary discovery, each party to a lawsuit is obligated to list all relevant documents that are in the possession, power or control, and for which no privilege is claimed, in an affidavit of documents. In the Federal Court, a “relevant document” is considered to be any document on which the party intends to rely or that adversely affects the party’s case or supports another party’s case. There is a continuing obligation on all parties to disclose additional relevant documents upon becoming aware of their existence in the course of the litigation.

Examinations for discovery take place after the parties have exchanged affidavits of documents and after the pleadings have closed. In most cases, only a single representative for each party is examined, who has a duty before the examination to inform themselves with respect to any matter in question in the action. The person being examined must answer any relevant question, with a “relevant question” being a question relating to any unadmitted allegation of fact in a pleading or that concerns the identity of a person who might have knowledge related to a matter in question in the action.

The adverse party has the right, at its discretion, to examine for discovery any assignor of a pat-

ent, including an inventor of the patent in suit. If the inventor is later called as a witness, this transcript can be used to impeach the witness in cross-examinations, as appropriate, but cannot be filed as evidence at trial without leave of the court.

A party may rely on any part of its examination for discovery of an adverse party as its own evidence at trial by reading into evidence portions of the transcript of an examination for discovery. The party being examined may not rely on the transcript, except to introduce into evidence related portions those introduced by the examining party, as allowed by the Court. Only the examination for discovery of another party to the lawsuit can be relied on by an opposing party as the Federal Courts Rules to not authorise entering into evidence the transcript from the examination of a non-party or an assignor (eg, an inventor of a patent).

## 2.11 Initial Pleading Standards

A patent infringement action in the Federal Court is commenced by way of a statement of claim. In its claim, the plaintiff must allege material facts to enable the defendant and the Court to understand the grounds of the action. As part of this obligation to allege material facts, the plaintiff must set out in the pleading its interest in the patent(s) being asserted, for example as the patentee, assignee or licensee of the asserted rights. A licensee may commence a patent infringement action on its own, but the patentee must be a party to such an action as a co-plaintiff.

The plaintiff must also plead material facts related to the alleged acts of infringement by the defendant. These acts of infringement must be specifically pleaded to set out the relevant facts that give rise to the claim of infringement,

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ie, how the defendant has allegedly infringed the plaintiff's patent.

A party must provide adequate particulars of each allegation or claim in the pleading. When the particulars provided in a pleading are deemed inadequate, the other party may seek and obtain particulars at any time during the proceeding. If needed, an order for further particulars can be sought from the Court by way of motion.

Pleadings may be amended at any time during a proceeding, although some amendments will require leave of the court. A party may amend its pleading without leave if the other side has not yet pleaded over or otherwise on consent.

## 2.12 Representative or Collective Action

In general, any claim seeking representative or collective redress can be filed as a class action in Canada. In other words, there is no category of claims that has been held to be per se inappropriate for class action litigation by the courts. However, class actions in the context of patent rights have been rarely pursued, if ever, in Canada.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

Patent misuse or abuse is addressed in the Patent Act, which provides a broad definition and provides for an administrative summary procedure before the Commissioner of Patents to address such misconduct. There are four circumstances deemed to constitute abuse of a patent:

- if the demand for the patented article in Canada is not being met to an adequate extent or on reasonable terms;
- if, by reason of the refusal of the patentee to grant a licence or licences on reasonable

terms, the trade, industry, or the trade of any person or class of persons trading in Canada is prejudiced, and it is in the public interest that a licence or licences should be granted;

- if any trade or industry in Canada, or any person or class of persons engaged therein, is unfairly prejudiced by the conditions attached by the patentee to the purchase, hire, licence or use of the patented article or to the using or working of the patented process; or
- if it is shown that the existence of the patent, being a patent for an invention relating to a process involving the use of materials not protected by the patent or for an invention relating to a substance produced by such a process, has been utilised by the patentee so as unfairly to prejudice in Canada the manufacture, use or sale of any materials.

As this suggests, the circumstances that constitute abuse may include a patentee's failure to work or to adequately work an invention in Canada, the patentee's refusal to license a patent at all or on reasonable terms, or improper licensing practices with certain prejudicial and not necessarily anti-competitive effects.

Any time after the expiration of three years from the date of the grant of the patent, any interested person may apply to the Commissioner of Patents alleging an abuse of the exclusive rights under the patent and asking for relief, such as an order for a compulsory license on terms that are expedient or to revoke the patent.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

An action for infringement may be brought by the patentee or by any party "claiming under"



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the patentee. The Patent Act requires that a patentee be made a party to any action for infringement, unless otherwise expressly provided. Licensees, whether exclusive or non-exclusive, are able to bring an action for infringement. Further, a party whose market position is impacted by an infringement may bring an action for the harm caused by the infringement even if the party is not a licensee.

### 3.2 Direct and Indirect Infringement

A party may be liable to a patentee (or person claiming under, eg, licensee) for either direct or indirect infringement. Direct infringement is any act which interferes with the rights of the patentee to make, use or sell the subject matter of the claims of the patent. Further, an indirect infringement occurs where a party exerts influence on another party who then carries out an act which is within the exclusive rights to make, use or sell the subject matter of the patent claims.

Remedies available for patent infringement include:

- an injunction against further making, using or selling until the patent has expired;
- an order for the delivery up or destruction of the infringing product;
- a reasonable royalty from the date of publication to the date of issuance of the patent; or
- a claim for damages suffered by the patentee or an account of profits made by the infringer due to the infringement.

There are also punitive and exemplary damages available in circumstances where the conduct of the infringer calls for such additional damages.

### 3.3 Process Patents

A product imported into Canada will be considered to infringe if the process by which the pat-

ent was made would have been an infringement if carried out in Canada.

### 3.4 Scope of Protection for an Intellectual Property Right

The scope of the exclusive rights provided by a patent are determined by a purposive construction of the claims. There is a single claim construction and no doctrine of equivalents is available in Canada. Instead, the essential elements of the claims are identified with reference to the objectively determined intention of the inventor. The essential elements are then compared with the allegedly infringing product or process to determine whether there is infringement or not.

Claim construction is not influenced by the prosecution history with the exception that the prosecution history may be put into evidence to rebut any representation made by the patentee in the action or proceeding as to the construction of a claim.

### 3.5 Defences Against Infringement

Defences available to a party accused of infringement include a “prior use” defence which permits a party to continue an infringing act if that act was first performed prior to the “claim date” of the patent claim in question. The claim date is the filing date or the priority date of the claim. Defences of laches and acquiescence are available under Canadian law. Patent exhaustion may also be applicable, including the right to repair.

### 3.6 Role of Experts

In most patent infringement actions each of the adversarial parties will retain experts to provide opinion evidence relating to technical and accounting matters. The experts work with counsel but are required to be impartial and to assist the court on technical matters. Although

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“hot tubbing” of experts is potentially part of the Canadian practice, it is rarely used and not required. It is very rare for the court to have its own expert in patent infringement cases. Experts must file written reports before trial and are not subject to pre-trial examination.

### 3.7 Procedure for Construing the Terms of the Patent’s Claim

Although it is possible for a party to seek to have patent claims construed before trial, in most cases the claim construction is subject to expert evidence and is carried out by the court as part of the ultimate decision-making as reflected in the reasons for judgment.

### 3.8 Procedure for Third-Party Opinions

Although an amicus brief is potentially available in patent infringement cases, it is virtually never sought by the court.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

Proceedings for patent revocation, or invalidation, are typically brought in the Federal Court of Canada. The Federal Court has exclusive jurisdiction to issue declarations that a patent is invalid in rem, or at law. Patent validity can be challenged through an impeachment action brought by any “interested person” or as a counterclaim to a patent infringement action. Courts have interpreted the “interested person” requirement broadly and there is no requirement for patent infringement litigation to have been contemplated, threatened or even foreseeable. Provincial superior courts, which may adjudicate patent infringement, cannot declare a patent invalid in rem, but can adjudicate the enforceability or

validity of a patent only as between the parties and can declare a patent invalid in personam.

There are several grounds for invalidating a patent in a court proceeding. Invalidity attacks of anticipation (lack of novelty) and obviousness (lack of inventiveness) are based on prior public disclosures. Grounds of insufficient disclosure, overbreadth, ambiguity, and inutility are based upon the bargain theory that a patentee should only be granted a monopoly in return for full and clear disclosure of a useful invention. Other technical grounds for invalidity include unpatentable subject matter, double patenting and material untrue allegations in the petition.

While not common, patents can also be challenged at the Patent Office through re-examination proceedings. In re-examination proceedings, only anticipation and obviousness invalidity attacks are available, and only based on prior written disclosures. Prior public use or sale cannot be asserted on re-examination. The other invalidity attacks discussed above are not available to be asserted on re-examination. Additionally, re-examination should be used with caution by those seeking to avoid the patent, given that a patentee may use re-examination to amend its claims to avoid the cited prior art, resulting in stronger patent claims.

### 4.2 Partial Revocation/Cancellation

The Patent Act provides that the presence of any invalid claims in a patent does not affect the validity of the remaining claims. For prior art-based attacks, it is not uncommon for the broadest independent claims to be invalid, while some narrower dependent claims remain valid. However, other invalidity attacks, such as insufficient disclosure or material untrue allegations in the petition, are not measured against the claims

and may result in the entire patent being invalidated if successful.

### 4.3 Amendments in Revocation/ Cancellation Proceedings

Patent claims cannot be amended through litigation in the Federal Court of Canada. Claims can only be amended through proceedings before the Canadian Patent Office.

During a re-examination proceeding, a granted patent re-enters prosecution before the Patent Office based on a newly identified prior art reference. A patentee is granted the opportunity to amend the claims, as if prosecution of the underlying application was pending. Re-examination can allow the patentee to strengthen a patent claim to avoid the cited prior art and is a significant reason for re-examination proceedings not being commonly used to challenge Canadian patents.

Notwithstanding any pending patent impeachment action, a patentee has the opportunity to apply for re-issuance of a patent during the first four years after grant. Re-issuance allows the patentee to surrender the existing patent and receive an amended patent if certain conditions are satisfied. The patentee must establish that the original patent was defective or inoperative by reason of insufficient description, or by reason of the patentee claiming more or less than it had a right to claim. The patentee must also establish that the error arose from inadvertence, accident or mistake, without any fraudulent or deceptive intention. Re-issuance can correct minor errors in the specification or claims and can be used to narrow or broaden the claimed monopoly. However, re-issuance is not intended to save a fundamentally invalid patent.

Notwithstanding any patent impeachment action, a patentee may also file a disclaimer to narrow a patent's monopoly. The patentee must establish that by mistake, accident or inadvertence and without any wilful intent to defraud or mislead the public, the patent claimed more than the patentee was entitled to. Once a disclaimer is made, the subject matter identified is excluded from the patent monopoly and not assertable, even if the disclaimer is not accepted and deemed ineffective.

### 4.4 Revocation/Cancellation and Infringement

Patent validity and patent infringement are often adjudicated together. Patent impeachment actions brought as a counterclaim to patent infringement actions will almost always be heard together with the infringement action.

Re-examination proceedings at the Patent Office may be commenced in parallel to patent infringement proceedings before the courts. The Federal Court has the jurisdiction to stay re-examination proceedings pending the resolution of infringement or impeachment proceedings where it is in the interests of justice to do so.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

Almost all patent infringement litigation in Canada takes place in the Federal Court. The Court does not have divisions or districts and venue-shopping is not typically an issue. The Court is bilingual and proceedings may be in French or English or a mixture. There is no special set of rules for patent proceedings but the Court is highly experienced in patent matters.

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Most patent infringement disputes are brought as actions (previous regulations which permitted pharmaceutical disputes to be pursued by way of application are now replaced by an action-based approach). Although the Federal Court is more receptive to dispositive pre-trial hearings (summary judgment and trial of an issue, for example), it remains the case that most patent infringement actions that are not settled will go to a trial where liability is determined. In many cases the question of monetary remedies is deferred to a second hearing to occur only where liability is established.

The trial is invariably before a single judge of the Federal Court. Although there is a discovery process that is potentially extensive, no pre-trial examination of experts or specific witnesses is typically permitted. Expert reports are exchanged before trial but experts typically give oral testimony in chief despite being restricted to opinions set out in their reports. Most evidence of fact witnesses is provided in person (or by video link) for both evidence in chief and in cross-examination. A “will-say” statement is typically provided before a witness appears at a trial hearing.

The parties to a patent infringement trial are able to appeal the result to a three-judge panel of the Federal Court of Appeal. No leave to appeal is required.

## 5.2 Decision-Makers

The Federal Court, where almost all patent infringement actions take place, does not have juries. There is a roster of judges in the Federal Court who are primarily assigned to patent cases. However, this is not required by a formal rule but is an administrative preference of the Court, only. There are several judges on the Federal Court who practised as patent lawyers before

being appointed to the bench but there are also several judges who have no specific technical or patent background who regularly hear patent cases.

The request for a French-language speaking or bilingual judge will tend to result in a hearing in the Province of Quebec. However, this is not universally the case and there is no ability to select a particular venue or judge in the Federal Court practice.

Although patent infringement cases may be brought to a particular provincial court, as opposed to the Federal Court, it is not frequently done and there is no ability to select the decision-maker in the provincial court.

## 5.3 Settling the Case

Although mediation or other alternative dispute resolution (ADR) is not required in a patent case, the Federal Court will encourage the parties to seek ADR before trial during mandatory pre-trial conferences. The Federal Court provides no-fee ADR services. It is typical to have one or more formal mediation sessions with a mediator and facilities both provided by the Federal Court.

## 5.4 Other Court Proceedings

Once a patent infringement action is commenced in court, it is unlikely that the action will be stayed. Although post-grant proceedings may take place in the Patent Office, such proceedings are not often pursued and courts will be unlikely to stay proceedings due to actions in the Patent Office.

It is possible for multiple actions to be taking place in different courts relating to a single patent, for example where infringement and validity are contested in the Federal Court and at the same time ownership issues are in dispute in

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a provincial court. In such a circumstance, it is possible for one of the two actions to be stayed.

## 6. Remedies

### 6.1 Remedies for the Patentee

A patentee that prevails in establishing infringement is entitled to damages from infringement. As an alternative to damages, the successful patentee may seek the disgorgement of the defendant's profits from infringement. This is an equitable remedy available at the discretion of the trial judge. In addition to damages or profits, a patentee may also obtain a reasonable royalty for acts performed after the publication of a pending application that would constitute infringement after the patent grants. Pre-and post-judgment interest are available on monetary remedies awarded.

A defendant does not need to have notice of a patent or to act wilfully to be liable for damages caused by infringement. However, there are no provisions for elevated damages for wilful infringement. Punitive damages may be available in exceptional circumstances where the defendant's conduct is egregious, high handed, callous and oppressive nature. In considering punitive damages, the court may also consider whether the damages awarded are sufficient to punish and deter infringement.

A successful patentee is almost always awarded a permanent injunction until the expiry of the patent. This is a remedy that will only be denied in "very rare circumstances" on consideration of all the equitable factors and surrounding circumstances. The court may deny an injunction where a patentee has delayed or failed to prosecute its patents in good faith, or where it pursues an overly aggressive licensing strategy, especially if

the patentee is a non-practising entity. A patentee may also obtain an order for delivery-up or destruction of infringing materials.

Awards of legal fees are discretionary but are typically made in favour of the successful party. By default, costs are awarded according to Tariff B of the Federal Courts Rules, SOR/98-106. The tariffs assign a range of dollar values recoverable for the various steps taken in a proceeding. However, in complex patent cases between sophisticated parties, there is a trend towards awarding costs at 25-50% of legal fees paid to counsel plus full recovery of reasonable and necessary disbursements.

### 6.2 Rights of Prevailing Defendants

A defendant that succeeds in avoiding infringement is typically awarded legal fees. Legal fees may be determined according to the Federal Court's tariff or as a percentage of fees paid to counsel as discussed at **6.1 Remedies for the Patentee**. Reasonable and necessary disbursements are also usually available.

Awards of legal fees are discretionary and can be reduced where a defendant has acted inequitably or complicated the proceeding with unmeritorious invalidity arguments.

A prevailing defendant may also be entitled to damages if they were wrongly held out of the market place by an interlocutory injunction or by the operation of the regulatory scheme governing second entry pharmaceuticals provided by the Patented Medicines (Notice of Compliance) Regulations, SOR/93-133.

### 6.3 Types of Remedies

Patentees are entitled to legal remedies, like damages, and/or equitable remedies including injunctions and a disgorgement of the profits

from infringement. The Federal Court of Canada is a statutory court, without any inherent jurisdiction, so only remedies within the powers expressly granted to the Federal Court are available.

## 6.4 Injunctions Pending Appeal

As noted at 6.1 Remedies for the Patentee, an injunction is almost always granted following a finding of patent infringement. While not commonly exercised, the court has the discretion to delay the coming into force of an injunction and may do so where it is in the interests of justice, having considered the relevant circumstances and balancing equitable factors. In delaying the onset of an injunction, the court may consider the time and effort required to switch to a non-infringing alternative and the effect that an immediate injunction would have on the Canadian public, including through unemployment of the infringer's workforce.

In the Federal Court of Canada, where most patent infringement proceedings are brought, an injunction granted will remain in force while any appeal is pending. If an appellant wants to have the injunction stayed pending determination of an appeal, the appellant must make a motion to the Federal Court of Appeal seeking a stay of the injunction. To succeed in obtaining a stay, the appellant must establish that its appeal raises a genuine issue, that the appellant will suffer irreparable harm if no stay is granted, and that the balance of convenience favours granting a stay. This is a difficult test to satisfy and most appellants fail in establishing the irreparable harm required.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

Decisions of the Federal Court on the infringement and validity of patents create a right of appeal to the Federal Court of Appeal. Decisions of the Federal Court of Appeal may be appealed to the Supreme Court of Canada if leave to appeal is granted. The procedures for appeals in patent litigation are the same as appeals in other types of litigation.

Decisions of the Patent Office may be challenged through a judicial review application, or in some circumstances by way of an appeal, brought in the Federal Court. Decisions of the Federal Court on judicial review applications are appealable to the Federal Court of Appeal as of right.

### 7.2 Type of Review

Appeals from decisions of the Federal Court are subject to a standard of review of correctness on questions of law and a deferential standard called "palpable and overriding error" on questions of fact or mixed questions of fact and law.

The interpretation of the claims of a patent is a question of law and subject to a correctness standard, however some deference is typically afforded to the trial judge since claim interpretation is heavily reliant on expert evidence. Questions of patent infringement and validity are questions of fact or mixed fact and law and are subject to the palpable and overriding error standard.

Applications for judicial review from decisions of the Patent Office are heard by the Federal Court and are subject to a deferential standard of review of reasonableness.



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## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

There are no required steps that must be taken before an action for patent infringement can be commenced by filing a statement of claim. This allows a patentee to limit the initial costs of a patent infringement lawsuit to the preparation of a statement of claim and modest court filing fees.

Preliminary procedural issues in a patent infringement action can often be addressed on consent or informally before a case management judge, allowing the parties to control costs.

### 8.2 Calculation of Court Fees

Court fees for proceedings in the Federal Court of Canada are provided in Schedule A of the Federal Courts Rules, SOR/98-106. Patent proceedings are treated the same as other proceedings in the Federal Court and modest fixed fees are payable for various steps taken. For example, a plaintiff commencing an action must pay a filing fee of CAD150. Where a hearing exceeds three days, the parties split a daily court fee of CAD150.

### 8.3 Responsibility for Paying the Costs of Litigation

Each litigant is responsible for paying fees for certain steps taken in a proceeding, as provided in Schedule A of the Federal Courts Rules, SOR/98-106.

While awards of legal costs are fully discretionary, the Federal Court of Canada typically operates on a loser pays basis, where the successful party has a portion of its legal costs paid by the unsuccessful party. Complex patent cases between sophisticated litigants often result in the successful party being granted 25-50% of

its counsel fees and full recovery of reasonable expenses incurred, including fees paid to expert witnesses.

In determining the amount to be awarded, the Court will consider the outcome of the proceeding as well as other factors including:

- the amounts claimed and recovered;
- the importance and complexity of the issues;
- the amount of work required;
- the conduct of the parties;
- any offers to settle; and
- any public interest in the litigation.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

ADR is commonly used in resolving patent proceedings. It is estimated that 19 out of 20 patent infringement actions before the Federal Court of Canada are settled without requiring a trial. Before a patent action can proceed to trial, the parties must have considered and attempted settlement negotiations. This commonly involves judicially assisted mediation. The Federal Court of Canada provides mediation services to litigants free of charge. Experienced members of the Federal Court judiciary act as mediators and explore the possibility of negotiated settlement.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

There are no imposed requirements for the transferring of patent rights. It is recommended that transfers be in writing and signed by the



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parties involved to reduce uncertainty about the transfer. It is recommended that any transfer clearly identify:

- the parties involved;
- the intellectual property being assigned such as the registration numbers;
- any particular rights under the registered intellectual property, such as field of use and geography; and
- the consideration/royalties to be received.

Assignments or transfers of patent rights may be registered with the Patent Office but this is optional. There are benefits to registration of transfers because a transfer of a patent that has not been recorded is void against a subsequent transferee if the transfer to the subsequent transferee has been recorded. Copies of the assignments may be recorded with the Patent Office so these documents are available on the public record but this is also optional.

## 10.2 Procedure for Assigning an Intellectual Property Right

See 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights.

## 10.3 Requirements or Restrictions to License an Intellectual Property Right

There are no imposed requirements for the licensing of patent rights. It is recommended that the licence be in writing and signed by the parties involved to reduce uncertainty about the licence. See 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights, for the particulars that any licence should clearly identify.

Since a licensee may pursue patent infringement and financial remedies in court under the Patent Act as a “person claiming under the patentee”, a licence agreement may also deal with the rights and responsibilities for pursuing third-party infringement of the intellectual property rights.

There is no requirement to register a patent licence with the Patent Office.

## 10.4 Procedure for Licensing an Intellectual Property Right

See 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights.

**Contributed by:** Bruce Stratton, Geoffrey D Mowatt, Alan Macek and Bentley Gaikis,  
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**DLA Piper (Canada) LLP** is part of a global law firm with lawyers located in more than 40 countries. DLA Piper's Canadian Intellectual Property and Technology Group serves clients on a full range of intellectual property, privacy and technology issues around the world. DLA Piper's Canadian patent practice in Toronto consists of five partners and five associates. The lawyers advise clients on all issues relating to patents, with particular expertise in patent litigation. With significant trial experience, the practice's

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## Trends and Developments

### Contributed by:

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### Patent Litigation in China 2022: Practice and Prospects

The year 2022 is particularly worthy of the spotlight in patent law practice in China. The advancement of a series of leading judicial cases and the implementation of policies crystallise the experience of China's judicial practice and response to the evolving demands of the patent law practice. In terms of judicial practice, several landmark cases have demonstrated China's determination to participate in the rule-making of global IP rights governance and its position to continuously strengthen the deployment of IP protection decisions in various fields. In addition, the automotive industry association released the Guidelines of Standard-Essential Patent (SEP) Licence for the Automotive Industry (2022 edition), providing an outline for SEP licensing negotiations in the automotive industry, a pioneering industry in the technological revolution. As for the administrative regulations, the draft amendment of the Provisions on the Prohibition of the Abuse of Intellectual Property Rights to Exclude or Restrict Competition further regulates and restricts the patent pool entities' operation and regulates the behaviour of an undertaking in the process of standard development and implementation.

This article compiles and analyses the significant events in 2022 in the patent field in China, and the authors provide an interpretation, looking at this extraordinary year.

### Judicial Practice

*Chinese courts: more active and deeper involvement in the development of global IP rights governance rules*

In September 2022, the SPC issued a final ruling on the jurisdictional challenge in the SEP global royalty rate dispute case, OPPO v Nokia, reconfirming the jurisdiction of Chinese courts in adjudicating SEP global royalty rate disputes after a year. The court's reasoning of the ruling in OPPO v Nokia is similar to that in OPPO v Sharp, issued in August 2021, where the Chinese court for the first time confirmed the jurisdiction over SEP global royalty rate disputes of the Chinese court. In the ruling of OPPO v Nokia, the SPC reassured the court's authority to adjudicate the licence conditions on a global scale.

This case was tried at the Chongqing No. 1 Intermediate Court on 27 October 2022, and if the case continues to move forward, the judgment might be issued in 2023. This is a milestone in that the SPC has taken a position on the 5G SEP global dispute for the first time. In addition, since no Chinese or overseas courts have yet issued any judgments on the 5G SEP global royalty rate, it will profoundly impact global 5G SEP judicial practice and licensing negotiations if a Chinese court takes the lead in deciding the rate for 5G portfolio in this case.

## *China's first administrative adjudication on major patent infringement dispute case officially landed*

On 27 July 2022, the China National Intellectual Property Administration (CNIPA) issued the first administrative adjudication on a major patent infringement dispute in China, ordering the respondent, Guangdong Dongyangguang Pharmaceutical Co Ltd (“Dongyangguang Pharmaceutical”), to immediately withdraw the display of the accused infringing pharmaceutical products from the listed pharmaceutical procurement platform; and ordering the respondent to immediately stop manufacturing, selling and offering to sell products that infringe the patent rights of the petitioner, Boehringer Ingelheim Pharmaceuticals, Inc (“Boehringer Ingelheim”).

This case is the first national administrative adjudication on major patent infringement disputes since the implementation of Measures for Administrative Adjudication on Major Patent Infringement Disputes (“Measures”), marking a concrete practice of the system of administrative adjudications on major patent infringement disputes at the level of national authorities. In this case, the Linagliptin tablets developed by Boehringer Ingelheim were approved for import by the China National Medical Products Administration (CNMPA) in 2013. Dongyangguang Pharmaceutical applied to the CNMPA for a marketing licence for generic linagliptin tablets in 2018. This application was approved in July 2020. Dongyangguang Pharmaceutical began selling and offering to sell the linagliptin product in February 2021. Boehringer Ingelheim, on the one hand, filed a lawsuit with the Shanghai Intellectual Property Court for the infringement of its patent right of ZL03819760.X, and on the other hand, filed a request for an administrative adjudication on a major patent infringement dispute with the CNIPA based on its patent

ZL201510299950.3 (a divisional application of the 760.X patent), requesting that Dongyangguang Pharmaceutical be ordered to stop manufacturing, selling and offering to sell the generic medicine.

The CNIPA held that the accused infringing products fell within the scope of protection of the patent at issue and that the respondent shall stop manufacturing, selling and offering to sell the accused infringing products. This article will analyse the following two issues involved in the adjudication.

- Firstly, the scope of protection of the parent patent is different from that of the divisional patent. After filing a lawsuit based on the parent patent, the patentee can still apply for an administrative adjudication on a major patent infringement dispute based on the divisional patent. The respondent claimed that since the infringement dispute of the parent patent has been on the docket in the Shanghai Intellectual Property Court, the case was no longer eligible for administrative adjudication. In this regard, the CNIPA held that although the petitioner had filed a lawsuit based on the parent patent, the parent and divisional patent infringement disputes were not the same because the patents in the two procedures were different. The evidence, facts and grounds for infringement were also different. Therefore, the CNIPA could accept the case.
- Secondly, this case need not be suspended again due to the second round of the invalidation procedure. The panel held that this case had been suspended once due to the invalidation procedure. Considering the fairness and efficiency of the administrative adjudication of major patent infringement disputes, the panel decided not to suspend the processing of the case for a second time.

In China, IP owners protect their IP rights mainly by filing a lawsuit before a court or filing an administrative petition. Compared with court proceedings, it is said that administrative action has high efficiency, but some patent owners worry about the professionalism of local intellectual property departments. In this context, the CNIPA published the Measures on 1 June 2021, stipulating that the CNIPA has the authority to decide major cases related to patent infringement, providing more options and more feasible guidelines for patent owners to protect their rights, and establishing the criteria of administrative adjudication applications. The Measures enable the petitioners to seek an administrative adjudication on a major patent infringement dispute directly to the CNIPA without having to worry about the professionalism of local intellectual property departments and the possible jurisdictional conflicts. It is expected that the Measures will make the administrative proceeding a more attractive option for patent owners to defend their rights in complicated cases.

*The total amount awarded in the patent infringement dispute between AUX and Gree Rises to RMB220 million (USD32 million), but the patent at issue is facing a risk of being invalid*

Two patent infringement disputes between well-known air conditioner manufacturers AUX and Gree have aroused widespread public attention since 2021. The patents at issue in both cases were compressor patents. At the end of 2021, the Ningbo Intermediate Court first made a judgment, finding that Gree's actions constituted infringement of the patent at issue and awarded Gree RMB160 million in damages. In August 2022, the Hangzhou Intermediate Court made another patent infringement judgment in the case of AUX v Gree in the first instance, with damages amounting to RMB55 million. With the

same patent, AUX has accumulated an award of nearly RMB220 million, reaching a new record of damages for patent infringement cases in the home appliance industry in China. It is worth noting that the Hangzhou Intermediate Court, based on the expert report provided by Plaintiff AUX, found that the technical contribution of the patent at issue was 20%.

To fight back, Gree filed an invalidation request against the patent at issue. The CNIPA determined that the patent at issue was invalid in part. Gree then filed the administrative action against the CNIPA's decision to the Beijing IP Court, holding all claims shall be invalid. In December 2022, the Beijing IP Court upheld Gree's claims in the first instance judgment, deciding that the invalidation decision shall be withdrawn. If the remarkable judgment comes into effect, it would probably destroy the achievements of AUX in the Ningbo and Hangzhou Intermediate Court. Therefore, it is foreseeable that AUX will appeal against the judgment issued by the Beijing IP Court.

*Role shifting of Chinese telecom companies from implementers to patent owners*

In recent years, Chinese companies in the telecom field, which worked as traditional manufacturers before, have been actively increasing their investment in R&D, and as a result, accumulating more SEP resources. They are accelerating their activity in patent licensing and operation. Now it is seen that they are actively leveraging patent portfolios for royalties or using them as a means of offsetting royalties in cross-licensing. The role of Chinese telecom companies is gradually changing.

In early 2022, the Shenzhen Administration for Market Regulation ("Shenzhen Intellectual Property Administration") organised the selection of

the “Top Ten Shenzhen IPR Events of 2021”, of which the candidate event No. 15, “The First Time a Chinese Enterprise Took the Initiative to Request the Court to Determine the Global Royalty Rate”, attracted widespread attention. ZTE filed a request before the Shenzhen Intermediate People’s Court to determine the royalty rate between ZTE and a Chinese mobile phone company for its global patent portfolio of 4G LTE SEPs. This is the first royalty rate-setting case between two Chinese companies based on the FRAND principle. In addition, relevant information on patent licensing negotiations news between ZTE and Vivo, OPPO was also released successively in 2022.

Besides ZTE, other Chinese patent owners and implementers have increasingly engaged in litigation in the SEP field. On 10 May 2022, Huawei filed two patent infringement lawsuits with the Jinan Intermediate Court, alleging that Netgear’s Wi-Fi 6 products infringed two Chinese patents, ZL201811536087.9 and ZL201810757332.2. Previously, Huawei had filed two patent infringement lawsuits against Netgear and its third-party online stores in German courts in March 2022. Apart from that, Huawei sued Amazon and seven other companies for patent infringement in the Suzhou Intermediate Court (Case No: (2022) Su 05 Min Chu No 916). The outcome of the above patent licensing disputes will become a focus of attention in the SEP field in the coming 2023.

## Policy Trend

### *The release of the Guidelines of SEP Licence for the Automotive Industry (2022 Edition)*

The Guidelines of Standard Essential Patent Licence for the Automotive Industry (2022 Edition) (“Guidelines”) were released in September 2022. The Guidelines are the first industrial SEP licensing guidelines in China and are jointly drafted and issued by the IP Committee of China

Society of Automotive Engineers (China-SAE), the Promotion Group of IMT-2020 (5G), and the working group of automotive SEP. Previously, various countries and jurisdictions have issued a series of policy or guidance-type documents for SEPs; for example, Japan issued the Guidelines for Good Faith Negotiation of Standard-Essential Patent (SEP) Licences in 2022. China has clarified the focus of the global automotive industry SEP licensing in the form of a guideline. Although the Guidelines mainly involve framework provisions, it is foreseeable that the Guidelines, as the first SEP licensing guideline for China’s automotive industry, will profoundly impact the future of China’s automotive industry SEP licensing negotiations.

Multiple core principles regarding the licensing level and the royalty calculation are put forward in the Guidelines.

- Regarding the licensing level, the Guidelines clarify that any level in the automotive industrial chain is entitled to obtain licences. In the meantime, it is appropriate to fully respect and consider the characteristics of the industry for both parties. The Guidelines provide that “any good faith patent implementer is entitled to obtain an SEP licence and SEP owners are obliged to license to an implementer who intends to obtain a licence, regardless of the level in the industry chain”. This provision is usually considered to be a principal provision. However, at the same time, the Guidelines also emphasise that “it is appropriate to fully respect and consider the industry characteristics and business customs, positively discuss and negotiate in seeking a licensing model accepted by both parties”, leaving ample room for the negotiating parties to choose the licensing model freely.



- Regarding the royalty calculation basis, the Guidelines propose that the basis should be set as the product unit that actually contributes to the automotive product. At the same time, the Guidelines aim to relieve the fundamental contradictions in SEP licensing in the automotive industry by clarifying the basic principle of royalty calculation basis to encourage differentiated licensing schemes on a case-by-case basis. The Guidelines propose that “the basis should be set as the product unit that actually contributes to the Automotive Product by SEP technology”. At the same time, taking into account the uncertainty of the licensing levels discussed above, the Guidelines add two basic principles for the calculation of royalty, that is, firstly, regardless of whether the basis is the parts and components of an automotive product or the automobile, the actual value contributed by the SEP technology to the automotive product should be taken into consideration; secondly, regardless of the licensing level, the SEP royalty for the same automotive product should be approximately the same, and the royalty should not differ significantly among various licensing levels.
- Regarding the royalty calculation method, the Guidelines clarify that methods such as “top-down” and comparable license methods may be adopted when calculating SEP royalties and emphasises that a reasonable cap should be imposed. In consideration of achieving a balance of interests between the licensing parties, the Guidelines put forward the principle of limitation to aggregate royalty rates: “a reasonable cap should be imposed against the aggregate amount of SEP royalties for automotive products. This cap could be a certain fraction of the reasonable profits in the licensed products industry”. The Guidelines do not render a preferential opinion over

calculation methods, including the comparable licence and top-down methods.

### *The Provisions on the Prohibition of the Abuse of Intellectual Property Rights to Exclude or Restrict Competition has been open to the public for comments*

To implement the amended Anti-monopoly Law, the State Administration for Market Regulation (SAMR) developed a draft of the Provisions on the Prohibition of the Abuse of Intellectual Property Rights to Exclude or Restrict Competition (“2022 Draft Amendment”) in June 2022, which has been open to the public for comments. Compared to the Provisions about the Prohibition of the Abuse of Intellectual Property Rights to Exclude or Restrict Competition revised in October (“2020 Provisions”), the 2022 Draft Amendment further regulates and restricts the operation of patent pool entities and also regulates the behaviour of the undertakings in the process of developing and implementing the standards.

The tightened regulation on patent pool entities will likely become a new trend. Compared with the 2020 Provisions, in Article 14 of the 2022 Draft Amendment, the exchange of price information among the patent pool entities is newly banned; and licensing the patents in a patent pool at unfairly high prices is added as one of the anti-competition acts. These changes will provide the SAMR with more grounds to regulate the anti-monopoly acts of the patent pool entities.

IP rights abuse in the standard development and implementation practice is possible even without a dominant market position. Article 15 of the 2022 Draft Amendment introduces the new rules about IP rights abuse leveraging standard development and implementation practices.

The abusive acts described in Article 15 are all related to horizontal agreements among competing undertakings in the process of developing and implementing standards, including excluding specific undertakings from participating in the standard development practices, excluding technical solutions from specific undertakings from the relevant standards, prohibiting specific undertakings from implementing relevant standards, and prohibiting the implementation of competing standards.

The licensor might face an increased risk of anti-monopoly when seeking injunctive relief in an SEP dispute. Compared with the 2020 Provisions, the new provision of “seeking injunctive relief” in Article 16 of the 2022 Draft Amendment is refreshing. If this provision is retained in the formally promulgated version, it will effectively limit licensors from arbitrarily and improperly seeking injunctive relief because they will face increased antitrust risk. At this point, in addition to seeking relief from the Chinese courts, the licensees can also respond to the threat of injunction from the SEP right holders by filing a complaint with the administrative department.

## Conclusion

After an extraordinary 2022, China has had a remarkable performance in terms of judicial practice and policy guidance in patent law practice. During this year, China’s legislative, judicial and administrative authorities responded to the international community’s concerns about China’s patent system through a series of landmark judicial cases and amendments to provisions. Looking ahead to 2023, it is believed that China will do more in reforming and innovating its patent system. So let’s look forward to it together.

Contributed by: Yan Wang, Jian Zhang and Haiping Liu, Han Kun Law Offices

**Han Kun Law Offices** is a leading, full-service law firm in China. Over the years, Han Kun has been widely recognised as a leader in complex cross-border and domestic transactions. Its main practice areas include private equity, M&A, international and domestic capital markets, investment funds, asset management, competition/antitrust, banking and finance, data protection, intellectual property and dispute resolution. It currently has nearly 800 professionals located in its six offices in Beijing, Shanghai, Shenzhen,

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# CZECH REPUBLIC

## Law and Practice

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

Czech law allows for the protection of various forms of intellectual property (IP) through a number of means, all of which are based on written legislation, ie, statute. Case law cannot create new ways of protecting inventions, but it helps to shape and define the statutory provisions.

#### National Patent

For true inventions, formal protection through a patent is available. Patents can be obtained through a number of routes.

A national patent lasting up to 20 years can be obtained from the Industrial Property Office (IPO) following a full examination of patentability of the applied-for invention. National patent applications can be extended to result in patents through the Patent Cooperation Treaty (PCT) – more than 150 countries are members. Equally, the PCT procedure based on a foreign application can result in the grant of a Czech national patent.

#### European Patent

European Patents can be obtained from the European Patent Office (EPO), provided that they designate the Czech Republic and are validated after grant. European patents can be based on national applications or result from the PCT international procedure. Their effect is identical to that of national patents.

#### SPC (Supplementary Protection Certificate)

In certain fields of technology (human or veterinary medicaments and chemical plant protection products) supplementary protection certificates may be obtained from the IPO. These extend the term of protection of a patent by up to five years.

#### Utility Models

Utility model protection is available for technical innovation that may not have the innovative level of patents, where the benefit of full term of protection of a patent is not needed and/or where rapid formal protection without examination is desirable. Their term of protection is ten years, but a utility model grants in roughly six months. Utility models cannot protect methods/processes or uses.

#### Trade Secrets

Trade secrets protection can be relied on to protect technology and general know-how if these can be kept secret. Any information or fact which has commercial value, is identifiable and is being kept secret can be protected from being disclosed or acquired without the owner's permission.

#### Unfair Competition

The prohibition of unfair competition, ie, conduct in commerce which is capable of harming competitors and at odds with good morals of competition, protects technical innovations even where they are not otherwise protectable through one of the formal routes, such as patents or utility models and may even extend their duration to a certain extent. It particularly protects against "slavish imitation" of existing products. Case law plays an important role in unfair competition law, as the written law grants the court a lot of discretion when allowing it to interpret what amounts to a conflict with good morals of competition.

### 1.2 Grant Procedure

Some IP rights require that the technical innovation is registered prior to it being granted protection by the law. Trade secrets and unfair competition do not require any formal steps to be undertaken.



## National Patent

National patents result from the filing of a national patent application with the Industrial Property Office, or the PCT international procedure based on a foreign application proceeding to the national phase in the Czech Republic. The first to file an application can obtain a patent, although if it is proven in court that the applicant had no right to file for the protection of the invention, the patent application or granted patent can be assigned to the rightful inventor or its legal successor. The patent application has to be published no later than 18 months from the date of priority. The IPO subjects the application to a preliminary examination to prevent publication of clearly unsuitable applications. The patent applicant must request full examination of the patent within a certain deadline. Should the IPO then find that the application fulfils all statutory requirements, in particular that the invention is new and inventive over the prior state of the technology, that it is clear and industrially applicable, it will grant the patent. The patent is enforceable upon publication of its grant in the official journal.

## European Patent

European patents can be obtained through the filing of a European Patent application with the IPO or EPO, or the PCT international procedure based on a foreign application proceeding to the national phase before the EPO. The key steps of the procedure are the same as described above for national patents, but different timelines apply. A granted European Patent designating the Czech Republic is effective upon publication in the EPO journal. However, if it is not validated within six months, through the filing of a translation and payment of appropriate fees with the IPO, it is deemed to have never been effective in the Czech Republic.

## SPC (Supplementary Protection Certificate)

Supplementary protection certificates must be applied for with the IPO within six months of the grant of the patent or the registration/marketing authorisation of the product. The IPO then examines whether a certificate can be granted, and if all conditions are satisfied it issues the certificate. The SPC becomes effective once the patent expires.

## Utility Model

Utility models are granted by the IPO following an examination of formalities of the application. Substantive examination of novelty and innovative level are not carried out. The IPO aims to grant utility models within three to six months; however, where difficulties occur this can take longer. Utility model applications are not published and the utility model is enforceable upon the publication of its grant in the journal.

## Trade Secrets

Trade secrets and know-how are protected without any need or in fact possibility for formal registration. The courts will examine whether something is a trade secret once the owner seeks to enforce it. Trade secret protection applies to identifiable information or facts which have commercial value and are being kept secret.

## Unfair Competition

Unfair competition conduct is again declared to be such by the courts when the person claiming to be entitled to protection from it files the claim in court. No prior formal registration is necessary or possible. Unfair competition is defined as “conduct in commerce which is capable of harming customers or competitors and is at odds with good morals of competition”. Unfair competition conduct is prohibited by law.

## 1.3 Timeline for Grant Procedure

The length of the registration/grant procedure varies between rights. Trade secret and unfair competition protection applies automatically.

### National Patent

The national patent registration procedure before the IPO usually lasts one to five years. However, if the application is complex or if the applicant so requests, it can take significantly longer. There is no requirement for the patent applicant to be represented, although this is very strongly advised. The official fees for the full procedure usually range between EUR500 and EUR1,000. The costs of representation (from preparation of patent application, up to grant) usually costs significantly more, with EUR5,000 to EUR10,000 being a realistic expectation. In very simple cases EUR1,000 to EUR5,000 can be expected.

### European Patent

European patent applications usually proceed to grant within three to five years, but in complex matters this can be much longer. The applicant does not have to be represented, unless it is not from one of the states where the European patent can have effect. In that case they must appoint an official representative who is on the official list or is a legal representative under the national laws of a member state. The official fees are circa EUR6,600. The costs of representation usually fall between EUR5,000 and EUR15,000.

### SPC

Supplementary protection certificate proceedings usually last one to two years. The official fees are circa EUR200. The cost of representation is usually between EUR1,000 and EUR3,000.

### Utility Model

Utility model applications usually result in grant within three to six months. Problematic applications may take longer. The official fees are circa EUR100. The cost of legal representation varies; however, EUR1,000 to EUR5,000 can be expected.

## 1.4 Term of Each Intellectual Property Right

The duration of each type of right varies. In some cases, it is strictly defined by statute. In the case of trade secrets and unfair competition the duration is potentially unlimited; however, the judges in each case decide whether protection still applies or whether it ever came into existence.

### Patents

Patents have a maximum term of protection of 20 years from the date of the filing of the patent application. This applies for both national patents and European patents. Maintenance fees have to be paid every year to keep a granted patent valid. SPCs can extend the term of protection for up to five more years in relation to a particular product not the whole scope of the patent.

### SPC

Supplementary Protection Certificates have a maximum term of protection of five years from the date of expiry of the patent on which they are based. An additional “paediatric extension” of six months may also become available. Calculation of an SPC’s actual duration is determined by the method described in **1.6 Further Protection After Lapse of the Maximum Term**. SPC protection only relates to a particular product and not the whole patent.

## Utility Model

Utility models have a maximum term of protection of ten years from the date of application, or if branched off from a patent application, ten years from the patent's application date. Utility models initially provide four years of protection, and can be extended on application twice, each time by three years. The extensions are subject to an official fee.

## Trade Secret

Trade secret protection has no maximum term of protection and can potentially last indefinitely. While the information remains secret and useful, it may not be used without the owner's permission.

## Unfair Competition

Protection from unfair competition also has no maximum term of protection. However, protection should not significantly outlast the term of protection of a patent or utility model: ie, at some point even slavish imitation may become permissible. The courts in each case decide whether protection still exists or whether it existed at all.

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

Each right has a specific set of rights that it creates for the owner and a set of obligations that the owner must abide by to maintain it.

### Obligations

To maintain a national or European Patent or an SPC an annual maintenance fee must be paid. If this is not paid, the right shall lapse. Grace periods for late payments apply.

A utility model's term extensions have to be applied for within the last year of the utility model's current duration.

In the case of trade secrets, the owner has to take reasonable steps to keep the secret protected from discovery or disclosure.

The person seeking protection from unfair competition should not itself be acting in unfair competition.

### Rights

A valid right generally enables the owner to exclude others from using the protected technical solution, meaning that no person may manufacture, use, offer, introduce onto the market, or store, import or otherwise deal with a product which falls within the scope of protection of the right, if the patent owner did not grant permission for such conduct. The use and offering of protected methods is similarly restricted.

A patent, SPC or utility model is enforceable if it is formally placed on the relevant register, which is maintained by the IPO. No further requirements apply. The register is accessible for free to all.

If infringement of the rights occurs the right-holder, or a registered licensee, can enforce the right in court. In such a case an injunction can be ordered against the infringing conduct, prohibiting it. In addition, the withdrawal of the product from the market and destruction of goods can be ordered by the court. Similarly, the offering and use of infringing methods can be prohibited.

Restoration of the status quo, or otherwise remedying the situation caused by infringement of rights can be ordered. This applies to trade secrets and unfair competition generally. Infringement of patents, SPCs or utility models automatically amounts to unfair competition conduct so they also benefit.

Customs may be relied on to physically seize goods infringing patents, SPCs or utility models. The right-holder can also demand access to information about the scale of infringement of its patents, SPCs or utility models and if it is not provided voluntarily a court can order its disclosure.

### *Damages*

Damages are available for infringement of rights. Damages amount to compensation of actual damage as well as lost profit. In addition, a surrender of unjustified enrichment by the infringer can be demanded. Reasonable compensation for immaterial harm, ie, non-economic harm, can be obtained as well. Such monetary compensation has to be proved exactly. However, in the case of breach of a patent, SPC or a utility model the compensation can be sought in the form of a lump sum amounting to at least double a fictitious licence that would have authorised the infringement.

Publication of an apology at the infringer's expense can be obtained.

Publication of the judgment can be authorised by the court.

### **1.6 Further Protection After Lapse of the Maximum Term**

Additional protection extending past the maximum term of protection of a patent is provided by the SPC. The additional protection applies to a certain product and not to the whole scope of the patent.

SPCs have a maximum term of protection of five years from the date of expiry of the patent on which they are based. Their actual duration is determined based on when a patent application was filed and when the product was approved

for marketing. If the product's marketing approval or registration took place later than five years from the date of patent application, then for every day over those five years, one day of protection is provided under the certificate – up to the maximum of five years. Under the “paediatric extension” an additional six months of protection can be obtained in the case of pharmaceuticals, where the product is tested for safety and efficacy in the paediatric population.

Unfair competition can slightly extend the protection of patents, and utility models in particular in relation to slavish imitation. The court will in each case separately determine whether given the totality of the circumstances a technical solution should still be protected from the particular conduct or not.

### **1.7 Third-Party Rights to Participate in Grant Proceedings**

Anyone can submit observations on the patentability of a patent, before it is granted. Such a person does not have full rights in the patent application proceedings. The IPO or EPO will generally ask the patent applicant to respond and take all such information into account when deciding whether to grant a patent.

Theoretically the same applies to SPCs, although it rarely happens in practice.

Since utility model applications are not published, it is not possible for third parties to interfere in their grant.

### **1.8 Remedies Against Refusal to Grant an Intellectual Property Right**

If a national patent or a utility model application is not granted, the applicant can appeal the first instance decision of the IPO to the President of

the IPO. The appeal has to be filed within one month and usually lasts one to two years.

The decision of the President of the IPO can then be subjected to judicial review proceedings before the administrative courts. This is, in principle, a full review process, where issues of law and fact can be raised. The first instance decision of the administrative division of the City Court in Prague can be appealed through a “casation complaint” to the Supreme Administrative Court. The first instance proceedings take three to five years and the appeal one to three years.

Theoretically, a constitutional complaint can be lodged with the Constitutional Court if a breach of fundamental rights occurs.

In SPC matters, a preliminary question may be referred by the courts to the Court of Justice of the European Union (CJEU). The IPO cannot make a CJEU referral.

At the EPO, a refusal to grant a patent can be challenged through an appeal to the Boards of Appeal, and potentially to the Enlarged Board of Appeal.

## 1.9 Consequences of Failure to Pay Annual Fees

To maintain patents and SPCs and to extend the duration of utility models fees have to be paid.

Failure to pay a patent or SPC annual maintenance fees on time, ie, within the last year of current protection, results in the right lapsing. A six-month grace period for payment of the maintenance fee applies; however, the fee is doubled. The patent becomes ineffective against any third party that begins to take steps to use the patented technology while the maintenance fee remains unpaid.

Failure to request an extension of a utility model results in the utility model expiring.

A party that missed a deadline can apply to have it reinstated, if it does so within two months of finding out, and no more than one year has passed since the deadline. An application has to be lodged and accompanied by the fee payment and the IPO has to issue a decision reinstating the time limit and thus the right. An appeal to the President of the IPO and judicial review as described in **1.8 Remedies Against Refusal to Grant an Intellectual Property Right**, are available. Again, third parties may continue to carry on with conduct which was begun before the reinstatement took place – because the patent, SPC or utility model is not effective against them.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

Once a patent, SPC or utility model is granted and published, the owner cannot amend the right other than through an application for its revocation. In such application, the owner has to argue why the patent should not have been granted as it was, ie, in effect it has to argue that the right is partially invalid due to a lack of novelty, inventive step, added matter, etc. As a result, this is rarely done. Partial surrenders of patents are not possible.

In the case of European patents, the owner is entitled to submit a correction of the validation translation at any time, subject to payment of the appropriate fees.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

In case of infringement of a right there are a number of means of resolving the dispute open to the owner of the right.

#### Negotiation

The right-holder can seek to negotiate with the infringing party, before taking formal steps or at any time while these are pending or even after they conclude. A negotiated settlement agreement provides the parties with relative certainty about their future relations. The negotiated settlement can go beyond that which the court can order, and can thus provide a complex business solution to the dispute. Negotiation is often begun with a warning letter.

#### Mediation

Mediation is available to resolve an infringement dispute as well. Czech Republic has a system of registered mediators, who are specially trained. A mediator aims to bring the parties to settle the matter amicably. Mediators aim to outline their legal and practical view of the aspects of the dispute and the relative positions of the parties, so as to encourage them to settle. Mediation can be undertaken at any time: before, during and possibly even after litigation concludes. A mediator's finding is not binding.

A court can advise parties to attend mediation before litigation proceedings proceed. While not very common in industrial property disputes, it does sometimes occur.

#### Arbitration

Parties may agree to have the dispute decided by an arbitrator or a panel of arbitrators of their choosing. The arbitrator's award is final, binding

and enforceable. However, in certain cases it can be overturned by the courts.

#### Litigation

The right-holder can apply to the courts to seek protection from infringement – enforce their right to a patent, SPC, utility model, trade secret or the right to be free from unfair competition. The courts can order preliminary/interim injunctions before full proceedings are even begun.

#### Customs

The right-holder can apply to customs for a market watch, under which the customs aim to seize product suspected of infringing the patent, SPC or utility model. An external market watch aims to target products not on the EU market (imports) and the internal market watch can target products already on the market. Targeted inspections of premises are available. A customs seizure either results in voluntary destruction of the seized product or litigation aimed to determine whether the product infringes – if it does, it is destroyed.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

A third party that is convinced that it does not infringe a right can either maintain that the right is not in law valid or the product/method or that its conduct does not amount to infringement of the valid right.

A national patent, SPC and utility model can be challenged at the IPO by any person through an invalidity action. A legal interest does not have to be shown unless the right has already expired.

A European patent can be challenged at the EPO through an opposition filed within nine months of the publication of grant of the patent by any person without the need to show a legal interest.



After that date an assumed infringer, ie, a person being sued by the patent owner, can challenge the patent if opposition proceedings are pending. Once the opposition window closes and if no opposition is pending, the European patent can be challenged before the IPO through an invalidity action, as if it were a national patent.

A compulsory licence can be obtained from the IPO in relation to a patent where the patented invention is not being used at all or insufficiently, and at least four years have passed from the patent application date or three years from the grant date. Compulsory licences are extremely rare. They are only effective once granted and shown on the register of patents.

If the product or process does not technically correspond to that which is the subject of the patent, SPC or utility model an action for determination of non-infringement can be filed with the IPO. The applicant must have a legal interest in the determination, which is present if it genuinely intends to use or market the product or process. The IPO then decides whether the product or process, as it is described by the applicant, falls within the scope of protection of the patent, SPC or utility model.

While the law in principle allows for declaratory judgments on invalidity or non-infringement, these are only permissible where there is an urgent legal need for them. The courts have so far always ruled that there is no urgent legal need in determining whether a patent, SPC or utility model is infringed or valid. This is because the alleged infringer can fully defend itself in the infringement proceedings once they are brought by the right-holder.

## 2.3 Courts With Jurisdiction

The City Court in Prague has sole jurisdiction in industrial property matters at first instance. The High Court in Prague hears appeals. One of the nine Regional Courts has jurisdiction over trade secrets or unfair competition litigation. The High Court in Prague, or the High Court in Olomouc hear appeals. The Supreme Court hears admissible extraordinary appeals.

In matters where the final decisions of the IPO or customs are being challenged through judicial review, the City Court in Prague administrative branch has jurisdiction. The appeal in the form of a cassation complaint is decided by the Supreme Administrative Court.

The Constitutional Court hears constitutional complaints of the parties, or referrals by any of the courts.

A preliminary question may be referred to the CJEU on issues of EU law, by any of the courts.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

Several permanent arbitration courts or venues operate in the Czech Republic. The best known of these is the “Arbitration Court attached to the Czech Chamber of Commerce and the Agricultural Chamber of the Czech Republic”, which has several IP specialised arbitrators on its list.

## 2.5 Prerequisites to Filing a Lawsuit

If the patent, SPC or utility model is shown as valid on the official register maintained by the IPO, it can be enforced without any further prerequisites by the owner.

A licensee must have its licence registered with the IPO to be able to enforce it against infringers.



No prerequisites apply to enforcement of trade secrets or unfair competition.

Where the plaintiff wishes to claim costs of litigation, it must send a Section 142a o.s.ř. pre-litigation letter to the other side at least seven days before lodging the papers with the court. Failure to send has no effect on the claim itself, only on the right to costs, and even so the courts in IP matters often order costs where no letter was sent, if the defendant actively defends the case.

## 2.6 Legal Representation

There is no general requirement for the parties in intellectual property disputes or litigation to be represented.

Attorneys-at-law and patent attorneys can represent clients before the courts and administrative bodies.

Representation by attorneys-at-law is required before the Supreme Court, Supreme Administrative Court and the Constitutional Court.

## 2.7 Interim Injunctions

Interim (preliminary) injunctions (PIs) are available before and during proceedings.

To succeed with a PI request the PI applicant has to prove that:

- it has a valid right;
- this right is likely infringed by the defendant's conduct;
- the preliminary order sought is necessary given the general circumstances of the case; and
- the benefit of the PI order to the applicant is not exceeded by the detriment caused to the defendant.

Validity of the right, or rather the lack thereof, cannot be a reason for the court refusing a preliminary injunction.

By law no hearing can be held and the court must decide immediately and not later than within seven days. The City Court in Prague often decides within one to two days. The defendant is not informed of the PI application, or a decision rejecting/refusing the PI application. In practice, almost all cases are decided on an ex parte basis as a result.

The PI applicant has strict and unlimited liability for damage caused by the PI, if the PI fails otherwise than through the applicant's success in the action on merits. The effect of EU law, the CJEU decision in Bayer C-688/17, which appears to prohibit this form of liability, is so far unclear.

A bond of circa EUR2,000 has to be paid into court when filing the application. This can be increased by the court.

## 2.8 Protection for Potential Opponents

Defending against a PI application is notoriously difficult, given that the defendant is not informed of the PI application being filed, and the court decides within days in ex parte proceedings. In addition, no new evidence can be presented on appeal. An application to revoke a PI then does not assist the defendant, as the defendant has to prove that the PI should never have been ordered, which requires the court to examine evidence in full, ie, at a hearing in the action on merits. An ordered PI is thus difficult to remove for years and defending against it through the limited means before it is ordered is the only option.

One means of defence is aiming to submit a defensive brief with the court in the hope that

the court will look at it when deciding on the PI application. Defensive briefs are not anticipated by the law, but they are not prohibited by the law either. They are increasingly being used. Their effect appears to be minimal, however, as the courts have no system of searching for them. The existence of a single court of jurisdiction for patent, SPC and utility model matters assists, as only one defensive brief needs to be sent out. In an ideal scenario, the court would search its database when it obtains a PI and study the defensive brief and attached evidence before deciding or at least make the brief part of the court file, so that the defendant can rely on it on appeal. More often than not, the briefs simply never play any role and remain on the court's files indefinitely.

Another alternative is to call the court daily and aim to submit a written defence once the PI application is filed in the PI application proceedings directly. This should ensure that arguments and evidence can be relied on by the first instance court and on appeal. With daily monitoring the PI application may be decided once the defence reaches the court, as the City Court often rules within one to two days.

## 2.9 Special Limitation Provisions

The right-holder can obtain a permanent injunction if the infringing conduct is taking place or is threatened when the court issues the first instance decision. For the action on merit, it is not relevant when the infringement began. A PI cannot be ordered if it is not urgently needed: ie, if the right-holder suffers infringement for too long, a PI will no longer be available. If the conduct ceased as a result of a PI, the conduct is treated as continuing.

In the case of damages and other monetary claims a three-year subjective limitation period

applies. The moment when the owner found out who caused the damage/harm and the level thereof is decisive for the subjective period. The objective limitation period is ten years from the day of the damage or harm occurring.

The right to non-monetary remedies such as the right to an apology is not limited in time.

## 2.10 Mechanisms to Obtain Evidence and Information

The right-holder can generally request that the court seizes or otherwise acquires evidence which may not be available later, or only with great difficulty. This can be done even before action on merit proceedings begin.

It is possible to request preliminary seizure of a sample of allegedly infringing product and related documents before proceedings begin, or after they begin. The proceedings are the same as in interim injunction proceedings (see [2.7 Interim Injunctions](#)).

Third parties must generally disclose any evidence they have available in court, if the court so requests, unless they would themselves admit infringement. The defendant can refuse to testify. The defendant has to produce evidence clearly identified by the court in an order.

Information about scope of infringement can be sought from the defendant, however, not in a preliminary manner: ie, only once infringement is ruled upon will the court order the defendant to disclose such information.

## 2.11 Initial Pleading Standards

The infringement proceedings are generally front-loaded in that all arguments should be contained in the initial pleadings and all evidence attached or identified. However, for tactical or

practical reasons it is also possible to state the absolute bare minimum in the initial claim, and supplement arguments and evidence and make evidence requests later, as it is possible to do so until the end of the first oral hearing and with the court's permission even later. IP proceedings do not differ from other litigation.

## 2.12 Representative or Collective Action

Representative or collective actions are not available in industrial property disputes.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

Even if a lawsuit is clearly unfounded, there is no sanction under Czech law for bringing it, other than the obligation to pay the defendant's costs.

Certain conduct could amount to unfair competition, such as dragging customers into the IP dispute with another supplier by accusing the competitor of infringing rights.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

The owner of the right can enforce it in its own right.

A licensee can enforce the right once it is registered in the patent, SPC, or utility model register. It has to be either expressly authorised to enforce under the licence, or inform the owner of its intent to enforce, and if the owner does not bring proceedings itself within 30 days of such notification, the licensee can enforce.

### 3.2 Direct and Indirect Infringement

The right-holder can seek protection from both direct infringement, and from indirect infringement of a patent.

Direct infringement of a patent is:

- the manufacture, use, offering, introduction of a patent-protected product onto the market, or its storage, import or other dealing with it for such purposes;
- the use of a patented method/process or offering it; and
- dealing with a product made through a patented process.

There is a presumption of infringement of a process if the defendant's product is identical to that made by the patented method, where it is likely the patented process was used and the owner could not access evidence about the process.

Indirect infringement is such conduct where the defendant does not practice the invention, but supplies a key element of the invention to another or offers to do so, where the defendant knows the element can be used for the patented method, and the key element is not readily available on the market for a legitimate use. The supplier of the key element cannot benefit from the exemptions to patent law in particular under the non-commercial use, experimental use exemption.

The same applies to SPCs, although minor differences exist.

In the case of utility models no one may in commercial activity use, manufacture or introduce into circulation a protected product.

Other conduct, such as that aimed at assisting infringement (sometimes called secondary patent infringement), can be caught under the prohibition of unfair competition as it is not moral to assist others in infringing patents, SPCs or utility models.

### 3.3 Process Patents

In the case of process or method patents the process or method must be practised within the territory of the Czech Republic. However, since the offering of a process is infringing conduct in its own right, in such a case it is not relevant where in the world the process is carried out if the offer is made in the jurisdiction. The injunction would then only be directed to offering, and not the practising of the protected process.

### 3.4 Scope of Protection for an Intellectual Property Right

The scope of protection of patents, SPCs and utility models is determined by first looking to their claims, which are interpreted literally. In this process the description and drawings are relied on as well. It is examined whether all the technical features of the claim as they would be identified by the person skilled in the art are present in the product or process under examination. If all technical features are present the product or process falls within the scope of the claim. If a technical feature of the claim is missing in the product or process under examination, it must be determined whether the missing feature is in fact essential to the invention or whether it is not in fact present as a permissible technical equivalent.

The right-holder has to prove that the feature, despite being in the claim, is in fact not essential. The patent grant procedure may have resulted in superfluous technical features, which are in

fact not necessary to exercise the invention, and which should be disregarded.

The right-holder has to prove that an equivalent feature is present in the product or process, and that even with the substitution the patented invention is still realised. There is still very limited case law on the issue of equivalents.

There is no rule stating that prosecution history cannot be taken into account.

The courts carry out the analysis themselves. However, as all judges are legally trained only, they extensively rely on experts, especially those listed in the field of “Patents and Inventions/Industrial Property”, to interpret claims.

Anyone with a legal interest can apply to the IPO for a determination of non-infringement, where the IPO determines whether the product or process described in the application (ie, a product as such cannot be presented for examination) falls within the scope of protection of a patent, SPC or utility model.

An expert admitted with a Regional Court/Ministry of Justice in the field of “Patents and Inventions/Industrial Property” can be approached to prepare an expert report on whether a product falls within the scope of protection of a patent, SPC or utility model.

### 3.5 Defences Against Infringement

The defendant can raise a number of defences to infringement.

First it can claim that it is a prior user of the right. In such a case the right is not effective against it. The exact scope of such right remains unexplored, eg, it is unclear whether use must be

continual, whether improvements extinguish the right and how it can be assigned, if at all.

Second, patent rights could have been exhausted, as once the right-holder places the product onto the market in the EU or EEA, the patent can no longer be enforced in relation to that product. This permits free movement of goods within the EU and EEA.

A compulsory licence can allow an infringer to use the right, but only after such compulsory licence is granted by the IPO.

There is still no local case law on reasonable and non-discriminatory (FRAND) agreements in standard essential patents, and whether injunctions are unavailable if the right-holder does not engage in genuine negotiations. Given that existing EU case law has not created hard rules, it is difficult to know whether a right-holder will be unable to seek an injunction in such cases, if it does not engage in genuine negotiations.

### 3.6 Role of Experts

The judges are all legally trained and as a result the courts rely on experts to resolve technical issues. The parties can present expert reports prepared by experts, and these have the same weight as those presented by experts appointed by the courts, if they are prepared in accordance with the conditions of Section 127a o.s.ř.

The courts maintain a list of appointed experts, and one of the fields of expertise is “Patents and Inventions/Industrial Property”. Such experts are often retired officers of the IPO or patent attorneys. Such experts are often called on and permitted by the courts to interpret patent or utility model claims, ie, to determine whether a certain product or process falls within the scope of protection of the patent, SPC or utility model.

### 3.7 Procedure for Construing the Terms of the Patent’s Claim

There is no distinct procedure for interpreting patent claims; the court carries out patent interpretation itself when weighing the case as a whole, with the parties presenting the competing positions. The courts often rely on the above-described experts to interpret the claims for them through an expert report. The expert should also be heard and cross-examined in court.

### 3.8 Procedure for Third-Party Opinions

There is no system for the court to seek third-party opinions. However, an affected third party can seek to intervene in court proceedings. Such intervening party has near full rights in the proceedings, ie, it joins the side of the dispute on the success of which it has a legal interest and it presents its own argumentation, evidence and can even appeal. However, it cannot act adverse to the party on whose side it joined, and it cannot settle, withdraw or amend the main claim.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

A registered right can be revoked on application to the IPO. Any person can seek to revoke a registered right. Revocation proceedings can be begun even after a right has expired; however, in that case the applicant has to show a valid legal interest in doing so.

The courts cannot revoke a patent. However, they can decide that it is invalid and refuse to grant it protection.

Patent revocation can be based on the argument that:

- the conditions for patentability were never present (lack of novelty or inventiveness over the prior art, lack of industrial applicability, the subject matter is not patentable for lack of technical nature or excluded from patentability – eg, surgical or medical treatment);
- the invention is not described so fully or clearly to enable the person skilled in the art to practise it;
- the patent contains added matter over the scope of the application; and
- the patent owner is not the inventor or its legal successor.

Utility models can be revoked for similar reasons; however, the novelty and innovative level are less strict than in the case of patents.

SPCs can be revoked for reasons specified in the respective EU regulations. Generally, this is because the protected product to which the SPC applies was in fact not properly supported/anticipated by the basic patent, the product was already protected through a certificate, or some other error occurred in the granting process.

## 4.2 Partial Revocation/Cancellation

The right can be revoked only partially, where the reasons for revocation apply only to its part.

This does not apply to SPCs, which can only be revoked as a whole or not at all.

## 4.3 Amendments in Revocation/Cancellation Proceedings

To avoid full revocation of a right the owner can almost at any time make auxiliary requests, that amend the original wording of the right. This does not apply to SPCs.

In the case of patents, technical features can be taken from the description.

In the case of utility models, case law suggests that claim amendment can be carried out only through the incorporation of dependent claims into the main claim, and no rewording or taking of features from the description is permitted.

## 4.4 Revocation/Cancellation and Infringement

Infringement is ruled on by the courts. The courts can address the issue of whether a patent is valid, but this is extremely rare. In such a case, the court will refuse to provide protection to the patent or its invalid part; it cannot order its removal from the patents register.

To fully revoke a patent and have it removed from the register an application must be filed with the IPO.

The court can wait for the IPO decision on validity, but not in all circumstances and never in preliminary injunction proceedings. The court can also decide to resolve the validity issue itself.

The court must wait for an IPO decision in utility model matters before ruling in favour of the right-holder, or itself decide that the utility model is valid, because there was no substantive examination at the IPO before its grant. This is not the case in the case of preliminary injunctions, where validity is presumed.

The validity proceedings and infringement proceedings proceed at their own pace – the system is bifurcated. If a final infringement decision is made in favour of the right-holder and the patent is later revoked, the infringement proceedings can be reopened.



## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

Ordinary rules of procedure apply to industrial property and unfair competition litigation.

In cases involving trade secrets or unfair competition the regional court in whose jurisdiction the defendant is registered has jurisdiction.

Cases involving patents, SPCs and utility models are heard by a specialised senate/panel of three judges at the City Court in Prague (one of the regional courts), which is the only court of jurisdiction.

First instance proceedings take one to three years to reach judgment, depending on complexity. The first hearing takes place six to 12 months after a claim is filed. Usually two, and sometimes three, hearings are necessary. Each lasts a maximum of one day, usually only a few hours. There is no upper limit on the number of oral hearings.

The first hearing is often organisational and generally results in the court admitting most of the evidence presented in the matter so far and deciding to appoint an expert. At the second hearing the expert is heard, or experts are heard, and the court decides, or adjourns to fully consider the expert's evidence, or to have it reviewed by a further expert.

All witnesses and experts can be cross-examined: although formally it is the court that asks the questions, in practice this is often dispensed with and parties address their questions to the witness or expert directly.

The judgment can either address infringement and damages, or the court can issue an interim judgment on infringement and reserve its judgment on damages until after the appeal on infringement is heard. Damages claims are not common; most cases proceed as pure infringement cases seeking an injunction. Damages are then claimed at a later date through separate proceedings – limitation periods must be kept in mind.

### 5.2 Decision-Makers

Industrial property cases are decided by panels of three judges at the City Court in Prague or the High Court in Prague who specialise in industrial property. All judges are legally trained and have no formal technical education.

The parties cannot influence where and who hears their case.

### 5.3 Settling the Case

The court has to encourage parties to settle. The court does so before beginning proceedings and throughout the proceedings. The court can advise parties to attend mediation. However, the defendant cannot force a case to be settled as it is the plaintiff who is ultimately in charge of the litigation.

### 5.4 Other Court Proceedings

If invalidity/revocation proceedings are pending before the IPO or opposition proceedings before the EPO, the infringement court can decide to stay and await the decision. It should only do so where it is advantageous to do so given the circumstances, ie, it should not do so when the other decision is far away.

Otherwise, the infringement courts cannot delay; in particular, no anti-injunction proceedings are



available, and foreign decisions or proceedings play no tangible role.

## 6. Remedies

### 6.1 Remedies for the Patentee

The right-holder can demand that:

- the infringing conduct stops, eg, the product is not made, offered, used, disposed of, stored, imported or otherwise dealt with;
- the infringing state of affairs is remedied, eg, the product is withdrawn from the market, and is destroyed, or an apology is made at the expense of the defendant;
- the damage caused is compensated (including lost profit);
- the unjustified enrichment of the infringer is surrendered;
- reasonable compensation for immaterial harm is paid;
- a court judgment is published at the expense of the defendant;
- information about the infringement is provided by the defendant; and
- it receives costs, ie, actual reasonable expenses incurred in the proceedings and legal expenses at statutory levels (see **6.2 Rights of Prevailing Defendants**).

The court does not have to order the destruction of goods. The court decides on the wording and scope of publication of an apology, based on what it thinks is appropriate.

### 6.2 Rights of Prevailing Defendants

The successful defendant can seek costs, which include actual, reasonably incurred expenses (primarily the court fee, cost of acquisition of evidence, notary public fees, translation and expert cost) and cost of legal representation. Legal rep-

resentation costs are recoverable at statutory levels, which means that in cases where no damages are sought the recovery is circa EUR1,000 per instance per defendant.

If a party has partial success it can usually only recover costs in part.

### 6.3 Types of Remedies

The remedies for the various industrial property rights are in practice the same. However, only in the case of patents, SPCs and utility models can the plaintiff demand that the monetary compensation for damage, unjustified enrichment and reasonable compensation for immaterial (non-economic) harm is paid in the form of a lump sum equal to at least twice the licence fee that would have authorised the infringement. This is not available in unfair competition cases, where the pecuniary compensation must be precisely calculated and proven.

### 6.4 Injunctions Pending Appeal

The first instance judgment is not effective or enforceable if it is appealed. All orders are thus ineffective until the appeal court decides. This does not apply to the preliminary injunction orders which continue.

A fresh interim injunction could also be sought to provide protection pending the appeal.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

Appeals in industrial property matters proceed under ordinary rules of procedure.

In the case of patent, SPC and utility model appeals, the City Court in Prague and the High

Courts in Prague have exclusive jurisdiction and sit in three-member panels/senates. All judges are legally trained and specialise in intellectual property.

## 7.2 Type of Review

The appeal proceedings allow for a review of both fact and law. However, new evidence cannot be presented as a general rule, unless it can be shown that one of the exceptions applies, such as the evidence did not exist at the time of first instance judgment, or to undermine the credibility of evidence relied on in the judgment, or to prove errors of procedure.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

No costs have to be incurred before a lawsuit is initiated.

Preparing a warning letter generally costs between circa EUR500 and EUR1,500 depending on case complexity.

The formal pre-litigation letter that is required for the plaintiff to be able to claim costs can cost circa EUR200 to EUR1,500. Where a warning letter was sent first, the costs are very low.

For the defendant, preparing a protective brief can cost between EUR3,000 and EUR7,000, depending on case complexity. Daily monitoring of court can cost circa EUR2,000 per month.

### 8.2 Calculation of Court Fees

The court fee, where no financial claims are made, is circa EUR100 per order sought. For PI applications, the court fee is circa EUR50.

Where damages are sought, the court fee is 5% of the sum sought where the sum is between circa EUR1,000 and circa EUR1.5 million. Above that sum, the fee is circa EUR80,000 plus 1% of the sum sought which is above the EUR1.5 million value (if the sum sought exceeds EUR10 million, the 1% fee increase no longer applies).

### 8.3 Responsibility for Paying the Costs of Litigation

Each party bears its own costs of sustaining the proceedings, ie, costs of legal counsel, acquisition of evidence, notary public fees, translation fees and expert fees.

The plaintiff has to pay the court fees and the PI bond. The defendant pays the court fee only if counterclaiming.

The court pays the costs of steps it undertakes including the acquisition of evidence, eg, commissioning of expert reports and translations. The court can demand an advance payment from the party which proposed that the evidence is acquired.

The losing party is ordered to compensate the successful parties, and the state/court's costs as described in **6.2 Rights of Prevailing Defendants**. In the case of only partial success in the matter, costs are awarded in part.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

Alternative dispute resolution is not common in intellectual property disputes.

Negotiation, mediation and arbitration is available if the parties agree.

The benefit of alternative dispute resolution is that it can be much quicker than litigation.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

Industrial property rights placed on a register must be assigned in writing and the assignment recorded with the IPO.

### 10.2 Procedure for Assigning an Intellectual Property Right

The assignment must be in writing and an application must be lodged with the IPO for its registration, which usually takes a few weeks to a few months.

This does not apply to trade secrets or unfair competition.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

A licence to registered industrial property does not have to be in writing.

A licence to a registered right is only effective against third parties once it is registered by the IPO. In that case it must be in writing. A licence is effective between the parties even if unregistered and not in writing.

An exclusive licence must be in writing.

### 10.4 Procedure for Licensing an Intellectual Property Right

A licence must specify:

- the scope of the licence;
- the duration;
- the territory to which it applies; and
- what financial compensation is due to the licensor, or expressly state that the licence is granted gratuitously.

An exclusive licence must be in writing.

Contributed by: Petr Kusý, Čermák a spol

Čermák a spol is a law and patent office; a boutique firm specialising in intellectual property and related fields. It is active in the prosecution of patents, where through its patent attorneys before the Czech Industrial Property Office, the EPO and other patent offices, and after the grant of a patent, it is able to both defend against validity challenges to the patent, and enforce the patent against infringers through its attorneys-at-law. With over 40 employees and

numerous external assistants, Čermák a spol is one of the largest IP firms in the country. It has a dedicated partner office in Slovakia and established contacts around the world. Given the firm's long-term presence on the market, dating back to 1990, the firm has represented most of the key players in all fields of technology, including most of the leading companies in the pharmaceutical, chemical, telecommunications or mechanical engineering sectors.

## Author



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## Law and Practice

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

The French Intellectual Property Code (IPC) provides three types of intellectual property rights for the protection of inventions: patents, utility certificates and supplementary protection certificates (SPCs).

French patents arise from the filing of an application with the French Office for Intellectual Property (INPI).

Similarly, a French utility certificate can be obtained but for a shorter duration.

SPCs are further discussed in **1.6 Further Protection after Lapse of the Maximum Term**.

France is party to the European Patent Convention (EPC) and may therefore be designated in a European patent. Starting 1 June 2023, European patents may have unitary effect. Where this unitary effect is granted, those patents will be designated as “unitary patents” and the Unified Patent Court UPC will have exclusive jurisdiction over their validity and infringement. France is also party to the Patent Cooperation Treaty (PCT) and may consequently be designated in a PCT application.

In addition, French law (Article L.151-1 et seq, French Commercial Code) protects trade secrets (ie, information that is secret, has commercial value because of its secrecy, and has been subject to reasonable steps to keep it secret against its unlawful acquisition, use and disclosure).

France is a statute-based jurisdiction and uses case law for the purposes of construing applica-

ble statutes. The IPC contains the core of French patent law.

### 1.2 Grant Procedure Patents

The grant procedure for both French and European patents begins by filing an application before the INPI or the European Patent Office (EPO), respectively.

As for the French procedure, the INPI examines the application within two to five months. The INPI now has the authority to refuse an application for lack of inventive step, where previously the INPI could only refuse a patent for lack of novelty or non-industrial applicability. Then, the INPI transmits to the applicant a prior art search report with its opinion on the patentability of the invention. The applicant can respond to the INPI’s observations within three months and/or amend its application. Within a period of three months from publication, the applicant may receive observations from third parties to which they must reply. At the end of this period, the INPI establishes a final report and, if the registration fees are paid, the patent is generally granted within six months.

The EPO procedure differs slightly as the prior art search report and the opinion on patentability are transmitted before any substantive examination of the application. The publication of application occurs 18 months after the filing date. Within six months from the publication, the applicant can decide to abandon or pursue with an examination on the merits by the EPO. During this period, the EPO may require the applicant to provide additional information.

As from 1 June 2023, the unitary effect of a European patent may be requested within one month of the grant of the patent. During the transitional



period, which will last seven years (renewable once) starting with the coming into effect of the Unified Patent Court Agreement (UPCA), the applicant must only provide a translation of the patent in one language (in English for patents granted in French or German and in any EU language for patents granted in English). After this transitional period, no translation will be required.

## Utility Certificates

The grant procedure for a French utility certificate is essentially the same as the above-mentioned French patent procedure, with the exception that it does not involve any prior art or substantive validity examination by the INPI. Publication of the application occurs 18 months after the filing date or priority date.

## Trade Secrets

There is no grant procedure for trade secrets as protection is automatically conferred to the person lawfully in control of confidential information for which reasonable steps have been implemented to preserve its secrecy.

### 1.3 Timeline for Grant Procedure Patents

The grant procedure for French and European patents can last several years and will depend on the complexity of the invention and its technical field. On average, it takes from two and a half to four years before the INPI and four years before the EPO.

Representation by a qualified attorney is not mandatory before the INPI, but is recommended. Similarly, applicants can file European patent applications themselves, unless their residence or place of business is located outside an EPC contracting state.

Official taxes are payable to the INPI: EUR26 for the filing of the application, EUR520 for the search report and EUR90 for the granting of the patent. Fee reductions may apply for individuals, educational or research non-profit organisations and small companies.

As for European patents, the total procedure costs approximately EUR6,100 (or EUR5,875 for online applications).

Patent attorneys' fees range from EUR5,000–6,000.

## Utility Certificates

The grant of a utility certificate usually takes two years after the filing. The above patent fees equally apply to utility certificates, with the exception of the search report fee.

### 1.4 Term of Each Intellectual Property Right

Protection for both French and European patents lasts for 20 years from the application date, provided annual fees are duly paid.

Utility certificates are granted for a period of ten years from the application date.

Trade secrets are protected indefinitely.

### 1.5 Rights and Obligations of Owners of Intellectual Property Rights

#### Patentee Rights

The patentee has the exclusive right to exploit the patented invention.

In particular, the patentee has the exclusive right to use the invention to manufacture and put on the market the patented products or those obtained by the patented process. The patentee is also entitled to assign or license its rights

and decide who can use, make, distribute or sell the patented invention. Unauthorised use of the invention qualifies as an infringement for which the patentee may request injunctions and obtain damages.

## Patentee Obligations

In France, any third party can request the grant of a compulsory licence before the Paris Court of First Instance (Article L.613-11, IPC) if, in the absence of any lawful excuse, at the end of a three-year period after the grant, or four years from the application date, the patentee:

- has not exploited the patented invention or made effective and serious preparatory measures to do so;
- has not marketed the patented products in sufficient quantity to satisfy the French market's needs; or
- has abandoned the exploitation of the patent for more than three years.

Lastly, an annual fee shall be paid to maintain the patent in force.

## 1.6 Further Protection After Lapse of the Maximum Term

The protection cannot be extended beyond the 20-year period from the application date (Article L.611-2, IPC). However, the following patents are eligible for an SPC:

- a medicinal product;
- a process for obtaining a medicinal product;
- a product necessary for the manufacture of a medicinal product; or
- a process for the manufacture of a medicinal product.

SPCs aim at extending the period of protection by taking into consideration the time required

to obtain a marketing authorisation (MA). SPC applications must be filed within six months after the grant of the first MA, or alternatively within six months of the grant of the patent if the MA is granted before the patent.

SPCs take effect on the expiry of the patent for a duration that cannot exceed seven years after this expiration and 17 years from the grant of the MA (Article L.611-2, IPC), provided that the total protection period, patent included, cannot exceed 20 years.

## SPC Waivers

The EU regulation 2019/933 on SPCs has created waivers to the protection conferred by an SPC to ensure competitiveness. Importantly, the manufacture of a product or a medicinal product containing the concerned product, for the purposes of exporting to third countries, or any related act strictly necessary for the manufacture or export of such a product, is now permitted.

Furthermore, MA holders can now conduct all preparatory acts for the marketing of the generic in an EU member state six months before the expiry of the SPC.

## 1.7 Third-Party Rights to Participate in Grant Proceedings

Any third party may, up to three months after the publication of the search report, submit written observations to the INPI related to the novelty or inventive step of an invention (Articles L.612-13 and Article R.612-63, IPC). As for utility certificates, third parties can submit observations until their grant (Article R.616-1, IPC).

Applicants can reply to the observations within a one-time renewable period of three months (Article R.612-64, IPC).

After the publication of a European patent application, and as long as its examination is ongoing, third parties may file observations concerning the patentability of the invention.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

The refusal of the INPI to grant a patent or utility certificate is notified to the applicant. An applicant can file before the INPI a request for a review of the decision (*recours gracieux*). Such a request is admissible only if the decision is deemed to be unlawful, no ground of expediency is accepted. Thereafter, the INPI can withdraw its decision within four months.

Alternatively, an applicant can appeal the INPI's decisions before the Paris Court of Appeal within one month (extended by one month for residents of French overseas territories and two months for foreigners) from the notification of the decision. The decision handed down by the Court of Appeal may also be appealed before the Supreme Court (*Cour de cassation*), either by the applicant or the INPI.

Where a European patent is refused, the applicant can appeal to the EPO's Boards of Appeal within two months of the notification of the decision. The applicant may further lodge an appeal before the Enlarged Board of Appeal.

## 1.9 Consequences of Failure to Pay Annual Fees

Failure to pay annual fees of a French patent by the due date can lead to the lapse of the exclusive rights. The payment is due on the last day of the month of the application anniversary date (Article R.613-46, IPC). Failure to do so can be remedied, within a grace period of six months, subject to the payment of the fees plus a penalty

amounting to 50% of the belated fees (Article L.612-19, IPC).

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

French law allows patentees to request before the INPI, in writing, the abandonment or amendment (*ex parte*) of one or several patent claims (as well as the description and the drawings), to reduce the scope of protection of the invention (Articles R.613-45 and L.613-24, IPC). In cases of co-ownership, such waiver or limitation must be requested by all co-owners. The request must include the full text of the amended claims and, where applicable, be accompanied by the amended descriptions and drawings. The INPI generally issues its decision within 12 months from the date of reception of the request (Article R.613-45-1, IPC).

If filed after the introduction of an opposition, a request to amend is deemed inadmissible as long as the decision on the opposition is subject to appeal, unless it is ordered by a court decision ruling on the invalidity of the patent. Similarly, if an amendment request is pending on the date an opposition is filed, the request will be dismissed, unless it was ordered by a court decision ruling on the invalidity of the patent.

In the context of opposition proceedings, the patentee is entitled to amend the claims, provided that such amendments:

- correspond to one of the grounds of opposition raised by the opponent; and
- comply with the patentability requirements under the IPC.

See 4.3 Amendments in Revocation/Cancellation Proceedings with respect to amendments

in inter partes revocation/cancellation proceedings.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

Before French courts, patent infringement is a tort under civil law and the patentee can either initiate civil or criminal proceedings (Articles L.615-1 and L.615-14, IPC).

A civil procedure on the merits can be initiated either through regular or accelerated proceedings. For the latter, the claimant must obtain (ex parte) the authorisation to summon the defendant on a fixed day under special emergency rules.

Preliminary measures are deemed to prevent imminent infringement or to stop infringement (see **2.7 Interim Injunctions**). Several preliminary measures are available for claimants, including:

- preliminary injunctions to stop the alleged infringing acts, eventually under a penalty;
- the seizure of the goods or their withdrawal from distribution; and
- a financial provision to the benefit of the claimant, if the existence of the damage is not seriously questionable.

Summary proceedings generally last between three and five months in first instance, and six months in appeal.

Infringement of a European patent with unitary effect will give rise to an infringement action before the UPC (see **2.3 Courts With Jurisdiction**).

### Criminal Action

Criminal proceedings are rarely initiated for several reasons, including:

- the requirement to prove the infringer's bad faith;
- the unavailability of injunctions;
- the absence of specialised intellectual property judges; and
- the low cap of recoverable damages.

In practice, criminal proceedings are more popular in cases concerning pirated goods or where the claimant seeks to establish the criminal liability of a corporate director.

### Customs

Border customs measures are equally available under Regulation (EC) 1383/2003 as well as under Article L.614-32 of the IPC. Such measures are useful to detect the entry into French territory of infringing goods and allow the patentee to gather infringement evidence before the release by the customs of the detained goods or the initiation of a court action.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property Opposition Action

The Law on Business Growth and Transformation (the "PACTE Law") has created an opposition procedure before the INPI against patents registered from 1 April 2020 (Articles L.613-23 et seq and R.613-44 et seq, IPC). Oppositions can be filed:

- within nine months following publication of the grant of the patent;
- by any third party; and
- if the subject matter of the patent is not patentable, if the patent does not describe sufficiently the invention for a person skilled

in the art, or if the subject matter of the patent extends beyond the content of the application.

If the opposition is upheld, the patent can be revoked in whole or in part, or be maintained in an amended version (Article L.613-23-4, IPC). The INPI's opposition decisions, which are issued approximately 17 months from the filing of the opposition, can be appealed before the Paris Court of Appeal.

### Revocation/Invalidation Action

Pursuant to Article 31 of the French Civil Procedure Code (CPC), a revocation or invalidation action may be initiated by any third party with a legitimate interest, defined as a direct and personal interest, on the date of the introduction of the proceedings. French judges have specified that “the interest in bringing an action for revocation must be recognised for any person who sees his economic activity in the field of invention actually or potentially but certainly hindered by the claims whose invalidation is sought”, but also for “plaintiffs who are not competitors of the patent holder but consumers and patients [...] provided that such an action is in favour of the public interest” (Paris Court of First Instance, 16 March 2017 and 24 January 2020).

### Action for a Compulsory Licence

To apply for a compulsory licence, the applicant must prove (Article L.613-12, IPC) that:

- it can exploit the invention in a serious and effective manner; and
- it cannot get a licence from the patentee.

Thereafter, the court sets the terms and conditions of the compulsory and non-exclusive licence (Articles L.613-12 and L.613-13, IPC).

### Declaration of Non-infringement

A declaration of non-infringement can be brought by any third party providing evidence of serious preparatory acts for industrial exploitation and having asked the patentee to state whether the patent would be infringed by such exploitation (Article L.615-9, IPC). If the patentee fails to answer within three months, or in the case of a disagreement, the third party can bring an action before the Paris Court of First Instance, requesting that it hold that the exploitation does not fall within the scope of the patent at stake.

### 2.3 Courts With Jurisdiction

At first instance, patent disputes fall within the exclusive jurisdiction of the Paris Court of First Instance handled by specialised judges of the third Chamber (divided into three sections of three judges). Appeals are examined by the fifth Division of the Paris Court of Appeal.

Once the UPC is operational, it will assume exclusive jurisdiction for disputes concerning unitary patents.

As a result, the French courts will have exclusive jurisdiction for French patents and for the French parts of European patents with no unitary effect. The UPC will allow a European patentee or a third party to use a single channel to protect or challenge unitary patents instead of filing several actions before different European jurisdictions. The first instance will include local divisions located in EU member states party to the UPCA, and a central division located in three countries, each specialised in a technical domain. The Court of Appeal will be in Luxembourg.

The “sunrise period”, within which European patents and European patent applications can opt out from the UPC system, is expected to

run from 1 March 2023 to the full opening of the UPC on 1 June 2023.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

The INPI has no jurisdiction over patent infringement disputes.

A local division and a section of the central division of the UPC will be located in Paris.

## 2.5 Prerequisites to Filing a Lawsuit

The first prerequisite is to gather evidence of the alleged infringement by any means available (see **2.10 Mechanisms to Obtain Evidence and Information**).

Subsequently, the patentee (or exclusive licensee) usually sends a formal notice requesting the cessation of the infringement.

If the value of the dispute does not exceed EUR5,000 (which is rare in patent matters), the claimant is required to attempt conciliation before bringing the action (Articles 54 and 750-1, CCP). This formality may be waived in cases of urgency or when an ex parte decision is needed.

Then, if the infringer fails to respond to the formal notice, or if the patentee is not satisfied by the outcome, patent proceedings can be introduced by serving a writ of summons upon the defendant before the Paris Court of First Instance.

## 2.6 Legal Representation

Before the French courts, parties shall be represented by an attorney-at-law from the Paris Bar. Attorneys from other French Bars may also represent the parties before the courts during oral hearings, but must appoint a member of the Paris Bar to serve as representative.

For any dispute before the Supreme Court, parties must be represented by specialised attorneys.

Before the UPC, representation will be compulsory, either by lawyers authorised to practise in an EU member state or by European patent attorneys entitled to act before the EPO. Both will be authorised to practise before every court and division of the UPC.

## 2.7 Interim Injunctions

Article L.615-3 of the IPC allows any person with standing to bring an infringement action. This includes the right to request, either ex parte or inter partes, any preliminary relief to prevent imminent infringement or to stop infringement by the alleged infringer or its intermediaries.

Preliminary injunctions are usually granted where:

- the patent is likely to be found valid;
- its infringement is likely;
- there is a significant risk of damage for the patentee resulting from the infringement, and
- the interim injunctions requested are strictly proportionate.

For instance, it has been found that requests to prohibit the sale of alleged infringing products and their withdrawal from distribution channels are disproportionate since the patent invoked was to expire in the following weeks and was not being operated (Paris Court of First Instance, 20 January 2020).

In a recent order, and for the first time in France, the President of the Paris Court of First Instance has ruled admissible an application for interim injunctions grounded on a European patent



application (Paris Court of First Instance, 3 June 2022).

Preliminary proceedings may be started either before or after the action on the merits. In the second scenario, the action on the merits must be brought within 20 business days (or 31 calendar days) starting from the date of the court order. Failing to do so triggers the automatic cancellation of the measures granted.

Similarly, Article 62 UPCA provides that the UPC may order interim injunctions to prevent or stop infringement and will take into account the prejudicial effects of the measures before ordering them.

## 2.8 Protection for Potential Opponents

In France, protective letters against potential ex parte injunctions or a seizure (*saisie-contrefaçon*) are not admitted. However, such restriction is balanced by the fact that:

- ex parte interim injunctions remain rare; and
- potential opponents may challenge the order authorising the *saisie-contrefaçon* (see **2.10 Mechanisms to Obtain Evidence and Information**).

## 2.9 Special Limitation Provisions

Before French civil courts and the UPC, the limitation period for infringement actions is five years from the day on which the patentee knew or should have known that the infringement had occurred.

As for criminal actions, they must be filed within six years of the day on which the offence was committed.

Finally, before the French courts as before the UPC, no limitation periods apply to patent nullity actions.

## 2.10 Mechanisms to Obtain Evidence and Information

In France, there is no discovery procedure. Therefore, the parties remain free to disclose the evidence of their choice subject to what is set out below.

### Infringement Seizure (*Saisie-Contrefaçon*)

In practice, infringement seizure is one of the most widely used and efficient probative measures in France. To perform it, the claimant must obtain an order from the President of the Paris Court of First Instance by way of an ex parte request precisely specifying the scope of the seizure. The seizure can only be performed by a bailiff, generally alongside an expert or patent attorney.

The bailiff may seize samples of infringing goods and any documents needed for the assessment of the infringement and the damage suffered.

The UPCA provides that, at the request of an applicant who has presented reasonably available evidence to support that the patent is being or is about to be infringed, the UPC may, even before the commencement of the proceedings on the merits, order:

- the detailed description, with or without the taking of samples;
- the physical seizure of the infringing products, and of the materials and implements used in the production and/or distribution of those products and the documents relating thereto; and
- the inspection of the premises.



In France as before the UPC, seizures are only valid provided the claimant brings proceedings on the merits within 20 working days or 31 calendar days.

## **Bailiff's Report**

The patentee may also gather evidence by means of a bailiff's report. The bailiff takes note of the offer to sale of the litigious products and the purchase by an independent third party. French case law tends to apply strict rules protecting the interests of the person seized and imposes the independence of the bailiff and the purchaser.

## **Information About Distribution**

Furthermore, Article L.615-5-2 of the IPC (before French courts) and Article 67 of the UPCA (before the UPC) provide for a right of information allowing the patentee to request any documents and information necessary to determine the origin and the extent of the distribution networks of the alleged infringing products or processes.

## **Judicial Powers**

French judges are also vested with investigative powers and are entitled to issue injunctions requesting the production of evidence against one party, if necessary, under a penalty payment (Articles 11 and 138, CPC). They may also, at the request of one of the parties, order the production of any document held by a third party provided there is no legitimate impediment.

### **2.11 Initial Pleading Standards**

As a preliminary step, the claimant must demonstrate in the writ of summons its legitimate interest to sue and confirm the validity of the patent by the production of the payment statement.

Before French courts, several pre-trial hearings will be set for the filing of submissions and

exhibits in reply to the arguments raised by the other party. However, if a claimant has opted for expedited proceedings, all arguments and evidence must be gathered when serving the writ and additional claims or new evidence might not be allowed afterwards. In any event, once the closing order is issued by the court, the parties cannot further amend their claims or introduce additional arguments or evidence. Only the facts, legal arguments and evidence disclosed in the written submissions and communicated between parties can be discussed during oral pleadings.

Before the UPC, action for infringement will be brought by lodging of a statement of claim, which must contain similar information (listed in Rule 13 of the Rules of procedure) to those required before French courts.

In this respect, the procedure before the UPC will mainly differ from the French one in that, most of the time, each party may file only two statements, and the pre-trial procedure will only start after the lodging of the statement of defence.

### **2.12 Representative or Collective Action**

No class action regarding intellectual property matters can be brought, neither before French courts nor before the UPC.

### **2.13 Restrictions on Assertion of an Intellectual Property Right**

In France, as before the UPC, no defence for inequitable conduct can be raised.

Based on the principle of *res judicata*, a party can be estopped from filing a claim if it has previously brought the same claim and lost.

No acquiescence defence exists (ie, the delay taken by the patentee before the proceedings

cannot be used as a defence, except when the statute of limitations period has run out).

In general, French competition law does not prevent the patentee from obtaining compensation in the case of an infringement. Nevertheless, patentees are sometimes restricted in their assertion of rights to prevent anticompetitive behaviours, such as an abuse of a dominant position. For example, following the Huawei decision of the CJEU of 16 July 2015, French courts would consider whether a FRAND licence was offered beforehand, in which case the patentee should be allowed to bring an infringement action and seek an injunction without this being regarded as an abuse of a dominant position.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

An infringement action can be initiated by:

- the patentee;
- each co-owner for their own benefit in the case of co-ownership, provided that the others are informed (unless otherwise stated in the co-ownership agreement); or
- an exclusive licensee, provided the licensing agreement does not stipulate otherwise, and if, after formal notice, the patentee has failed to institute proceedings (in such a case, the patentee has the right to intervene).

As for non-exclusive licensees, French law provides that they are not entitled to take such action, even with the patentee's consent. They can only intervene in the proceeding to obtain compensation for damages they have personally sustained. On this point, French law differs from the UPC as the UPCA provides that a non-exclu-

sive licensee will be able to initiate proceedings if expressly allowed in the licence agreement.

If the patent has been assigned, the assignee can only initiate proceedings if the assignment agreement has been registered and published. The assignee cannot claim damages for infringing activities that occurred prior to the assignment publication, unless expressly agreed upon between the parties.

Criminal actions can be brought by the patentee, its exclusive licensee, the prosecutor or the French customs.

### 3.2 Direct and Indirect Infringement

#### Direct Infringement

The following acts are deemed to be direct infringement (Article L.613-3, IPC):

- the manufacturing, offering, placing on the market, use, import, export or transshipment of the patented product;
- the stocking of the patented product for the above-mentioned purposes;
- the use of a process covered by the patent or, where the third party knows or where the circumstances make it obvious that the use of the process is prohibited without the consent of the owner of the patent, the offer of its use on French territory; and
- offering, placing on the market, using, importing, exporting, transshipping or holding for the aforementioned purposes a product obtained directly by the process covered by the patent.

Under Article 25 of the UPCA, the following acts are deemed to be direct infringement:

- making, offering, placing on the market or using a product which is the subject matter of

the patent, or importing or storing the product for those purposes;

- using a process which is the subject matter of the patent or, where the third party knows, or should have known, that the use of the process is prohibited without the consent of the patent proprietor, offering the process for use within the territory of the contracting member states in which that patent has effect; or
- offering, placing on the market, using, or importing or storing for those purposes a product obtained directly by a process which is the subject matter of the patent.

### Indirect Infringement

Indirect infringement occurs where an unauthorised person delivers or offers to deliver the means of implementing an “essential part” of the patented invention, when the person knows or should know, given the circumstances, that those means are used to implement the protected invention (Article L.613-4, IPC and Article 26, UPCA). The prohibition does not apply if such means are common commercial items.

Indirect infringers can only be liable for damages if they knew that their activities were infringing. For this reason, warning letters should be sent to put indirect infringers in full knowledge of the infringement.

Special attention should be paid to the drafting of any letter informing clients of the alleged infringement. Indeed, under French law it can qualify as disparagement and unfair competition against the infringer insofar as the addressees of the letter cannot verify the merits of the claims and do not have access to the infringer’s objections (French Supreme Court, 9 January 2019).

### 3.3 Process Patents

Acts relating to products obtained directly by a process which is the subject matter of the patent amount to infringement and are also prohibited.

It should be underlined that placing on the market, offering for sale or importing into France can be held even against a foreign operator.

### 3.4 Scope of Protection for an Intellectual Property Right

In principle, the scope of protection is determined solely by the claims, in light of the description and drawings.

Claim construction should be as accurate as possible in regard to the claims, without, however, being too literal, and shall not distort the subject matter protected by the patent.

French case law has defined a doctrine of equivalents under which an infringer may be held liable for patent infringement even if the infringing product or process does not fall within the literal scope of the claims, but is nevertheless equivalent to the claimed invention. In this context, the infringement is constituted if the essential means of the patent are equivalent, meaning that, despite being different, they perform the same function to reach an identical or similar result, and provided the said function is novel.

When invoked by a party, judges take the prosecution history into account as part of the factual context, both when interpreting the claim and when considering whether there is infringement pursuant to the doctrine of equivalents.

In particular, they pay attention to any narrowing of the claim(s) that has been made to avoid any conflict with relevant prior art and to secure the grant of the patent. In such cases, the extent

of protection can be limited to the particular claimed means and the doctrine of equivalents would not apply.

### 3.5 Defences Against Infringement Invalidity and Procedural Defences

Before French courts, the alleged infringer can dispute the claimant's capacity or authority to initiate proceedings, and can assert procedural defences including the lack of claimant's standing to sue, nullity of the writ of summons and/or the running of the statute of limitations. Good faith cannot constitute a valid defence, except for indirect infringers.

Furthermore, defendants can always challenge the validity of the patent on the basis of:

- lack of novelty;
- lack of inventive step;
- lack of industrial application;
- excluded subject matter;
- insufficiency;
- added matter beyond the content of the application; or
- extension of the scope of the patent claims after amendment.

Other available defences are set out below.

Before the UPC, once the applicant has lodged the statement of claim, the defendant will have one month to file preliminary objections disputing the jurisdiction and competence of the UPC, the competence of the division, and the language of the statement of claim.

Moreover, the defendant will have three months to file a statement of defence. This statement can include an assertion that the patent is invalid on the same grounds as before French courts.

As before French courts, other defences will be available.

### Non-infringing Acts

Under Articles L.613-5 et seq of the IPC and Article 27 of the UPCA, the rights conferred by a patent shall not extend to some situations, these include:

- private non-commercial use;
- experimental use relating to the subject matter of the patented invention;
- preparation for individual use in a pharmacy;
- acts, studies and tests required for the filing of an application for a marketing authorisation or the grant of an advertising visa (the Bolar exemption);
- acts performed to create, discover or develop new plant varieties;
- objects intended to be launched into outer space introduced into French territory;
- the farmer's privilege, allowing farmers to use the product of their harvest for propagation or multiplication on their own farm; and
- the breeder's privilege, allowing breeders to use the protected livestock for agricultural purposes.

### Personal Prior Possession

French law and the UPCA state that any person who, in good faith on the date of patent filing or priority, was in possession of the patented invention, is entitled to exploit the invention.

The French court welcomed such an exception when Fresenius, the patentee for a drug for the treatment of autoimmune diseases initiated an infringement action against Amgen, a drug manufacturer selling in France (Court of First Instance of Paris, *Fresenius Kabi Deutschland GMBH v Amgen*, 14 February 2019).

The decision recalls the four requirements to benefit from the exception:

- the technique must be possessed in good faith and be identical to the invention; and
- the prior possession must be established on French territory and prior to the filing date, or the priority date, of the patent application.

### Exhaustion of Rights

A patentee cannot prevent the sale, marketing or import or export of a patented product within the EU if it had already been put onto the market in another member state by the patentee or with their consent (Article L.613-6, IPC and Article 29, UPCA).

### Competition Law

French courts take into consideration fair, reasonable and non-discriminatory (FRAND) issues related to standard-essential patents (SEPs) before granting injunctions on the basis of such rights. See also **2.13 Restrictions on Assertion of an Intellectual Property Right**.

### 3.6 Role of Experts

French judges may appoint legal experts to assist them on technical issues or on the assessment of damages, either on their own initiative or at the request of the parties.

Legal experts shall issue a written report which can subsequently be challenged by the parties. Expert reports are not binding on judges.

The parties themselves can also support their case with private experts' opinions.

Before the UPC, experts will play a central role. The UPC may, at any time, appoint court experts for specific aspects of the case. Parties will also be allowed to lodge written witness statements

and to make applications for the hearing of witnesses in person. Moreover, the UPC may order, of its own motion, that a witness be heard in person. The president, the judges of the panel and the parties may put questions to the witness.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

There is no separate procedure for construing a patent's claims. Before French courts, issues related to validity, claim construction and infringement are assessed within the same proceedings.

Before the UPC, an action for revocation must be brought before the central division. Revocation actions will be divided between the sections of the central division according to the technical field to which the contested patent belongs. The Paris seat will have jurisdiction to rule on patents relating to performing operations, transportation, textiles, paper, fixed constructions, physics, and electricity.

Moreover, if the revocation is a counterclaim during an infringement action, the local/regional division ruling on the infringement of the patent will:

- rule on the counterclaim for invalidity, but request the assignment of a technical judge;
- refer the counterclaim to the central division and stay the infringement action; or
- at the request of the parties, refer the whole case to the central division.

### 3.8 Procedure for Third-Party Opinions

In the context of infringement proceedings, French courts may order any party, including third parties, to produce documents or request a consultation with, or the expertise of, a technician in the relevant field (Articles 11, 232 and

263 et seq, CPC). However, such a measure is rarely used.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

Revocation/cancellation can be brought independently or by way of counterclaim in the context of an infringement action.

French courts may revoke/cancel a patent if (Article L.613-25, IPC):

- the subject matter of the patent is not patentable (namely that it lacks novelty, inventive step, is not capable of industrial application and/or is generally excluded from patentable subject matters);
- the patent does not clearly and completely describe the invention for a person skilled in the art;
- the subject matter of the patent extends beyond the content of the application filed; or
- the scope of protection has been extended after limitation or opposition.

The UPC will ensure that the patent at stake meets the requirements of the EPC (novelty, inventive step, sufficiency of disclosure, no added matter as well as patentability).

As explained in section **3.7 Procedure for Construing the Terms of the Patent's Claim**, the distribution of revocation/cancellation actions among the divisions of the UPC will depend on several factors (if it is a main claim or a counterclaim, the panel and parties will, etc).

### 4.2 Partial Revocation/Cancellation

French and European patents can be revoked/cancelled partially, as a result of an invalidity decision (Article L.613-27, IPC and Article 65(3), UPCA).

### 4.3 Amendments in Revocation/Cancellation Proceedings

Patentees can amend their patent claims in the context of revocation/cancellation proceedings before the French courts. Such an amended patent will be the subject matter of the revocation/cancellation action. It should, however, be noted that a party who, in the course of the same proceedings, makes several limitations to their patent in a dilatory or abusive manner, may be ordered to pay a civil fine up to EUR3,000, without prejudice to any damages that may be requested.

Patentees will not be allowed to amend patent claims before the UPC. However, they will be allowed to request a limitation before the EPO. The UPC may stay its proceedings when a rapid decision can be expected (Article 33 (10), UPCA).

### 4.4 Revocation/Cancellation and Infringement

There is no bifurcation before French courts, claims related to both validity and infringement are assessed in the same proceedings.

Before the UPC, the division having jurisdiction to rule on the validity of the patent will in principle not be the one ruling on its infringement.

Indeed, most infringement actions will be brought before a local/regional division whereas, as explained in section **3.7 Procedure for Construing the Terms of the Patent's Claim**, an action for revocation must be filed before the central division.



When the revocation will be a counterclaim during an infringement action, the local/regional division ruling on the infringement of the patent can:

- rule on the counterclaim for invalidity, but request the assignment of a technical judge;
- refer the counterclaim to the central division and stay the infringement action; or
- at the request of the parties, refer the whole case to the central division.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

Rules applicable to intellectual property proceedings follow the procedural laws of the CPC. Special procedural provisions, including the IP-specific summary proceedings, proceedings on the merits and infringement seizures, are set out in the IPC and described, notably, in **2.1 Actions Available Against Infringement** and **2.10 Mechanisms to Obtain Evidence and Information**.

In France, the Commercial Code provides a specific form of protection for trade secrets, which is of interest in patent litigation, both for the claimant and the defendant.

In the context of an infringement seizure, Article R.615-2 of the IPC provides that the judge, either ex officio or at the request of the defendant, may sequester seized documents in order to preserve their confidentiality.

During the course of the proceedings, the judge may also implement procedures to preserve the confidentiality of the evidence exchanged (Article L.151-1 et seq French Commerce code). The judge may examine the document individually,

seek the opinion of the parties, and then decide to limit the disclosure of the document by way of a summary or restrict the access to certain persons (in a so-called confidentiality club).

The UPCA also provides, in a similar way to French law, that confidential information shall be protected.

In cases of patent infringement, first instance proceedings before French courts usually take two to three years. A series of pre-trial hearing will take place during which each party will file submissions and communicate evidence.

A final pleading hearing, during which each party's counsels make their arguments, takes place after the closure of the written proceedings. The first instance court decision is usually issued within one or two months following the pleadings and usually provides a ruling on the infringement and the remedies at the same time.

The UPC's ambition is to render first instance decisions within one year from the date of filing of the case.

### 5.2 Decision-Makers

Although patent litigation is handled by specific chambers of the Paris court, with exclusive jurisdiction over patent-related matters (as detailed in **2.3 Courts With Jurisdiction**), the judges do not have a technical background and no jury system exists.

Before the UPC, there will be no jury neither. The local and regional division will consist of legal judges, with no technical background. The panels of the central division and of the Court of Appeal will consist of legal and technical judges, the latter having technical background.



## 5.3 Settling the Case

Settlements in the course of French patent infringement proceedings are common. The patentee can try to settle the case amicably through a settlement agreement or through other forms of alternative dispute resolution (ADR) techniques (see **9.1 Type of Actions for Intellectual Property**). Over the last year in France, approximately 50% of patent infringement cases were settled prior to trial.

It should be noted that the judge may recommend, at any time during the proceedings, a conciliation or mediation measure to the parties, especially if they do not justify any steps taken to reach an amicable resolution of the dispute.

Before the UPC, the parties may settle the case at any time in the course of proceedings (Article 79, UPCA). The settlement agreement shall be confirmed by a decision of the Court.

Mediation and arbitration will also be available.

## 5.4 Other Court Proceedings

Proceedings initiated before French courts can be continued without having to stay the case pending other national courts proceedings.

However, the French courts can take into consideration the decisions of other courts, both as regards the validity of the patent and infringement.

In addition, an infringement action based on a French patent can be stayed when the patentee has also applied for a European patent over the same invention. Such a suspension is only lifted after the grant, rejection or withdrawal of the European patent.

Likewise, if French judges are asked to rule on the infringement of the French part of a European patent, while an opposition before the EPO is pending, the judges might stay the infringement action until the outcome of the European opposition proceeding.

When determining whether to stay the proceedings in other circumstances, judges will focus on ensuring a proper administration of justice, and will take into account:

- the seriousness of the invalidity grounds invoked;
- the impact of the stay on the duration of the proceedings; and
- the extent of any harmful consequences for the patentee.

Lastly, it should be noted that anti-suit injunctions are not allowed in France and that French courts may order the withdrawal of application for an anti-suit injunction filed in foreign courts, seeking to prohibit a company from bringing patent proceedings in France.

With regard to the UPC, a stay may be ordered where the patent at stake is also subject to proceedings before the EPO, a national authority or the central division (as part of a revocation action), provided that a decision in such proceedings may be expected to be given rapidly.

The UPC can also stay the proceedings where a decision by the Court of Justice of the European Union is necessary, as well as under exceptional circumstances (eg death or insolvency of a party or an objection to a judge taking part in proceedings).

## 6. Remedies

### 6.1 Remedies for the Patentee

Should the patentee succeed in their infringement action, available remedies would include permanent injunctions, damages, recall and destruction, and publication.

#### Injunctive Relief/Provisional Damages

Pursuant to Article L.615-3 of the IPC and Article 62 of the UPCA, in the case of a likely infringement, a patentee may request provisional injunctions.

#### *Permanent injunction*

Both French law and the UPCA provide that courts may order permanent injunctions against the infringer aimed at prohibiting the continuation or the resurgence of the infringement.

In France, an injunction is an automatic consequence of a decision in which the court has admitted infringement, except:

- when the patent has expired at the date of the decision;
- when a SEP/FRAND issue prevents any injunction;
- when a compulsory licence has been granted; or
- when a national defence exploitation is at stake (Article L.615-10, IPC).

Injunctions are generally subject to penalties to ensure their enforcement.

#### *Monetary damages*

Before French civil courts, damages suffered must be repaired in full although punitive damages are prohibited.

Likewise, Article 68 of the UPCA provides that the injured party shall, to the extent possible, be placed in the position it would have been in if no infringement had taken place.

For the assessment of damages on the merits, French judges (Article L.615-7, IPC) and panels of the UPC (Article 68, UPCA) have to distinctly consider:

- the negative economic consequences suffered by the injured party, including lost profits, and any other losses incurred;
- any unfair profits earned by the infringer, including investment savings regarding the intellectual, material or promotional work; and
- where appropriate, elements other than economic factors, such as the moral prejudice caused to the right-holder by the infringement.

Alternatively, the courts may, at the request of the patentee, award a lump sum as damages.

The UPCA also provides that where the infringer did not or could not know that it was engaging in the infringing activity, the Court may order the recovery of profits or the payment of compensation.

It is worth noting a steady increase in the amounts of damages granted by the Paris courts, over the past few years. Most notably, the Paris Judicial Court has granted a provisional amount of EUR28 million for infringement and unfair competition in its 11 September 2020 Eli Lilly and al v Fresenius Kabi decision.

#### **Recall and Destruction**

French law and the UPCA allow judges to order the recall of infringing products from their dis-

tribution channels and their destruction, carried out at the expense of the infringer.

## Publication

French courts and the UPC can also order the publication of the decision, at the expense of the infringer, in full or in part, in public media. In any event, the claimant may publish the judgment in whole or in part on its own website, without the prior court's authorisation. However, the claimant must act carefully when publishing the judgment in order to avoid any claim for unfair competition by denigration.

## Criminal Remedies

In criminal proceedings, wilful infringement is required for a successful outcome, which may lead to criminal sanctions of up to three years of imprisonment and a fine of up to EUR300,000 (Article L.615-1, IPC). For legal entities, the fine can amount to up to five times the amount set for individuals (Article 131-38, Criminal Code).

## 6.2 Rights of Prevailing Defendants

Firstly, in the case of preliminary action, the enforcement of an injunction can be conditional on a financial provision from the claimant, to ensure compensation to the defendant if the infringement action is subsequently rejected or the measures annulled.

Secondly, prevailing defendants in any type of action can request the recovery of the costs incurred in the proceedings (see **8.3 Responsibility for Paying the Costs of Litigation**).

Before French courts, the winning defendants may also claim compensation for the damages caused by reckless and/or vexatious proceedings by the claimant.

## 6.3 Types of Remedies

In France and before the UPC, the same remedies – which are listed in **6.1 Remedies for the Patentee** – apply to each type of technical IP right.

## 6.4 Injunctions Pending Appeal

Since 1 January 2020, provisional enforcement is now available as of right. Therefore, unless otherwise provided, all decisions issued by the court are immediately enforceable (ie, despite a pending appeal).

In the case of an appeal, provisional enforcement may only be lifted by the president of the Court of Appeal and in very specific situations.

Before the UPC, an appeal will generally not have a suspensive effect unless the Court of Appeal decides otherwise upon request of one of the parties. However, an appeal against a decision on revocation or related to Article 32(1)(i) of the UPCA will always have suspensive effect.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

The right of appeal is granted in all matters against judgments at first instance (Article 543, CPC).

Parties have one month to appeal a first instance decision from the notification date (Articles 528 and 538, CPC). Foreign companies are granted an additional two-month delay (Article 643, CPC). As for Court of Appeal decisions, parties have two months (plus one or two months) to appeal before the Supreme Court (Article 612, CPC).

Before the UPC, an appeal may be brought within two months against final decisions of the Court of First Instance and decisions terminating proceedings as regards one of the parties.

Moreover, an appeal may be brought within 15 days against:

- orders on the use of the language in which the patent was granted as the language of the proceedings;
- orders to present and preserve relevant evidence in respect of the alleged infringement;
- orders requesting a party not to remove from its jurisdiction any assets located therein, or not to deal in any assets, whether located within its jurisdiction or not;
- orders intended to prevent any imminent infringement, to prohibit the continuation of the alleged infringement or to make such continuation subject to the lodging of guarantees; and
- orders to provide to the applicant information as to the alleged infringement.

Orders other than the above may be either the subject of an appeal together with the appeal against the decision (within two months) or may be appealed with the leave of the Court of First Instance within 15 days of the Court's decision to that effect.

Regarding decisions of the *judge-rapporteur* relating to preliminary objections, if the preliminary objection is allowed the order may be appealed independently from the decision on the merits and within 15 days. If the preliminary objection is rejected, it may only be appealed together with the appeal against the decision on the merits.

Finally, a party adversely affected by a decision of the *judge-rapporteur* as to costs only may lodge an application for leave to appeal to the Court of Appeal within 15 days of service of the decision of the Court.

## 7.2 Type of Review

In France, although parties may invoke new arguments and produce new documents or evidence, submitting new claims is prohibited, except in order to have adverse claims dismissed or to respond to questions arising from disclosure of new facts or a third-party intervention (Articles 563 and 564, CPC).

The judgment of first instance can be challenged on both legal and factual grounds (Article 561, CPC).

As for the Supreme Court, only issues of law can be examined (Article 604, CPC).

According to the UPCA, an appeal may be based on points of law and matters of fact. Requests, facts and evidence which have not been submitted by a party during proceedings before the Court of First Instance may be disregarded by the Court of Appeal. Ruling on their introduction, the Court of Appeal will take into account whether the party seeking to lodge new submissions is able to show that they could not reasonably have been made during proceedings before the Court of First Instance. The relevance of the new submissions for the decision on the appeal and the position of the other party regarding this matter will also be considered.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

Costs arising before filing a lawsuit are essentially those of the attorneys-at-law, patent attorneys, experts and bailiffs, which are needed for collecting relevant information and evidence, assessing the merits of the case and engaging in pre-litigation actions (for instance, issuing warning letters, *saisie-contrefaçon*) and conducting the proceedings.

### 8.2 Calculation of Court Fees

There are no court fees to commence proceedings before French courts. However, the filing of an appeal is subject to the payment of EUR225.

Actions before the UPC will have fixed court fees. For example:

- EUR20,000 for revocation actions; and
- EUR11,000 for infringement actions, declarations of non-infringement, application and appeal as to provisional measures.

Moreover, additional value-based court fees, assessed by the claimant, shall be paid at the same time. Their amount will vary from EUR0 to EUR325,000.

### 8.3 Responsibility for Paying the Costs of Litigation

Under Article 700 of the CPC, the prevailing party can request that the losing party pay the legal costs incurred by the proceedings. Such awards may cover fees relating to attorneys-at-law, patent attorneys, experts and bailiffs. To do so, the winning party will usually produce an exhibit proving the total amount of costs incurred. In any case, there are no separate proceedings relating to costs recovery.

Regarding the UPC, reasonable and proportionate legal costs and other expenses incurred by the successful party shall be borne by the unsuccessful party, unless equity requires otherwise, up to a ceiling adopted by the Administrative Committee by reference to the value of the proceedings.

The table of recoverable court fees has not yet been published yet but such fees could amount to EUR38,000 for proceedings with a value equal to or above EUR250,000 euros and will be capped at EUR2 million for proceedings with a value of more than EUR50 million.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

Even though arbitration, mediation and conciliation are available, these alternative dispute resolution (ADR) techniques are rarely used in France.

Typically, the recourse to arbitration must be agreed on a contractual basis and is unavailable for matters that are governed by public order.

Contractual disputes, as well as ownership-related issues, can be submitted to arbitration. In contrast, issues of a patent's invalidity are part of the exclusive jurisdiction of the Paris Court of First Instance (Article L.615-17, IPC). Therefore, if an arbitrator holds a patent invalid, such a decision shall have effect only between the parties (Articles 2059 et seq, French Civil Code).

Mediation is also possible. A mediator can be appointed and shall consult with the parties and the lawyers on a confidential basis and help them to find an amicable solution. The proceedings –

stayed during this period – can be resumed if the parties fail to settle.

Another possible solution for negotiating an amicable settlement is to ask for a conciliation. These are handled, free of charge, by judges themselves and the parties remain free to accept the solution offered by the judges.

Article 35 of the UPCA provides that a mediation and arbitration centre is established and will have its seats in Lisbon and Ljubljana.

At any time during the proceedings, the parties may have recourse to the services of the mediation and arbitration centre in order to settle the case.

The centre shall provide facilities for mediation and arbitration of patent disputes falling within the scope of the UPCA. Settlement reached through the use of the facilities of the centre will be enforceable in any contracting member state. However, a patent may not be revoked or limited in mediation or arbitration proceedings.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

The assignment of a patent application or patent must be in writing and registered with the INPI in order to be enforceable against third parties (Articles L.613-8 and L.613-9, IPC). Where a French and European patent cover the same invention, separate assignments are strictly prohibited.

According to Article 3 of the EU Regulation 1257/2012, unitary patents may be transferred

only in respect of all the participating member states. Transfers will be recorded in the Register for unitary patent protection. Once registered, the assignment will be enforceable against third parties.

### 10.2 Procedure for Assigning an Intellectual Property Right

The parties may draft a non-disclosure agreement beforehand in order to ensure the confidentiality of the negotiations.

General rules of contract law govern patent assignment.

For the assignment to be lawful:

- the assignor must have the right to assign such rights;
- the assigned rights must be in force;
- the price must be fixed or, at least, determinable; and
- the duration of the contract must be specified.

The assignment, although effective between the parties upon its signature, must be registered to be enforceable against third parties.

Regarding the assignment of unitary patents, if the document establishing the transfer is not in one of the EPO's three official languages, the EPO may require a certified translation into one of those languages.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

A licence agreement must be in writing to be valid (Article L.613-8, IPC). Aside from this restriction, parties are generally free to determine the licence terms, including the exclusivity and the duration of the licence, the royalty rate and the

conditions of exploitation. To be enforceable against third parties, the licence must be registered with the relevant office.

French and European antitrust authorities are rigorous with respect to patent licences or technology transfer agreements, particularly those within the pharmaceutical sector.

Unlike assignments, licences relating to a unitary patent may be for the whole or part of the territory. They must be recorded in the Register for unitary patent protection in the same way as for assignments.

## 10.4 Procedure for Licensing an Intellectual Property Right

The licensee must have the right to license such rights, the contract must have a valid object, the price must be fixed or determinable, and the duration of the contract must be specified.

The licence agreement must precisely define its scope. The identification of the patent, whether the licence is granted exclusively or not (ie, preserving the possibility for the patentee to exploit the invention itself), the duration, the territory at stake and the calculation of the royalties are all essential elements that must be provided in the agreement.

Regarding the licensing of unitary patents, if the document is not in one of the EPO's three official languages, the EPO may require a certified translation into one of those languages.



**Gowling WLG** has an IP team in France that offers expertise on all aspects of intellectual property and information technology as well as related areas, including data protection, unfair competition, e-commerce, communication and marketing law. In particular, the team has a longstanding expertise in patents, both in contentious and non-contentious (licensing); has a deep-rooted understanding of French litigation procedure; handles complex pan-European patent litigation; drafts and negotiates licensing

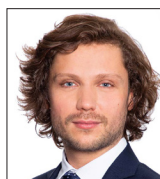
contracts and NDAs; conducts due diligence in the context of M&A; and collaborates closely with other offices of **Gowling WLG**. The firm is able to offer clients a global strategic approach to patent litigation in the three key European jurisdictions: the UK, Germany and France. The French team advises major French and international groups and SMEs across a range of sectors, such as chemistry, biotech, tech, cosmetics, automotive and pharma.

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## Law and Practice

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

An inventor can obtain protection for his invention in Germany via a German patent or a German utility model.

A *German patent* can be obtained either via the national route by applying at the German Patent and Trade Mark Office (GPTO) or via the regional route, ie, by applying for a European patent.

Furthermore, patent protection for Germany can also be obtained via a *Unitary Patent* as the Unitary Patent system is starting now in 2023.

A *German utility model* can be obtained either by applying to the German Patent and Trade Mark Office or deriving it from a pending German or European patent application.

Intellectual property rights in Germany are based on statutory law, eg, by the German Patent Act, the German Utility Model Act or the International Patent Convention Act and the Unified Patent Court Agreement. However, the interpretation of the laws are based on precedent decisions. This applies in particular to IP proceedings, where current case law is important in the material assessment, eg, of inadmissible extension and inventive step.

### 1.2 Grant Procedure

#### German Patents

In order to obtain patent protection in Germany, one can file a national patent application directly with the GPTO. Alternatively, one can apply for a German patent via the international filing system of the World Intellectual Property Organization (WIPO) or the regional examination and granting system of the European Patent Office (EPO).

For obtaining a Unitary Patent with protection for Germany both the WIPO and the EPO system may be utilised for filing.

As German patents are examined, intellectual property rights patent applications will be examined according to the requirements of the German Patent Act or the European Patent Convention. This comprises by example whether the claimed invention is novel and inventive over the prior art which was publicly available at the filing date of the patent application. To obtain an earlier effective date, the priority of another patent application can be claimed, provided that no more than 12 months have passed between the priority and the filing of the application.

The patent application is published 18 months after filing and constitutes prior art itself.

After requesting examination (for German application latest within seven years after filing), the patent application is examined in terms of patentability, in particular novelty and inventive step. If the examiner of the GPTO, the WIPO or the EPO has doubts, the applicant is invited to comment in writing on the objections, and to amend the claims within the scope of the original application. Additionally, an oral hearing (GPTO) or oral proceedings (EPO) may be requested by the applicant during the examination procedure in order to comment on objections of the GPTO or the EPO.

If the application is considered to be patentable, the applicant will be informed. After the grantable version is agreed, the granted version of the patent is published. The date of the publication of the grant is the date when the patent comes into force with all its rights.

In view of the upcoming Unified Patent Court (UPC), it is possible to determine at the EPO, within the consent of the grantable version, whether the patent will be considered as a European patent or a European patent with unitary effect, ie, a Unitary Patent.

## German Utility Model

The German utility model is not an examined but a registered intellectual property right. A speciality of German utility models is that, according to the German Utility Model Act, methods cannot be protected. Another difference from German patents is that utility models have a grace period of six months, during which publication by the applicant is not prejudicial to novelty. Moreover, prior use is only prejudicial to novelty if it has taken place in Germany.

The registration procedure for a utility model is also started by filing an application with the GPTO.

In addition to a direct application with the GPTO, a utility model can also be obtained in Germany by deriving it from an earlier pending patent application or utility model. Such a utility model is considered as an independent application and has the same time rank as the earlier patent application or utility model.

Given these features, utility models may advantageously be used in infringement proceedings when quick action is to be taken against an infringer, and the patent grant procedure can no longer be awaited. However, as German utility models are unexamined intellectual property rights, the uncertainty about the utility model's validity may hinder the progress of the infringement proceedings.

## Supplementary Protection

The supplementary protection under German unfair competition law is not granted by way of a formal procedure. In order for an invention to be granted supplementary protection under competition law, certain requirements must be met. The protection arises as soon as, and as long as, all the required conditions are fulfilled.

## 1.3 Timeline for Grant Procedure Patents

The patent grant procedure can take a few years due to the examination of patentability at the GPTO and/or EPO, depending on the technical field and the complexity of the invention. It has been observed that grant procedures typically take two to four years. However, if necessary, the duration can slightly be influenced by the applicant's management of the procedure; in particular, the EPO provides a number of ways to speed up the examination, eg, PACE request.

Applicants not having their residence, place of business or branch office in Germany (German patent) or in an EPO member state (European patent) must have a professional representative, ie, a German (patent) attorney before GPTO and a European patent attorney before EPO. For residents it is not mandatory but highly recommended.

Typically, the official fees up to the grant for a German patent including the third and fourth annuity are below EUR1,000, whereas for a European patent (with or without unitary effect) they are about EUR6,000 without validating the patent in the contracting states.

## Utility Models

The granting procedure for utility models is considerably shorter, taking only a few weeks to a

few months, since there is no examination of patentability.

Regarding the representation, the same applies as for the German patent.

The official fees for requesting the registration of a utility model are below EUR100.

## 1.4 Term of Each Intellectual Property Right

German and European patents (with or without unitary effect) have a term of 20 years from filing. With supplementary protection certificates (SPCs) this term can be extended for human or veterinary medicines and plant protection products.

Utility models have a term of ten years from filing.

There is no explicit provision on the term of protection of the supplementary protection under competition law as it is to be granted as long as all prerequisites are fulfilled.

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

The owner of a German patent, European patent and a German utility model has the right to an injunction, information about past infringing acts, damages, destruction of infringing products, recall and publication of the infringement judgment.

In case of an infringement of the supplementary protection of competitive performance, claims may include, in particular, injunctive relief, removal of the infringement, information and damages.

## Renewal Fees

The applicant is obliged to pay annual renewal fees for the patent applications and patents, wherein the amount progressively increases with the year.

The annual fee for the German Patent has to be paid from the third year in advance for the year to follow, wherein the fee increases from EUR70 for the third year to EUR2,030 for the twentieth year.

The annual fee for the European Patent application also has to be paid from the third year at the end of the month, whereas the fee increases from EUR505 for the third year to EUR1,690 for the twentieth year.

After the grant, the fees for the European Patent only have to be paid in the designated countries. For the European patent with unitary effect, fees are to be paid for the member states of the UPC starting from EUR35 for the second year to EUR4,855 for the twentieth year. As a rule of thumb, from four designated countries on, the costs for the European patent are lower than the sum of national costs.

For the German Utility Model, three maintenance fees must be paid: EUR210 after three years, EUR350 after six years and EUR530 after eight years.

## Public Information

The GPTO and the EPO both have registers with public information on the patent applications and patents filed with the offices. However, these registers do not comprise information about patents in relation to certain products.

## 1.6 Further Protection After Lapse of the Maximum Term

There is the possibility in Germany for further protection after the term has lapsed. It is the so-called Supplementary Protection Certificate (SPC) for human or veterinary medicines and plant protection products, which can be requested for a German Patent and a European Patent. The SPC can give protection for the claimed product for a maximum of additional five years after the expiry of the original patent. As with the patent, annual fees must be paid for the SPC.

## 1.7 Third-Party Rights to Participate in Grant Proceedings

After publication of the application and before the grant of the patent an observation by third parties can be filed at GPTO and EPO.

With regard to the German patent application, the third-party observation involves only the provision of new prior art. The filing at GPTO has to be made in writing and does not require a reasoning. This is in contrast to the European patent application. Beside observations on novelty and inventive step, third-party observations may also be directed to clarity, sufficiency of disclosure and added subject-matter. At the EPO the written filing can be made via an online tool and anonymously, wherein a reasoning is mandatory.

Both the GPTO and the EPO inform the applicant about the third-party observation and allow them to comment on it during the grant procedure. The submitting third party, however, is not involved in the procedure. Thus, a carefully drafted third-party observation may be a cost-effective alternative compared to opposition proceedings for an already granted patent. However, it has to be considered that one does not become a party of the examination proceedings with a third-party

observation and thus one has only limited influence on further proceedings.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

If a German patent application is refused, the patentee receives a negative decision from the office. The applicant can file an appeal against this decision with the GPTO. If the GPTO cannot uphold the appeal, it will be forwarded to the German Federal Patent Court, which will then decide the outcome.

If the grant of a European patent is refused, the patentee can appeal against a negative decision to the Boards of Appeal. In certain cases of general interest, the patentee may appeal to the Enlarged Board of Appeal against a negative decision from the Boards of Appeal.

## 1.9 Consequences of Failure to Pay Annual Fees

The German patent, the German utility model and the European patent are deemed to be withdrawn, when annual or maintenance fees are not paid. All fees are due on the last day of the month in which the anniversary of the date of filing falls and must be paid within two months. The fees can then be paid together with a penalty fee (EUR50 for German patent and German utility model; 50% of the respective annual fee for the European patent) until the end of the sixth month after the due date. If the payment has not been made by then, the IP right expires.

After expiry of these deadlines, the applicant can apply for re-establishment of right at the GPTO or the EPO. Re-establishment has to be requested within two months after the removal of the cause of non-compliance, but at least (with a very few exceptions) one year after the expiry of the missed due date. In the request it has to



be justified that the due date has expired despite all due care being taken.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

After the grant, the patentee can limit the claims of a German patent, a German utility model and a European patent, as far as the subject-matter does not go beyond the content of the original application and the amendment does not extend the scope of protection.

This can be done in the course of validity proceedings, namely for the German patent and European patent in opposition or nullity proceedings and for the German utility model in cancellation proceedings. In addition, a limitation of the claims can be made by request on a national basis at the GPTO or on a regional basis at the EPO.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

The German legal system basically provides for two approaches to reach an out-of-court solution in an infringement case.

First, a *request for authorisation* (“Berechtigungsanfrage”) is a relatively moderate way to contact an alleged infringer to obtain an out-of-court solution. Here, the alleged infringer is asked, why he thinks he is authorised to use the IP right. This letter does not threaten the alleged infringer and does not trigger a cease-and-desist declaration. It rather invites the alleged infringer to present non-infringement arguments.

Second, as an alternative or an addition, a *warning letter* may be used. This measure can be

used to obtain a cease-and-desist declaration from the infringer relatively quickly. However, due to strict case law regarding liability in the instance of unlawful warning letters, this measure has to be considered carefully.

It has to be considered that both out-of-court approaches may trigger counter-measures by the alleged infringer.

Additionally, mediation is a further option for avoiding a court decision. The Unified Patent Court has introduced a Patent Mediation and Arbitration Centre (PMAC) for this.

*Court proceedings* in Germany provide several remedies.

A request for a preliminary injunction is provided by German law, wherein the grant of a preliminary injunction – according to case law – requires:

- first, that the matter is urgent, ie, the patentee has learned about the patent infringement just recently; and
- second, that both the infringement and the validity of the patent in suit are established clearly so that a revision in main proceedings is unlikely.

German case law further specifies these requirements.

The grant of a preliminary injunction may also be obtained *ex parte*, if specific circumstances allow for it. However, it is quite usual that a request for a preliminary injunction is followed by an oral hearing, or at least the supply of additional information and the possibility of responding in writing.

Main proceedings initiated by an infringement complaint can of course also be initiated to enforce all claims provided by the German Patent Act (injunctions, information/rendering of accounts, damages, revocation, destruction, etc).

## 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

There are several remedies to remove the effects of technical IP rights in Germany.

### Opposition

An opposition can be filed by any third party against a patent within nine months after the publication of the grant without any special legal interest. The opposition against the German patent must be filed at the GPTO, whereas the opposition for the European patent (with or without unitary effect) must be filed at the EPO.

Any person may file such an opposition, with the exception of the patentee themselves. No legal or commercial interest is necessary. However, the opposition has to comprise a detailed explanation of each reason for opposition that has been raised.

Each party bears its own costs for the proceedings.

Additionally, an intervention in opposition proceedings is possible after the expiration of the opposition period for a third party confronted with an infringement complaint under certain conditions.

### Nullity/Revocation Action

After nine months from the publication of the grant, any third party can initiate nullity proceedings against a patent as long as no opposition proceedings are pending.

For filing a nullity action at the German Federal Patent Court, a court fee has to be paid. It is not necessary to prove any legal or commercial interest if the patent is in force.

A nullity/revocation action against a German patent and against the German part of a European patent which has been opted out of, the Unitary Patent system must be filed with the German Federal Patent Court. Against the German part of a European patent which has not been opted out of, the nullity/revocation action may be filed either with the German Federal Patent Court (during a transitional period of at least seven years) or with the central division of the Unified Patent Court (UPC). A revocation action against a European patent with unitary effect can be filed with the central division of the UPC.

If the nullity action was filed with the German Federal Patent Court, the appeal to the first instance decision is handled by the German Federal Court of Justice, which is the highest civil jurisdiction in Germany. For revocation actions filed with the UPC, the second instance is conducted before the Court of Appeal in Luxembourg.

The judgments in German nullity proceedings also comprise a cost decision, ie, which costs the parties have to bear. In general, the losing party has to bear the court fees and statutory attorney fees of the other party.

### Cancellation of Utility Model

For a German utility model, cancellation proceedings at the GPTO may clarify whether the registered invention is patentable. The request for cancellation can be filed by any person in writing at the GPTO, wherein there is no requirement for a particular legal interest when the utility model is in force.

The decisions can be appealed at the German Federal Patent Court.

### Declaration of Non-infringement

Generally, a declaration of non-infringement can be obtained under certain conditions.

With regard to the German patent and the German part of a European patent which has been opted out of the Unitary Patent System, a negative declaratory action can only be initiated before the patent infringement chambers of the civil courts. An action for declaration of non-infringement of a European patent which has not been opted out of can be filed at a patent infringement chamber of the German civil courts or the central division of the UPC. With regard to the European Patent with unitary effect, the action for declaration can be filed at the central division of the UPC.

However, in Germany such an action is only admissible if there are no infringement proceedings already initiated by the patentee to the third party in Germany.

### Compulsory Licences

Actions for compulsory licences are possible in Germany but very rare. An exception has been a case regarding HIV medication in 2021.

The UPC does not provide a provision concerning compulsory licensing. Instead, the national laws of the participating member states should deal with compulsory licences for European patents with unitary effect.

## 2.3 Courts With Jurisdiction

### National

Due to the German bifurcated system, there must be differentiation between infringement

and nullity proceedings, which are handled by different courts.

Infringement proceedings are handled by specialised chambers of the Regional Courts in the first instance, wherein the patent infringement chambers of the Regional Courts of Düsseldorf, Mannheim, Munich and Hamburg are most commonly used. The second instance is handled by the respective specialised senate of the Higher Regional Courts. The Federal Court of Justice handles the revision, ie, the third instance in patent infringement proceedings.

Nullity proceedings are handled by the German Federal Patent Court in the first instance and the German Federal Court of Justice in the second instance. There is no third instance.

### UPC

The first instance courts of the UPC comprise a central division as well as a decentralised structure with local and regional divisions in the member states. Four local divisions of the UPC are located in Germany in the cities with the most experienced patent infringement chambers, namely Düsseldorf, Munich, Mannheim and Hamburg. In addition, a section of the central division is located in Munich.

The Court of Appeal located in Luxembourg will decide on appeals against decisions of the courts of first instance.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

There are no specialised bodies or organisations for the resolution of IP disputes.

## 2.5 Prerequisites to Filing a Lawsuit

In Germany, there are no prerequisites to filing a lawsuit. However, when the infringer immedi-

ately acknowledges the complaint (partly or in full) without hesitation, and if there has not been an out-of-court approach to the patent infringer, the plaintiff has to bear the corresponding court and reimbursable lawyer fees.

For Standard Essential Patents, so-called SEPs, the parties have to show that they are willing licensors and willing licensees according to the Court of Justice of the European Union (CJEU) and German case law. Thus, specific requirements have to be fulfilled by both parties in order to have a chance to either obtain or prevent an injunction.

## 2.6 Legal Representation

### National

In infringement proceedings at German courts, parties need to be represented by a lawyer in order to deal with the technical issues and validity better. Infringement proceedings are often handled by a team of lawyers (attorney at law) and patent attorneys.

In nullity proceedings, it is vice versa. Although lawyers are permitted to act in nullity proceedings, it is usual practice in Germany that nullity proceedings are led by a patent attorney.

### UPC

Before the UPC, parties can be represented by lawyers authorised to practise before a court of a contracting member state.

In addition, parties may alternatively be represented by European Patent Attorneys who are entitled to act as professional representatives before the European Patent Office and who have appropriate qualifications, such as a European Patent Litigation Certificate (EPLC). Most German patent attorneys have completed the law course “Recht für Patentanwälte” (Law for

Patent Attorneys), which is also considered an appropriate qualification.

## 2.7 Interim Injunctions

### National

Interim or preliminary injunctions are available in Germany.

The requirements for an interim injunction are: that the matter is urgent (see **2.1 Actions Available Against Infringement**); and that the patent is clearly infringed and valid (eg, survived first instance validity proceedings). This means that the question of patent infringement and validity needs to be answered clearly enough so that it is very unlikely that this answer would be revised in the main proceedings.

In very clear cases, eg, infringement and validity has been confirmed already, say in extremely time-critical cases of infringement at trade fairs and the like, it might be possible that ex parte injunctions are issued.

### UPC

Interim or preliminary injunctions are also available before the upcoming UPC.

With regards to urgency, the legal framework states that the court must take into account any unreasonable delay in applying for an interim injunction, so that the practice of the UPC on urgency must be awaited. The UPC should also take the validity of a patent into consideration; however, it will depend on how the requirement “reasonable proof that the patent is legally valid” is interpreted in practice.

Ex parte provisional measures will be possible at the UPC, in particular in cases where any delay is likely to cause irreparable damage to

the applicant or where there is a demonstrable risk of evidence being destroyed.

## 2.8 Protection for Potential Opponents National

German courts accept protective letters, which usually further reduce the risk of an ex parte interim injunction. The intention of such protective letter is to achieve at least an oral hearing if not the refusal of the interim injunction. A potential claimant will only be informed about a protective letter once a respective request for a preliminary injunction for the respective patent is filed.

The protective letters do not apply for normal infringement proceedings.

In infringement proceedings, the stay of the proceedings may be requested based on a high likelihood that the patent will be revoked or amended in a way in the opposition or nullity proceedings that there is no more infringement. Furthermore, for SEPs the potential opponent may raise under certain conditions the argument that the license offer of the claimant is not fair, reasonable and non-discriminating. Additionally, the German Patent Act has recently been amended by introducing a codified proportionality defence to injunctions in patent infringement proceedings.

### UPC

A protective letter could also be filed at the UPC. Where a protective letter has been filed by the defendant, the court shall consider an oral hearing with both parties.

## 2.9 Special Limitation Provisions

There are no special limitation provisions for patent infringement in Germany.

Germany has a limitation period of three years from the end of the year in which the patentee became aware of the infringement (or has not become aware of the infringement due to gross negligence). The UPC, instead, provides for a period of limitation of five years after the date on which the applicant became aware, or had reasonable grounds to become aware, of the last fact justifying the action.

An exception to the rules described above are supplementary protection claims. According to the German Unfair Competition Act, these claims regularly become time-barred six months after the claimant has become aware of them or should have become aware of them.

## 2.10 Mechanisms to Obtain Evidence and Information

German courts developed a combination of preliminary proceedings with inspection proceedings. These special proceedings can allow the patentee an unannounced on-site visit to the alleged infringers' facilities to investigate potential infringement. Products may be seized; experts may be allowed to examine the products and production methods to write a report. For those proceedings, a certain probability of infringement is required, but there is no need for definite proof in advance. Measures to secure confidential information obtained against the patentee may be ordered by the German courts.

The UPC also provides an application for preserving evidence and order for inspection, wherein the application has to be lodged at the division where the infringement proceedings are pending or at the division where the applicant plans to start proceedings.

## 2.11 Initial Pleading Standards

In Germany, the initial pleadings have to provide sufficient information to the court to allow an understanding of the infringement allegation, where the judges need to be in a position to check if all preconditions for the requests are met. This generally requires a clear identification of the parties, a description of the patent and the scope of protection, a description of the attacked embodiment and a reasoning that it falls within the scope of protection of the patent. Offers to provide proof should be included in the initial pleadings.

As two briefs are usually exchanged in infringement proceedings, further arguments and evidence can be supplemented in the second brief. Arguments may be backed up by party expert opinions. Formal proof (witness statements, expert opinions, etc) may be required if the party contests the truth of the facts provided by the other party.

In opposition proceedings before the EPO, all reasons for opposition have to be named and reasoned when the opposition is filed. Furthermore, additional prior art can be introduced only under certain conditions. The situation is similar in nullity actions at the German Federal Patent Court.

## 2.12 Representative or Collective Action

In the German legal system, representative or collective actions are not permitted.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

The most relevant restriction on asserting IP rights applies to Standard Essential Patents (SEPs). Special requirements, which have been defined by case law by the European Court of Justice and German courts, have to be fulfilled

by the owner of an SEP in order to be able to claim for an injunction in court, in particular regarding the offer of a fair, reasonable and non-discriminatory (FRAND) licence.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

In Germany, infringement proceedings can be initiated by the owner of the patent and an exclusive licence holder, where both have almost the same rights regarding their right to sue. Other legal persons, in particular non-exclusive licence holders, can only initiate infringement proceedings when they are allowed by contract. For this, the patent proprietor or the exclusive licensee must authorise the non-exclusive licensee to assert the claims for injunction, recall and destruction in its own name (so-called declaration of legal standing, "Prozessstandschaftserklärung"). Non-exclusive licence holders can further bring claims for compensation and damages or information, if the claims have been assigned by the patent proprietor. A patent holder that has authorised a non-exclusive licensee to bring a claim does not have standing to sue in addition to the licensee.

The UPC also distinguishes between exclusive and non-exclusive licence holders. Exclusive licence holders are entitled to bring action before the UPC under the same circumstances as the patent owner, whereas non-exclusive licence holders are allowed to do so only in so far as expressly permitted by the licence agreement.

### 3.2 Direct and Indirect Infringement

Under German law, there is a difference between direct and indirect infringement. Direct infringement requires that the alleged infringing product



fulfils all features of the asserted patent claim. Indirect infringement may be found, eg, if the alleged infringing products are only means relating to an essential element of the invention or, in the case of supplying goods, that are essential for implementing the patented invention. In both cases the supplier has to know, or it has to be objectively clear, that the supplied goods are both suitable and intended to implement the invention. This is further defined by German case law.

In the case of indirect infringement, the patent proprietor has almost the same claims (injunction, damages, information) as in the case of direct infringement.

However, if the product can also be used in a non-infringing way in the instance of indirect infringement, the patent owner only has a claim for the mildest possible way to avoid infringing use. This may be a warning sign as to possible infringement. Likewise, the claim for information is restricted to infringing uses and damages are due only for infringing uses.

The UPC also differentiates between direct and indirect infringement, wherein the wording of the article corresponds to the respective paragraph in the German Patent Act.

### 3.3 Process Patents

Generally, the offering and supplying as well as all steps of the process must be carried out within the territory of Germany.

### 3.4 Scope of Protection for an Intellectual Property Right

The scope of protection of a patent is defined by its claims, which have to be interpreted. Starting with the claim wording, the description and the figures shall be used to interpret the claims.

In this regard, how the person skilled in the art would understand the wording of the patent claim must be identified. The common general knowledge at the time of filing or priority can be taken into account. Also, prior art documents that are cited in the patent may also be considered for the claim's interpretation.

In Germany, the file estoppel is usually not considered for the claim interpretation. However, in specific cases it may become relevant in which way features introduced in the granting procedure must be interpreted in order to delimit them from the prior art.

### 3.5 Defences Against Infringement

*Prior use right* may be used as a defence before German courts if the defendant had already begun to use (produced/brought to the market) the attacked product before the application date of the patent. Co-ownership of the patent can be used as a means of defence. As co-owner, the defendant is entitled to use the patent without the consent of the other owner. At the UPC, the defendant shall enjoy the same rights of prior use or right of personal possession of that invention as in the member state, ie, Germany.

An *exhaustion of rights* of the patentee can be used as a defence when the product may have been brought onto the German market with the consent of the patentee. The exhaustion of rights may also be used as a defence before the UPC when the product has been placed on the market of the European Union with the consent of the patentee.

A so-called *FRAND defence* is a possible means of defence with regard to a SEP if the alleged patent infringer can argue that the plaintiff is abusing a dominant position by refusing to conclude a patent licence agreement with the defendant



on FRAND terms (see also **2.8 Protection for Potential Opponents** and **2.13 Restrictions on Assertion of an Intellectual Property Right**).

In Germany, the defendant has to *apply for a stay* in the infringement proceedings, as, due to the German bifurcation system, it is not possible to claim non-validity of the patent in the infringement proceedings. A stay is usually only granted if the patent is obviously invalid, for example not novel over prior art, that has not yet been considered in the examination procedures.

For compulsory licence, see also **2.2 Third-Party Remedies to Remove the Effects of Intellectual Property**.

### 3.6 Role of Experts

In Germany, there is differentiation between an expert used by the parties and an expert appointed by the court.

The expert used by the parties can be used to underline the respective argumentation. The parties may use the expert opinion at any time. The expert's statements are considered as facts or opinions provided by the party and do not constitute as such any proof of the parties' submissions. If the facts presented by the parties appear to be contradictory for the court, the court may, upon request, appoint an expert.

The court-appointed expert has to answer specific questions prepared by the court in order to resolve the contradictory facts. In view of the exhaustive experience of the infringement courts, such situations can often be clarified without court-appointed experts.

The UPC also distinguishes between experts who are used by the parties and can also act as

witnesses upon request, and court experts who can be appointed by the court.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

In German infringement proceedings, there is no separate procedure for construing the terms of a patent's claims.

### 3.8 Procedure for Third-Party Opinions

In German infringement proceedings, there is no system by which the court can seek or receive third-party opinions.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

In Germany, no standing to sue is required for requesting to revoke patents and utility models after grant. The only exception is for the case where the patent has already expired. In such a case there needs to be legal interest for the nullity plaintiff, ie, a pending parallel infringement action, for filing a nullity action against the expired patent.

All third-party remedies described in **2.2 Third-Party Remedies to Remove the Effects of Intellectual Property** also apply here. Only the remedies which go beyond that will be described in the following.

#### UPC Counterclaim for Revocation

Within infringement proceedings pending at the first instance of the UPC, a counterclaim for revocation is a measure of defence, when the validity of the invoked patent seems questionable. The counterclaim for revocation has to be filed together with the statement of defence with the responsible first instance division of the UPC.

## Reasons for Revocation of a Patent

There are minor differences between the GPTO, the EPO and the German Federal Patent Court with regards to the reasons. However, the main formal and material reasons for revocation of a patent are as follows:

- lack of patentability (lack of novelty or lack of inventive step);
- lack of enablement (invention not reworkable);
- inadmissible extension of the subject-matter in view of the original application and the parent application (added matter);
- subject-matter not regarded as invention (eg, scientific theories, mathematical methods), or exempted from patentability (eg, plant or animal varieties, method for treatment of the human and animal body), or not susceptible of industrial application; and
- in Germany it can be asserted that the invention has been seized, which can only be claimed by the aggrieved person.

## Cancellation of Utility Model

For a German utility model, cancellation proceedings at the GPTO can be initiated (see also **2.2Third-Party Remedies to Remove the Effects of Intellectual Property**). The reasons for cancellation are similar to those of a patent, wherein the main reasons are as follows:

- lack of patentability (ie, lack of novelty and lack of inventive step);
- inadmissible extension (added matter);
- lack of protectability (ie, lack a technical nature);
- lack of industrial application; or
- inadmissible double-protection (an identical, older intellectual property right exists).

In infringement litigation based on a German utility model, non-protectability can be asserted as

a defence. Also, the validity of the utility model has to be examined by the infringement court, even though a parallel cancellation request has been filed. The effect of the decision on the validity of the utility model in infringement litigation is limited to the parties in those proceedings.

## 4.2 Partial Revocation/Cancellation

A partial revocation or cancellation of a patent or utility model is possible in cases where only specific claims have been attacked with the nullity or cancellation action.

Furthermore, the patentee may further limit the claims in order to overcome the objections set out in the opposition, nullity or cancellation action (also **4.3 Amendments in Revocation/Cancellation Proceedings**). If these limited claims are allowable, this will result in a partial revocation or cancellation of the patent or utility model.

## 4.3 Amendments in Revocation/Cancellation Proceedings

It is possible to amend the scope of protection during the revocation or cancellation proceedings by filing auxiliary requests with amended claims. However, the amendment must not lead to an extension of the scope of protection.

## 4.4 Revocation/Cancellation and Infringement National

Due to the German bifurcation the revocation and infringement are not heard together, which in the past has led to a time gap between the two procedures. In order to reduce this time gap, the Patent Act was amended in 2022 to considerably speed up nullity proceedings. The main change is that the time limits for the submissions of parties have been fixed and that the prelimi-

nary qualified notice should be given within six months after service of the action.

With this amendment the chances are higher for the infringement court also to consider the preliminary qualified notice of the German Federal Patent court when assessing the request for a stay of the infringement proceedings in view of possible invalidity of the patent.

However, regarding the stay of proceedings, German infringement courts regularly apply a high standard and will only grant a stay if the patent is obviously invalid, ie, not new or not inventive (see also **2.8 Protection for Potential Opponents**).

## UPC

Whether or not revocation will be heard together at the UPC depends on the local or regional division to which the infringement action was brought. Indeed, the division, after having heard the parties, has discretion regarding the further course of the proceedings, having the following three options.

- First, the local or regional division may proceed with both the infringement action and with the counterclaim for revocation. In that event, the division has to request the allocation of a technically qualified judge.
- Second, the local or regional division may, with the consent of both parties, refer the entire case to the central division where infringement and revocation will be dealt with together.
- Third, the local or regional division may refer the counterclaim for revocation to the central division and itself either suspend or proceed with the infringement action, depending on the circumstances of the case.

In the first and second options revocation and infringement are heard together. Only in the third option are the infringement and revocation proceedings dealt with by different courts, leading to the (German-style) bifurcation of the proceedings. In this instance, the local or regional division may stay the proceedings or continue the proceedings, wherein the oral hearing before the central division, if possible, should be held before the date of the oral hearing in the infringement proceedings. It remains to be seen how this will be implemented in practice.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

#### National

The procedure is generally determined by the German Civil Procedural Code.

Depending on the venue, there may be slight differences in the way the proceedings are conducted, wherein the typical timeline of civil proceedings is as follows.

- The plaintiff files a suit with the court and the court serves the complaint on the defendant.
- The defendant then has the chance to file a statement of defence within a term set by the court.
- After this the parties usually exchange another round of briefs in which they can further specify their arguments and provide further evidence or party expert opinions.
- The action is then heard orally in the main hearing.
- At the end of the proceedings, a judgment is announced at a set date.

This timeframe differs based on court and workload, and is usually in the range of 10 months to 18 months.

Fact witnesses and experts can be heard in the course of the main hearing, which is usually a single hearing. Only in exceptional cases are additional hearing dates required.

The presiding judge may permit the parties, and shall permit their attorneys upon request, to address questions directly to the witness. “Cross-examination” is thus possible; however, it has no character as in UK patent infringement proceedings.

The remedies of injunction and rendering of account for past infringements are decided in a first round of proceedings. Afterwards, the damages are fixed in separate proceedings.

## UPC

With regard to the UPC, the course of the first instance proceedings is defined in the Rules of Procedure. In infringement proceedings, four submissions are exchanged: the complaint, the statement of defence, the reply, and finally the rejoinder.

The four submissions are also foreseen in the parallel proceedings of the counterclaim for revocation and the application for amendment of the claims. After the exchange of the submissions, a three-month interim procedure is conducted in which the hearing is prepared. The oral hearing is to take place shortly after the interim proceedings. Ideally, the duration of the proceedings should be between 9 and 11 months.

## 5.2 Decision-Makers

In all German or UPC proceedings, only specialised intellectual property judges are involved.

## National

In German infringement proceedings, at first instance and in the second instance, the panel consists of three judges with a legal background.

In nullity proceedings at the German Federal Patent Court, the panel consists of five judges, two with a legal background and three with a technical background.

At the Federal Court of Justice, which is responsible for the second instance of nullity proceedings and third instance of infringement proceedings, the panel has five judges with a legal background.

The parties do not have influence over the choice of judges for the respective courts.

## UPC

With regard to the UPC, each panel of the first instance has three judges. The local or regional division has three legally qualified judges and an additional technical judge can be requested. The panel of the central division consists of two legally qualified judges and one technical judge. The panel of the appeal court has five judges: three legally qualified judges and two technically qualified judges.

## 5.3 Settling the Case

The parties can settle the litigation at any time without additional formal requirements. The parties may also jointly request a stay of proceedings, if additional time for settlement negotiations is required.

Even though settlement and mediation are provided by German procedural law and the courts are bound to ask the parties whether there is a chance for settlement, this non-mandatory option is currently less relevant for IP matters.

The UPC provides a patent mediation and arbitration centre.

## 5.4 Other Court Proceedings

If the patent or utility model is revoked in the first instance opposition, nullity or cancellation proceedings, the infringement proceedings are usually stayed until the final judgment in the appeal.

Judgments of other European jurisdictions have to be considered by the German courts according to case law; however, the German courts assess how these judgments will influence their decisions.

German Courts consider anti-suit injunctions, but usually they are not successful. However, some anti-anti-suit injunctions have been successful recently in Germany.

## 6. Remedies

### 6.1 Remedies for the Patentee

The main remedies for the patent owner in infringement cases are:

- permanent injunction;
- damages;
- provision of information/rendering of accounts on infringing acts; and
- destruction and recall.

For further details see **6.3 Types of Remedies**.

In principle, the judge is bound by the claim and has no discretion in this respect. In particular, the court has no discretion with regard to injunctions. If there is an (direct) infringement, he must grant the injunction. However, in the case of actions for damages, the court is entitled to

decide at its own discretion whether, and to what extent, damages have been incurred.

### 6.2 Rights of Prevailing Defendants

The plaintiff must reimburse the statutory attorney costs of the defendant together with other expenses of the proceedings such as expert opinions or translations. The statutory attorney costs are calculated based on the value in dispute.

### 6.3 Types of Remedies

The following remedies are available for the plaintiff when the court finds infringement of an IP right.

#### Permanent Injunction

Upon request, the court will grant a permanent injunction. There is no requirement for irreparable harm, no weighing of interests (or other aspects) which need to be fulfilled. The injunctive relief is available for practising and non-practising entities (see also **2.8 Protection for Potential Opponents** and **6.1 Remedies for the Patentee**).

#### Damages

The right-holder is entitled to damages if the infringer acted at least negligently, which is mostly the case, since the duties of care for avoiding negligence are strict. Three ways of calculating damages from which the right-holder can choose are established by German case law. These calculations can be based on the plaintiff's loss of profits, based on a reasonable royalty rate or based on the infringer's profit. There are no enhanced damages for wilful infringement.

#### Provision of Information

Provision of information about the past infringements may be requested by the plaintiff. This includes information about the origin and the distribution chain, the numbers manufactured,

supplied, obtained and ordered, and the prices paid for, and the profits made with the infringing products.

## **Destruction and Recall**

In addition, the right-holder may request the infringer to destroy all infringing products in its possession and recall the infringing products, unless this would be unreasonable. These claims are available regardless of negligence or intent on behalf of the infringer.

Notably, the claim for destruction extends to manufacturing equipment exclusively, or almost exclusively, used for manufacturing the infringing product.

## **Publication**

The publication of the decision can be requested by the plaintiff at the infringer's expense when the right-holder has a legitimate interest. The nature and scope of the publication will be specified in the judgment. This remedy is hardly ever granted by German courts.

## **Legal Costs**

The infringer has to pay the necessary legal costs if the plaintiff wins (see also **6.2 Rights of Prevailing Defendants** regarding the calculation). The reimbursement also covers the court fees paid for filing the complaint.

## **6.4 Injunctions Pending Appeal**

If a patent is found valid and infringed at first instance, the decision is preliminarily enforceable and not automatically stayed when an appeal is filed. Such a preliminarily decision may require the provision of security by the enforcing party. But the enforcing party is obliged to pay damages, also for loss of profit, when the first-instance judgment is enforced but later repealed.

## **7. Appeal**

### **7.1 Special Provisions for Intellectual Property Proceedings**

With regard to infringement proceedings, there are no additional requirements in view of IP rights proceedings with the exception of the appeal term.

With regard to nullity proceedings, there is the special characteristic that the Federal Court of Justice is the appeal instance.

### **7.2 Type of Review**

The appeal courts are not completely limited to the review of errors of law of the first instance. New facts can be presented within certain limits and preconditions: for example, when the reasons are not due to an error of the party.

The EPO appeal proceedings are focused on the revision of the arguments presented in the first instance. Additional arguments may be filed only in exceptional cases.

## **8. Costs**

### **8.1 Costs Before Filing a Lawsuit**

Before filing a lawsuit, the costs are limited to the costs for lawyers and/or patent attorneys, calculated usually on an hourly rate or legal fee.

For a justified claim, the fees for warning letters or protective briefs will also be reimbursed to the amount of the legal fee.

In Germany, the costs for the online filing of the protective brief are EUR100, while the protective brief at the UPC will cost EUR200.



## 8.2 Calculation of Court Fees

In Germany, the court fees are calculated on the basis of the value of the dispute, which represents the economic interest that the patent owner pursues with the complaint.

At the UPC, the fee for an infringement action consists of a fixed court fee and a fee based on the value in dispute.

## 8.3 Responsibility for Paying the Costs of Litigation

In Germany, as at the UPC, the losing party is required to reimburse the prevailing party and bears the costs of litigation. For partial prevailing or exceptional circumstances, costs may be ordered on an equitable basis or each party may be ordered to bear its own costs.

For a value in dispute of EUR1 million, the reimbursable fees (lawyer fees, court fees, first instance, one party) in Germany are about EUR45,000, whereas at the UPC the reimbursable fees are EUR112,000.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

In view of the fact that mediation does not always provide the expected result, and in view of low litigation costs in Germany, infringement proceedings are initiated instead of alternative dispute resolution.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

In principle, IP rights can be inherited and transferred without limitation or restriction, an exception thereto being the transfer of copyright during the creator's lifetime. The transfer of these rights is possible without any formalities; even an oral assignment is effective. However, it shall be noted that IP rights cannot be acquired in good faith. Therefore, it is important to document a transfer of IP rights in writing. If challenged in infringement proceedings, the entitlement needs to be proven; thus, written assignment is the safest way.

### 10.2 Procedure for Assigning an Intellectual Property Right

The assignment of an IP right is governed by the general rules of the German Civil Code and can in principle take place without any form by concurrent declarations of intent. It is sufficient that the transferor offers the assignment and the transferee accepts the offer. As a consequence of the transfer of the IP right, the transferee acquires the same rights and obligations as the transferor. This is preferably done in writing, but this is not mandatory (see also 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights).

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

IP rights may be licensed by the owner or the exclusive licence holder. In Germany, licensing of an IP right is preferably done in writing, but can also be done orally, with a few exceptions. The licences can be entered in the respective register, but this is not mandatory.



## 10.4 Procedure for Licensing an Intellectual Property Right

The owner of the IP right (licensor) and the licensee conclude a licence agreement in which the subject-matter of the licence is defined. The agreement is governed by the general rules of the German Civil Code. In Germany, a distinction is made in principle between exclusive and non-exclusive licences.

Regardless of whether it is exclusive or non-exclusive, a licence can be limited in terms of location, time and subject-matter. In return for the transfer of the IP rights, the licensee usually agrees to pay an appropriate licence fee.

**Braun-Dullaues Pannen Emmerling (BDPE)** has patent litigation as its core business. While other firms generally heavily rely on patent prosecution, BDPE has a clear focus on patent litigation, setting it apart from other boutique law firms. Our patent attorney team is already one of the most active in patent litigation before German courts and the EPO, only three years after commencing its operation within this set-up, especially when it comes to standard essential patents (SEPs) in mobile communications and

connected car sectors. BDPE further focuses on power electronics, in particular solar energy. The founding partners of BDPE have been well known for their excellent expertise in litigation and the industry for many years. As a result, they created a law firm which is not only highly specialised in IP litigation but where the attorneys are real business partners who understand the business of their clients.

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## Law and Practice

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

The intellectual property rights available to protect inventions in Hungary are patents, utility models and know-how. These forms of protection are all based on statutory law – Act XXXIII of 1995 (Patent Act), Act XXXVIII of 1991 (Utility Model Act) and Act LIV of 2018 (Act on Trade Secrets and Know-how) – but Hungarian and European case law is also duly considered by the authorities.

### 1.2 Grant Procedure

The grant procedure for patents and utility models requires an application to be filed with the Hungarian Intellectual Property Office (HIPO). A formal examination is carried out and, if all requirements are met, a substantive examination of the requirements of novelty, inventive step and industrial applicability follows for patent applications, but no examination of novelty and inventive step is carried out in the case of utility model applications.

After a period of not less than 18 months from the filing date of the application, the HIPO makes the application available for the public. The applicant may also request an earlier publication. Publication gives rise to provisional protection, on the basis of which the applicant may seek relief against alleged infringers, but in patent cases the infringement procedure is stayed until final protection is obtained.

There is no grant or registration procedure for know-how; protection arises automatically pursuant to the law.

### 1.3 Timeline for Grant Procedure

The granting procedure for patents usually takes two to three years, and six to 12 months for utility models. Representation by a patent attorney or a lawyer is mandatory for foreign but not domestic clients before the HIPO, although it is mandatory for everyone before the courts. The average cost to grant a patent is EUR1,000 (excluding lawyers' fees and depending on the length of time taken); for utility models it is EUR110 (excluding lawyers' fees).

### 1.4 Term of Each Intellectual Property Right

Patents last 20 years from the filing date, while utility models last ten years from the filing date. The duration of know-hows is potentially unlimited, provided the legal requirements are met.

### 1.5 Rights and Obligations of Owners of Intellectual Property Rights

The holder of the patent has the exclusive right to exploit the invention, on the basis of which the patentee is entitled to prevent any person that does not have their consent from:

- making, using, putting on the market or offering for sale a product that is the subject matter of the invention, or stocking or importing the product for such purposes;
- using a process that is the subject matter of the invention or offering the process for use where such other person knows, or it is obvious from the circumstances, that the process cannot be used without the consent of the patentee; or
- making, using, putting on the market, offering for sale or stocking or importing for such purposes a product obtained directly by a process that is the subject matter of the invention.

There is no public information listing applicable patents in relation to certain products or processes, not even in the pharmaceutical space.

## Utility Models (Article 12 of the Utility Model Act)

Utility model protection affords the holder the exclusive right to exploit the utility model or to license another person to exploit it, as provided for by legislation. The exclusive right of exploitation shall include the manufacture, use or importation of the subject matter of the utility model, or putting it on the market within the framework of economic activity.

The owners of the above IP rights are entitled to seek remedies against alleged infringers and may allow their licensees to take such action. The costs relating to the above IP rights are to be borne by the owner(s).

## 1.6 Further Protection After Lapse of the Maximum Term

Supplementary Protection Certificates (SPCs) are available for medicinal products on the basis of EU Regulation Nos 469/2009 and 1901/2006 (paediatric extensions) and for plant protection products on the basis of EU Regulation No 1610/96. Such additional protection is available for a maximum of five years for certain pharmaceutical and plant protection products that have been approved for sale in Hungary and are covered by a national patent (an additional six months of protection is available for medicinal products that are also used for paediatric applications).

## 1.7 Third-Party Rights to Participate in Grant Proceedings

During the patent granting procedure, any person may file an observation with the HIPO to the effect that the invention or the application

does not comply with a requirement of patentability. Such observation shall be taken into consideration when the requirement objected to in the observation is examined. The person making the observation shall not be a party to the patent granting procedure but shall be notified of the outcome of their observation.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

If a final decision of the HIPO fully or partially refuses the grant of a registered intellectual property right, such as patents or utility models, an appeal (ie, a request for reconsideration) may be filed with the Metropolitan Tribunal within 30 days of the date of the notification of the decision. The decision of the Metropolitan Tribunal may be further appealed at the Metropolitan Appeal Court.

## 1.9 Consequences of Failure to Pay Annual Fees

Patents, SPCs and utility models lapse if the annual fees are not paid. A possible remedy is to pay an extra 50% late payment fee within six months of the missed deadline. If patent or SPC protection has lapsed due to non-payment of the annual fees, protection shall be restored at the request of the applicant or the patentee. The restoration of patent protection may be requested within three months following the expiry of the six-month grace period, upon the payment of a fee.

If utility model protection has lapsed due to failure to pay annual fees, the HIPO shall, on request, restore the protection upon the payment of a fee if the failure occurred for good reason.

The fee to be paid for restoring the protection of any above IP right is twice the amount of the



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annual fee, and is to be paid within a year of the lapse occurring.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

Owners of intellectual property rights cannot themselves initiate any post-grant proceeding to amend the scope of the issued intellectual property right, but in the course of an invalidity action initiated by a third party they have the right to limit the scope of their right when patents or utility models are concerned.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

In the event of infringement, the owner of a technical intellectual property right may consider civil or criminal routes of enforcement or customs measures. Civil law enforcement includes initiating a preliminary injunction proceeding and/or a main lawsuit related to patent or utility model infringement. Wilful infringement of intellectual property rights is also considered a criminal offence and may incur penalties. Customs measures are available in the framework of EU Regulation 608/2013.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

Importantly, it is not possible to file a protective letter with a court in Hungary. Third parties who find themselves in potential conflict with a patent or other technical intellectual property rights (eg, a utility model) may have the following options.

- A non-infringement action in front of the HIPO may be started against a patent by anyone who is concerned that an infringement action will be initiated against them by the patentee.

In the request, the product or method of the applicant has to be compared to the patent in question. A pending non-infringement action causes the stay of the corresponding infringement action, but does not stay the preliminary injunction proceeding. If non-infringement is declared with a binding effect, there can be no infringement action against the same product or method.

- A revocation action in front of the HIPO against a patent can be commenced by anyone. If there are several revocation requests against the same patent, the proceedings are often joined. A pending revocation action causes the stay of the corresponding infringement action but does not stay a corresponding preliminary injunction proceeding. A first instance decision by the HIPO declaring the invalidity of the patent is a strong argument against ordering a preliminary injunction. It is possible for the parties to make a settlement in the revocation action; however, the HIPO still has the authority to continue the revocation ex officio, but this seems to be a rather theoretical possibility as there are no cases where the HIPO would have exercised this right, as far as is known. The defendant of a patent infringement lawsuit may also choose to challenge the validity of the patent in suit directly as a counterclaim.
- A compulsory licence may be obtained in the event of lack of genuine use of the patent or dependency of patents, as well as under EC Regulation 816/2006 or for addressing a public health emergency.

Compulsory licences on the grounds of either dependency or lack of use are adjudicated exclusively by the Metropolitan Tribunal. A successful lawsuit for a compulsory licence ensures that the licensee can use the patent and the patentee has to receive remuneration. Compulsory

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licences shall be registered in the patent register. Please note that no known compulsory licences have been issued by the courts so far, with only one case having been initiated in the past 20 years, as far as is known.

An additional type of compulsory licence was enacted in 2020, in the Patent Act in connection with the COVID-19 pandemic: the so-called public health compulsory licence is to be granted by the HIPO during periods declared by the government as a health crisis, such as the COVID-19 pandemic. In such situations, a compulsory licence can be granted for patented drugs, active ingredients or medical devices, and for patented processes or equipment for the production of such for the purpose of fulfilling domestic needs and – in a limited scope – for export. Detailed rules are provided in the Patent Act.

## 2.3 Courts With Jurisdiction

The Metropolitan Tribunal of Budapest has first instance jurisdiction for patent and utility model infringement lawsuits, as well as preliminary injunction proceedings. The Metropolitan Appeal Court acts as second instance, and the Curia (Supreme Court) provides judicial review for questions of law.

For revocation actions, the first instance authority is the HIPO, and any appeals against its decisions are dealt with by the Metropolitan Tribunal acting as first judicial instance. The Metropolitan Appeal Court acts as second judicial instance, and the Curia provides judicial review.

This ensures four instances for revocation (the HIPO preceding three judicial instances) but only three for infringement. Also, it means that patent litigation is bifurcated in Hungary, and infringe-

ments and revocations are assessed independently in separate proceedings.

As of 1 January 2022, however, the defendant in a patent infringement lawsuit may also choose to challenge the validity of a patent directly in the form of a counterclaim. In this case, the revocation action is one instance shorter: the level of the HIPO proceeding is skipped and the proceeding starts directly before the Metropolitan Tribunal in a unified infringement revocation proceeding.

Lawsuits related to ownership, licensing or remuneration, including any dispute arising from contracts involving patents, belong to one of the tribunals of Hungary (courts acting in the central town of each county), depending primarily on the address of the defendant.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

As a specialised authority, the HIPO acts in revocation and non-infringement actions. There is no specialised court for patent litigation (patent infringement, compulsory licensing, judicial level of revocation), although the Metropolitan Tribunal has exclusive competence for these cases and there are designated senates at each judicial level that handle all IP rights cases, and can therefore be regarded as specialised senates.

## 2.5 Prerequisites to Filing a Lawsuit

There are no prerequisites to filing a lawsuit for patent infringement. However, according to the Patent Act, if a preliminary injunction is granted, the main lawsuit shall be initiated within 15 calendar days or the preliminary injunction will be lifted.

In the case of a lawsuit for compulsory licence, the plaintiff (ie, the party seeking the licence)

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shall demonstrate that the patentee was not willing to grant a licence in reasonable time. This can be regarded as a prerequisite as it implies a mandatory communication between the parties prior to the lawsuit.

In Hungary, licensees can also commence patent infringement lawsuits in their own name, provided that the licensee is registered as such in the patent register and can prove that it called the plaintiff to step up against infringement and the plaintiff remained passive for 30 days.

## 2.6 Legal Representation

Foreign individuals and entities appearing at the HIPO must be represented by either a lawyer or a patent lawyer, or a team of such. In court proceedings, legal representation is required by law for both foreign and domestic parties.

## 2.7 Interim Injunctions

In intellectual property cases, preliminary injunctions are available based on the general rules of the Code of Civil Procedure, but with special rules – eg, in the Patent Act.

The right holder seeking a preliminary injunction shall demonstrate the probability of infringement as well as the necessity and proportionality in the request. Regarding necessity, a special presumption exists in the Patent Act by which necessity shall be presumed if the invention is under patent protection, if the plaintiff is the patentee or registered licensee, and if fewer than 60 days have lapsed since the plaintiff gained knowledge of the infringement and fewer than six months have passed since the actual commencement of the infringement.

However, this presumption can be overturned; in the course of evaluating this, the court shall attribute special consideration to certain facts,

particularly if the patent has been revoked at least at first instance and in the case of European patents in any European Patent Convention (EPC) member state. The proportionality requirement means weighing up the balance of public interest according to the Patent Act, taking into account the interests of third parties.

Theoretically, a preliminary injunction may also be ordered in the event of a direct threat of infringement, before the infringing product is actually launched on the market. However, in these cases the court tends to require convincing and specific evidence that the start of distribution or manufacturing is imminent.

The preliminary injunction is typically aimed at a cease-and-desist order, as well as the seizure and withdrawal of the products from the channels of commerce. Hungarian law applies specific injunctions, meaning that the court specifically identifies the infringing product by name or other identifier.

Either party may appeal a preliminary injunction, although it is enforceable regardless of an appeal. Upon the request and arguments of the defendant, the court often effectively grants a preliminary injunction, subject to a bond to be deposited by the plaintiff.

If the circumstances that gave rise to the preliminary injunction change, the defendant may request the injunction to be lifted and the court will decide on the request, evaluating whether or not the change of circumstances justifies the lifting of the injunction. If the preliminary injunction is lifted, the injunction defendant may seek appropriate compensation from the plaintiff. One relevant Hungarian court case gave rise to judgment C-688/17 (Bayer), which interpreted Article

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9(7) of Directive 48/2004/EC on the Enforcement of Intellectual Property Rights.

Ex parte preliminary injunctions are also made available by the law in the event of urgency, such as the threat of irreparable harm. However, as far as is known, the court has so far never decided on a preliminary injunction request in ex parte proceedings in patent cases. Instead, preliminary injunction requests have always been served on the defendant. However, in trade secret cases, preliminary injunctions have already been granted in ex parte procedures.

## 2.8 Protection for Potential Opponents

It is not possible to file a protective letter with the court in Hungary, although potential opponents may commence proceedings for non-infringement. If sued in a preliminary injunction proceeding, the opponent may also request the court to make a bond the condition of the preliminary injunction entering into effect; the amount of the bond is subject to the arguments of the parties.

Very often, when a revocation action is pending, the court determines the bond based on the expected profit loss of the defendant for the duration of the revocation proceedings. According to the rules of the Code of Civil Procedure, the bond shall be automatically transferred to the defendant if the court dismisses the petition of the plaintiff for the declaration of the infringement. If infringement is declared in the judgment, the bond shall be returned to the plaintiff.

## 2.9 Special Limitation Provisions

There is no special limitation period for intellectual property matters; the general five-year limitation applies for all civil law claims. However, judicial practice confirms that the right to remedies such as declaration of infringement and cease-and-desist orders is tied to the owner-

ship character of registered intellectual property rights and thus such claims do not prescribe.

If the plaintiff is unable to start an action for a reason that is not their fault, the limitation period is stayed. Also, there are certain acts that interrupt the limitation period and cause it to restart, such as the initiation of a lawsuit if it is concluded on the merits. Importantly, a mere warning letter does not interrupt the limitation period.

## 2.10 Mechanisms to Obtain Evidence and Information

Possibilities for obtaining information in patent infringement lawsuits are mostly made available in the context of Directive 48/2004 on the Enforcement of Intellectual Property Rights, as well as the Hungarian Patent Act's earlier harmonisation with the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS).

The right to information from the defendant is available as part of a preliminary or final injunction. In this context, the court may order the defendant to provide information on the quantities of the infringing products, sales information and information about commercial partners. The same order can be obtained against parties who possess infringing products or have obtained or provided services relating to the infringement on a commercial scale.

Also, during a patent infringement lawsuit the plaintiff may ask the court to order the defendant to provide information or evidence on the infringing product/process, and also to provide financial information. Besides this, the plaintiff may seek an order on the preliminary obtaining of evidence, which would allow the plaintiff to have the court inspect the defendant's premises to request information in due course.

Notably, neither the preliminary obtaining of evidence nor the enforcing of the right of information against third parties is common in Hungary. Also, courts tends to deny a request to oblige the defendant to provide information in a preliminary injunction proceeding, since the court considers it irreversible, which is against the nature of a provisional measure.

## 2.11 Initial Pleading Standards

The initial pleadings must be very detailed, according to the rules of the Code of Civil Procedure. The court claim and the preliminary injunction request shall contain detailed arguments and all available evidence relating to the infringement. Preliminary injunction requests shall also include detailed arguments regarding necessity and proportionality.

Importantly, following the initial round of court claim and the statement of defence, there is no automatic right to file further motions; the plaintiff may only respond to the court claim if the court calls the plaintiff to do so. Parties are thus advised to submit their arguments and evidence in their first submission to the court. An important feature of the Hungarian proceedings is that all foreign language documents submitted as evidence shall be submitted in Hungarian as well.

In revocation actions, the rules are not so strict before the HIPO. There are several rounds of exchanging writs by the parties, and evidence can also be filed during the proceedings before the HIPO, subject to respecting the timing of the hearing – ie, that evidence and pleadings filed too close to the hearing may be ignored by the HIPO. However, following the first instance proceeding of the HIPO, the same rules apply as above when the proceeding reaches the judicial level.

## 2.12 Representative or Collective Action

Collective actions are not known for IP litigation in Hungary.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

The Patent Act (and other relevant acts, such as the Utility Model Act) contains no provision relating to restrictions, except for the protection of confidential information. The question of patent misuse or abuse has arisen following CJEU judgment C-688/17 (Bayer) in the context of awarding compensation to the defendant when a preliminary injunction was subsequently lifted, but the case is still pending.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

In patent infringement cases, the claimant is normally the owner of the patent. If there are co-owners, any of the owners has the right to enforce the patent. Furthermore, the registered licensee (either exclusive or non-exclusive) may submit an action on their own behalf, if the patent owner was invited to take appropriate steps against the alleged infringer and failed to do so within 30 days. Furthermore, licensees may act as co-plaintiffs of the patentee or intervene in infringement proceedings initiated by the patentee.

In the case of trade secrets, normally the owner of the right files an action against the infringer; the licensee may file such action only if it has such right on the basis of the licence agreement.

## 3.2 Direct and Indirect Infringement

### Direct Infringement

In instances of direct infringement of an exclusive right, the patentee shall be entitled to prevent any person from doing the following without consent, under Article 19 of the Patent Act:

- making, using, putting on the market or offering for sale a product that is the subject matter of the invention, or stocking or importing the product for such purposes;
- using a process that is the subject matter of the invention or offering the process for use where such other person knows, or it is obvious from the circumstances, that the process cannot be used without the consent of the patentee; or
- making, using, putting on the market, offering for sale or stocking or importing for such purposes a product obtained directly by a process that is the subject matter of the invention.

In practice, courts interpret the forms of exploitation listed in Article 19 of the Patent Act strictly, and no other activity is considered to be infringing.

### Indirect Infringement

In the case of indirect infringement, the patentee is entitled to prevent any person that does not have consent from supplying or offering to supply a person – other than a person entitled to exploit the invention – with means (instruments, appliances) relating to an essential element of the invention, or carrying out the invention. This applies when the person knows, or it is obvious from the circumstances, that those means are suitable and intended for carrying out the invention.

For available remedies, see **6. Remedies**.

## 3.3 Process Patents

A special legal presumption is established in the Patent Act regarding process patents. Article 19(7) states that, pending proof to the contrary, a product shall be deemed to be produced through the patented process (in suit) if the product is new, or if there is conclusive evidence that the product has been manufactured by the patented process, and the holder of the patent could not define the process actually applied after having taken the steps generally expected in the given situation. Conclusive evidence to verify that the product has been produced by way of the patented process constitutes the probability that it is the only process that has been made available to the public.

There are no special rules for the situation if parts of the allegedly infringing process are practised outside Hungary, and this has not yet been addressed in court practice.

## 3.4 Scope of Protection for an Intellectual Property Right

Under Article 24 of the Patent Act (which is in line with Article 69 of the European Patent Convention 2000), the scope of protection of the patent shall be determined by the claims. Claims shall be interpreted on the basis of the description and the drawings. The scope of the patent covers any product or process in which each characteristic of the claim is realised.

The doctrine of equivalence is also implemented into the Patent Act – ie, to determine whether the patent protection extends to a product or process, account shall be taken of any characteristics of the product or process that are equivalent to those specified in the claims.



## 3.5 Defences Against Infringement

As the Hungarian patent litigation system allows bifurcation (ie, the defendant of a patent infringement lawsuit may choose whether to start revocation directly as a counterclaim or separately before the HIPO), the natural defence against an infringement case is to file a revocation action. The infringement lawsuit is suspended whenever the revocation proceeding is initiated separately before the HIPO, be it before or during the infringement lawsuit, but preliminary injunction procedures are never suspended.

According to Article 37 of the Patent Act, any person believing that proceedings for patent infringement may be instituted against them may file a non-infringement procedure, requesting a decision ruling that the product or process exploited or to be exploited by them does not infringe a particular patent. Such a procedure shall be filed with the HIPO before the submission of the infringement action. In this instance, courts usually also suspend the infringement proceeding until the final decision in the non-infringement procedure.

Other defences (or rather limitation of the exclusive rights of the patentee) also exist, such as the Bolar exemption, patent exhaustion, prior use rights, farmers' privileges, transport traffic and compulsory licences.

Regarding the Bolar exemption, Article 19(6)(c) of the Patent Act contains a wide exemption in Hungary for specified pharmaceuticals as of 1 January 2022. According to this exemption the, the exclusive right of the patentee shall not extend to acts carried out for experimental purposes relating to the subject matter of the invention, including experiments, studies and related tasks necessary for obtaining an authorisation to place a pharmaceutical product on the market

in the EEA or in a third country, particularly the manufacturing, use, distribution, offer for sale, storage, importing or exporting – regardless of whether or not these acts are done by the applicant for the marketing authorisation or by another person in a commercial relationship with the applicant for this purpose.

For non-pharmaceutical products, a more general and technology-neutral experimental exemption applies in Article 19(6)b, according to which the exclusive right of the patentee does not extend to acts done for experimental purposes in connection with the subject-matter of the patented invention.

Furthermore, according to Article 19(6), acts that are performed for the purpose of private use and/or are considered as non-economic activities are also exempt, as is the non-regular preparation of a medicine in a pharmacy, upon a doctor's prescription.

The prior use of the invention is also treated as a limitation of the exclusive rights of the patent holder, if someone had begun making or using the subject matter of the invention in good faith, before the date of priority, in the territory of the country and within the framework of their economic activities.

Article 20 of the Patent Act regulates patent exhaustion, whereby the exclusive right of exploitation conferred by patent protection shall not extend to acts concerning a product put on the market in the territory of the EEA by the patentee or with their express consent, except where the patentee has legitimate interests in opposing the further marketing of the product.

According to the farmers' privilege, the sale or other form of commercialisation of plant propa-



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gating material to a farmer by the patentee or with their express consent implies authorisation for the farmer to use the product of the harvest for propagation or multiplication on their own farm. Similarly, the sale or other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the patentee or with their express consent implies authorisation for the farmer to use the patented livestock for agricultural purposes.

### 3.6 Role of Experts

According to Hungarian practice, the court shall appoint a court expert if necessary – ie, if the court does not possess the required professional knowledge on a particular fact. Either party may file a motion for the appointment of a court expert, and the court may appoint a court expert ex officio. Essentially, the court formulates the questions to the expert, who then provides their expertise in writing. The court may invite the court-appointed expert to the hearing if the written expertise is not clear enough and/or there is any contradiction. At court hearings, the expert is first questioned by the judges; the parties may question the expert only if the judges allow it.

According to new Hungarian procedural rules, two other kinds of experts are also recognised: a private expert and an expert appointed in another proceeding. Under the new rules, both court-appointed experts and private experts must be chosen from the official list of registered experts.

The main difference between the different types of experts is that if the court appoints an expert, there can be just one expert for the same question, whereas if private experts are used, both sides can propose their own private expert's opinion. In revocation actions before the court, however, it is not possible to use party-appointed private experts.

The party shall choose from among the experts, pursuant to the principle of efficiency in legal procedures, which does not allow for a party to offer multiple, parallel expert opinions as evidence regarding the same issue. However, only court-appointed experts can be used in revocation proceedings at the court.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

There are no separate procedures for construing the terms of the patent's claims.

### 3.8 Procedure for Third-Party Opinions

Generally, there is no system in Hungary for the court to accept amicus briefs. A provision specific to IP cases is that the HIPO is entitled to submit its legal standpoint to the court about the case in proceedings for the judicial review of the decisions of the HIPO (eg, in revocation actions), even though the authority is not a party to the proceedings. The HIPO tends to exercise this right from time to time in more significant cases.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

The revocation of a patent may be requested by anyone without time limit and without any legal or commercial interest, except where the patent is granted for someone who is not entitled to it; only the real and true inventor or predecessor of the inventor may file such a request.

If a patent is invalid, it shall be revoked ex tunc, with retroactive effect, from which it follows that no patent infringement can be established on the basis of a revoked patent. However, importantly, the Hungarian patent litigation system allows bifurcation, which means that the revo-

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cation action starts before the HIPO unless it is initiated as a counterclaim against the infringement petition by the defendant of an infringement lawsuit.

According to Article 42(1) of the Patent Act, the patent shall be revoked *ex tunc* if:

- the subject matter of the patent does not satisfy the requirements laid down in the Patent Act (lack of novelty, inventive step, industrial applicability, exclusion from patent protection);
- the description does not disclose the invention in a clear and complete manner (insufficiency);
- the subject matter of the patent extends beyond the content of the application as filed at the date of filing or – in the case of division – beyond the content of the divisional application (added matter); or
- it was granted to a person who was not entitled to it.

The revocation of patents – either national patents or the Hungarian part of European patents – falls under the competence of the HIPO at first instance, or under the Metropolitan Court if the revocation action is introduced as a counterclaim by the defendant in an infringement lawsuit.

A registered patent may also be cancelled if the renewal fees have not been paid, or due to withdrawal by the patent owner.

## 4.2 Partial Revocation/Cancellation

A patent can be revoked in whole or in part. According to Article 42(2), if the grounds for revocation affect the patent in part only, the scope of the patent shall be limited accordingly.

## 4.3 Amendments in Revocation/Cancellation Proceedings

The patent owner may request an amendment of the claim in a revocation procedure, and may file the suggested wording of the amendment. The scope of protection conferred by the amended claim must be narrower than that of the original. In addition, the amended claims shall be disclosed in full in the original application, and shall fulfil all the patentability requirements.

There is no cancellation proceeding for patent owners in Hungary.

## 4.4 Revocation/Cancellation and Infringement

Revocation and infringement proceedings are not generally heard together, according to the bifurcated Hungarian patent litigation system. The main infringement procedures must be suspended until the final decision in the revocation procedure; the decision in the revocation procedure always prevails over the decision of the main infringement procedure.

Softening the strict bifurcation system, as of 1 January 2022, the defendant of the patent infringement lawsuit may also choose to file the revocation request in the form of a counterclaim against the infringement petition, in which case both infringement and revocation actions are decided in the same court proceeding. In any case, the decision in preliminary injunction procedures always prevails over the final decision in the revocation procedure, so the patent owner has a chance to stop the infringing activity until the end of the revocation procedure.

There are different rules for litigating utility models. In a utility model infringement lawsuit, the court may decide not to suspend the lawsuit if the patentee presents a so-called positive opin-

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ion on protection, which can be obtained by the HIPO. In utility model infringement proceedings, if the court does not suspend the lawsuit, it may adjudicate the merits of the invalidity objection of the defendant and dismiss the infringement petition on this basis. This is, however, not an erga omnes decision on invalidity.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

The general rules contained in the Code of Civil Procedure (Act CXXX of 2016 – CCP) contain special provisions relating to court proceedings concerning the meritorious decision of the HIPO in respect of intellectual property rights (patents, utility models). These special provisions relate primarily to the definition of the competent court, the composition of the court, exclusion, publicity and representation.

An IP-specific provision for court proceedings for infringement and revocation is that the exclusive jurisdiction of the Metropolitan Tribunal of Budapest shall apply. The court acts in a panel consisting of three professional judges, two of whom will have a technical background. At the request of either of the parties, the court may decide to hold the hearings in closed sessions, even in the absence of the conditions set forth in the CCP.

In addition to the general cases of exclusion set forth in the CCP, the persons who participate in passing the decision of the HIPO, as well as their close relatives (according to the Civil Code), shall be prohibited from taking part in the case and from participating as a judge. In cases brought in connection with intellectual property rights, in addition to lawyers, patent attorneys may take

action in the proceedings as representatives, including in cases of mandatory legal representation.

Main infringement proceedings may take one to two years at first instance, depending on the complexity of the case and how many experts are needed. Cross-examination is not practised in Hungary; it is primarily the judge who asks questions of the experts or witnesses but the judge may allow the parties to ask questions directly as well. Experts are typically heard at first instance, but can also be heard at second instance if such a need arises.

During the trial, there is a preparatory and one or several main hearings but, in theory, if the case is simple the preparatory hearing may turn into a main one and the court can actually bring a decision on the first hearing. The length of the proceeding is increased by years if there is a revocation action at the EPO or at the HIPO against the patent, due to which the infringement lawsuit is suspended.

As the option of challenging patent validity before the court as a counterclaim to infringe is very new (applicable from 1 January 2022), there is no practice with regard to the length of the combined infringement revocation lawsuit. Higher instances of the case typically involve one hearing and are usually decided in a year. If a declaratory judgment and damages are sought together, it is typical for the court to first make an interim decision on infringement and to only proceed with the pecuniary claims once the interim decision becomes final.

There are also some special rules relating to preliminary injunctions (see **2.7 Interim Injunctions**).

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## 5.2 Decision-Makers

Each revocation and non-infringement proceeding before the HIPO is heard and decided by a panel of three members, two of whom are patent examiners and one of whom is a legal member.

The Metropolitan Tribunal of Budapest has exclusive jurisdiction for reviewing the decisions of the HIPO. In such cases, the court shall act in a panel of three judges (one legal and two technical).

The Metropolitan Tribunal of Budapest also has exclusive jurisdiction for IP rights infringement lawsuits, including preliminary injunction proceedings. It has a specialised IP panel consisting of three judges, two of whom have a technical background.

In both the review of the HIPO's decisions and infringement lawsuits, the court of second instance is the Metropolitan Tribunal of Appeals (or Metropolitan Appeal Court) in Budapest, which proceeds with three legal judges. Similarly, the Curia proceeds with a panel of only legal judges.

The types of patent lawsuits that do not fall under the exclusive jurisdiction of the Metropolitan Tribunal of Budapest (eg, entitlement lawsuits, employee remuneration, licence disputes) are adjudicated by local courts corresponding to the seat of the defendant, decided by one or three legal judges, depending on the instance of the proceedings.

In all the above examples, the parties have no influence on who is appointed as decision-maker, since it is defined by law (exclusive jurisdiction) and judges are assigned in accordance with the respective rules applicable for the courts.

In cases of trade secret infringement, the competent court corresponds to the seat of the defendant, and the first instance court proceeds with a single judge.

## 5.3 Settling the Case

There is no statutory provision regarding commercial entities' obligatory attempt to settle their dispute out of court prior to the court procedure. Also, the Hungarian litigation system does not involve any form of mandatory settlement conference. It is often the case, however, that parties wish to settle the proceedings themselves, which they can do at any point, as long as a final and binding decision has not been made. There are essentially two ways to do this.

- First, the parties may settle out of court and mutually request the court to terminate the lawsuit. Here, the court only orders on costs if needed, and the case is terminated without *res iudicata*. In this instance, the obligations of the parties are contractual obligations towards each other, and can be enforced as such.
- The other form is that the parties may also ask the court in infringement lawsuits (but not in proceedings for the review of the decisions of the HIPO) to approve their agreement, in which case the order made by the court in this subject has the effect of a judgment and results in *res iudicata*. Quite often, parties mutually request the stay of the proceeding for the duration of their settlement negotiation.

Parties may also settle during the HIPO phase of a revocation action. However, the HIPO is entitled to continue the proceeding *ex officio*. As far as is known, the HIPO has never exercised this right, although logically the settlement of the

parties should not determine the validity of the IP rights.

## 5.4 Other Court Proceedings

The Hungarian system is generally bifurcated, which means that validity and infringement proceedings are decided in separate proceedings and in different forums: patent infringement proceedings fall within the exclusive competence of the Metropolitan Tribunal at first instance, while revocation actions are initiated before the HIPO, the decision of which can be appealed before the Metropolitan Tribunal.

If parallel revocation proceedings are pending, according to the established court practice of the Metropolitan Tribunal, the infringement proceedings are always stayed until the final conclusion of the revocation proceedings. The exception is that, as of 1 January 2022, the defendant in an infringement lawsuit may decide to file a revocation action as a direct counterclaim in the infringement lawsuit, so that the court decides on both issues in a unified proceeding. Importantly, the ongoing revocation action does not stay the preliminary injunction, and does not prevent the court from making a decision and – if justified – granting a preliminary injunction.

According to recent court practice, the revocation action against the Hungarian-validated part of a European patent may be stayed until the resolution of the EPO opposition proceeding if such is still pending.

## 6. Remedies

### 6.1 Remedies for the Patentee

If the court finds the patent to be infringed, it shall order a final injunction (eg, declaration of infringement, cease-and-desist obligations).

Importantly, the court may only order such remedies that were contained in the statement of claims of the patentee; even in that case, the court may not order it in a form that was not specifically requested by the plaintiff. Following the implementation of Directive (EU) 2016/943 (Trade Secret Directive), unlike in the case of registered technical IP rights, in trade secret litigation the court has a degree of discretion regarding the remedies ordered, subject to proportionality.

As to monetary remedies, the patentee may request the return of any enrichment (profit or an unpaid licence fee) gained through the infringement of the patent, or may demand compensation for damages in accordance with the provisions of civil liability.

The main difference between the return of enrichment and damage compensation is that the first one is objective and the second one depends on the infringer's liability. The plaintiff shall, however, prove the amount of enrichment, and that it resulted directly from infringement. Damages, on the other hand, depend on the liability of the defendant.

If the patentee failed to submit the Hungarian translation of a European patent as required by law, and the infringer's home address or registered office is located in Hungary, the infringement may not be imputed to that person unless the patentee is able to verify that the infringer should have understood the original text of the European patent even in the absence of a translation.

There are no punitive monetary sanctions under Hungarian law.

The court may order the provision of information, the delivery and destruction of the infring-

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ing products, the publication of the decision in newspapers or magazines, or on the internet, at the expense of the infringer, and the recall of the infringing products from the channels of commerce.

If the fact of an infringement of an effective IP right is established, the court grants an injunction without considering the other facts of the case (eg, the revenue loss of the defendant or the interest of third parties or wilful infringement).

Remedies are enforced in line with the general rules of foreclosure, with special rules applying for IP cases that involve recurring penalties for non-complying defendants regarding injunctive relief orders.

## 6.2 Rights of Prevailing Defendants

If the court rejects the infringement claim, the defendant shall be awarded the legal expenses that have arisen in connection with the lawsuit (lawyers' fees, translation costs, duty fees, etc).

Due to the bifurcated system, a preliminary injunction may be granted against the defendant, and the patentee can then start the infringement proceedings within the legal deadline, and as a usual defence the defendant files a revocation request against the patent-in-suit. If the patent has been revoked as a result of the revocation proceedings, and the preliminary injunction is lifted, the defendant may claim damages. Regarding the legal basis of such damages, CJEU judgment C-688/17 (Bayer), which was a referral initiated by the Metropolitan Court of Budapest, is to be taken into account.

## 6.3 Types of Remedies

Available remedies are determined uniformly by the Patent Act, regardless of different intellectual property rights.

## 6.4 Injunctions Pending Appeal

An appeal will suspend the enforceability of the first-instance decision on the merits, unless the judgment of the court of first instance expressly states that the decision is enforceable notwithstanding an appeal.

Preliminary injunctions are always enforceable, irrespective of an appeal.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

Under Hungarian law, there are no special legal provisions for intellectual property rights appeal proceedings. This also applies to patent/utility model infringement and validity proceedings, which are equally governed by the general rules of civil procedures contained in the CCP. In these cases, which come under the exclusive jurisdiction of the Metropolitan Tribunal of Budapest, the Metropolitan Tribunal of Appeals is competent to adjudicate the appeals with a panel of three legal judges. In infringement lawsuits, the Appeal Court shall hold a hearing, while a hearing is only held upon the request of either party in proceedings for the review of HIPO decisions.

### 7.2 Type of Review

Judgments and meritorious orders are subject to appeal in all proceedings, either contentious (eg, infringement lawsuits) or non-contentious (eg, preliminary injunction proceedings and reviews of HIPO decisions). The deadline for appeal is 15 days from the receipt of the decision. In intellectual property cases, the Metropolitan Tribunal of Appeals adjudicates the appeals and conducts a full review of the facts and points of law within the limits determined by the appeal submitted.



The appellant must accurately set out the grounds on which the appeal is based by indicating the specific provision or part of the decision challenged by the appeal. The appeal shall contain a definitive request for the changes to be made by the court of second instance in the specific provision or part of the judgment of first instance that is contested, or for abolishing such provision or part, and shall provide its reasons respectively.

In the appeal phase of the proceedings, the submission of new facts or evidence is limited. There is no appeal against the decision of the Metropolitan Tribunal of Appeals. A final and binding decision can be referred to the Supreme Court of Hungary (Curia) for judicial review, but this is only possible regarding questions of law.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

Costs arising for the plaintiff prior to a lawsuit typically relate to the following categories:

- obtaining evidence – this typically includes the costs of test-purchasing a sample of the infringing product and the technical analysis of it, if required, or obtaining expert opinions;
- the costs of pre-trial correspondence with the other party, although this is not mandatory; and
- the preparation of the court claim and its legal arguments.

### 8.2 Calculation of Court Fees

Revocation actions and non-infringement proceedings have a fixed procedural fee of approximately EUR440 for the HIPO stage. During the court phase, the duty fee is determined by a hypothetical value of the proceedings, which is

set by law. This makes the duty fee rather minimal. The duty fee in revocation proceedings is not dependent on the value of the patent or the market concerned.

In infringement lawsuits, the duty fee is 6% of the value of the lawsuit. However, according to practice, the value of the lawsuit can only be determined when the claim contains a pecuniary claim – eg, a claim for damages. If there is no pecuniary claim, the value of the lawsuit is hypothetical, and the duty fee is very low (less than EUR50 per patent and per defendant). The same (somewhat increased) volume of duty fee is to be paid at higher court instances.

### 8.3 Responsibility for Paying the Costs of Litigation

In principle, the losing party shall be responsible for paying court fees, expenses and the other party's legal costs. All expenses must be validated by invoices, including the fee of the legal representative. However, the HIPO and the court have the right to reduce the legal costs that are to be awarded to the winning party, and often do so.

The court may also decide that each party is to bear its own costs, especially if the winning ratio is close to 50% (eg, by only partially granting what the plaintiff requested). Such a decision is quite common in technical intellectual property cases. Also, if a party causes extra costs (eg, if its delaying tactics make a further hearing necessary), the court may order the party to bear these costs regardless of the winning ratio.

The legal costs awarded by the court are to be paid once the decision becomes final and binding.



## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

There is no specific regulation regarding arbitration on the actions of IP rights in Hungary. However, the Hungarian courts have exclusive competence.

According to Article 44 of the Hungarian Patent Act, the HIPO shall have authority in procedures for the revocation (invalidation) of patents (at first instance). Therefore, a decision on the validity of a Hungarian patent will not be recognised by the HIPO or Hungarian courts and, as a result, cannot have effect on a patent's validity (either national or validated European patent) as registered by the HIPO.

No legal regulation prohibits the use of ADR in patent infringement situations, but there have been no such situations that would have been settled by arbitration, as far as is known.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

An intellectual property right can be assigned in Hungary in a written agreement; otherwise, due to the general provisions of contract law in the Civil Code, the transaction is deemed null and void. The assignment must be registered with the HIPO, enclosing at least a short assignment form, and there is no need to submit the detailed agreement of the IP assignment transaction. Service inventions made under employment are automatically assigned to the employer on disclosure, on the condition that the employer

accepts said inventions in writing within 90 days of the disclosure.

### 10.2 Procedure for Assigning an Intellectual Property Right

The assignment needs to be submitted to the HIPO, preferably using a simplified assignment form. However, there is no restriction on the content of the assignment agreement, provided that it clearly contains the identification data of the intellectual property, the assignor, the assignee, and the fact of assignment of the IP right. The assignment is then entered into the IP Registry maintained by the HIPO. The date of assignment shall correspond to the date according to the assignment document.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

The licensing provisions are included in the Patent Act, and apply to all other kinds of industrial property rights. An intellectual property right may be licensed in Hungary in a written agreement; otherwise, due to the general provisions of the contract law in the Civil Code, the transaction is deemed null and void.

All kinds of intellectual properties (ie, industrial properties), including their applications, copyrights and trade secrets (know-how), and their combination may be licensed. The licence may be non-exclusive or exclusive, with the opportunity to grant the right to sub-licence. However, the general rule offered by IP law is for non-exclusive rights with no right to sub-licence; therefore, exclusivity and sub-licensing must be concluded in writing by the parties.

The licensor shall guarantee both the freedom to operate and the technical operability of the IP; this may be excluded by the parties in writing. If the intellectual property is the result of a

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research agreement according to the Civil Code, the parties cannot waive the obligation to represent the legal clearance by the researcher. The licence terminates upon the expiry of the protection of the IP, or earlier, on the date set by the parties in the agreement.

## 10.4 Procedure for Licensing an Intellectual Property Right

The licensing transaction may be registered with the HIPO, although such registration is not an obligation. However, the licensee may only claim the exclusivity of the licence in front of a third party who acted in good faith if the licence has been registered with the IP Registry.

There is no restriction on the content of the licensing agreement, provided it clearly contains the identification data of the intellectual property, the licensor, the licensee and the fact of licensing of the IP right.

The licence is then entered into the IP Registry maintained by the HIPO. The date of the licence shall correspond to the date of the licensing agreement.

Hungarian IP law acknowledges the compulsory licence, but it is rarely used in practice. Please see **2.2 Third-Party Remedies to Remove the Effects of Intellectual Property** regarding the types of compulsory licence. The public health compulsory licence has been enacted due to the pandemic; although compulsory licence cases are quite rare in general, the public health compulsory licence is of specific interest.

# HUNGARY LAW AND PRACTICE

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Danubia Patent & Law Office LLC is a full-service Hungarian IP law firm providing services covering patents, trade marks and all fields of protecting, enforcing and defending IP rights. The firm's professional staff consists of registered European patent and trade mark attorneys, as well as associated attorneys at law, operating under the brand Danubia Legal and specialising mainly in trade mark and patent enforcement. Danubia is involved in almost all significant pharma patent and SPC litigation cases in Hungary, representing the big pharma (origi-

nator) companies such as Bayer, Merck, Pfizer, Lilly, Roche, AstraZeneca, Servier, Boehringer Ingelheim, Abbvie, Biogen and Astella. The firm also obtains European patents and community trade marks and designs from the EUIPO and EPO, and has notably represented clients before the Court of Justice of the European Union. Danubia is also an important player in the country's IT litigation field, and in the mechanical and electrical patent litigation fields, mostly representing domestic clients.

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# HUNGARY LAW AND PRACTICE

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## Law and Practice

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

The two key types of intellectual property rights in India are patents and industrial designs.

### 1.2 Grant Procedure

#### Procedure for Patent Application

The patent application is filed, the application is published after 18 months (early publication within a month is available upon request), examination is requested (48 months from priority) or an expedited request is made, examination/prosecution follows (lasting from six months to over three years), and finally the patent is either granted or refused (in which case an appeal is possible).

#### Procedure for Design Application

The design application is filed, numbered and dated; it is examined for objections and if there are none it is accepted. If there are objections, these can be removed and if, upon re-examination, these are found to be compliant the application will be accepted. If the applicant contests the objections at a hearing and this further application is refused, appeal to the High Courts is possible. If the appeal is allowed the application will be accepted. Acceptance is followed by notification in the Official Journal and the issuing of a certificate.

### 1.3 Timeline for Grant Procedure

It takes about two and a half to three and a half years for patent applications to be granted.

It takes about 12–18 months for design applications to be granted.

Inventors can file and prosecute applications. However, in most cases applications are pros-

ecuted through patent agents, specially applications originating from foreign jurisdictions.

The average official fees for filing and request for examination are around USD350.

Average official fees for filing of application are around USD50.

The above fees do not take into consideration if any petitions are filed. Nor do they take into account the service fee of attorneys for filing and prosecuting the application.

### 1.4 Term of Each Intellectual Property Right

A patent term lasts 20 years.

Industrial design terms last ten years, and they can be further renewed for five years.

### 1.5 Rights and Obligations of Owners of Intellectual Property Rights

Rights-holders have the right to stop/injunct unauthorised parties from making, using, selling or offering for sale a patented product or process. The patentee would be required to institute a suit by paying the requisite court fees before the concerned court to stop/injunct the unauthorised parties from doing the infringing act.

### 1.6 Further Protection After Lapse of the Maximum Term

No term extensions are available under Indian law, other than the five-year renewal of an industrial design term mentioned in **1.4 Term of Each Intellectual Property Right**.



## 1.7 Third-Party Rights to Participate in Grant Proceedings

Indian law provides for the filing of pre-grant oppositions which are full-fledged inter-party proceedings.

Per Rule 55(1A) and 55(2) of the Patents Rules, 2003, the representation of opposition should be filed at the appropriate Patent Office, the controller gives notice to the applicant along with a copy of the representation (Rule 55(3)), the applicant may file a reply statement and evidence (Rule 55(4)) and the controller may refuse to grant a patent or require an amendment of complete specification (Rule 55(5) and 55(6)).

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

The applicant can either file a review application before the Intellectual Property Office or prefer an appeal before the High Courts.

## 1.9 Consequences of Failure to Pay Annual Fees

The patent will lapse if the annuity/renewal fee is not paid within the due date. An extension of six months can be sought from such due date. Further, the law provides for filing a restoration application within eighteen months from the date on which the patent ceased to have effect.

The official extension fees are around USD35 per month and the official fees for making an application of restoration are around USD200.

Design registrations which cease to have effect by reason of failure to pay the fee for the extension may be restored within one year from the date on which the design ceased to have effect provided an application for the restoration of the design has been made.

The official fees for making an application of restoration are around USD60.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

A post grant opposition can be filed within 12 months from the date of publication of grant of a patent.

A notice of opposition is given to the controller, the controller constitutes an opposition board, the patentee then gives its reply statement and evidence within two months of receipt of the written statement, the opponent must provide their evidence in reply within one month of that. Thereafter the board gives its report with reasons and with joint recommendation after considering all pleadings on record, at which point a hearing on the matter will take place.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

The key action/remedy available to the owner of a technical intellectual property right, such as a patent, against infringement of that right is to institute a lawsuit before the court of appropriate jurisdiction and seek an injunction against the defendant doing the infringement. Injunctions can be temporary/interlocutory and permanent/final. If the owner is successful in the suit for infringement, it is entitled to relief of damages or accounts or profit.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

Third parties who wish to remove the effects of a technical intellectual property right, such as a patent, can pursue the following courses of action:

- file a post-grant opposition seeking invalidation of the patent – a post-grant opposition must be filed by an interested person before the Patent Office within one year of the grant of the patent;
- file a revocation petition seeking invalidation of the patent – a revocation petition can be filed any time during the subsistence of the patent and, like a post-grant opposition, a revocation petition has to be filed by an interested person, although the same is filed before a High Court and not before the Patent Office;
- file a counterclaim seeking invalidation of the patent – this remedy is triggered if a suit is filed against the party, in such cases, the party/defendant can challenge the validity of the patent by way of a counterclaim and the same has to be filed in the court where the suit has been instituted;
- institute a suit seeking declaration of non-infringement – any person may file a suit seeking a declaration that their use of a patented product process does not or would not constitute an infringement of a claim of a patent;
- seek a compulsory licence – at any time after the expiration of three years from the date of grant of a patent any person interested can seek a compulsory licence by making an application before the Patent Office on grounds that public requirement is not met or that the patented invention is not worked in the territory of India; and
- seek revocation of a patent for non-working – after a compulsory licence has been granted, any person interested can seek revocation of the relevant patent for non-working.

## 2.3 Courts With Jurisdiction

For suits, the District Court is the court of first instance, followed by the respective High Courts

and then the Supreme Court of India. If, pursuant to the filing of the suit by the patentee, a counterclaim is filed by the defendant challenging the validity of the patent, both suit and counterclaim are transferred to the respective High Court.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

There are no specialised bodies or organisations for the resolution of intellectual property disputes. However, some High Courts have specialised Divisions. The Delhi High Court's Intellectual Property Division (IPD), for example, consists of three judges specialising in IP matters.

## 2.5 Prerequisites to Filing a Lawsuit

If the suit does not envisage urgent relief, the parties need to engage in a pre-suit mediation. In cases where urgent reliefs are being sought, the courts have generally taken a liberal view and waived the condition of engaging in a pre-suit mediation.

## 2.6 Legal Representation

Before the courts, the parties need to be represented by a lawyer.

## 2.7 Interim Injunctions

The relief of interim injunctions is available in India, including ex-parte interim injunctions. The circumstances under which an interim injunction is granted are that the plaintiff has a strong prima facie case and the comparative loss/gain caused to the parties if the order were granted being reasonable in comparison to the loss/gain if it were not.

## 2.8 Protection for Potential Opponents

The opponent or a defendant, in cases where the plaintiff is residing outside India and has no immovable property in India, can ask the court to direct the owner to deposit security for pay-

ment of costs incurred or likely to be incurred by the opponent/defendant for contesting the suit.

## 2.9 Special Limitation Provisions

A suit for patent infringement must be instituted within three years from the date of cause of action/date of infringement.

## 2.10 Mechanisms to Obtain Evidence and Information

In all civil matters, including intellectual property matters, a party can deliver interrogatories or make an application for discovery of documents. Such applications have to be made before the trial of a suit has commenced and the said documents/answers to interrogatories can be used during trial.

## 2.11 Initial Pleading Standards

Initial pleadings should contain all the factual narratives. Evidence, although not mandatory during filing of a suit, but may be filed to support the pleadings. There are as such no special provisions for suits in intellectual property proceedings that differ from non-intellectual property commercial lawsuits, although, the Delhi High Court has promulgated the Delhi High Court Intellectual Property Rights Division Rules, 2022 and the High Court Of Delhi Rules Governing Patent Suits, 2022 which are special rules tailored towards speedy resolution of IP disputes.

## 2.12 Representative or Collective Action

The Indian legal system does not permit representative or collective actions for IP disputes. Parties can, however, file intervention applications if they wish to. An intervenor ought to show that it has an interest in the outcome of the proceeding.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

There are no statutory restrictions on a patent owner asserting its rights against others.

# 3. Infringement

## 3.1 Necessary Parties to an Action for Infringement

An action for patent infringement can only be brought by the patentee or the exclusive licensee of the patent.

## 3.2 Direct and Indirect Infringement

The Patents Act does not differentiate between direct and indirect infringement. Although, the Indian courts have applied the doctrine of equivalents in cases where there was no evidence of direct infringement. As there is no statutory difference between the two modes of infringement, the remedies available are also the same.

## 3.3 Process Patents

In a suit for infringement of a process, if the process by which the product is obtained is especially within the knowledge of the infringer or defendant it may be impossible for the plaintiff to know exactly how the product has been obtained by the defendants. Thus, the court may direct the defendant to prove non-infringement, if the subject matter of the patent is a process for obtaining a new product; or there is a substantial likelihood that the identical product is made by the process, and the patentee or a person deriving title or interest in the patent from them, has been unable through reasonable efforts to determine the process actually used. However, the patentee or a person deriving title or interest in the patent from them first proves that the product is identical to the product directly obtained by the patented process.

### 3.4 Scope of Protection for an Intellectual Property Right

Scope of protection of a patent claim in a patent infringement suit is determined by way of construing the claims of the patent. Normally, literal infringement is applied, but doctrine of equivalents is also applied when there is no literal infringement. Prosecution history estoppel as a principle is also applied as a defence to the doctrine of equivalents and for construing the claim terms.

### 3.5 Defences Against Infringement

In any suit for patent infringement, every ground on which it may be revoked shall be available as a ground for defence. Additionally, the following defences are also applicable:

- Bolar exemption;
- research exemption; and
- government use.

### 3.6 Role of Experts

Experts can be used to provide technical inputs in a suit for patent infringement by either of the parties. Courts can also appoint an independent expert for their aid and assistance.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

There is no separate procedure or proceeding for construing the terms of the patent's claims. Although, the Delhi High Court in its Patent Suit Rules, 2022 may ask the parties to file a "claim construction brief" which would enumerate all the claims relied upon, break down the construction of each of the terms contained in the claims, the meaning thereof, and also the overall scope and effect of all the claims relied upon.

### 3.8 Procedure for Third-Party Opinions

The courts can seek third-party opinions by way of appointing an amicus curiae.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

#### Revocation Proceedings in General Including Period of Limitation

Revocation/cancellation of a patent can be either as a post-grant opposition before the Patent Office or as a revocation application (which can be filed as an original proceeding before a High Court even in the absence of a suit) or a counterclaim in a suit for patent infringement [(214)15 SCC 360].

A post-grant opposition seeking revocation of a patent can be filed under Section 25 sub-Section (2) of the Patents Act, 1970 (as amended till date) and can be filed after grant of a patent but within one year from the date of publication of the grant of the patent.

A revocation application under Section 64 of the Patents Act, 1970 (as amended till date) preceding a suit for infringement or in the absence of a suit for infringement can be filed at any time after grant of a patent. However, if a post-grant opposition has already been filed, then the same may be an impediment to preferring a revocation application.

Unlike a pre-grant opposition, in order to initiate any proceeding for revocation of a patent, the person instituting such proceeding must be a "person interested". Section 2(1)(t) of the Patents Act, 1970 provides an inclusive definition as to who this "person interested" is – it includes a person engaged in, or in promoting, research

in the same field as that to which the invention relates.

Of course, while seeking revocation as a defence to a suit for infringement there would be no requirement for showing that the party who has been sued is a person interested.

Evidently, the requirement of “standing to sue” for the purpose of a revocation proceeding is very wide and may not necessarily be limited to being a “person aggrieved” something which is a requirement under the Trade Marks Act to seek cancellation of a registered trade mark.

Presently, there is no period of limitation for seeking a revocation proceeding under Section 64 when such proceeding is filed as an original proceeding in the absence of any suit for infringement.

## **Jurisdiction**

The post-grant opposition can be instituted at any of the four Patent Offices at which the patent application which culminated in the patent sought to be revoked was filed.

If no suit for infringement is pending, a revocation petition/application can be filed at any High Court in India within whose jurisdiction the “cause of action” arises.

Per Section 104 of the Patents Act, 1970, when the revocation proceeding is filed as a counterclaim in a suit for infringement, the jurisdiction would be the High Court within whose jurisdiction the suit for infringement was filed, since a suit for infringement must be instituted in any District Court having jurisdiction to try such suit and depending on various factors, including but not limited to pecuniary limits may be filed directly before the appropriate High Court where

the cause of action has arisen or where there is reasonable apprehension for such cause of action to arise (*quia time suit*). However, once a counterclaim is preferred as a defence then the suit for infringement and the counterclaim will necessarily have to be transferred to the High Court.

## **Reasons/Grounds for Revocation**

At the outset it is important to point out that revoking a patent is discretionary and if the ground for revocation made out can be obviated by way of amendment or is not based on material breach, the patent may not be revoked.

While, the major grounds in respect of a post-grant opposition under Section 25(2) and a revocation proceeding under Section 64 (original revocation/counterclaim in a suit for infringement) overlap, for example on the grounds of novelty, obviousness/inventive step, patentability exclusions, prior use, insufficiency, etc, there are additional grounds available only under Section 64 – eg, scope of claims not being sufficiently or clearly defined or fairly based on the matter disclosed in the specification, that the patent was obtained on false suggestion or representation, leave to amend the specification was obtained by fraud, that the patent was granted on the application of a person not entitled under the provisions of this Act to apply therefore.

Furthermore, under Section 64, the ground of prior claiming necessarily requires that the claim in the earlier patent was/is a patent granted in India and the relevant claim was a valid claim therein.

## **4.2 Partial Revocation/Cancellation**

As explained in 4.1 **Reasons and Remedies for Revocation/Cancellation**, the revoking of a patent is discretionary, thus if the patentee were

to seek amendment of claims in a revocation proceeding, such action may be possible. However, since the revocation is discretionary and an amendment may be sought, the grounds have to be effectively made out with precision.

### 4.3 Amendments in Revocation/Cancellation Proceedings

Voluntarily seeking amendments by way of a formal request in revocation proceedings is specifically allowed under Sections 57 and 58 of the Patents Act, 1970 (as amended till date), whether in a revocation proceeding before the Patent Office or High Court. Such request will have to be specifically considered by the relevant authority.

However, a patentee may instead orally propose amendments without a formal request during a hearing in the post-grant opposition proceeding or revocation proceeding to the relevant authority, which may or may not be considered by such authority while deciding revocation.

Of course, voluntarily seeking post-grant amendments may very likely require that such amendment is advertised in the Patent Office Journal and may itself be subjected to opposition by third parties on the point of whether such amendment is in accordance with Section 59 of the Patents Act, 1970, which governs amendments and specifically provides the following limitation to amendments:

*“No amendment of an application for a patent or a complete specification or any document relating thereto shall be made except by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no amendment of a complete specification shall be allowed, the effect of which would be*

*that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment.”*

### 4.4 Revocation/Cancellation and Infringement

If a post-grant opposition proceeding is preferred then, the same being before a forum that is different from that before which a suit for infringement can be filed, there is no requirement that the hearings in the two proceedings when concerning the same patent(s) be held simultaneously.

Similarly, if a revocation is preferred at one High Court preceding a suit for infringement on the same patent(s) which may be at another High Court there is no law on the order in which either proceeding may proceed.

Further, if a revocation application before the High Court is preferred and thereafter there is a suit for infringement based on the same patent(s) at the same High Court or when the revocation proceeding is, for example, a counterclaim as a defence in a suit for patent infringement, then in such cases, on the date when the second proceeding is instituted, the two proceedings move ahead simultaneously. However, in the event of interim orders/protections, if any are sought, in a particular proceeding, then whether it would move simultaneously with the other would be dependent on the proceeding and the timing of filing of each proceeding.



## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

Apart from the Delhi High Court, no other High Courts or District Courts in India have special procedural provisions for intellectual property rights proceedings. Recently, the Delhi High Court introduced specialised procedures for patent and IP rights matters. In normal circumstances, a patent suit generally takes five to seven years to get adjudicated finally – ie, after trial. An interim injunction application generally takes one to two years to get adjudicated. Trials are generally conducted before a local commissioner and consists of series of sittings or hearings. Fact witnesses and experts are not heard by the court but they are cross-examined. All the remedies of permanent injunction, invalidity and damages, if any, are generally decided at the same time. Although, on insistence of parties, the court may proceed to decide any of the aforesaid issues.

### 5.2 Decision-Makers

IP cases are decided by legal judges of the court. Currently, there are no provisions for specialised intellectual property/technical judges in the Indian legal system. The parties do not have any influence on who will decide the case.

### 5.3 Settling the Case

The defendant may at any time opt for the matter to be referred to mediation. The court will then, on the basis of the facts and circumstances of the case, choose to refer or refrain from referring the case for mediation. The mediator is generally appointed by the court itself.

### 5.4 Other Court Proceedings

In cases of trade mark infringement, the suit for infringement remains stayed if there is a paral-

lel revocation proceeding. In cases of patent infringement, there is no statutory bar to an infringement suit progressing pending resolution of revocation proceedings in another forum.

## 6. Remedies

### 6.1 Remedies for the Patentee

The statutory remedies for the patentee in a suit for patent infringement are injunctive relief and damages or accounts of profit. The court, at its discretion, can also impose punitive costs if the defendants are wilful and repeat infringers. In cases of non-compliance with court orders, the patentee can institute contempt proceedings against the non-compliant defendants.

### 6.2 Rights of Prevailing Defendants

There are no statutory rights for a prevailing defendant. Although the court has the discretion to provide costs to the prevailing defendant if there was no merit to the patentee's case.

### 6.3 Types of Remedies

A patentee can institute a suit for infringement and seek injunctive relief and damages or accounts of profits from the defendant.

### 6.4 Injunctions Pending Appeal

If a patent is found valid and infringed, post-trial, an injunction would necessarily follow. Filing of an appeal against the grant of injunction would not automatically stay the injunction, unless there is an express order staying the injunction by an appellate court. An order of injunction is enforceable pending appeal unless there is an express stay of the injunction order by an appellate court.



## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

The appeal from an intellectual property rights proceeding before the Patent Office/Trade Marks Office presently lies to the respective High Court having jurisdiction over the Patent Office/Trade Mark Office where the said intellectual property was filed. Prior to April 2021, a specialised tribunal, namely the Intellectual Property Appellate Board (IPAB), was tasked with appeals from orders specified in the respective statutes. However, post the Tribunals Reforms Act, 2021, the IPAB has been abolished and the appeals now lie to the respective High Courts.

While, the general rules with respect to filing procedures as applicable to appeals filed before the respective High Courts apply, the High Courts are also in the process of framing certain Intellectual Property Division (IPD) Rules with respect to practice and procedure for the exercise of appellate jurisdiction arising out of IP rights and related statutes. The Delhi High Court has also put its own rules in place, namely, Delhi High Court Intellectual Property Rights Division Rules, 2022, inter alia, with respect to nomenclature, time-lines, fees and general procedure.

The various other High Courts (eg, Madras High Court having jurisdiction over the Chennai Patent Office, the Bombay High Court having jurisdiction over the Mumbai Patent Office and the Calcutta High Court having jurisdiction over the Kolkata Patent Office) do not yet have specific IPD Rules in place and are presently following the general procedure for appeals before such courts.

### 7.2 Type of Review

An appeal is a full review of the facts of the case on the merits and not limited to legal questions. Although the manner in which the Controller of Patents has gone about the reasoning plays an important role.

Appeals are possible from various kinds of order as specified in the statute.

For example, from an order of refusal of a patent application, the High Court in appeal may either remand a matter back for reconsideration in its entirety or on a specific point which the High Court is of the opinion was not properly or sufficiently considered or was ignored. Alternatively, it is possible for the High Court in appeal to also grant the patent in appeal while setting aside an order of refusal of the patent application by the Controller of Patents and even direct claim amendments and grant the patent.

It is important to point out at this juncture that a review is a separate procedure where by way of a review petition, a patent applicant/patentee may seek a review by the controller of patents of its own order and the petition is heard by the officer who passed such order and is primarily with respect to errors apparent, etc.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

Before filing a lawsuit, costs/expenses may arise if the plaintiff decides to institute pre-suit mediation under the Commercial Courts Act, 2015. There is no statutory mandate to send a legal notice/cease-and-desist notice before instituting a law suit, and a plaintiff can proceed straight to filing a law suit if urgent reliefs are being prayed for in the suit.

## 8.2 Calculation of Court Fees

Court fees are calculated as a percentage of the damages prayed for in the suit. Generally, court fees are 1% of the damages that is prayed for.

## 8.3 Responsibility for Paying the Costs of Litigation

The responsibility for paying the costs of litigation is on the respective parties. Court fees for instituting the litigation are borne by the plaintiff. Attorneys' fees are paid by the respective parties. The court may require the losing party to reimburse the prevailing party for the cost of litigation, depending upon the facts and circumstances of each case.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

The alternative routes that parties adopt in cases of IP disputes include:

- pre-institution mediation as provided for under the Commercial Courts Act, 2015; and
- arbitration in cases of licence disputes and contractual breach.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

Assignment must be in writing and duly signed by the parties in presence of two witnesses; the latter is not mandatory. Monetary consideration is preferred. The law requires recordal of assignments both at the pre-grant and post-grant stage, wherein the request is accompanied by

either the original assignment or a true copy of it. Power of attorney from the assignee is required for recording the assignment.

### 10.2 Procedure for Assigning an Intellectual Property Right

Assigning an IP right involves filling in Form 6 for a claim or request regarding a change in applicant for patent (for pending applications) and filling in Form 16 for application for registration of title/interest in patent or share in it or registration of any document purporting to affect the proprietorship of the patent (for granted patents).

Both forms are to be accompanied by the assignment deed (either original or a true copy thereof).

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

Licences are required to be recorded only for granted patents on Form 16 supported by the licence agreement. Monetary consideration is not mandatory for licence agreements.

### 10.4 Procedure for Licensing an Intellectual Property Right

To license an IP right, Form 16 for application for registration of title/interest in patent or share in it or registration of any document purporting to affect the proprietorship of the patent (for granted patents) must be filled out. For recordal of assignments in respect of designs, both Form 10 and 11 need to be filled out. For recordal of assignments in respect of designs, both Form 10 and 13 need to be filled out.

It is to be accompanied by the licence deed (either original or a true copy thereof).

Contributed by: Amrita Majumdar, Dominic Alvares and Samik Mukherjee, **S. Majumdar & Co.**

**S. Majumdar & Co. (SMCO)** was founded in 1993 as a full-service IP law firm and assists its clients in filing, prosecuting, and enforcing their IP rights. The firm comprises of more than 45 professionals, spearheaded by Mr. Subhatosh Majumdar, and spread across offices in cities of Kolkata, Mumbai, and New Delhi. The SMCO team is coveted for its significant expertise in patents, especially in contentious matters where it has represented major pharmaceutical and electronics majors in enforcing or defend-

ing their intellectual property. Notable recent work includes representing Sun Pharmaceuticals Industries Ltd. in high-stakes patent litigation for the drug Xeljanz (Tofactinib) before the Delhi High Court; representing Panacea Biotec in enforcing its patent with regard to its flagship hexavalent vaccine before the Delhi High Court; representing two pharmaceutical majors before the Delhi High Court and Supreme Court in defending against the claims made in regard to the blockbuster drug Dapagliflozin.

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## Trends and Developments

### Contributed by:

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LexOrbis see p.184

### Intellectual Property Division Latest Trends and Developments

The abolition of the Intellectual Property Appellate Board (IPAB), by way of the Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance 2021, as published in the Gazette of India, dated 4 April 2021, has resulted in a tremendous increase of high court matters in all jurisdictions where such tribunals were situated. Since, there have also been amendments to the Trade Marks Act 1999, Copyright Act 1957, Patents Act 1970, Geographical Indications Act 2000 and Plant Variety and Farmer's Rights Act 2001, the litigation practice and system as a whole has seen a drastic transformation.

After the abolition of IPAB, not only the matters which were pending before it were transferred to the respective high courts having jurisdiction to hear such matters, but the orders passed thereafter by the Controller General of Patents & Designs and the Registrar of Trade Marks, are being challenged directly before the high courts by way of fresh appeals/cancellation petitions/revocation.

To effectively implement the Tribunal Reforms Act 2021, the High Court of Delhi created an Intellectual Property Division (IPD) to hear all IP-related matters, including appeals and other IP-related cases. The High Court has also framed Intellectual Property Division Rules 2021, for the purpose of handling and regulating the practice and procedure of IP cases before the IPD. This initiative has further strengthened trust in the Indian legal system for parties situated abroad. The purpose behind these changes was to pro-

vide speedy and effective delivery of justice by removing an extra layer of litigation which makes the delivery of justice time consuming and expensive. The courts can now provide uniformity and consistency in IP jurisprudence as they now have jurisdiction to cover both the registrability and enforcement aspect of IP rights.

For instance, while deciding an appeal from the decision of Controller of Patents in the matter of Avery Dennison Corporation v Controller of Patents and Designs, the Honourable Delhi High Court held that simplicity does not defeat an invention and that simple inventions are also patentable. The concept of evergreening of patents, wherein legal and business strategy is adopted to lengthen the term of a granted patent in a jurisdiction that is about to expire, in order to retain royalties from third parties by introducing new patents, was an argument taken by the respondent. The respondent argued that subject patent was an attempt at evergreening the patent, since its prior art was also that of the appellant. According to the 2005 amendment in Section 3(d) of the Indian Patent Act 1970, unless there is a significant difference in properties attributed to efficacy of invention, a patent isn't granted on the ground of obviousness and non-inventiveness. The point that was further considered while checking the inventiveness and non-obviousness of the patent in question in the Avery Dennison Corporation case was the time gap between the prior art and the invention under consideration, as well as some other minute and simple changes which could not have been seen by someone else during the gap because of the inventive steps being involved

in the patent in question, as well as the non-obviousness.

Further, the Honourable Delhi High Court, in the matter of Agriboard International LLC v Deputy Controller of Patents & Design; CA (COMM. IPD-PAT) 4/2022, held that while conducting an inquiry into obviousness, the Controller of Patents & Designs should avoid hindsight bias and the legal conclusion in the impugned orders must have been reached on the basis of facts gleaned from the prior art and should not include knowledge gleaned from the patent disclosure. There must be a coherent thread leading from the prior art to the invention, the tracing of the thread must be an act which follows in an obvious manner. In this regard, reference is made to relevant extracts from the said judgment, which have been reproduced below.

“In the opinion of this Court, while rejecting an invention for lack of inventive step, the Controller has to consider three elements:

- the invention disclosed in the prior art;
- the invention disclosed in the application under consideration; and
- the manner in which subject invention would be obvious to a person skilled in the art.

Without a discussion on these three elements, arriving at a bare conclusion that the subject invention is lacking inventive step would not be permissible, unless it is a case where the same is absolutely clear. Section 2(1)(ja) of the Act defines [...] inventive step [...] as [...] a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.”

In *Interdigital Technology Corporation v Xiaomi Corporation*, CS(COMM) 295/2020, the Honourable High Court encountered a case of anti anti-suit injunction. Xiaomi successfully obtained a global anti-suit injunction against the plaintiff, namely Interdigital Technology Corporation, from Wuhan Court. Herein the plaintiff put forward its arguments on the necessity of an anti anti-suit injunction in the interest of justice. It emphasised how the subject matter of the suit in both the proceedings was different and that if the injunction obtained there would have been applied in India, then it would be an injustice, as it would not be possible to initiate proceedings against Xiaomi. This landmark judgment is an example of obtaining justice as the infringement of technology would have continued if the anti anti-suit injunction would not have been granted in its favour. It is important to note that the prayers made by parties in recent matters are similarly affecting the cross-territory rights of the parties and the expansion of the surge of extra-territorial enforcement of the concepts of global injunction is gaining popularity and disputes are no more limited to one's immediate territory.

The other major development was the change in the official fees payable by educational institutions in reference to the Patents Rules 2003, which have been reduced through the Patents (Amendment) Rules 2021. The central government, via its notification dated 21 September 2021, had released the Patents (Amendment) Rules 2021, emphasising a rebate of up to 80% on patent fees for educational institutions. This reduction in the fee for patent filing and prosecution for educational institutions by 80% has been extended to all educational institutions which, before the Patents (Amendment) Rules 2021, was available to all recognised educational institutions owned by the government. This is seen as a remarkable move in strengthening

the IP industry, giving importance to individual and institutional creativity expansion, enhancing growth of the economy as a whole.

Further, the Honourable Delhi High Court, on the recommendation of a specially constituted committee, issued a press release on 6 July 2021, wherein the directive for creation of an IPD of the Court was announced, inter alia to avoid multiplicity of proceedings and conflicting decisions in the fields of intellectual property. One of the points that was raised by the committee was to bring clarity with respect to nomenclatures to be given to petitions before the IPD. Pursuant to the same, the Delhi High Court published an office order, dated 7 July 2021, wherein it provided separate nomenclature for IPR matters to be listed before the IPD. In fact, a separate nomenclature has been provided for the orders/judgments that will be pronounced by Delhi High Court.

It can be iterated that high patenting fees certainly acted as a hindrance in the past for information-providing educational institutions. The challenges faced by the patent applicants was that while applying for patents, innovators had to apply for these in the name of institutions that were required to pay exorbitant patenting fees. However, after these amended rules, by getting newer research and technologies patented at a comparatively lesser price in contemporary times, a huge surge in the development of newer technologies can be seen.

In one of the decisions by the Supreme Court in *Knit Pro International v The State of NCT*, it was decided that infringement of copyright falls under cognisable and non-bailable offences. In this way, ease of doing business can be affected, as would-be infringers will think twice before committing copyright infringements on the basis of criminal liability. Apart from this, there has been a recent update in parliament, which is considering a bill that decriminalises offences pertaining to several statutes including acts under the IPR laws. The Trade Marks Act 1999, the Patents Act 1970, the Copyright Act 1957 and the Geographical Indications Act 1999 are proposed to be amended by the Jan Vishwas (Amendment of Provisions) Bill 2022. The Bill proposes to remove Section 68 of the Copyright Act 1957, which provides for punishment for making a false statement for deceiving/influencing any authority or officer. It is supposed to reduce the judicial burden by reducing stringent punishments, but how far there is a requirement of bringing in such amendment is a matter of debate. Even Section 44 of the Geographical Indications Act 1999 and Section 109 of the Trade Marks Act 1999, attracts punishment for a person who knowingly produces false register entries as evidence, which is proposed to be removed according to the Bill.

## Conclusion

This article has discussed the recent developments in shaping the smooth functioning of IPD in India. These developments can be seen as more beneficial than detrimental.



# INDIA TRENDS AND DEVELOPMENTS

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LexOrbis is a premier, full-service IP law firm with over 250 personnel, including 120-plus attorneys at its three offices in India in New Delhi, Bangalore and Mumbai. The firm provides business-oriented and cost-effective solutions for protection, enforcement, transaction and commercialisation of all forms of IP in India and globally. It represents clients from a wide range of industries, including automotive, aerospace, biotechnology, computers, chemicals, defence equipment, electronics, IT, software and mobile apps, entertainment, oil and gas, pharma-

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# INDIA TRENDS AND DEVELOPMENTS

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

The Israeli legal system provides protection for inventions by way of patents and trade secrets. In addition, protection may also be provided by way of the law of unjust enrichment (unfair competition).

Unlike some countries, there is no protection for utility models. Other forms of intellectual property (such as copyright, layout-design (topography) of integrated circuits, trade marks, industrial designs, plant breeders rights) exist.

Since the Israeli legal system is a common law one, intellectual property law is primarily governed by legislation and regulations therein and by case law laid down by the courts.

### 1.2 Grant Procedure

Patent applications are filed with the Israeli Patent Office (ILPTO). The requirements of patentability are set forth in the Patents Act and clarified in court judgments and in the Practice Guidelines for Patent Examination published by the ILPTO.

#### Examination

After filing the patent application, it usually takes a few years until examination commences. There is no need to request an examination. Under certain circumstances, the applicant may request an expedited examination (eg, in cases of elderly inventors, “green technology applications”, applicant’s declaration that the Israeli application is the first application and is intended to serve as a basis for priority claim, or where a third party has begun to exploit the invention).

A third party may also submit a request for an expedited examination accompanied with an affidavit, in the following circumstances.

- Examination of the application of the patent according to the set order may cause the applicant for expedited examination, who works in the field of the invention, a delay in the development or production of a product or a process claimed in the patent application.
- The time that has passed since the application was filed, or since the date of entry into the national phase, is unreasonably lengthy, and more specifically, significant time has passed when contrasted with the beginning of the examination of another application of the same type.
- Public interest.
- Extenuating circumstances providing justification.

Companies may use this option against competitors and to reduce the period of uncertainty in the market.

There is also the possibility of a modified examination, whereby a patent is granted based on a corresponding foreign patent, without undergoing substantive examination in Israel. Patent prosecution highway (PPH) examination is also available for some countries.

#### Publication

Shortly after a local application is filed, the Registrar of Patents will publish the name of the applicant, the application date and information regarding priority (if claimed).

The patent application remains confidential for 18 months from the date of filing or, if priority is claimed, for 18 months from the date of the ear-

liest priority document. Shortly after the expiry of that 18 months, the fact that the application is laid open for inspection is published again by the Registrar of Patents. Until 2012, patent applications would have remained confidential until acceptance of the application (see below) by the Patent Office.

International (Patent Co-operation Treaty, PCT) applications are also published under the same principles, but since these applications are usually filed shortly before the 30-month deadline for filing the national phase expires, they become available to the general public shortly after filing.

Third party observations may also be submitted – see **1.7 Third-Party Rights to Participate in Grant Proceedings**.

After the examination is concluded and the application is accepted by the patent examiner, the acceptance of the application is published online.

## Opposition

During a period of three months following that publication, third parties may lodge a pre-grant opposition to the grant of the patent. If no opposition is filed during this period, the patent is granted, and a patent certificate will be issued. If an opposition is filed, the patent will be granted only after that opposition is dismissed and, if appealed, only after that appeal is dismissed.

### 1.3 Timeline for Grant Procedure Representation

Representation is not mandatory, but highly recommended.

#### Duration

The length of the grant procedure varies significantly between different technological fields.

The length has also changed over time (in recent years examination has been shortened in duration due to an increase in the number of patent examiners).

Based on the ILPTO Annual Report of 2021, the average prosecution period has shortened in the last few years. According to the Patent Office this is due to reorganisation and more efficient examination procedures. Their report shows for how long recent prosecutions lasted (in months).

- 2021: mechanics electronics and physics (11.8), computers communications and medical devices (12.6), chemistry and pharma (16.6), biotechnology (20.3) and average (14.86).
- 2020: mechanics electronics and physics (11.4), computers communications and medical devices (11.6), chemistry and pharma (17.3), biotechnology (19.5) and average (14.99).
- 2019: mechanics electronics and physics (13), computers communications and medical devices (13), chemistry and pharma (18), biotechnology (22) and average (16.4).
- 2018: mechanics electronics and physics (13), computers communications and medical devices (14), chemistry and pharma (22), biotechnology (27) and average (19).
- 2017: mechanics electronics and physics (17), computers communications and medical devices (15), chemistry and pharma (24), biotechnology (30) and average (21.5).
- 2016: mechanics electronics and physics (16), computers communications and medical devices (17), chemistry and pharma (28), biotechnology (30) and average (22.8).

#### Costs

The costs of the grant procedure for the national phase in Israel, from filing to grant, including

professional fees and official fees, also varies between technological fields (and based on the amount of work required from the local patent attorney).

- Life sciences: USD7,000–8,500.
- Technology: USD7,000–7,500.
- Hi-tech: USD6,500–7,500.
- Physics: USD6,500–7,500.

Please note that the duration and average costs relate only to the examination period and do not include opposition proceedings, which can significantly increase the costs and duration of the grant procedure.

## 1.4 Term of Each Intellectual Property Right

Patents are granted for a period of 20 years from the date of the application.

It is possible to receive a patent term extension (PTE) of up to five years for applications dealing with medicines, certain medical devices and veterinary products registered with the Ministry of Health. PTEs are not available for agrochemical inventions.

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

A successful patentee who prevails in an infringement action is entitled to the remedies prescribed in the Patents Act, namely injunctions and damages, as well as any other remedy the court may determine.

When ruling on damages, the court may take into consideration the acts of the infringer, the scale and magnitude of the infringing acts, the profits made by the infringer and the reasonable royalties that the infringer would have had to pay,

if they had been given a licence to exploit the patent. The foregoing list is not exhaustive.

The court may also rule for punitive damages for an amount that does not exceed the actual damages ruled (namely, double damages), if the infringement was committed after the patentee or the exclusive licence owner warned the infringer prior to the infringing act. As such, under some circumstances it is advisable to send warning letters to the alleged infringer prior to filing a suit.

As to the obligations of the patentee, they have to pay renewal fees only after the patent is granted. The fees payable and the periods of renewal are as follows.

- First term (six years) – USD240.
- Second term (four years) – USD480.
- Third term (four years) – USD720.
- Fourth term (four years) – USD1,200.
- Fifth term (two years) –USD1,682.

It is also possible to pay the renewal fees in advance for the entire 20-year period with a slight cumulative discount (USD3,604 rather than USD4,322).

It should be noted that all official fees are charged in Israeli new shekels (ILS). US dollar amounts appearing in this review are approximate and calculated based on an exchange rate of ILS3.46 to USD1. Thus, adjustments may need to be made to reflect currency fluctuations. In addition, these fees are linked to the consumer price index and updated annually.

There is no public information listing applicable patents in relation to certain products or processes (for example, in the pharmaceutical space).



## 1.6 Further Protection After Lapse of the Maximum Term

As noted in 1.4 Term of Each Intellectual Property Right, it is possible, pursuant to Section 64D of the Patents Act, to receive a PTE for up to five years for applications dealing with medicines and medical devices. There is no PTE for agrochemical inventions. The PTE order must be granted before the basic patent lapses.

## 1.7 Third-Party Rights to Participate in Grant Proceedings

Third parties may participate during grant procedures via the procedures set out below.

### Pre-grant Opposition

After the examination procedure has been concluded, the acceptance of the application is published in the Official Monthly Gazette (available online). Any third party can oppose the patent's grant within three months from the date of publication.

The grounds for filing an opposition include:

- there being a reason for which the Patent Registrar is authorised not to accept the application;
- the application not meeting the requirement set forth in Section 4(2) (ie, novelty by public use, which the Patent Office is not required to examine); or
- the opponent being the true owner of the invention rather than the applicant.

The patentee may apply for an amendment during revocation proceedings only for the purposes of clarification, removing an error in the specification, or restricting the claims. The Registrar will permit the amendment if they are convinced that the amendment will not broaden the scope

of the claims and will not add anything to the specification not already included from the start.

### Post-grant Revocation (Cancellation)

Any person may file an application with the Patent Office to revoke a granted patent, without needing to show locus standi. An application for revocation may be filed at any time and the statute of limitation does not apply. The grounds for filing a revocation application are identical to the grounds for filing a pre-grant opposition. The Registrar may accept the application (and revoke the patent), deny the application or accept the application partially (eg, by deleting/narrowing some of the claims).

### Third-Party Observations

According to the statutory provisions of the Patents Act, during the course of examination, any third party is entitled to submit copies of relevant prior art publications to the PTO. The examiner may use these during the examination as long as they were sent within two months from the due date for the applicant's response to the request under Section 18 (demand to send any cited publications and other pertinent prior art publications known to the applicant).

### Third-Party Request to Initiate Examination

In addition, third parties are allowed to file an application, supported by an affidavit, for immediate examination, for one of the following reasons.

- There is reason to believe that examination based on the order in which the applications were filed will cause the applicant (of the request for immediate examination) to postpone the development/manufacture of the process/product that is claimed in the patent application.

- The amount of time that has passed from the date on which the application was filed is unreasonably long and is significantly longer than any other application of the same kind.
- Public interest or any other special circumstances.

Lastly, it is always possible to challenge the validity of the patent as a defence during an infringement trial.

### **1.8 Remedies Against Refusal to Grant an Intellectual Property Right**

Patent examiner decisions, including decisions not to grant a patent, are subject to an administrative appeal before the Registrar of Patents. The applicant may appeal the Registrar's final decision to the district court. The judgment of the district court, sitting as a court of appeal, may only be appealed to the Supreme Court with leave.

### **1.9 Consequences of Failure to Pay Annual Fees**

There is a six-month grace period for the payment of renewal fees. The fee is approximately USD60 for each month the patent renewal fee has not been paid (plus the regular renewal fee as detailed above). If all fees are paid during the grace period, the patent is deemed never to have lapsed.

After this grace period, it is still possible to restore the patent, but it would require filing an appropriate application, supported by an affidavit (and payment of additional fees of approximately USD210), and it is at the Patent Registrar's discretion whether to allow the restoration of the patent.

In order to succeed with restoration, the Registrar must be convinced that the renewal fee

was not paid due to a reasonable cause and that the patentee did not wish for the patent to lapse and asked for the restoration as soon as possible after the patentee (or the one responsible on their behalf) learned that the renewal fees had not been paid in a timely manner.

If the Registrar of Patents accepts the application for restoration, it will be published for a three-month pre-grant opposition period. Anyone may oppose the application for restoration within three months of the application being published, on the grounds that the Registrar had no basis for allowing the restoration of the application.

If no opposition is filed (or if any oppositions filed are dismissed), the Registrar will order restoration, but it may make the restoration subject to conditions.

### **Prior User Rights**

Anyone who began exploiting the invention after publication of expiry of the patent due to non-payment (namely, after the six-month grace period) shall be entitled to continue to exploit the invention – though only for the sake of their own business – even after the patent is restored. This right cannot be transferred, except together with the business in which that invention was used.

### **1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights**

The patentee may apply for an amendment for the purposes of clarification, removing an error in the specification, or restricting the claims. The Registrar will permit the amendment if they are convinced that the amendment will not broaden the scope of the claims and will not add anything to the specification not already included.

The Registrar's decision to permit the amendment will be published online and any person may oppose the amendment.

In addition, the patentee may file an application with the Patent Office to revoke or cancel their granted patent. Revocation or cancellation of a granted patent, per the request of the patentee, will be recorded in the Patent Journal and the granted patent will be declared null and void.

The revocation/cancellation proceeding is available to third parties as well. Any person may file an application with the Patent Office to revoke a granted patent, on grounds identical to the grounds for filing a pre-grant opposition, at any time, and the statute of limitation does not apply.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

Patent infringement cases are heard before the district court. Arbitration of patent disputes may take place before arbitrators operating within private arbitration institutions (mainly retired judges) or other attorneys in private practice.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

Third parties that wish to undo the effects of a patent may:

- file a pre-grant opposition (see **1.2 Grant Procedure**), there is no standing requirement for lodging an opposition;
- use post-grant revocation procedures (see **1.7 Third-Party Rights to Participate in Grant Proceedings**), there is no standing requirement for filing a revocation request;

- ask for a declaration of non-infringement (see **2.8 Protection for Potential Opponents**), the court shall not grant the declaration unless the applicant gave the patentee full particulars of the product or process they wish to use and the respondent has refused to make it or has not made it within a reasonable period; or
- in theory, file an application for a compulsory licence (see **2.13 Restrictions on Assertion of an Intellectual Property Right**), notably, an application for a compulsory licence provides a remedy to the applicant and does not result in the revocation or narrowing of the patent (this procedure has not been used since the early 1990s).

### 2.3 Courts With Jurisdiction

The Israeli judicial system consists of three tiers: magistrates' courts, district courts and the Supreme Court. Patent infringement cases are heard exclusively before district courts at first instance.

Each of the six district courts has local jurisdiction within its district. Local jurisdiction among the six district courts is determined based on the general principles of the choice of venue applicable to all civil litigation; of particular relevance to IP cases are the rules based on the defendant's residence or place of business or the place of the infringing activity.

A claim against a foreign entity that has no place of business in Israel may be brought before the District Court of Jerusalem, which has residual authority.

A leave of court is required in order to affect service out of the jurisdiction. If the defendant is unable to challenge the leave, the court will

deem itself to have acquired international jurisdiction over the defendant.

Judgments handed down by district courts may be appealed to the Supreme Court without requiring leave. Other decisions, such as decisions in interim relief proceedings, may be appealed only with leave.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

The Committee for Compensation and Royalties is a specialised body for resolving intellectual property disputes concerning employees' entitlement to remuneration for service inventions.

## 2.5 Prerequisites to Filing a Lawsuit

Only persons or entities recorded as patentees, or as exclusive licensees, may file an infringement lawsuit. All co-patentees (and the exclusive licensee, if they exist) must be joined as parties to an infringement action in order to have standing to sue.

Thus, except recordation of rights to the patent, there are no prerequisites (such as warning letters or engaging in mediation) for filing a lawsuit.

For court fees for filing a lawsuit, see **8.2 Calculation of Court Fees**.

In large-scale cases the court fees may reach significant amounts. The usual practice is to indicate merely a nominal amount for court fees; however, at the damages phase of the trial, the court fee for the full amount of the damages sought must be paid. One half of the court fees is paid as a condition to filing the lawsuit. The second half is payable before the trial date.

## Security for Costs

At the defendant's request, the court may require the plaintiff to provide security for costs. Where the plaintiff is a limited liability company, the burden is on the plaintiff to prove that it is able to bear the costs that may be awarded against it. In the absence of such a demonstration, the court will be inclined to order security for costs. The court may, however, where it deems this appropriate, refuse to order such security, having regard (inter alia) to the strength of the plaintiff's case.

Where the plaintiff is an individual, and although formal power to require security for costs exists, the court will usually refrain from making such an order. However, where the individual plaintiff is a foreign resident lacking assets within the jurisdiction, the court will be inclined to issue such an order (unless the plaintiff is a resident of a country that is party to a treaty with the state of Israel in which the state of Israel agreed to waive the requirement of security for costs for residents of the other contracting country).

It should be noted that in an opposition procedure before the Registrar of Patents, the opponent is deemed to be the plaintiff and may, therefore, be required to provide security for costs.

## 2.6 Legal Representation

Representation before courts and the Registrar is not mandatory and parties can represent themselves in proceedings. Nevertheless, representation is highly recommended.

Representation before courts is done solely by attorneys-at-law licensed by the Israeli Bar Association. In addition, patent attorneys may, by leave of court, argue in court on non-legal matters related to an invention or a patent, provided that the opposing party's attorney-at-law

is present. In proceedings before the Registrar of Patents, the party may be represented by a licensed patent attorney.

Following a recent amendment to the Bar Association Law, foreign lawyers may represent clients in Israel in a limited capacity, namely by counselling on the laws of the foreign jurisdiction where the foreign lawyer is certified and drafting documents to which the law of that foreign jurisdiction applies. Accordingly, foreign lawyers are not permitted to represent or counsel clients regarding patent infringement litigation in Israel.

Foreign lawyers licensed to represent a party or interrogate witnesses on behalf of a party in a foreign jurisdiction may actively take part in proceedings before an Israeli court for the taking of evidence pursuant to a foreign state's letter of request in accordance with the Mutual Legal Assistance Between Countries Law, 1998.

## 2.7 Interim Injunctions

Preliminary remedies are available in the Israeli legal system; these include preliminary injunctions, Anton Piller-type search-and-seizure orders, receivership orders, attachment (lien) orders and other interim reliefs. In addition, the court has the power to grant any appropriate remedy under case circumstances.

A preliminary remedy is typically requested simultaneously with, or shortly after the filing of, the statement of claims. The court may grant a preliminary remedy prior to filing the statement of claims if it is found that such a measure is justified in the circumstances, in which case the claim must be filed within seven days or as prescribed by the court.

## Requirements

In order to receive a preliminary remedy, the applicant must show that immediate intervention by the court is needed to preserve the status quo and to prevent irreparable harm. The applicant must also show that it has a prima facie case and a reasonable chance of proving it. The court will also consider whether the preliminary remedy is just and appropriate in the circumstances.

In the court's decision to grant a preliminary remedy, and regarding the type, span, and conditions of the preliminary remedy, the court considers, inter alia:

- whether the balance of convenience is in favour of the applicant – ie, the harm that might come to the applicant should the preliminary remedy not be granted, versus the harm that might come to the responder should the preliminary remedy be granted, as well as harm that may be caused to a different entity or to any matter of public concern;
- whether it is possible to grant another remedy that will cause lesser harm to the respondent, that achieves the purpose for which the preliminary remedy was requested;
- the good faith of the parties, regarding the essence of the matter in discussion and regarding the suit filed and the application for preliminary remedy; and
- the delay (laches), if any, by the applicant in the filing of the statement of claims and in preliminary remedy, having regard to the circumstances at issue.

## Procedure

Interim relief proceedings are normally conducted inter partes. An ex parte remedy may be available if the applicant persuades the court by prima facie evidence that deferring the grant of the remedy until an inter partes hearing may defeat

the purpose of the order or cause the applicant severe harm. When hearing an application for an ex parte order, the court will exercise greater caution than in inter partes proceedings.

Applications for search-and-seizure orders and temporary attachment orders are the exception to the general rule and are normally heard ex parte unless the court is satisfied that an inter partes hearing would not frustrate the purpose of the requested order. An ex parte order other than one for attachment must be followed by an inter partes hearing within, and no later than, 14 days. The applicant continues to bear the burden of persuasion during the inter partes hearing notwithstanding the grant of the ex parte order.

Applications for an interim remedy are made in writing. The respondent then has 20 days (or less according to the court's decision) to respond to the application. All factual contentions in the application, response and reply must be supported by an affidavit. As a general rule, the parties have a right to cross-examine the affiants during the hearing of the application. The judge may issue the decision at the conclusion of the hearing or may defer the decision. Applications for interim remedies should be resolved within 14 days.

The president of the remedy court, or a judge to whom such powers have been delegated, may order the main case to be expedited in lieu of hearing an application for interim relief. Where the issues are complex, judges may be inclined to follow this route.

In general, for an interim remedy to be issued, the case should be relatively clear and strong. In recent years, there has been a decrease in the tendency of trial courts to issue interim remedies.

## **Security for the Defendant's Damages Resulting from an Expired Temporary Remedy Order**

As a precondition for an interim remedy to become effective, the applicant is required to provide a personal undertaking not limited by any amount and, in addition, a third-party guarantee (typically, a bank guarantee) at an amount set by the court to indemnify the defendant for its damages if the claim terminates or if the order expires. The court may exempt the applicant from the requirement of providing a guarantee out of considerations of justice and for special reasons, but the requirement of providing a personal undertaking not limited by any amount is mandatory. In addition, the court may require the applicant to post a bond if the court deems this just. The court, as a general rule, will require a bond in respect of an ex parte order unless it deems it just to exempt the applicant from this requirement.

On termination or expiration of a temporary remedy order, the defendant (respondent) may file, within 90 days, an application to order the plaintiff to compensate the defendant for damages it suffered from the order, and the court will rule thereon. In this context, regard must be paid to the decision in the matter of *Unipharm v Sanofi* where the court ordered that a company that manufactured generic drugs, and which opposed a patent application that was subsequently withdrawn by the patent applicant, may be entitled to disgorge part of the patent applicant's profits where it was found that the patent application was prosecuted improperly in an attempt to extend the patent protection for a pharmaceutical about to become off patent.



## 2.8 Protection for Potential Opponents Declaration of Non-infringement

A third party can ask the court for a declaration that their exploitation of the invention disclosed in the patent does not constitute an infringement. The patentee and the exclusive right owner are the respondent in this application. The applicant must give the patentee full details of the product or process they wish to use. It should be noted that in these proceedings the applicant cannot argue that the patent is invalid. Furthermore, the grant or refusal to grant the declaration of non-infringement shall not be decisive on the question of the patent's validity.

## 2.9 Special Limitation Provisions

There are no special statutory limitation provisions regarding intellectual property matters, and these matters are subject to the general seven-year limitation period prescribed by law.

The seven-year limitation period on infringement actions commences on the date when the cause of action accrued. The limitation period "race" is suspended if:

- the plaintiff did not initiate the lawsuit because the defendant deceived it (including consciously hiding a fact (or facts) constituting the cause of action); or
- the defendant exerted its influence against the plaintiff, threatened it or took advantage of its weakness.

If the plaintiff was unaware of the fact constituting the cause of action, for reasons not dependent on it, and this could not have been prevented even by taking reasonable care, the limitation period begins upon the plaintiff learning of the relevant fact.

Case law shows an accepted position that in patent infringement each act of infringement gives rise to a new claim; thus, a claim seeking injunction is not time-barred by the statute of limitation even when the infringement commenced more than seven years before the claim was brought. However, damages cannot be recovered for a period in excess of the seven-year limitation period. An exception to this rule is that an employee's claim for payment of remuneration for a service invention owned by an employer becomes time-barred seven years after the date of filing of the patent application for the invention.

## 2.10 Mechanisms to Obtain Evidence and Information

Discovery, inspection and written interrogatories proceedings are available in Israel, albeit in a less extensive manner than in, for example, the USA.

The exchange of requests for discovery, inspection and written interrogatories occurs soon after the conclusion of the exchange of pleadings. An unsatisfied party may file a motion to compel the opposite side, as part of a list of requests submitted before the first pre-trial. The parties may also request a leave for appeal with regard to several issues, such as discovery documents, inspection of documents and the claim of privilege. The entire process may take several months, sometimes more than a year.

There are no depositions. Moreover, there is no pre-complaint discovery in Israel.

Interim orders such as Anton Piller-type search-and-seizure orders and receivership orders may also assist a party in the collection and preservation of evidence.



Discovery is not available against non-parties. However, a third party may be summoned to produce particular documents under subpoena duces tecum issued by the court on a party's application. Disclosure from non-parties must be limited to specific documents.

## 2.11 Initial Pleading Standards

A lawsuit is initiated by filing a statement of claims, which starts the exchange of pleadings. The statement of claims must set forth the facts that, if subsequently proven, will establish the plaintiff's cause of action, and thus requires substantially more detail than a complaint filed in, for example, the USA.

Nevertheless, the plaintiff need not prove any evidence at the stage of filing the statement of claims but will typically undertake private fact-finding and gathering of evidence before bringing a legal action, because the statement of claims must set forth in some detail the facts that support the plaintiff's cause of action.

The defendant must respond with a defence statement within 60 days of being served with the statement of claims. The defence statement must set forth all the material facts underlying the defences raised by the defendant. The plaintiff is entitled, but not obliged, to respond to the defence statement with a response statement within 14 days.

The case then proceeds to pre-trial hearing, which is intended for delineating issues in dispute between the parties and in which the parties are encouraged to resolve discovery and interrogatory controversies. If not settled, the case proceeds to trial. Before to the pre-trial, the parties must arrange an internal meeting (without the involvement of a judicial or a quasi-judicial person such as a judge, arbitra-

tor or mediator), which is intended for the same purposes described above (ie, delineating the issues in dispute, resolving discovery and interrogatory controversies and considering alternative proceedings such as mediation and arbitration). Before the first pre-trial, the parties are requested to report to the court regarding their previous efforts made at this internal meeting.

The judge prescribes the schedule for the submission of evidence, orally or by way of written affidavits and expert opinions. The evidence (and summations – see below) may not include factual allegations not substantially raised in the party's pleading, unless a party seeks and obtains leave to amend its pleading. The grant of such leave is discretionary.

There may be another oral hearing before the judge to ensure that all the evidence has been submitted. Thereafter, a trial hearing is held where the witnesses and experts are cross-examined. Afterwards, the parties will exchange summations orally and the judge should hand down the judgment within 90 days (although this requirement is not always adhered to).

## 2.12 Representative or Collective Action

There are no collective actions (such as class actions) for intellectual property proceedings. However, a patentee is exposed to class actions if, for example, it violated antitrust laws, as in the case of Sanofi (see 2.13 Restrictions on Assertion of an Intellectual Property Right).

As a general rule, if a rights owner files suit against more than one defendant regarding infringement of the same rights and more or less the same factual background, the suits will be unified (and vice versa if several plaintiffs file suits against the same rights owner).

## 2.13 Restrictions on Assertion of an Intellectual Property Right

### Compulsory Licences

The provisions of the Israeli Patents Act were amended in order to accord with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) regarding compulsory licences. Nevertheless, these provisions have little significance in practice and have not been in use since the early 1990s.

These provisions hold that, if the patentee or the exclusive licence owner is misusing its “monopoly power”, the Registrar may grant a compulsory licence to exploit the patent to third parties who petitioned for a compulsory licence, provided that the motion was filed after the later of either three years from the grant of the patent or four years from the application date.

Examples of the misuse of monopoly power include:

- when all the demand for the product is not satisfied in Israel on reasonable terms;
- when the conditions attached by the patentee to the supply of the product or to the grant of a licence are not fair under the circumstances, do not take account of the public interest and arise essentially out of the existence of the patent;
- when exploitation of the invention by way of production in Israel is impossible or restricted by the importation of the product; or
- when a patentee refuses to grant a licence for a local producer on reasonable terms.

Upon request, the Registrar may also grant a compulsory licence, for medical purposes, for either a patented product that can be used as a medicine or a patented process for the production of a medicine.

### *Compulsory licence to exploit an earlier patent*

If a patented invention cannot be exploited without infringing an earlier patent, then the Registrar may grant a licence to exploit the earlier invention to the extent necessary, and under the conditions that the later invention serves a different industrial purpose and that it shows a considerable advance over the earlier invention.

### Antitrust Law and Patents

Section 49(b) of the Patents Act expressly provides that the grant of a patent does not allow the patentee to unlawfully exploit the invention in a manner that breaches any other enactment. As such, even though there are no special provisions in the Patents Act regarding the incidence of the Antitrust Law, one must keep in mind that there might be a liability in accordance with the Antitrust Law regarding misuse of rights.

Specifically, in a decision issued by the district court that was approved by the Supreme Court, in the case of *Unipharm v Sanofi*, it was held that the patent applicant, Sanofi, misled the ILPTO and breached its duty of disclosure since it filed a PCT application which claimed priority over an application containing an erroneous example. Sanofi continued to claim priority even though it knew about the error and did not include sufficient details concerning the reason for the error and the circumstances.

This judgment creates, by way of judicial legislation, a new course of action under the doctrine of unjust enrichment. It allows a private competitor to bring a suit against an innovative pharmaceutical company (that was found to have improperly prosecuted a patent application), seeking accounting and disgorgement of its profits as a punitive measure, without regard to the damage to that private competitor.

The district court further held that it was irrelevant whether or not the error would have easily been overcome, as argued by Sanofi. In effect, the district court held that because of Sanofi's perceived omission, it was not entitled to raise this argument and it was not decided on the merits.

In addition, patent applicants are now subject to a very broad duty of disclosure, the boundaries of which are unclear. This may in turn lead to an increase of inequitable conduct in future litigation, an indication of which can already be found in recent case law by the ILPTO.

Regarding improper prosecution and breach of disclosure duty, the district court found that Sanofi's actions amounted to abuse of a dominant position under Israeli antitrust law, but did so without discussing the relevant conditions stipulated by law in order for a company to be considered a monopoly.

These findings, overturned on appeal, determined that the antitrust law violation is not included in the definition of abuse of a dominant position and therefore does not violate antitrust law. Based on the Unjust Enrichment Law, the Supreme Court remanded the case to the district court to evaluate Sanofi's profits for the period of delay and to determine the amount of redress to be awarded to Unipharm, based on Sanofi's said profits. There is currently an application pending for further hearing in this matter before the Supreme Court.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

The necessary parties to an action for infringement are the patentee or the exclusive licensee; they are the only parties that can file an action for infringement. Therefore, non-exclusive licence owners cannot file an action for infringement. In the case of a jointly-owned patent, each partner is entitled to bring action for infringement.

Co-patentees and exclusive licensees who chose not to actively join the action for infringement with the plaintiff must be joined by the plaintiff as defendants. A person who is joined as a defendant but does not take part in the proceedings will not be required to participate in the payment of litigation costs.

### 3.2 Direct and Indirect Infringement

Direct infringement is expressly defined in the Patents Act as the violation of the right of the patentee to prevent any other person from exploiting the invention, either as defined by the claims or in a similar manner which involves the essence of the invention.

Israeli courts have also recognised infringement by joint tortfeasors (such as aiding or inducing infringement) who are then jointly and severally liable. Liability as joint tortfeasors is based on the provisions of the general Torts Ordinance concerning joint tortfeasors.

Furthermore, the courts have recognised a court-made doctrine of contributory infringement. Contributory liability does not require a showing of concerted action between the direct infringer and the contributory infringer. The concept of contributory infringement has been applied under the following accumulated condition:

- the defendant supplied some, but not all, of the components of the patented invention and those components formed a substantial part of the invention;
- the defendant knew, or should have known, that the components would be used for infringing; and
- the components could not form part of a staple commercial product with a substantial non-infringing use.

In such instances of liability, it has not been definitively ruled whether a specific instance of direct infringement must be shown, and it remains an open issue regarding whether the direct infringer must be joined.

The remedies for indirect infringement are the same as those for direct infringement.

### 3.3 Process Patents

The protection afforded by a process claim applies not only to use, sale and the like of the potential process but also to the product which is a direct product of the process.

In cases of alleged infringement of a patent claiming a process for manufacturing a product, the burden of proof is shifted to the defendant to show that it is not using the patented process if the patentee can show that:

- the patentee cannot ascertain, by reasonable means, which process has been used to produce the identical product; and
- it is highly reasonable that the identical product was produced using the patented process.

### Scope of Protection for Process Patents outside Israel

Because it is an infringement to deal with a product which is the direct product of a patented process, importation of a product produced abroad using a manufacturing process that would have infringed if used in Israel constitutes an infringement of the Israeli patent. In one case (CA 436/77 Ikapharm Ltd v Gradstan Limited, 33(1) 260 (1978)), the court held that the appellants had failed to provide evidence proving that a process used in Spain did not infringe the patent and therefore ruled that the process patent had been infringed by importation of the direct product of the process.

### 3.4 Scope of Protection for an Intellectual Property Right

The Patents Act defines infringement as exploitation of the invention in the manner defined by the claims or in a similar manner that, in light of the claims, involves the essence of the invention.

Thus, in addition to protection against literal infringement, the Patents Act also confers protection against infringement of the “essence of the invention” (its gist) sometimes also referred to as the “doctrine of equivalents”.

In addition, the Supreme Court has emphasised the principle of reading the patent document as a whole. As such, the specification cannot be used to broaden the scope of the claims and cannot be used selectively and it is the rule that interpretation of the claims should be purposive. It has been ruled that claim construction aims at ascertaining the inventor’s intention expressed in the patent document, as understood by a person having an ordinary skill in the art in the relevant field given the knowledge existing on the determining date.

A patentee is expected to formulate the patent claims with a reasonable degree of clarity. The Supreme Court has enunciated several criteria to assist in determining whether this degree of clarity is achieved, including:

- the complexity of the field of the invention and the difficulty of describing the invention clearly;
- the ability of the language to describe the invention in a better way; and
- that unwarranted ambiguity operates against the author toward a narrower reading of the claims, whereas the invention's greater contribution to the field allows for a more liberal construction of the exclusive right afforded by the claims.

Where the proper interpretation of the patent document is unclear, the Israeli and foreign file wrappers may aid in the interpretation. It should be noted, however, that the Supreme Court left the question of whether the doctrine of file-wrapper estoppel is applicable in Israel open.

Claim construction is an issue of law.

### 3.5 Defences Against Infringement

The available defences against infringement are set out below (in a non-exhaustive list).

- Non-infringement (the claims do not cover the accused product or method).
- Non-infringement (exceptions to the definition of "exploitation of an invention"; these include statutory "experimental use" and "Bolar-like" exceptions).
- Invalidity.
- Lack of standing to bring suit – a challenge to ownership of the patent is a defence since the right to bring an action for patent infringement belongs to the patentee or to the exclu-

sive licensee provided the licence has been duly recorded in the patents register; any of the co-owners or the exclusive licensee may sue alone, but the suing party must join all other co-owners (and the exclusive licensee, where an exclusive licence was granted); failure to comply with the foregoing will result in claim dismissal.

- Prior use rights (see **1.9 Consequences of Failure to Pay Annual Fees**).
- Statute of limitation and laches – laches is a strong defence in interim relief proceedings; it will, however, only be considered a defence in the main action in rare and exceptional circumstances.
- Equitable estoppel – as a general principle, a plaintiff may be estopped from bringing an action if their conduct, through action or inaction, was such that the defendant reasonably inferred that the plaintiff would not enforce the patent against them, and the defendant relied on that conduct and materially changed their situation based on that reliance; acquiescence will not be easily inferred.
- Patent exhaustion – the Patents Act does not expressly deal with this matter; however, in the case of *Bristol-Myers Squibb Company v The Minister of Health*, the question of whether parallel importation of patented medicine to Israel is allowed was examined and although the issue arose obiter dicta (such that no decision was made on the merits), the judge expressed an opinion in favour of the international exhaustion of rights.
- Compulsory licence and compulsory licence to exploit earlier patent – compulsory licences are theoretically available (see **2.13 Restrictions on Assertion of an Intellectual Property Right**); however, allegation to entitlement to a compulsory licence (not actually granted) is not a defence.

- To date, there have been no fair, reasonable and non-discriminatory (FRAND) litigations in Israel.
- Market overt – as held by the Supreme Court, the market overt defence does not apply to the sale of the patent itself as an asset. There is controversy among scholars with respect to the question of whether “market overt” grants the purchaser of a patented article immunity from the claim of patent infringement; however, a purchaser of a patented article from a liquidator or other judicial authority, acquires the article free from third-party claims including a claim of patent infringement (CA 4052/19 Y.S.M for building v Tadbik).

### 3.6 Role of Experts

#### Experts Engaged by the Parties

Experts are frequently engaged by the parties, both in Patent Office litigation and in infringement litigation before district courts. Foreign experts may file their opinions in English. During trial, the experts will be cross-examined on their opinions.

#### Court-Appointed Experts

In proceedings before the Patent Office, no experts are appointed by the Registrar. If necessary, the Registrar is aided by one of the examiners.

A district court trying an infringement action may appoint an expert. The court-appointed expert may be cross-examined by both parties (plaintiff and defendant). The default rule is that a court-appointed expert renders parties' expert opinions inadmissible. Pending final judgment, the parties will typically be ordered to share the costs of the court-appointed expert.

The district court also has the power to appoint an assessor (a scientific advisor) who assists the

judge in taking evidence and may render advice to the judge, but shall not take part in rendering the judgment. The costs for the court-appointed scientific advisor are paid by the State Treasury.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

In Israel, there is no claim construction hearing (“Markman hearing”) in which the judge examines the evidence of the parties in order to understand the appropriate meaning of the key words of the patent claims.

### 3.8 Procedure for Third-Party Opinions

There are two main procedures for which the court can receive third-party opinions.

First, receiving a third-party opinion as an amicus brief. The tool “amicus brief” was not recognised in Israeli law until 1999. In that year, in the Kozli case, the court allowed a body that was not a formal party to the proceedings, to submit summations in the status of an amicus brief for the first time. Today, the courts have the authority to allow individuals, entities and institutions that are not formal parties to a legal proceeding to present their position before the court, subject to obtaining permission from the court.

Second, receiving an opinion by the Attorney General (AG). As part of their role of safeguarding the public interest, the AG is authorised to join any proceedings as a representative of the state, provided that a public right or public interest is involved in it.



## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

Any person may file an application with the Patent Office to revoke a granted patent, and standing to sue is not required.

The grounds for filing a revocation application are identical to the grounds for filing an opposition.

An application for revocation may be filed at any time and the statute of limitation does not apply. The Registrar may accept the application (and revoke the patent), deny the application or allow the application partially (eg, by deleting/narrowing some of the claims). If the revocation application is allowed, the patent will be deemed as if it was never granted.

The patentee is entitled to request cancellation of a granted patent (as distinguished from a revocation thereof). If such a request is allowed, the patent will cease to be in force from the date of cancellation. Any person may oppose a request for cancellation and require that the patent be revoked.

### 4.2 Partial Revocation/Cancellation

Partial revocation may occur following an application for partial revocation, or following a revocation application that has been only partially accepted.

The Registrar has the discretion to partially revoke the patent by narrowing, or revoking part of, the patent claims.

### 4.3 Amendments in Revocation/Cancellation Proceedings

The patentee may apply for an amendment during revocation proceedings for the purposes of clarification, removing an error in the specification or restricting the claims. The Registrar will permit the amendment if they are convinced that the amendment will not broaden the scope of the claims and will not add anything to the specification not already included.

### 4.4 Revocation/Cancellation and Infringement

Unlike Germany, for example, infringement and validity arguments (in infringement litigation) are heard before the same court. In terms of procedure, the issue of damages is bifurcated. At the first stage, the court addresses issues of validity and infringement, with the judgment at this stage addressing the grant of an injunction and usually an order for accounting. At the second stage – the bifurcated damages proceeding – the parties conduct a trial over the accounting and calculation of damages. The parties usually settle the dispute during this proceeding and do not conduct it in its entirety.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

There are no special procedural provisions for intellectual property rights proceedings. See 2.11 Initial Pleading Standards.

In terms of procedure, the issue of damages is often bifurcated. See 4.4 Revocation/Cancellation and Infringement.



## 5.2 Decision-Makers

Infringement cases are heard before professional judges possessing a legal background; there are neither technical judges nor juries in Israel. There are also no specialised intellectual property judges. The parties have no influence on the allocation of their presiding judge.

## 5.3 Settling the Case

The parties may resolve the dispute via mediation (which is regulated by law). Mediation is voluntary and, even though the judges usually encourage the parties to resolve the dispute using mediation, currently there is no mandatory settlement conference. The court may also, with the parties' consent, refer the case to arbitration.

## 5.4 Other Court Proceedings

If an application for revocation is filed with the Patent Office after a patent infringement action has been initiated before a district court, the Patent Office will not hear that application unless the court permits it.

Where a patent infringement action has been initiated before the district court, when a revocation application is already pending before the Patent Office, the court has the power to stay the proceedings before the Patent Office.

The court trying an infringement action may also stay the proceedings before it, pending resolution of a revocation action before the Patent Office (judges may sometimes encourage the parties to first resolve the validity issue by instituting a revocation action before the Patent Office).

If the Patent Office revokes the patent, revocations act in rem. If the Patent Office dismisses the revocation action, the district court is free to

invalidate the patent (subject to the general rules of issue preclusion).

## Anti-suit Injunctions

The court has the power to stay the proceedings before it, pending judgment in foreign litigation. The court may decide to refrain from hearing a claim filed under the doctrines of *lis alibi pendens* or *inappropriate forum*.

The court may also issue anti-suit injunctions, though only in cases where it has been proven by the applicant that the claim filed in the foreign forum is vexatious or filed in *mala fides*. In the case *Inter-lab Ltd v Israel Bio-Engineering Project Ltd*, the court enumerated a non-exhaustive list of considerations that must be considered in exercising the power to issue an anti-suit injunction. First, the expected harm to the party seeking the injunction, if it is not granted, and harm on the other side if such an order will be issued against them. Second, whether the commands of the foreign proceeding are done for the purpose of threat or extortion, and whether they violate substantive principles of justice must be examined. Lastly, one of the most important considerations, decided according to the circumstances of each individual case, is whether the grant of the anti-suit injunction will be "just". If granted, the anti-suit injunction is considered an impersonal remedy. Accordingly, in the converse situation, the court in Israel may consider itself not bound by a foreign anti-suit injunction issued by a foreign court.

## 6. Remedies

### 6.1 Remedies for the Patentee

As set forth in 1.5 *Rights and Obligations of Owners of Intellectual Property Rights*, the remedies available to a successful plaintiff in

an infringement case are injunction, damages (including provisional damages) and delivery up. The judge has the power to fashion any additional remedy they find appropriate.

As set forth in **6.2 Rights of Prevailing Defendants**, generally the prevailing party is entitled to reimbursements of their court and attorney's fees. In practice, however, reimbursement is almost always partial.

Financial remedies will be enforced by Execution Office. The Execution Office can also seize and sell properties located in Israel.

Remedies for non-compliance with orders given by a court (contempt of court) are enforced by the imposition of a fine or imprisonment in a separate proceeding from the patent litigation.

## **6.2 Rights of Prevailing Defendants District Courts**

As a general rule, the prevailing party is entitled to reimbursement of its reasonable legal costs. However, in practice, reimbursement is almost always partial. The court also has the power to award costs in interim proceedings, but will sometimes defer its decision until after a decision on the merits is made.

The courts also have regard to the parties' conduct, which may result in denying an award of costs to the winning party (in whole or in part), and even in the court providing for an award in favour of the losing party, or in providing for an award to the state treasury.

According to Section 96(a) and 96(b) of the Civil Procedure Regulations, the application for an interlocutory injunction shall be accompanied by the applicant's personal undertaking to compensate the person against whom the order is

directed for any damage caused to them by the interlocutory injunction, if the action ceases or the order expires for any other reason.

As far as attorneys' fees are concerned, the courts usually award attorneys' fees (without extensive factual inquiry), which are significantly lower than the actual attorneys' fees incurred.

The prevailing party is also entitled to reimbursement of all reasonable out-of-pocket expenses. Court fees are generally viewed as a reasonably incurred cost and are reimbursed by the losing defendant in full, though the court has discretion to refuse this reimbursement, in part, where it finds that the amount initially claimed (and on the basis of which court fees were paid) were unduly high.

Costs appearing in the court docket (such as payments ordered by the court to witnesses for their lost time, which are relatively low) are reimbursed as a matter of right. Reimbursement of other costs, such as expert fees, travel and accommodation costs, translation costs, photocopies, couriers, and the like require submission of an application, proving the costs in a detailed manner, and the costs are then scrutinised to ensure their reasonableness as a condition for reimbursement.

## **ILPTO**

The practice before the ILPTO in oppositions and revocation actions is different. Following judgment, the prevailing party is entitled to submit an application that details, on an itemised basis, not only out-of-pocket costs but also attorneys' fees paid. All items are scrutinised, and practice shows that the amount of attorneys' fees reimbursed is substantially higher than in district court litigation.

Accordingly, in district court infringement litigation, the recovery may be well below 15%. However, in proceedings before the ILPTO, the recovery may be 50% or more and legal fee awards may be as high as hundreds of thousands of US dollars.

### 6.3 Types of Remedies

According to the Commercial Wrongs Act, a successful plaintiff in a trade secret infringement case may be entitled to injunction and damages, including statutory damages of up to ILS100,000 per infringement (approximately USD32,258).

### 6.4 Injunctions Pending Appeal

If the patent was found to be valid and later infringed, at first instance, the common practice is that an injunction is granted and the default rule is that execution is not stayed.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

There are no special provisions concerning the appellate procedure for intellectual property rights proceedings.

### 7.2 Type of Review

The appellate courts typically refrain from interfering with findings of fact made by the trial court. The court sitting in appeal over the decisions of the Patent Office will typically defer to the findings of the Patent Office, premised on the notion that the Patent Office is a body with high professional expertise. The court may intervene with a decision of the Patent Office when the question arising in the appeal involves the correct interpretation of the law as can be seen in the recent Tel Aviv District Court decision in VCA 32365-05-20 Intra-Cellular Therapies Inc. v The

State of Israel – The Patent Office (12.4.2022). In the Supreme Court decision in LCA 386/22 Boehringer Ingelheim Pharma GMBH & CO.KG v The State of Israel – The Patent Office (11.12.2022), which was a patent term extension case, the court held that deference may be appropriate even with respect to legal questions, owing to the expertise of the ILPTO.

The Supreme Court sees decisions on interim relief as discretionary and will therefore not readily interfere. (see, eg, LCA 338/22 Amgen (Europe) GmbH v Rafa Laboratories (30.3.2022)).

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

There are no protective briefs. It is common practice that, upon request from the other party, one should add copies of warning letters that were sent related to every motion filed with the court.

### 8.2 Calculation of Court Fees

According to a schedule to the Court Regulations (Fees), the filing fee rate is 2.5% of the claimed amount up to ILS24.7 million (approximately USD7.9 million) and 1% of any additional amount.

Section 6(a) of the Court Regulations (Fees) states that the court fee shall be paid in two equal instalments: the first when filing the action and the second up to 20 days prior to the date scheduled for the first evidence hearing.

### 8.3 Responsibility for Paying the Costs of Litigation

Please see 6.2 Rights of Prevailing Defendants.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

The use of ADR is more widespread in general commercial disputes than in the field of intellectual property. However, the awareness of ADR in patent litigation has significantly increased in recent years and mediation is generally encouraged by the courts.

Due to the high workload in the Israeli court system, judges encourage parties to use mediation (which is regulated by law), but doing so is possible only with the consent of both parties.

Arbitration is also regulated by law and allows the parties to agree upon the possibility of appealing the arbitrator's verdict.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

There is no legal obligation to record assignment agreements for registered patents or pending applications at the Patent Office. Failure to record such assignments does not influence the validity of the application or the patent granted thereon, nor does it have any bearing on the relationship between the parties to the agreement. Nevertheless, recording the change is recommended for a number of reasons, including the following.

- Recordation is required in order to allow the assignee to assert the right against third parties (the Patents Act is silent in this regard and does not explicitly state whether an exclusive licensee may collect damages in

respect of an infringement that occurred prior to the date of recordation of the licence).

- Unlike in the USA, failure to record may cause delay when immediate enforcement actions are required (since the right to file these actions is preserved of the registered patentee/exclusive licensee) and such recordation is required prior to filing an action.

### 10.2 Procedure for Assigning an Intellectual Property Right

The application for assignment may be filed by the assignee or by their legal representative.

According to an administrative directive issued by the Patent Registrar, two documents will be required in order to record an assignment agreement at the Patent Office.

#### The Original Assignment Agreement or a Certified Copy Thereof

According to the directive, the assignment agreement must indicate the exact transaction, the date of the transaction, the signature of the assignor and a specific reference to the Israeli patent or patent application involved, identified by its official serial number. If the original agreement was not made in Hebrew, Arabic or English, a certified translation into one of these languages must be provided by an Israeli or foreign notary.

If the agreement is signed by a liquidator or trustee, it is necessary to submit the document evidencing the appointment of that person and their authorisation to sign on behalf of the legal entity for which they had signed the agreement.

If the agreement indicates that it is executed in accordance with, or subject to, the provisions of a previous agreement, it will be necessary to file an affidavit on behalf of the party requesting the

recording (or their attorney), stating that the previous agreement does not include any provisions which may revoke or restrict the recording of the requested change.

If the agreement includes confidential information, one may file both an abbreviated version of the agreement, along with the duly notarised complete unabbreviated version thereof and request that the Patent Office clerks return the complete unabbreviated version once the agreement is duly recorded so that the only document to remain on record will be the abbreviated version.

Alternatively, it is possible to file the abbreviated version of the agreement only, as long as the applicant explains to the Patent Office why certain parts were redacted, what the general content of these parts was, and confirms that these parts do not include any provisions which may revoke or restrict the recording of the requested change.

If the application for assignment is requested following an order of a foreign court or a will (testament), the applicant must present a decision, order or ruling of an Israeli court (or the Israeli registrar of wills in respect of the inheritance) in order for the change to be executed.

#### **A Duly Signed Power of Attorney in the Name of the Assignee, Indicating the Full Name and Address of the Assignee and the Date of Signature**

No legalisation or notarisation of the signature is required. Furthermore, it is not necessary to file the original form or a certified copy thereof (a simple copy will suffice).

#### **Costs for Recording an Assignment**

There is an official fee of approximately USD69. Professional fees vary significantly.

#### **10.3 Requirements or Restrictions to License an Intellectual Property Right**

The Patentee may give an exclusive or non-exclusive written licence to exploit the invention. An exclusive licence confers the exclusive right to act as if the licensee were the patentee, and it prohibits the patentee from exploiting the invention in Israel. A non-exclusive licence confers the right to exploit the invention to the extent, and on the conditions, prescribed in the licence. A non-exclusive licensee does not have a right to file an action for infringement.

The recording of licences for registered patents or pending applications is not mandatory under the Patents Act. Moreover, non-recording of the licence does not affect the validity of the patent (or patent application) involved, nor does it have any bearing on the relationship between the parties to the agreement. Nevertheless, a recording of an exclusive licence is required in order to assert that licence against third parties. Therefore, a patent licence agreement that was not registered in the Patents Register is generally in effect only for the parties to the agreement.

#### **10.4 Procedure for Licensing an Intellectual Property Right**

The procedure for recording and licensing an agreement, as well as the cost involved, is similar to that for recording an assignment (see **10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights**).

Contributed by: Eran Bareket, Gilat, Bareket & Co., Reinhold Cohn Group

**Gilat, Bareket & Co., Reinhold Cohn Group** is the leading intellectual property consulting firm in Israel and offers a full range of IP-related services and expertise, including protection, asset management, due diligence, litigation and legal services. The firm operates in all areas of IP, such as patents, trade marks, designs, copyrights, open source and plant breeders' rights. The group includes the patent attorneys firm Reinhold Cohn & Partners and the law firm Gilat, Bareket & Co., which specialises in litigation and the legal protection of intellectual property

rights in patents, technology, brands, designs, creative works and inventions. The firm's key practice areas include filing suits for patent infringement in courts, representing clients before the Patents Registrar, rendering opinions regarding infringement and freedom to operate, and counselling on service inventions. The author would like to thank his colleagues for their assistance in connection with this (Adi Ann Berkovic) and past (Emilia Perry, Rotem Avisar, Stav Tuval, Keren Lindenfeld and Tomer Rosenfeld) editions of this chapter.

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

For the protection of inventions, the Italian legal system contemplates:

- patents;
- utility models; and
- supplementary protection certificates, extending the duration of the protection conferred by patents protecting medicinal products (Regulation 469/2009/EC).

These are based on statutory law.

### 1.2 Grant Procedure

The patent granting procedure has the following stages.

- Filing of the application, online (with the Italian Patent and Trademark Office – IPTO) or on paper (with the local Chamber of Commerce).
- Check of formal requirements by the IPTO.
- No examination, but a “prior search procedure”:
  - (a) there is no proper prior examination system at the IPTO but Italian national patent applications that do not claim priority over other applications undergo a prior search;
  - (b) this search is outsourced to the EPO examiners, based on a contractual agreement between the Italian government and the EPO;
  - (c) the search report is sent to the applicant, who is given a deadline to provide comments or amend claims if the search report so requires;
  - (d) this process is generally limited to one single exchange of comments or amendments by the applicant; and
  - (e) at this stage, the applicant may also

change the application into a utility model application.

- Grant/rejection and relative publication.

The utility model and SPC granting procedures differ from the granting procedure of patent applications in that there is no “prior search procedure” step.

### 1.3 Timeline for Grant Procedure

Patent and utility model granting procedures typically last approximately 24 months.

The inventor does not need representation to file an application.

The average costs to grant are:

- EUR50, in the case of an e-filing; and
- EUR120–600 in the case of a paper filing and depending on the number of pages.

The prior search procedure costs an additional EUR200 if the applicant did not already provide an English translation of the claims. Each additional claim after the tenth costs EUR45.

An SPC granting procedure typically lasts approximately four to six months.

### 1.4 Term of Each Intellectual Property Right

Patents last 20 years from the filing of the application.

Utility models last ten years from the filing of the application.

SPCs take effect at the expiry of the basic patent and shall last for a period equal to the period elapsing between the date on which the application for a basic patent was lodged and the

date of the first authorisation to place the product on the market in the European Community, reduced by a period of five years. This notwithstanding, the duration of the certificate may not exceed five years from the date on which it takes effect. An extension of duration of the SPC by six months may be obtained under the provisions of Article 36 of Regulation 1901/2006/EC (“paediatric extension”).

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

The patent owner gains exclusive rights on the basis of which they may seek various types of remedies, including injunctions and damages.

The patent holder is obliged to pay annual fees.

Patents are published in the IPTO database, which is free to consult. In the pharmaceutical space, the IPTO publishes a list of granted SPCs that can be searched by reference to the name of the medicinal product involved.

## 1.6 Further Protection After Lapse of the Maximum Term

Italian law contemplates SPCs and relative paediatric extensions. See **1.4 Term of Each Intellectual Property Right**.

## 1.7 Third-Party Rights to Participate in Grant Proceedings

There is no true participation by third parties during grant proceedings. In practice, third-party observations may be filed. These will not be forwarded to the applicant. However, the examiner is at liberty to consider them and possibly translate them into its own observations. In this case, the examiner’s observations will be sent to the applicant and the latter will be given a deadline to comment.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

A refusal to grant is subject to appeal before the IPTO’s Board of Appeal with a deadline of 60 days.

## 1.9 Consequences of Failure to Pay Annual Fees

The legal consequence of a failure to pay the annual fees is revocation of the patent.

After six months from the due date for payment, during which payment is allowed subject to a late-payment fee, the IPTO (i) notifies the interested party that it has no record of payment and (ii), after a further 30 days from said communication, publishes the notice of revocation in the IPTO Official Bulletin.

Within six months from the above publication in the Official Bulletin, the patent owner, who proves timely payment of the annual fees, may file an appeal before the IPTO Board of Appeal requesting cancellation of the notice of revocation. A patent shall be deemed revoked if the appeal has been dismissed or, in any case, after six months from the publication of the notice of revocation.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

Post-grant amendments of patents may be obtained in two ways.

- In court, during a revocation action – the relevant procedure merely consists of a declaration of amendment filed with the judge.
- Through an application filed with the IPTO – the application undergoes a mere check of formal requirements by the IPTO and the grant of the amendment is generally obtained in approximately two months.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

Against infringement, a patent owner may bring:

- an infringement action on the merits;
- preliminary injunction proceedings (ante causam or in the framework of proceedings on the merits); and
- search/seizure proceedings aimed at collecting or preserving the evidence of the infringement.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

Third parties who wish to remove the effects of the technical intellectual property right may bring one of the following actions.

- Invalidation/revocation action – no particular admissibility requirement applies.
- Declaration of non-infringement action, either as proceedings on the merits or by means of preliminary proceedings – an interest to seek the declaration must be proven, typically the need to clear the way for launching an allegedly infringing product, whether or not based on cease and desist letters sent by the right-holder.

No opposition proceedings or post-grant review proceedings are available.

### 2.3 Courts With Jurisdiction

At first instance, the commercial chambers of 22 courts of first instance sitting throughout the Italian territory have jurisdiction: Ancona, Bari, Bologna, Bolzano, Brescia, Cagliari, Catania, Catanzaro, Campobasso, Florence, Genoa, L'Aquila, Milan, Naples, Palermo, Perugia, Potenza, Rome, Trento, Trieste, Turin and Venice.

At second instance, 22 Courts of Appeal sitting in the same districts as the above-mentioned courts of first instance have jurisdiction.

The Supreme Court sitting in Rome has jurisdiction at third instance.

The territorial jurisdiction of the above-mentioned courts is determined by reference to:

- the patent holder's elected domicile in the case of invalidation/revocation actions – this jurisdiction prevails also if the revocation claim is coupled with other claims in the same proceedings;
- the domicile of the defendant or alternatively the locus commissi delicti in declaratory judgment actions or infringement actions.

If the proceedings involve a foreign party, only 11 of the above-listed courts have territorial jurisdiction: Bari, Bolzano, Cagliari, Catania, Genova, Milan, Naples, Rome, Trento, Turin and Venice.

### 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

There are no specialised bodies or organisations for the resolution of intellectual property disputes.

Also, although possible in theory, arbitration is practically unknown in the context of patent disputes in the Italian jurisdiction.

### 2.5 Prerequisites to Filing a Lawsuit

There are no prerequisites to filing a lawsuit, such as the recordal of the patent or licence with the patent office, issuing a formal demand letter, warning letters, or engaging in mediation.

## 2.6 Legal Representation

Parties in intellectual property matters need to be represented by a lawyer.

## 2.7 Interim Injunctions

Inter partes and ex parte interim injunctions are available, although courts are quite reluctant to grant ex parte injunctions.

The following requirements must be met for an interim injunction to be granted:

- prima facie case – ie, plausible evidence of patent validity and/or infringement; and
- urgency/irreparable harm – ie, need for the injunction as the delay required to complete proceedings on the merits would produce irreparable effects.

No delay in seeking relief and balance of convenience are also considered by the Italian courts, although not specifically provided for in the law.

## 2.8 Protection for Potential Opponents

A potential opponent cannot protect itself through protective briefs as these are not allowed in Italy.

The law allows Italian courts to request the claimant to post a bond when granting a preliminary measure; however, this tool is hardly ever used.

## 2.9 Special Limitation Provisions

The limitation period for claiming damages caused by patent infringement is five years. There is no other relevant limitation period.

## 2.10 Mechanisms to Obtain Evidence and Information

The Italian legal system contemplates search/seizure proceedings.

These are saisie-type proceedings that can be resorted to if the right-holder:

- provides at least initial elements to substantiate a likelihood that its rights are being infringed; and
- proves that the requested measure is needed to obtain evidence which could not be obtained otherwise than by accessing the defendant's premises.

Search orders are typically granted ex parte on the assumption that putting the other party on notice would frustrate the execution of the search as the latter could easily conceal or displace the evidence to be collected.

Once issued, the search order empowers a court bailiff, normally accompanied by the claimant's counsels and representatives, to raid the alleged infringer's premises unannounced and "search" the evidence of the infringement within those premises.

Depending on the circumstances, the search order may specify the objects or documents to be searched and may encompass accounting or financial documents for the purposes of proving the existence of the infringement or violation as well as its magnitude. The collection of samples of allegedly infringing products is generally allowed.

Ex parte search orders generally have to be executed in a very short timeframe after issue by the court (typically eight days) and then have to undergo a confirmation phase upon an inter partes hearing which typically takes place within one or two weeks from the raid.

Once the order is confirmed inter partes, the right-holder will have to institute merits proceed-

ings within the mandatory deadline of 30 days. Failure to institute merits proceedings within the stated deadline will make the evidence collected during the search unusable.

## 2.11 Initial Pleading Standards

Although Italian proceedings are not strictly front-loaded – ie, the submission of additional evidence is allowed to some extent after the proceedings have been instituted – the initial pleading must contain a fairly substantial elaboration of the grounds on which the claims rest and provide relevant evidence.

After the case has commenced, general procedural rules provide for a system of fixed “preclusions” by which the parties are allowed to modify their claims and submit new evidence. As far as intellectual property cases are concerned, however, this system is to some extent undermined by the principle that each time the court appoints a court adviser to consider the technical merit of the case, the parties are then free to submit new evidence to that court adviser until they have produced their report. In practice, the Italian courts appoint court advisers in all patent cases, the impact of which is that claimants have ample opportunity to supplement arguments and evidence on validity and/or infringement after the case has been started.

## 2.12 Representative or Collective Action

The Italian legal system does not permit representative or collective actions (such as class actions) for intellectual property rights proceedings.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

Depending on the circumstances, competition law and contractual restrictions may be relied on in cases concerning standard essential patents,

where good-faith willing licensees can rely on such restrictions to avoid injunctive relief and/or seek a licence on fair, reasonable and non-discriminatory (FRAND) terms.

Furthermore, according to the most recent case law, the remedies requested by the right-holder must be scrutinised against the general principle of proportionality.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

The exclusive licensee is entitled to enforce the patent in its own name, seeking an injunction and/or damages.

Non-exclusive licensees are generally entitled to bring action as co-plaintiffs as the courts tend to view infringement claims by non-exclusive licensees as dependent on the primary right of action by the patent holders.

### 3.2 Direct and Indirect Infringement

As far as direct infringement is concerned, the patent confers on the owner the exclusive rights to prohibit third parties from producing, using, marketing, selling or importing for these purposes the patented product; if the subject matter of the patent is a process, the patent holder may prohibit third parties from applying the process, and from using, marketing, selling or importing for these purposes the product directly obtained by the patented process.

As far as indirect infringement is concerned, the patent holder may prohibit third parties from providing or offering to provide to subjects other than those entitled to use the patented invention, the means relating to an indispensable element

of this invention and necessary for its implementation, if the third party is aware of the suitability and destination of said means to implement the invention or should have such awareness through ordinary diligence. If the means are commodities, indirect infringement subsists only in the case of wilful inducement.

The same type of remedies (search/seizure, injunctions and damages) are available in either case.

### 3.3 Process Patents

If the subject matter of the patent is a process, the patent holder may prohibit third parties from applying the process, and from using, marketing, selling or importing for these purposes the product directly obtained by the patented process.

Whether (part of) the process is practised abroad does not impede infringement as long as the product directly obtained by the patented process is imported/marketed in Italy.

### 3.4 Scope of Protection for an Intellectual Property Right

According to Italian law, the scope of protection of a patent is determined by the patent claims, interpreted in light of the description and the drawings. It is then expressly provided that the scope of the claims must be interpreted so as ensure both the patentee's right to fair protection and legal certainty for third parties.

The doctrine of equivalents has existed in the Italian system for many years, and was translated into statutes in 2010. The relevant provision states that in determining the scope of protection, account must be taken "of features that might be equivalent to the claimed features". The relevant test most likely to be applied by Ital-

ian courts today is the "triple test", according to which an element is considered equivalent to the claimed features if it performs the same function, in the same way, and obtaining the same result.

There is no prosecution history estoppel in the Italian system, and the most recent case law has quite substantially reduced the impact of the declarations made by the applicant during prosecution in determining the scope of protection or the feasibility of a claim of infringement by equivalents.

### 3.5 Defences Against Infringement

Typical defences against infringement are non-infringement, invalidity and the application of specific exemptions, the most relevant of which are the experimental exemption and the Bolar exemption.

The prior-user right defence is also available; however, it has rather limited impact as the law stipulates that the prior user may continue to use the patented invention as long as such use remains within the limits of the prior use. According to the case law, this means that the prior user will not have the possibility to expand the use of the invention beyond the specific use they previously made, both from a quantitative and qualitative perspective.

Compulsory licensing is generally not a defence as Italian law expressly indicates that there is no obligation of a compulsory licence in favour of an infringer.

Violation of competition law and/or the contractual promise to offer licences on FRAND terms may be a defence in the case of standard essential patents, depending on the specific remedy sought. In particular, an Italian court would follow the CJEU case law in determining the circum-



stances in which an injunction may be granted based on a standard essential patent.

Patent exhaustion is also available as a defence, when the product claimed by the patent was put into the market by the patent holder or with its consent in the EEA.

### 3.6 Role of Experts

In Italian patent litigation, either in preliminary or merits proceedings, the evaluation of the relevant technical issues relating to validity and infringement is always subject to consideration by an independent adviser appointed by the court. This adviser will generally be chosen amongst relatively senior Italian patent agents with specific experience in the given technical field.

In practice, a technical discussion will take place before the court adviser through the submission of written briefs and replies to be prepared by the parties through their own counsel and technical consultants. The court adviser may also conduct experiments or inspections which the parties have a right to attend. After the technical discussion is completed, the court adviser will produce a draft report and will ask the parties to comment on the same, after which they will produce a final report to the court. The report of the court adviser is not binding and the court retains the right to overrule it. The technical phase before the court adviser is crucial and must be conducted with the necessary care and deployment of effort by the parties.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

In Italian patent litigation, there is no separate procedure for construing the terms of the patent's claims. The claims construction is carried out during the phase led by the court adviser,

through the exercise of exchanging technical briefs by the parties towards the production of a report by the court adviser (as discussed in **3.6 Role of Experts**).

### 3.8 Procedure for Third-Party Opinions

In Italian patent litigation there is no system by which the court can seek or receive third-party opinions (amicus briefs).

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

The reasons for revocation fully reflect the patent grant requirements established by the European Patent Convention.

There are no specific locus standi requirements to bring a patent revocation action in Italy.

### 4.2 Partial Revocation/Cancellation

Italian law contemplates the possibility that the court establishes that a patent is only partly valid. In this case, the relative limitation of the patent will be produced by operation of the ruling. This typically happens when the court finds for the invalidity of the independent claim, but for the validity of a dependent claim.

### 4.3 Amendments in Revocation/Cancellation Proceedings

The patent holder is at liberty to amend the patent during a revocation action by means of declaration of amendment submitted to the judge. There are no given time limits to do so. Typically, the patent holder will submit such a declaration of limitation once the court adviser has provided a preliminary conclusion that the patent lacks novelty or any other requirement that may be cured by way of a post-grant amendment.

In this case, the court will most likely ask the court adviser to issue a supplemental report on whether the limitation is admissible and whether it has the effect of curing invalidity.

#### **4.4 Revocation/Cancellation and Infringement**

Revocation and infringement proceedings are heard together in Italy as there is no bifurcation system.

### **5. Trial and Settlement**

#### **5.1 Special Procedural Provisions for Intellectual Property Rights**

The background legislation governing the procedure of any court proceedings dealing with the validity and infringement of, and entitlement to, intellectual property rights is the Italian Code of Civil Procedure (CPC).

Special provisions apply to IP proceedings, starting with the fact that IP proceedings are heard by IP-specialised courts (see **2.3 Courts With Jurisdiction**). Having specifically reserved judges makes IP proceedings faster than other contentious matters of civil law. The typical timeline for main (revocation and infringement) proceedings is between two and two and a half years. However, by a reform that will enter into force on 28 February 2023 (Legislative Decree No 149/2022), main proceedings have been streamlined by the elimination of several formal steps. As a consequence, it is expected that the overall average duration of main proceedings will be substantially reduced. Preliminary proceedings take between three and six months on average. Patent matters can take a little longer due to the involvement of experts (see **3.6 Role of Experts**).

Preliminary injunction proceedings are far more agile. Further to the submission of the parties' introductory motion and defensive briefs, a hearing is set and normally used to "test" the urgency requirement. If the urgency requirement is met, the case proceeds right away with the appointment of a court technical adviser (or CTA). A proper discussion hearing is then held once the CTA is prepared to adjudicate on the case.

Fact witnesses are not too common in patent matters, and are used only to confirm purely factual circumstances (ie, circumstances other than validity and infringement) that are relevant to adjudicate the case, for instance in entitlement proceedings. Expert witnesses are not contemplated. Experts can nevertheless appear as technical counsel for the parties, typically as part of the process that leads up to the delivery of a CTA opinion, and may be questioned directly by the judge. There is no cross-examination by the parties' counsel.

Remedies that do not normally require further assessment once validity and infringement have been determined are normally assigned with the judgment carrying the finding of infringement. These remedies typically include (both preliminary and permanent) injunctions, market recall, *astreinte*, assignment or, alternatively, destruction of the infringing goods seizures. Financial remedies – ie, damage awards or return of profits – are decided at a later stage and after further activities including the running of accounting/financial evaluations by a court-appointed financial/accounting adviser.

#### **5.2 Decision-Makers**

Main infringement/revocation proceedings are adjudicated with a majority decision of a panel of three IP-specialised judges at both first instance and appeal. Preliminary proceedings are adju-

dictated by a single, IP-specialised judge at first instance. A panel of three judges from the same first instance IP chamber rules on the appeal.

While experienced in patent matters, Italian patent judges have a purely legal, non-technical background, hence the reason why they normally require the guidance of a CTA when assessing a case.

Once a case is filed, the parties have no influence whatsoever in determining which judge or judges will end up deciding their cases. The only influence they can exercise in this respect is before filing a case, when forum shopping for a court perceived as overall better suited than others to hear and adjudicate a certain case.

### 5.3 Settling the Case

The Italian CPC contemplates settlement conferences, which must be attended by the parties, either in person or through their attorneys, along with their defence counsel. However, these conferences cannot be triggered by one party alone. They are either set on the basis of a joint request from all parties or scheduled by the judge at their own initiative.

### 5.4 Other Court Proceedings

Following a 2016 landmark judgment of the Italian Supreme Court, main infringement proceedings can be stayed upon request of the defendant where the latter has filed a parallel revocation action before a different court. This situation is possible on account of the combination between the special jurisdiction criterion applicable to patent revocation proceedings – which can be filed where the patentee has elected its domicile upon filing or, in the case of European patents, validated the patent – and the *locus commissi delicti* criterion applicable to infringement proceedings, which in turn may

well lead to (a number of) different courts, other than the one of the place of domicile of the patent, being competent.

There are no further, significant situations where separate court proceedings can influence (ie, lead to a stay of) previously filed infringement or revocation proceedings. Anti-suit injunctions are possible, but yet to be heard of in Italian practice. There is a general scepticism among scholars, who see them as interfering with the fundamental right of access to justice and with the principle of mutual trust and co-operation between European courts.

## 6. Remedies

### 6.1 Remedies for the Patentee

The main remedy is injunctive relief, normally assisted by an *astreinte* order or penalty due for each act in breach of the injunction. This is the case in both preliminary and permanent injunctions.

Damages are awarded in the form of lost profits, which are determined starting from a *de minimis* criterion equal to the reasonable royalty the infringer would have had to pay had it gone out seeking a licence from the patentee up until the profits that the patentee would have made on the infringer's sales. Return of infringer's profits is also an option. They are awarded either alternatively to damages or concurrently with damages; however, only for the portion exceeding damages. The Italian system does not contemplate punitive damages.

Further remedies include seizure (available in preliminary proceedings) and market withdrawal orders as well as destruction or assignment of the infringing goods and of the means that are

unequivocally necessary and functional to the manufacture and production of the infringing goods (available in main infringement proceedings).

Statutory provisions entrust the judge with discretionary powers to decline requests that infringing goods are destroyed when this would “prejudice the national economy” and convert such requests into damages awards. A further, statutorily entrusted discretionary power is that of ordering that withdrawal of the infringing goods from the market is only temporary, as needed to operate modifications that would make the goods non-infringing and therefore legitimate.

A general clause of the Italian IP Code provides that courts must always ensure proportionality between the remedies awarded and “the intensity of the infringement (ie, the offence) as well as third parties’ interests” has been used to start and progress a debate on whether the judge has discretion to refuse injunctive relief in cases where the latter can negatively affect public interests. The current position, which is reflected in a number of recent judgments, is that injunctive relief can never be denied, but modulated so as to strike a balance with those interests (for instance, by means of ordering “phase-out” periods).

## 6.2 Rights of Prevailing Defendants

The right to recover legal costs and attorney’s fees from the losing party applies to all winning parties, including (winning) defendants. Attorney’s fees are awarded based on a flat-rate scheme set forth in a specifically dedicated piece of legislation. The amounts awarded would normally not cover the actual expenditure.

Defendants are entitled to seek preliminary injunction damages in cases where a granted preliminary injunction is subsequently lifted further to the patent being revoked or found not to be infringed in subsequent main proceedings. The threshold for this kind of liability is that the patentee must have taken action with gross negligence or bad faith, which is typically quite a high bar to meet. Preliminary injunction damages are, for this reason, very rare.

## 6.3 Types of Remedies

The only remedy that is specifically applicable to invention patents only is the possibility of requesting the court to convert the patent into a utility model patent, if the invention patent is found invalid and provided that the requirements for the protection of utility models are met.

Italian utility models are different from utility models as known in other jurisdictions. They can be granted for mechanical appliances only and only for those new models or configurations that improve on the efficacy or ease of use of known machines, tools or equipment in general.

## 6.4 Injunctions Pending Appeal

Injunctions, whether preliminary or permanent, are effective and binding on the affected party as of publication of the related judgment. No enforcement steps are required.

An appeal does not automatically stay the injunction. A stay must be applied for by the appealing party. In preliminary proceedings, a stay is granted only in view of newly arisen facts or circumstances that were not known at the time of the injunction. In main proceedings, a stay is granted only in the presence of “serious and compelling reasons”, which include the likelihood of the judgment (and the remedies ordered thereto) being reversed on appeal. The

threshold is in both cases very high. Having an injunction stayed is normally very difficult.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

The most impacting provision on appeal is the ban of any new evidence (whether documentary or from witnesses) that the parties could have introduced during the first instance proceedings. New evidence is only accepted in cases where said evidence could not possibly be introduced during the first instance, for reasons beyond the control of the requesting party. This rule applies before the Appeal Court and in main proceedings only. The filing of additional evidence on appeal in preliminary proceedings is generally permitted.

### 7.2 Type of Review

Appeals imply a full review of the case, the only limit being the recourse to additional evidence in main appeal proceedings (see **7.1 Special Provisions for Intellectual Property Proceedings**).

Appeal judgments can be further appealed before the Supreme Court. As opposed to second instance appeal, Supreme Court appeals will imply a legal review only and no further assessment on the facts.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

Unlike in other law systems and jurisdictions, under Italian law, patent cases can be filed in court without giving prior notice to the defendant. Notice or warning letters may serve a strategic purpose or function depending on the case,

but are not mandatory in order to start a case in court. Also, under Italian law, tools such as protective briefs are not admissible.

Besides the costs that are typically requested to run an assessment of and prepare the case before filing, a significant cost item might be represented by search proceedings, which the patentee may need to file before starting infringement proceedings and with a view to collecting evidence of the infringement, in cases where the latter is available at the infringer's premises only. The costs of search proceedings range between a few thousand euros to six-digit figures, depending on the complexity of the case and the technology at stake.

### 8.2 Calculation of Court Fees

The court fees for commencing proceedings or bringing a counterclaim in already pending proceedings are determined based on the claim's value, regardless of the number of enforced patents or defendants (in main claim or counterclaim). Court fees are negligible compared to those in other jurisdictions. They range between a minimum of EUR86 and a maximum of EUR3,372 for first instance proceedings and a minimum of EUR129 and a maximum of EUR5,058 for appeal proceedings. Court fees for the proceedings before the Supreme Court range between a minimum of EUR86 and a maximum of EUR3,372.

### 8.3 Responsibility for Paying the Costs of Litigation

The "loser pays" principle applies in Italy (see **6.2 Rights of Prevailing Defendants**). The costs and attorneys' fees that courts award based on their binding, statutorily applicable flat-rate scheme do not necessarily (and normally do not) cover the winning party's actual expenditure.

Furthermore, upon issuing their decision, judges have a discretionary power to “balance” costs and attorneys’ fees (each party bears its own costs) in cases where each of the parties has seen some of its claims dismissed or if the court had to tackle completely new legal issues or reverse existing case law in deciding the case.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

Alternative dispute resolution such as arbitration proceedings are possible. It is to be noted that by Legislative Decree No 149/2022 the powers of arbitrators have been extended to the issue of preliminary measures in the course of arbitration; however, before the arbitration starts, the court maintains exclusive jurisdiction to issue preliminary measures. However, ADR is not a common way of starting or settling a patent case and there is little or no practice of the use of ADR in patent disputes.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

Patents and the exclusive rights stemming from patents are always transferable, except for the moral right to be named as the inventor. The assignment of a patent follows the rules governing the transfer of “registered assets” set forth in the Civil Code. In a nutshell, and while the general rule is that there are no particular formal requirements to meet, any transfer or subsequent assignment should be registered on the Italian Patent Register. A registered assignment can be opposed to parties claiming a prior right

to the patent and shifts the burden of proving their better right to them.

### 10.2 Procedure for Assigning an Intellectual Property Right

Assignment per se requires little in the way of formalities and can in principle happen verbally. Written evidence is nevertheless required to prove the existence of an assignment, which makes it advisable to sign a proper assignment agreement. Registration on the Italian Patent Register requires that either a copy of the actual assignment agreement or a confirmatory declaration signed jointly by both the assignor and assignee is presented and filed with the IPTO.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

Patent licensing is not subject to specific formalities. There is no requirement to register the licence with the IPTO, nor to give the latter prior notice before issuing the licence.

Licence agreements can nevertheless be registered with the IPTO by filing either a copy of the actual licence agreement or a confirmatory deed signed jointly by licensor and licensee. While registering a licence agreement is not a requirement, this is done often for evidentiary reasons: ie, to prove the licensee’s status of licensee, typically in cases where an exclusive licensee (who has standing to bring an infringement action of its own) wants to institute infringement proceedings and at the same time avoid filing the licence agreement in court.

### 10.4 Procedure for Licensing an Intellectual Property Right

Licensing does not require particular formalities. Written evidence is nevertheless required to prove the existence of a licence, which makes it advisable to sign a proper licence agreement.

Contributed by: Daniela Ampollini and Luca Pellicciari, **Trevisan & Cuonzo**

Registration on the Italian Patent Register requires that either a copy of the actual licence agreement or a confirmatory declaration signed jointly by both licensor and licensee is presented and filed with the IPTO.



Contributed by: Daniela Ampollini and Luca Pellicciari, **Trevisan & Cuonzo**

**Trevisan & Cuonzo** was established in 1993 and is one of the leading independent Italian law firms working with some of the most technologically advanced and innovative businesses and industry leaders around the globe. The firm has established a commanding reputation both domestically and internationally for its success and in-depth business and industry knowledge in intellectual property, commercial and product liability litigation. Since its establishment, the firm has earned a formidable reputation for its

success in patent litigation, winning landmark cases on behalf of the world's most innovative companies in the electronic, biotech, pharmaceutical, automotive, chemicals and consumer goods sectors. A large number of these cases have been fought on a multi-jurisdictional level, in close co-operation with lawyers and experts from different jurisdictions acting in parallel proceedings. The firm has a network of offices in Milan, Rome, Parma and Bari.

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# Trevisan & Cuonzo

## Law and Practice

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

The Japanese legal system covers two types of intellectual property rights in relation to the protection of inventions: patent rights and utility model rights. Both systems are based on statutory laws, namely the Patent Act and the Utility Model Act.

### 1.2 Grant Procedure

#### Patents

The Patent Act employs a substantive examination principle for the patent grant procedure. To obtain a patent right for an invention, a patent application must first be filed with the Japan Patent Office (JPO). A request for examination must also be filed within three years from the date of filing the patent application, or the patent application will be deemed withdrawn.

An examination will be carried out by an examiner of the JPO, who will decide whether the patent application fulfils all the requirements prescribed by the Patent Act.

If the examiner finds any reason for rejection, a notice of reason for rejection will be issued. An applicant who has received a notice of reason for rejection will be given the opportunity to file a written argument and/or an amendment in response to that rejection.

If the examiner finds no reason for rejection in the patent application, or finds that the rejection has been overcome, they will issue a decision to grant a patent for the patent application. A patent will be granted once the applicant pays the registration fees for the first three years.

#### Utility Models

In contrast to patent applications, the Utility Model Act does not require a substantive examination for applications for utility model registration (ie, for all applications that have passed formal examinations), the utility model right will automatically be registered without going through a substantive examination. The registration fees for the first three years must be paid at the time of filing the utility model application.

### 1.3 Timeline for Grant Procedure

#### Patents

According to statistics issued by the JPO, the average period from filing a request for examination to issuing a final decision (either a decision to grant or a decision to reject) was 15.2 months in 2021. Also, the average grant rate was 74.8% in 2021.

Domestic applicants do not need representation in order to initiate grant proceedings, but foreign applicants do need representation in order to initiate grant proceedings.

The typical costs incurred from filing to grant are JPY1 million, comprising official fees of JPY200,000 and lawyers' fees of JPY800,000. The official fees vary depending on the number of claims. Also, additional fees for translating certain documents (eg, the specification and notice of reason for rejection) may be incurred, where necessary.

#### Utility Models

The typical costs incurred from filing to grant are JPY200,000, comprising official fees of JPY20,000 and lawyers' fees of JPY180,000. The official fees vary depending on the number of claims. Also, additional fees for translating certain documents (eg, the specification) may be incurred where necessary.

## 1.4 Term of Each Intellectual Property Right

### Patents

The term of a patent right is 20 years from the date of filing the patent application. There are, however, some exceptions:

- if the establishment of a patent right is registered on or after the date on which five years have passed since the date of filing of the patent application, or the date on which three years have passed since the date of filing of a request for examination of the application, whichever is later (Base Date), the term may be extended by the period calculated by deducting a certain period from a period equivalent to the Base Date until the date of registration of establishment of the patent right; and
- the term may be extended by up to five years on request if the invention is unable to be used due to the time spent obtaining an approval or any other dispositions under a law intended to ensure safety, as prescribed by a Cabinet Ordinance.

### Utility Models

The term of a utility model right is ten years from the date of filing the utility model application. A utility model application or right may be converted to a patent application within three years from the date of filing the utility model application.

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

Both patent-owners and utility model-owners have the right to an injunction, the right to claim damages and the right to claim for unjust enrichment. Also, patent-owners and utility model-owners are under an obligation to pay annual renewal fees in order to maintain their rights.

It should be noted that, since a substantive examination is not required for applications for utility model registration, a utility model-owner may only exercise their utility model right against an infringer after giving a warning together with presenting a Utility Model Technical Opinion Report for the registered utility model. This Report is an assessment of the novelty and inventive step of a registered utility model right by a JPO Examiner, based on a search of prior art documents. A request for such Utility Model Technical Opinion Report can be made at any time after the application for a utility model has been filed.

In Japan, there is no public information listing applicable patents in relation to certain products or processes. Although there is a public database of patent information in Japan called [J-PlatPat](#), J-PlatPat does not have any functions to search applicable patents in relation to certain products or processes.

## 1.6 Further Protection After Lapse of the Maximum Term

There is no further protection for technical intellectual property rights after their maximum term has lapsed.

## 1.7 Third-Party Rights to Participate in Grant Proceedings

Anyone may file a third-party observation at any time after the filing of a patent application or an application for utility model registration, even after a patent or a utility model right has been granted. Third-party observations may include not only prior art information or a submitter's comments regarding the novelty or inventive step of the claimed inventions, but also other information or comments regarding other requirements, such as the addition of new matter, the support requirement, or the enablement

requirement. Third-party observations may be filed on an anonymous basis.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right Patents

An applicant may file an appeal with the JPO against a decision of rejection issued by a JPO examiner. The patent application will then be examined by a board of three appeal examiners to determine whether the decision to reject was appropriate. The applicant is allowed to make amendments to the scope of claims, specification or drawings at the time of filing an appeal against the decision of rejection. If those amendments are made, the application will first be re-examined by the examiner who issued the initial decision of rejection before it is transferred to a board of appeal examiners.

If the initial examiner finds that the amended application has been improved to the extent that it may be approved, a decision to grant will be issued without the application being transferred to a board of appeal examiners. However, if the initial examiner still believes that the application should be rejected, the application will be transferred to the appeal stage and examined by a board of appeal examiners.

### Utility Models

No remedy is available or applicable for utility model applications because the Utility Model Act does not require a substantive examination for the granting of a utility model right.

## 1.9 Consequences of Failure to Pay Annual Fees

If a patent-owner or a utility model owner fails to pay the annual fees by the specified deadline, they can still make a late payment by paying a surcharge in addition, and equal, to the annual

fee within the six-month grace period after the expiry of the deadline.

Furthermore, if there is a justifiable reason the patent-owner or the utility model-owner could not make the payment deadline, they can make a late payment (without the surcharge) within two months from the date on which that reason, or those reasons, ceased to exist but, in any event, no later than one year following the expiry of the deadline for the late payment. Please note that the amended Patent Act which relaxes the above requirement of “a justifiable reason” is scheduled to come into effect on 1 April 2023, and on and after that date, additional payment will be permitted except in the case of a “wilful” failure to make the payment deadline. The procedures for such late payment will be separately stipulated by an Ordinance of the Ministry of Economy, Trade and Industry.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

Both patent-owners and utility model-owners may file a request for a trial for correction with regard to correcting the description, the scope of claims or the drawings attached to the application.

The purpose of the correction is limited to the following.

- Restriction of the scope of claims (including deletion of claims).
- Correction of errors or incorrect translations.
- Clarification of ambiguous statements.
- Dissolution of the claim citation relationship.

The correction cannot be made beyond the scope of the matters disclosed in the description, the scope of claims or the drawings attached to the application.

Utility model-owners are allowed to make a request for correction only once, except for deletion of claims, whereas patent-owners may request a trial for correction as many times as they wish, except where the patent has been invalidated by an invalidation trial or revoked by a patent opposition. Patentees may not request a correction while a patent opposition or invalidation proceeding is pending, but may instead request a correction in the proceedings of the patent opposition or patent invalidation trial.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

If the owner of a technical intellectual property right (eg, a patent) finds that a third party is infringing upon their patent, they can take one or more of the following actions.

- Commence a regular patent infringement suit with a District Court.
- File a petition for a preliminary injunction with a District Court.
- File an import suspension application with the Customs Office.
- Use alternative dispute resolution proceedings, such as mediation or arbitration, if the other party agrees to it.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

Only an interested person may file a request for a trial for patent invalidation. The term “interested person” means a person who has, or potentially will have, their legal interest/standing directly affected by the existence of the patent right. On the other hand, in the Patent Opposition System that came into force on 1 April 2015, any person (not limited to interested persons) may file an

opposition to a patent within six months of the publication date of the Gazette containing the patent. The Japanese Patent Act also provides for three types of non-exclusive licence granted by the JPO Commissioner’s award (eg, compulsory licences). However, as of the end of 2022, no such compulsory licence has ever actually been granted in Japan.

### 2.3 Courts With Jurisdiction

The Tokyo District Court and the Osaka District Court have exclusive jurisdiction over litigation relating to patent rights and utility model rights in the first instance. In which court a plaintiff should file a lawsuit depends on the defendant’s corporate address and the location of the infringing activity. The Japanese Intellectual Property High Court (IPHC) has exclusive jurisdiction over appeals from District Court decisions. The IPHC is a special branch of the Tokyo High Court. Parties may appeal decisions of the IPHC to the Supreme Court.

### 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

The Japan Intellectual Property Arbitration Center (JIPAC) provides alternative dispute resolution services such as mediation or arbitration in the field of intellectual property. In addition, the International Arbitration Center in Tokyo (IACT) – an international arbitration organisation that is expected to provide disputes resolution services – commenced operation in September 2018.

### 2.5 Prerequisites to Filing a Lawsuit

There are no statutory prerequisites for filing a lawsuit. However, as patent rights and registered exclusive licences become effective upon the establishment of registration with the JPO, such registration will be required when a patentee or registered exclusive licensee brings a claim for damages and/or an injunction based on



that patent right or registered exclusive licence. It is, however, generally considered that such registration will not be required when a non-registered exclusive licensee brings a claim for damages based on a non-registered exclusive licence.

## 2.6 Legal Representation

In Japan, a party may choose at their own discretion whether to have legal representation. However, in practice, it is common for lawyers to represent parties in intellectual property matters. Patent lawyers can also represent parties for certain intellectual property cases under certain conditions.

## 2.7 Interim Injunctions

Preliminary injunctions are available in cases where such injunctions are necessary for a rights-owner to avoid any substantial detriment or imminent danger with respect to the rights in dispute. If a request for a preliminary injunction is granted, the rights-owner will usually be required to deposit a certain amount of money as security. The amount of that security will be determined by the court in consideration of the circumstances of the specific case. It should be noted that a relatively large amount of money may be required to be deposited as security.

Since a preliminary injunction substantially achieves an injunction against the other party's conduct before the lawsuit is finalised, in a preliminary injunction case, a hearing of both the rights-owner and the other party is required, and prima facie evidence of a similar level to the proof required in the lawsuit is often required. In general, preliminary injunctions are intended to resolve disputes more quickly than litigation; however, the speed of trial is often not so different from that of litigation because of the above-mentioned need for prima facie evidence.

## 2.8 Protection for Potential Opponents

A potential defendant can file a request for a patent invalidation trial before the JPO and/or initiate a lawsuit for a declaratory judgment to confirm the absence of the right to demand an injunction, etc. There is no need for a potential opponent to lodge a protective brief in order to take these actions. It should be noted that a potential opponent is not entitled to require the owner to post a bond under the Civil Preservation Act, but a court usually orders the owner to deposit a certain amount as a security when issuing an interim injunction order.

## 2.9 Special Limitation Provisions

There are no special limitations applicable only to intellectual property matters.

Claims for injunctions based on patent rights may be filed at any time if infringement of the patent rights exists or a threat of infringement of the patent rights is recognised.

The claim for compensation for loss or damage by tort of patent infringement is extinguished by prescription if the right is not exercised within three years from the time when the patentee comes to know the damage and the identity of the infringer, or if the right is not exercised within 20 years from the time of the tortious act, pursuant to the provisions of the statute of limitations provided in the Civil Code of Japan, which is a general law. Please note that the above prescription period may be renewed or the expiry of prescription period may be postponed, for statutory reasons.

## 2.10 Mechanisms to Obtain Evidence and Information

Although there is no discovery procedure in Japan, the Patent Act provides that a court can

order a party to produce documents upon the other party's request for the purposes of:

- proving infringing activities if prima facie evidence of such infringing activities is provided; or
- calculating damages if the court tentatively concludes that the intellectual property rights infringement has been established.

However, this will not apply where the accused infringer possessing the documents has reasonable grounds to refuse to produce them.

When the court finds it necessary to determine whether there are reasonable grounds, it may demand that the person with the documents present them for review in camera. Furthermore, on 1 July 2019, the amended Patent Act introduced a procedure in which the court can determine the necessity of document production by way of in-camera procedures. The amended Patent Act also introduced a procedure that allows expert advisers to participate in such a procedure.

Moreover, by way of the 2019 amendment to the Patent Act, an inspection system was introduced on 1 October 2020, under which an inspector designated by the court will be entitled to enter into the factories, offices, etc, of a defendant and collect evidence necessary to make a decision on the existence of facts regarding the alleged infringement. However, the requirements for conducting an inspection are strictly stipulated, as follows.

- It can be deemed that it is necessary to collect evidence (necessity).
- There are reasonable grounds for suspecting the existence of patent infringement conducted by the adverse party (probability).

- It is expected that no other means can be utilised to collect evidence (replaceability).
- It is not considered inappropriate to conduct an inspection due to an inappropriate burden being placed on the adverse party or any other circumstances (appropriateness).

## 2.11 Initial Pleading Standards

A complaint must contain both parties' names and addresses, and the plaintiff's lawyer's name and address (if appointed), the gist of the demand and the grounds for the demand. In particular, each accused product and act of infringing conduct must be specified in detail, and the relevant features of the product must be described and compared with each element of a claim. In general, supportive evidence – to prove both the act of infringing conduct and the relevant features of the product – is submitted together with the complaint. To identify these facts and find the relevant evidence, a patentee is expected to conduct a sufficiently detailed investigation and analysis of a case prior to initiating a lawsuit.

There are no special provisions for lawsuits in intellectual property proceedings that differ from those for non-intellectual property proceedings.

It is acceptable to supplement pleadings with additional arguments. A court examines the case through periodic hearing procedures (generally once a month), and each party is allowed to add its legal/factual arguments or evidence in the course of these procedures. The plaintiff may even expand or amend the claim or statement of claim until oral arguments are concluded. However, the courts may limit such additional arguments or evidence if it considers that they would substantially delay court proceedings.

## 2.12 Representative or Collective Action

The legal system does not allow for representative or collective actions for intellectual property rights proceedings, although if the subject matter of the suits is common to two or more persons, or is based on the same factual or statutory cause, these persons may sue or be sued as co-parties.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

### Civil Code

As an abuse of rights is prohibited under the Civil Code, the same will apply to the execution of patent rights, and therefore, where the execution of such rights is abusive, that execution will be restricted.

For example, the act of filing a lawsuit may cause tort liability where such litigation is found to be significantly unreasonable in light of the purport of the litigation system (eg, the allegation of infringement is entirely baseless and the owner of the intellectual property right is fully aware of the lack of legal grounds). In addition, based on judicial precedents, a patent right-holder who has made a declaration of fair, reasonable and non-discriminatory (FRAND) terms will not be permitted to claim for an injunction or for licence fees against a party who intends to be licensed under FRAND terms beyond those terms, as this will fall under an abuse of rights.

### Guidelines for the Use of Intellectual Property

In addition, the Japan Fair Trade Commission (JFTC) has stipulated that its Guidelines for the Use of Intellectual Property (IP Guidelines) under the Antimonopoly Act clearly show the principles of the use of intellectual property rights, including patent rights, under the Act. In January 2016, the JFTC partially amended the IP Guidelines and supplemented descriptions related to the

Standard Essential Patent under the Antimonopoly Act. If a patent right has been exercised in a manner that violates these Guidelines, there is a possibility that the act will be considered a violation of the Antimonopoly Act.

### Unfair Competition Prevention Act

Furthermore, if the owner of the intellectual property right makes or disseminates a false allegation of infringement of that intellectual property right, that act could constitute an act of unfair competition under the Unfair Competition Prevention Act, and the owner of the intellectual property right may be subject to a claim for injunction and/or damages.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

A patent-owner and an alleged infringer are usually the necessary parties to patent infringement litigation. A registered exclusive licensee is entitled to file an action without the patent-owner, based on an infringement of the registered exclusive licence, seeking the same remedies as the patent-owner. In this regard, there are arguments over whether non-registered exclusive licensees or non-exclusive licensees can initiate an action for infringement.

With respect to injunctions, it is generally considered that neither a non-registered exclusive licensee nor a non-exclusive licensee is entitled to claim for an injunction, whereas in the case of a claim for damages, a non-registered exclusive licensee may make such a claim, although a non-exclusive licensee is not permitted to claim for damages.

## 3.2 Direct and Indirect Infringement

For a direct infringement to be constituted, the product in question needs to satisfy all of the component features of a patented invention. If any one of the constituent features is not satisfied, a direct infringement has not been constituted.

However, even if the product does not satisfy all of the component features, the following cases will constitute indirect infringement, thus constituting patent right infringement.

- An act of the accused infringer producing, for instance, a product to be used exclusively for making a product of a patented invention, or a product to be used exclusively for the use of a patented invention.
- An act of the accused infringer producing a patented invention or a product that is to be used exclusively for the use of a process of a patented invention (excluding those widely distributed within Japan) and which is indispensable for that invention's resolution of the problem, knowing that the invention is a patented one and that the product is used for the working of that invention.
- An act of the accused infringer possessing for assignment, etc, or exporting a product of a patented product or a product that is produced by using a process of a patented invention.

In any of these instances, where direct infringement or indirect infringement is constituted, a patentee may claim for injunctions and damages against an infringer. In a claim for damages, provisions such as those on the presumption of the amount of damage or those on the presumption of negligence may be applied.

## 3.3 Process Patents

In the Japanese Patent Act, inventions are classified either as the invention of a product, the invention of a process, or the invention of a process for producing a product, and an act of working a patented invention is stipulated for each of these categories. Specifically, for the invention of a process, the act of using the process is stipulated as an act of working. Furthermore, for the invention of a process for producing a product, acts of using the process and acts of using, assigning, etc, exporting or importing, or offering to assign, etc, a product produced by the process are stipulated as acts of working. On the other hand, for the invention of a product, acts of producing, using, assigning, etc, exporting or importing, or offering to assign, etc, the product, are stipulated as acts of working.

There is no definite rule as to whether the infringement of a patent right in Japan can be recognised when part of the invention of a process is worked abroad. In cases where some of the steps in the invention of a process were carried out outside Japan, there is a District Court case which judged that this cannot be regarded as working the patent in Japan because the act which belongs to the technical scope of the patent is not completed in Japan; however, this court ruling is not considered to be a well-established rule generally applicable to the invention of a process in Japan.

## 3.4 Scope of Protection for an Intellectual Property Right

In principle, the scope for protection of a patent right (eg, the technical scope of a patented invention) is determined based upon the statements in the scope of claims. In addition, the meaning of each term used in the scope of claims is interpreted in conjunction with the statements in the description and drawings. The prosecu-

tion history of the application and the prior art may also be taken into consideration. Accordingly, to say that infringement of a patent right has taken place in principle, the subject product must satisfy all of the constituent features of the patented invention. However, even if the product does not satisfy all of the constituent features of the patented invention, there may be a case that amounts to indirect infringement or infringement under the doctrine of equivalents (see **3.2 Direct and Indirect Infringement**).

### 3.5 Defences Against Infringement

If a patent right has been exercised in an abusive manner (for example, when a patent right-holder who has made a declaration of FRAND subsequently makes a claim for an injunction against a party who intends to be licensed under FRAND terms or makes a claim for damages in excess of an amount equivalent to a licence fee under FRAND terms), a defendant may assert the defence of abuse of rights.

If the defendant has practised a patented invention or made preparation for such practice at the time of the filing of the patent application, the defendant can claim “prior use” as a defence.

If the patentee, when filing an application, makes assertions that exclude the technology that is to be included in the technical scope of a patented invention (based on the common meaning of the term being used), it is common for the technical scope of the patented invention to be construed in a limited manner as a result.

Where the products in question were being assigned from a patentee or person who has legitimate rights, no patent infringement will be admitted, as the patent right will have been exhausted.

In addition, the defendant may claim that their use of the patented invention was experimental and therefore beyond the scope of the patent right.

Even though the Patent Act provides for three types of non-exclusive licences granted by the JPO Commissioner (eg, compulsory licences), as of the end of 2022, no such compulsory licence has ever actually been granted in Japan.

The fact that the defendant’s infringing conduct was an exercise of their own patent right cannot be used as a defence against the patentee’s claim of infringement.

As to the statute of limitations, the patentee cannot claim damages for an infringement if more than three years have passed since the date on which the patentee became aware of an infringement and the identity of the infringer who caused the damage. There is an overall limit of 20 years from the act of infringement.

### 3.6 Role of Experts

Experts who get involved in patent litigation are mainly judicial research officials and expert advisers.

Judicial research officials are full-time court employees who conduct examinations on technical matters necessary for judicial decisions, and report to a judge. It is mostly JPO employees or patent lawyers who are appointed as judicial research officials.

Expert advisers are part-time employees, appointed by the courts, who get involved in proceedings to arrange issues and evidence, to examine evidence, and to enter into a settlement in the court proceedings. Expert advisers are usually involved in proceedings to arrange

issues and evidence (preparatory proceedings, etc) and to make oral explanations on technical matters. In patent litigation, in order to have a proper understanding of technical issues, expert advisers are often involved and conduct technical explanation sessions in preparatory proceedings. It is common for an expert in the technical field to which a patented invention belongs (usually a university professor or patent lawyer) to be appointed as an expert adviser.

In addition, in litigation, experts selected by a party may prepare expert opinions, which are submitted as evidence by the party, but rarely testify in court as witnesses.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

There is no separate procedure for claim construction.

### 3.8 Procedure for Third-Party Opinions

A system by which the court can seek third-party opinions in lawsuits relating to patent infringement was introduced on 1 April 2022 by the amendment of the Patent Act of Japan in 2021. Under this system, if a party requests it and the court finds it necessary, the court may request the public to submit documents stating public opinions on the application of the Patent Act of Japan or any other necessary matters after hearing the opinion of the other party. It is envisioned that this system will be used in patent infringement cases where the judgments may have significant impacts not only on an industry to which the parties belong but also on companies in other industries, such as cases related to standard-essential patents and/or advanced technologies in the fields of artificial intelligence (AI) and/or the internet of things (IoT).

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation Patents

There are two procedures available for seeking the revocation/cancellation of a patent – namely, an opposition or an invalidation trial before the JPO.

An opposition may be filed by anyone within six months from the issue date of a patent Gazette, based on the following grounds.

- Violation of requirements for patentability, such as novelty, inventive step, double patenting, etc.
- The addition of new matter.
- Violation of description requirements.
- Violation of a treaty.

An interested party may file an invalidation trial at any time after a patent has been granted, even if it has expired, based on the following grounds.

- Violation of requirements for patentability, such as novelty, inventive step, double patenting, etc.
- Addition of new matter.
- Violation of description requirements.
- Violation of a treaty.
- The patent having been granted on a patent application filed by a person who is not the inventor and who has not succeeded to the right to obtain a patent for the invention.
- The correction of the description, scope of claim or drawings attached to the application for the patent having been obtained in violation of the provisions under the Patent Act.



## Utility Models

There is only one procedure for the revocation/cancellation of a utility model registration, which is an invalidation trial before the JPO.

An interested party may file an invalidation trial at any time after a utility model has been granted, even after the utility model has expired, based on the following grounds.

- Violation of requirements for registration as a utility model, such as novelty, inventive step, double patenting, etc.
- The addition of new matter.
- Violation of description requirements.
- Violation of a treaty.
- The utility model having been granted on a utility model application filed by a person who is not the inventor and who has not succeeded to the right to obtain a utility model for the invention.
- The correction of the description, scope of claims or drawings attached to the application for the utility model having been obtained in violation of the provisions under the Utility Model Act.

## 4.2 Partial Revocation/Cancellation

An opposition or an invalidation trial for a patent or a utility model registration may be filed for each individual claim.

## 4.3 Amendments in Revocation/Cancellation Proceedings

Amendments (“corrections” in opposition or invalidation proceedings under the Patent Act or the Utility Model Act) may be filed in opposition or invalidation proceedings.

In opposition proceedings, a patent-owner may file amendments in the period for responding to a notice of cancellation issued by the board of

trial examiners who examined the request for opposition.

In invalidation trial proceedings, the owner of a patent or utility model right may file amendments in the period for filing an answer in response to a request for an invalidation trial. The owner may also file amendments in the period for responding to a notice of reasons for invalidation or an advance notice of appeal decision, both issued by the board of trial examiners who examined the request for invalidation trial.

## 4.4 Revocation/Cancellation and Infringement

In patent or utility model infringement litigation heard before the courts, both infringement and invalidation issues may be heard together because the defendant may challenge the validity of a patent or utility model registration as a defence before a court. The courts examine both infringement and validity together, and render a decision based on the examination of infringement and/or validity.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

There are no specifically applicable provisions with respect to trial and settlement for intellectual property rights proceedings. However, in practice, the trial will be divided into two parts. At the first stage (the stage for examination on infringement), the court’s focus is on determining whether the infringement of the intellectual property right is established. At the second stage (the stage for examination of damages), a court will assess the damages incurred by a plaintiff only after it has tentatively concluded the establishment of the infringement.



In this regard, the Intellectual Property Division of the Tokyo District Court has a trial model for patent infringement litigation. According to this trial model, it is assumed that six court hearing dates are held at the first stage (stage for examination on infringement). If courts find that there is no patent infringement, the courts will either (i) make recommendations for settlement after disclosing their opinions, or (ii) conclude oral arguments and render judgments. If courts find that there is patent infringement, the courts will either (i) make recommendations for settlement after disclosing their opinions, or (ii) proceed to the second stage (the stage for examination of damages). It is assumed that three court hearing dates are held at the second stage, and both parties make arguments and counterarguments with regard to amounts of damages. Then, the courts will either (i) conclude oral arguments and render judgments after forming final opinions on the amounts of damages, or (ii) make recommendations for settlement after disclosing their opinions.

However, as the progress of trials (including the number of court hearing dates) depends largely on the complexity of cases, trials rarely proceed as envisioned in the above trial model, and in complex cases trials are often prolonged for much longer than the trial model.

According to the statistics provided by the Intellectual Property High Court, the average time intervals from commencement to disposition in intellectual property-related civil cases in 2021 were 15.2 months (in all district courts) and 6.9 months (in all high courts).

In patent litigation, examination of fact witnesses or experts is rarely conducted. In cases of examination of witnesses, opportunities for cross-examination are provided.

## 5.2 Decision-Makers

A case is determined solely by a legal judge. The Japanese legal system has neither technical judges nor jury trials for intellectual property cases.

In the Tokyo District Court and the Osaka District Court, there are special divisions for intellectual property matters (four divisions at the Tokyo District Court and two divisions at the Osaka District Court), where judges who are experienced in intellectual property matters hear and decide cases. The judges in these courts and in the IPHC do not necessarily have technical backgrounds; the courts retain judicial research officials who have a technical background to help judges understand any technology issues involved in a case (see **3.6 Role of Experts**). The courts can also appoint and request expert advisers to assist judges with any case involving advanced, complicated or specialised technology issues.

Parties cannot influence who will judge a case, although a party can request to avoid a certain judge if they have reason to believe that said judge cannot be impartial, due to a particular relationship with the other party (eg, being a relative of one party).

## 5.3 Settling the Case

A judge usually takes the initiative on settlement negotiations, unless the parties clearly refuse to settle a case. In no event will a defendant be obliged to settle a case. Generally, courts prefer settlements rather than judgments to resolve cases. A judge may disclose or imply their unofficial, tentative opinion on a case to the parties in order to facilitate settlement negotiations. A judge will cease settlement negotiations if one party decides and requests to receive a court decision rather than a settlement.

## 5.4 Other Court Proceedings

Even if there are any pending parallel revocation or infringement proceedings, the current proceedings will not normally be stayed, and the courts will separately and independently make a judgment for a case. The courts can even dismiss a claim for infringement on the ground that the patent is invalid, without the need for a revocation proceeding. Therefore, it is possible for a conflict between two cases on the same subject matter to exist. However, in practice, the High Court, as the court of second instance, will make consistent judgments so that any contradiction in the first instance will be resolved.

There have been no cases where anti-suit injunctions have been issued against litigation in Japan, and it is unclear whether Japanese courts would take into account foreign anti-suit injunctions. In addition, in Japan, there is no statutory basis for granting injunctions against litigation by patentees, and there have been no examples of Japanese courts recognising anti-suit injunctions.

## 6. Remedies

### 6.1 Remedies for the Patentee

#### Remedies Available for the Patentee

The typical remedies available for a patentee are injunctive relief and damages. As part of injunctive relief, the patentee can also demand measures necessary to prevent infringement, including disposal of the infringing goods. Lawyers' fees can be recovered as part of the damages, although the recovery thereof is very limited (in practice around 10% of the total amount of actual damages admitted by the courts). A patentee can only seek compensatory damages. Claims for enhanced damages, such as punitive damages, are not eligible even in cases of

willful infringement. The Patent Act provides for certain presumptions of the damages that are to be calculated based on the profit from the infringement or the assumed royalties. A judge has the discretion to determine the appropriate remedies or amount of damages, provided that the discretion is only applied within the amount of the claim made by a plaintiff.

In addition, where an applicant has given a warning, together with documents stating the contents of the invention claimed in the patent application, that applicant may also claim compensation equivalent to the licence fee against any person who has worked the invention as a business after the warning and before the registration of the patent. Furthermore, even without such a warning, the applicant may claim compensation against those who, while being aware that the invention relates to a patent application that has been published, have worked the invention as a business before the registration. The right to claim compensation may only be executed after the patent has been registered.

A patentee may also demand measures necessary to restore its business credibility, but this remedy is rarely used.

#### Enforcement of Remedies

The methods for enforcement of remedies depend on the contents of those remedies. For example, with respect to judgments ordering patent infringers to pay damages, the remedies are enforced by seizing the infringers' properties and receiving dividends from the money obtained through auctions, etc. With regard to judgments ordering patent infringers to cease and desist from manufacturing the infringing products, if the infringers do not perform the obligations ordered in the judgment, the court in charge of enforcement will enforce the remedies

by ordering the infringers to pay to the obligees certain amounts of money which are found to be reasonable for securing performance of the obligation.

## 6.2 Rights of Prevailing Defendants

If a defendant prevails, the courts can order the plaintiff to pay court costs (eg, transportation fees to attend court hearings, expenses for delivering documents and daily allowances for witnesses); however, such costs do not include the defendant's legal fees or other costs incurred by the defendant in the course of the procedure. There is no right or remedy for a prevailing defendant to recover their own costs.

A prevailing defendant may seek damages arising out of the infringement litigation, including their lawyers' fees, if the litigation itself is considered to constitute a tort on the grounds that it is found to be unreasonable (eg, if an allegation of patent infringement is entirely baseless and the patentee is fully aware of the lack of legal grounds). However, the courts rarely accept such a claim.

## 6.3 Types of Remedies

There are no different remedies for different types of technical intellectual property.

## 6.4 Injunctions Pending Appeal

To stop the execution of an injunction granted at first instance, an infringer will, upon filing an appeal, have to file a petition to seek a ruling on the suspension of compulsory execution. Here, the infringer will need to provide a security deposit (to be returned after litigation).

Under the laws of Japan, injunctions are enforceable pending appeal. However, in practice, when infringers file an appeal, the infringers also file a motion for suspension of compulsory execution

in most cases, and such suspensions are usually granted if the motion is filed.

The above refers to judgments for injunctions of the first instances in main lawsuits. On the other hand, if right-owners request preliminary injunctions separately from (or in parallel with) the main lawsuits and the first instance courts grant the requests and issue preliminary injunction orders, it is difficult to stop enforcement of such preliminary injunction orders in practice, although there is a legal way to challenge such preliminary injunction orders (see 2.7 Interim Injunctions).

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

Generally, there are no special provisions concerning the appellate procedure for patent litigation. Note, however, that the IPHC has exclusive jurisdiction over appeals from decisions made by the Tokyo District Court and the Osaka District Court on patent litigations. A court normally consists of three judges, but if the case includes an important issue of law, five judges may sit to consider the matter and deliver their opinion.

### 7.2 Type of Review

As the court of second instance, the IPHC reviews not only issues of law but also the facts from the proceedings in District Courts in the first instance. The IPHC may also conduct factual findings of its own. A party may submit additional legal arguments, facts or evidence to the appeal court, unless such an additional claim is considered to be causing delay to the procedure and to be that party's fault. However, the Supreme Court, as the court of final instance, only reviews the legal issues of a case.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

With respect to patent infringement litigation, costs normally incurred are for:

- investigating a product or method;
- conducting searches for prior art references;
- sending warning letters; and
- preparing for litigation.

### 8.2 Calculation of Court Fees

Stamp fees and expenses for delivering documents are required in order to file a lawsuit. The amount of stamp fees is calculated according to a formula prepared by the court based on the value of the subject matter of the suit.

### 8.3 Responsibility for Paying the Costs of Litigation

In general, court costs (such as stamp fees, expenses for delivering documents and daily allowances for witnesses) are borne by the losing party, provided, however, that the proportion of the responsibility for the court costs is left to the court's discretion and that the courts may allocate the responsibility of court costs to the prevailing party in proportion to the part of their claim that is not accepted by the courts.

It should be noted that court costs do not include lawyers' fees and thus, generally speaking, each party must bear their own lawyers' fees. A plaintiff may seek compensation for their lawyer's fees as part of damages, but the recovery rate is left to the court's discretion and is usually quite limited, even if the plaintiff wins the case (in practice around 10% of the total amount of actual damages admitted by the courts).

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

Alternative dispute resolution (ADR) is not a common way to settle intellectual property cases in Japan. However, ADR such as mediation or arbitration is available, and JIPAC and IACT (see 2.4 **Specialised Bodies/Organisations for the Resolution of Disputes**) are the ADR organisations that provide for dispute resolution in the field of intellectual property.

Moreover, the Tokyo District Court and the Osaka District Court introduced mediation procedures for intellectual property rights matters on 1 October 2019. This procedure is designed to resolve disputes regarding intellectual property rights matters in a speedy and efficient manner by using a mediation committee made up of a judge from the special division for intellectual property matters and experts such as lawyers or patent attorneys, who orally express their opinions. In principle, the procedure is supposed to be concluded within around three hearing dates.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

Patent rights may be freely assigned. However, no assignment will take effect without having been registered on the patent registry, except in cases of general succession, such as inheritance or merger. Where a patent right is jointly owned, no joint owner may assign their share without the consent of all the other joint owners. Neither an agreement in writing nor an approval from the JPO is necessary for conducting an assignment.

## 10.2 Procedure for Assigning an Intellectual Property Right

Assignment of a patent right comes into effect by being registered on the patent registry. In the case of a general succession, such as through inheritance or merger, the assignment comes into effect without being registered, but the registration is made by providing notification of that assignment.

## 10.3 Requirements or Restrictions to License an Intellectual Property Right

In terms of licensing patent rights, there are licences granted merely by an agreement between the parties (non-registered licences) and licences granted upon registration at the JPO (registered as exclusive licences), in addition to an agreement between the parties. As for the former type of licence, there are no particular restrictions regarding formalities, such as the existence of a written agreement or notification to the JPO, etc. However, the latter type of licence requires registration at the JPO in order for it to enter into force. It should be noted that if a registered exclusive licence is granted, the scope of rights subject to that grant may not be executed by other parties, even the patent right-holder.

## 10.4 Procedure for Licensing an Intellectual Property Right

As the grant of a registered exclusive licence requires registration at the JPO in order for it to come into force, it is necessary to make an application to the JPO setting forth the content of the licence agreed by both parties, and to receive registration thereof. The granting of a non-registered licence comes into force merely by way of the execution of an agreement between the parties. Thus, generally, a licence of this kind is granted by preparing a licence agreement, as well as orally, or even implicitly.

**TMI Associates** has had intellectual property as an integral part of its practice since its establishment. The firm now has extensive experience and expertise in the area, including in patents and trade marks. The team is made up of lawyers and patent/trade mark attorneys, as well as patent/trade mark paralegals, and acts for

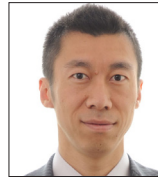
clients across a wide variety of businesses and technologies all around the globe. TMI Associates handles all aspects of intellectual property law, including patent/trade mark prosecution, trials before the Japan Patent Office, infringement litigation, IP due diligence, and import suspension applications before customs.

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TMI Associates



# MACAU SAR, CHINA

## Law and Practice

### Contributed by:

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**Riquito Advogados see p.261**

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

There are two main legal documents that regulate intellectual property rights in Macau:

- the Legal Regime of Industrial Property; and
- the Copyright and Related Rights Regime.

This survey will be limited to industrial property (in particular to invention patents), hence to an overview of the relevant provisions of the Legal Regime of Industrial Property.

Intellectual property rights for the protection of inventions are regulated in the Legal Regime of Industrial Property, which includes, inter alia, protection via invention patent, via utility patent and via industrial model and design.

An invention patent refers to a new technical solution for a product, a method or an improvement to existing technologies.

A utility patent refers to new technical solutions for issues of shape, structure or their combination, in products.

The registration of an industrial model or design refers to the protection of the shape, pattern, colour or their combination, applied in the new design of a product, which is aesthetic and capable of being applied at industrial scale.

Respective protection for these types of patents is based on statutory law.

### 1.2 Grant Procedure Patents

For both invention patents and utility patents, the grant procedure is regulated by the Legal

Regime of Industrial Property and consists of the following steps.

- The applicant files a request with the Economic Bureau of Macau (*Direcção dos Serviços de Economia*, or DSE) and pays the application fees within eight working days from the submission date.
- The DSE shall proceed with the formal examination of the application within two months from submission.
- If no irregularities are found on formal examination the application will be published in the Official Gazette within 18 months from the date of application, if there are irregularities the applicant is notified to rectify them within two months from the DSE's notice.
- Interested parties may oppose the registration, starting from the announcement in the Official Gazette and until the date of grant.
- Afterwards, the applicant shall request substantial examination within seven years from the date of the application.
- The notice of grant will be published in the Official Gazette if there is no opposition or the opposition is found to be without merit.
- If no appeal is filed against the grant of patent, within one month after the publication in the Official Gazette, the DSE will issue the registration certificate.

### Industrial Designs

The grant procedure for industrial models and designs is similar to the one provided for invention patents and utility patents, as detailed above.

### 1.3 Timeline for Grant Procedure Timeline

Please refer to **1.2 Grant Procedure** regarding the timeline for the grant procedure.

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## Representation

For applicants who do not hold a Macau SAR Resident Identity Card, or who are not legal entities registered in Macau SAR and incorporated according to the laws of Macau SAR, legal representation is necessary to initiate grant proceedings. Inventors may appoint an agent through the issuance of a power of attorney to:

- a lawyer registered with the Macau Lawyers Association;
- an individual holding a Macau SAR Resident Identity Card; or
- a legal entity registered in Macau SAR.

This power of attorney must have the signatories' identity, capacity and powers, duly certified by a notary, and must be accompanied by a certified translation if it is not issued in one of the official languages of Macau SAR.

For applicants who hold a Macau SAR Resident Identity Card, or are legal entities duly registered in Macau SAR, no attorney's representation is mandatory to initiate grant proceedings.

## Costs

The average cost for granting an invention patent is MOP3,300, including registration fees as well as fees regarding the substantial examination. The average cost for granting a utility patent is MOP2,900. For industrial models and designs, it is MOP3,500.

## 1.4 Term of Each Intellectual Property Right

For invention patents and utility patents, the duration of the patent shall be 20 years from the date of the application.

For industrial models and designs, the duration of the registration shall be five years from the

date of the application, renewable for periods of five years up to a maximum of 25 years.

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

For invention and utility patents, the owner has the exclusive right to use the patent in Macau SAR and the right to oppose any acts that constitute a breach of patent rights. In particular, this includes the right to prevent third parties, without their consent, from manufacturing, offering, storing, marketing or using a product covered by the patent; or from importing or holding such products for any of those purposes.

The title-holder has the obligation to use the patent in Macau SAR; otherwise, the Chief Executive of Macau can grant a mandatory, non-exclusive licence of that patent.

For industrial models and designs, the registration shall grant its title-holder the exclusive right to use the model or design and to prevent its use by third parties without their consent. In particular, third parties are prevented from offering, placing on the market, importing, exporting or using any product into which that industrial model or design is incorporated, or to which it is applied, as well as from storing any such products. Contrary to what is stipulated in the patents, the lack of use of industrial models or designs does not entail a potential grant in favour of third parties without the title-holder's consent.

Currently, there is no public platform or database in relation to particular products or processes.

## 1.6 Further Protection After Lapse of the Maximum Term

According to the Legal Regime of Industrial Property, there is no protection after the maxi-

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mum term of an intellectual property right has lapsed.

## 1.7 Third-Party Rights to Participate in Grant Proceedings

Please refer to 1.2 Grant Procedure.

Upon publication of the application in the Official Gazette, and until the date when the rights are granted, third parties have the right to approach the DSE in writing with objections to the patentability of the invention subject to registration. This opposition shall be notified to the applicant, who may reply within two months in the case of an industrial model or design, and four months in the case of an invention or utility patent.

Two decisions are possible in light of an opposition: either the objection is founded, or not. In the first case, the DSE shall dismiss the registration or proceed to partial granting in accordance. In the latter case, the DSE will grant the intellectual property right in full, as requested.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

In cases of dismissal of an application to grant intellectual property rights, the applicant may, in accordance with the Macau Administrative Procedure Code (*Código de Procedimento Administrativo*, or CPA), submit an administrative claim to the DSE, requesting a review of the decision. However, such a claim does not suspend the deadline for the applicant to appeal to the courts.

According to the Legal Regime of Industrial Property, a judicial appeal against any DSE decision to grant or not grant IP rights shall be lodged within one month of the date of publication of the decision in the Official Gazette, or the date of issuance of the respective certificate (if earlier and requested by the appellant). Subject

to particulars, the applicant or the title-holder of the intellectual property right in dispute, the claimants, and any of their successors, as well as, in general, every individual or entity directly and effectively harmed by the decision is entitled to submit such an appeal.

## 1.9 Consequences of Failure to Pay Annual Fees

Pursuant to Article 51 of the Legal Regime of Industrial Property, lack of payment of annual fees (*anuidade*) is sanctioned with the expiry of the relevant right (*caducidade*).

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

According to Macau SAR law, the scope of protection conferred by the patent shall be determined by the content of the claims, while the description and drawing serve interpretation purposes.

Amendments to the content of the claims may only be applied for once, and before obtaining grant of intellectual property rights. After obtaining grant, only non-essential elements may be amended. Such non-essential elements refer to corrections that do not affect the characteristics of the invention, the design or models, or constitutive signs of trade mark.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

#### Civil Actions

Intellectual property matters fall under the jurisdiction of civil courts and, therefore, the Code of Civil Procedure is applicable to litigation arising therefrom, in particular in respect of requests for

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a declaration of invalidity of intellectual property rights, or indemnity claims.

Voluntary arbitration may also be entered into by the parties, should they expressly wish to submit the issue to this alternative form of dispute resolution. Please also see **9.1 Types of Actions for Intellectual Property**.

### **Criminal Actions**

Breach of intellectual property rights may also entail criminal liability, pursuant to Articles 289 to 294 of the Legal Regime of Industrial Property. For example, obtaining a benefit for oneself or for a third party within the context of a business activity, without the consent of the title-holder of the respective industrial property right, is punishable by imprisonment for up to two years or a fine. A fine of 60–120 days would be typical in the following cases:

- Manufacturing artefacts or products protected by a patent or semiconductor product topography.
- Use or application of methods or processes protected by a patent or by a semiconductor product topography.
- Importing or distributing products obtained by any of the means referred to above.

### **2.2 Third-Party Remedies to Remove the Effects of Intellectual Property**

Under the general provisions of the Macau Code of Civil Procedure, any individual or legal entity with the necessary capacity may file a lawsuit to protect a violated right, or one that is at risk of being violated by an opposing intellectual property right, provided they are a legitimate party holding a legitimate interest in the proceedings.

This includes the right to request the grant of interim injunctions against the enforcement of intellectual property rights.

### **2.3 Courts With Jurisdiction**

Lawsuits concerning intellectual property matters are generally filed with the Judicial Base Court, but may go up to the jurisdiction of the Court of Second Instance and of the Court of Final Appeal, depending on a variety of legal and procedural requirements expressly provided for in the law.

### **2.4 Specialised Bodies/Organisations for the Resolution of Disputes**

Currently, there are no specialised bodies for the resolution of intellectual property disputes, they are handled by the civil courts.

### **2.5 Prerequisites to Filing a Lawsuit**

Prior registration of the patent with the DSE is necessary to be considered a legitimate plaintiff in a lawsuit for enforcement of industrial property rights. For the purpose of awarding damages, the mere act of requesting an intellectual property certificate will temporarily grant the holder the same legal protection as the definitive intellectual property certificate after due publication in the Official Gazette, provided it is ultimately issued by the authorities.

### **2.6 Legal Representation**

Legal representation in court is required for most cases. Lawsuits with a tax value exceeding MOP100,000, enforcement proceedings with a tax value exceeding MOP1 million, and appeals processes always require legal representation. Only lawyers admitted to the Macau Lawyers Association are allowed to represent the parties in a court of law.

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Where legal representation is not mandatory, the parties may choose to represent themselves or be represented by a trainee lawyer.

## 2.7 Interim Injunctions

It is possible for any of the parties to obtain interim injunctions (including *ex parte*) prior to or during the proceedings. There are several protective or preventive measures to secure rights at risk and, although none of those specifically provided for in the Macau Code of Civil Procedure explicitly applies to intellectual property rights, a so-called “common measure” may be requested from the court on the conditions that:

- the right (ostensibly) exists (*fumus boni juris*);
- there is a well-founded fear that another person may cause serious and irreparable damage to that right (*periculum in mora*); and
- the protective or preventive measure is suitable to protect it.

## 2.8 Protection for Potential Opponents

As is the case with interim injunctions, there are no specific means of protection explicitly available to the opponent in a lawsuit concerning intellectual property matters, although a common protective or preventive measure may be requested from the court, provided that the same conditions listed in **2.7 Interim Injunctions** are met.

## 2.9 Special Limitation Provisions

There are no special limitation provisions applicable to intellectual property matters. In the event of patent infringement, a civil action must be filed within the limitation period of three years and criminal liability must be sought within two to five years, depending on the type of crime in question.

## 2.10 Mechanisms to Obtain Evidence and Information

Certain mechanisms are available to obtain evidence and information from the counterparty or from a third party, such as depositions, interrogatories, requests for production of documents, and expert reports and testimony. In principle, any person aware of any facts or in possession of any evidence relevant to the proceedings is legally bound to co-operate with the court upon request. This includes, *inter alia*, providing witness statements and producing documents. Requests for production of documents may be addressed to the other party or to a third party. The requested documents must be clearly identified and their relevance to the matter established before the court issues the order to surrender the document. Hence, this mechanism does not work as a general means of obtaining evidence and information.

Any person, including the opposing party, may be called to testify before the court. Except for limitation as to the number of witnesses allowed, the court will not exercise any prior control on the witnesses or on their relevance to the case. Witnesses who reside in Macau may be compelled by the court, including by force if necessary, to attend the hearing and provide their deposition, without prejudice to certain individuals’ right to refuse to testify (eg, by virtue of their personal relationship with any of the parties). Should, at any moment during the hearing, a party become aware that any additional person may have knowledge of facts relevant to the proceedings, it may request that the court add that individual to the list of witnesses, in which case the admission will be at the court’s discretion.

As general rule, each party has the burden to both state the relevant facts and adduce supporting evidence in their pleadings. Amend-



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ments to the parties' pleadings are subject to significant limitations and therefore they are obliged to provide as much detail and to adduce as much supporting evidence as possible.

## 2.11 Initial Pleading Standards

As alluded to in **2.10 Mechanisms to Obtain Evidence and Information**, each party has the burden to both state all the relevant facts and adduce, or request the adducing of, supporting evidence in its entirety in their written pleadings, with few exceptions admitted to this rule. Only facts arising from supervening events or new evidence (including evidence not known to the parties at the time of the pleadings) may be stated and adduced after the written pleadings and only until the trial is complete. Considering the inquisitorial nature of the Macau legal system, the court may request that the parties state the facts or adduce the evidence that the court deems pertinent to the discovery of the truth and necessary for a fair trial and judgment.

## 2.12 Representative or Collective Action

Associations or foundations whose purpose is related to the interests in dispute, the Public Prosecutions Office, and Macau SAR citizens are entitled to initiate lawsuits against any public authority for the protection of collective or representative interests such as public health, cultural heritage, or the environment. Should any intellectual property matter fall under these interests, a representative or collective action would, in principle, be possible.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

The title-holder of an intellectual property right has the exclusive right to use/exploit that right within the Macau Special Administrative Region and to assert it against those who violate it by preventing third parties from manufacturing,

offering, stocking, marketing, or using it without consent. Although no opposition can be made to anyone who, in good faith and before the request of the intellectual property certificate was submitted, came to know of the invention by their own means and used it or made effective and serious plans to use it. It should, however, be noted that anyone hoping to benefit from the latter non-contravention provision bears the burden of proof in regard to it.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

Under Macau SAR Law, infringement of IP rights is a criminal offence; therefore, in order to commence infringement proceedings, an infringement claim should be reported before the body responsible for public prosecution (*Ministério Público*), who in turn will open an investigation.

If, during the investigation, sufficient evidence is collected supporting said infringement claim, the prosecution will bring charges against the infringer.

The infringement claim may be reported by any person (or legal entity); however, only the patent owner, licensee(s) (unless otherwise stated within the licensing terms), legally constituted business associations, and the Consumer Council and consumer associations, legally constituted, may intervene in court.

### 3.2 Direct and Indirect Infringement

Direct infringement occurs when the patent claims granted are violated. Indirect infringement occurs when, without the consent of the rights-holder, a person supplies or offers to supply any unauthorised third party with the means, relat-

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ing to an essential element of that invention, for violating granted patent claims.

In both situations (ie, direct or indirect infringement) the patentee, licensees and certain third parties, as mentioned above, have a claim for injunction and damages.

### 3.3 Process Patents

Process patents are not subjected to particular rules regarding infringement; however, it should be noted that Macau SAR courts shall only have jurisdiction over the alleged infringement if there is some connection between the infringement and Macau SAR.

### 3.4 Scope of Protection for an Intellectual Property Right

The scope of protection of an intellectual property right is defined by the patents' claims, which should be interpreted with the aid of its description and drawings.

Furthermore, in light of the acknowledged difficulty in appreciating the inventive step requirement, the judicial courts of Macau may turn to the doctrine of equivalents in order to define an objective approach. By means of this doctrine, equivalent infringement is possible, consequently expanding the scope of protection for an intellectual property right.

### 3.5 Defences Against Infringement

According to Macau SAR law, intellectual property rights are normally granted to the person (or entity) that first filed the invention and thus benefit a party with prior-use rights. Such rights may also be claimed by someone who uses any unregistered trade mark within a period of time not exceeding six months.

As a general rule, patent exhaustion is also applicable to all intellectual property rights, meaning that any non-authorised for-profit manufacturing, supplying, storing, importing, or use of a product covered by a patent, or its importation or possession for any of these purposes, are prohibited.

Lack or insufficiency of use is grounds for applying for a compulsory licence if the rights-holder, without good reason or legal basis, after a period of four years from the date of patent application or three years from the date of patent granting, hasn't put the invention into (sufficient) effect.

### 3.6 Role of Experts

In annulment and infringement proceedings, both parties may request the intervention of a court-appointed expert, who plays a very important role with regard to technical inventions.

Each party may suggest experts, while the opposing one may challenge or suggest someone different or more suitable. The court will appoint the expert(s) after hearing the opinions of both parties.

Once appointed, court experts must diligently perform their duties by providing the judge with a report that addresses the queries raised by the parties and/or by the judge him or herself. When ruling on the case, the judge freely assesses the evidence and is thus not bound by the reports' findings.

Where a compulsory licence application is approved, the DSE and all parties involved shall each appoint an expert to determine the conditions of the licence and the remuneration to be paid to the patent holder.

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### 3.7 Procedure for Construing the Terms of the Patent's Claim

Under Macau SAR Law, a specific procedure for construing the terms of the patent's claims is not required; however, the judge may request the parties to address specific aspects regarding validity and infringement.

### 3.8 Procedure for Third-Party Opinions

The court and/or any of the parties may select a subject or matter which they feel requires expert opinion or guidance due to its highly specialised nature and request that such expertise be provided, for the purpose of which one or more experts will be appointed. In this event, although the expert's report is produced out of court and delivered before the trial, the expert may then be called to testify before the court regarding any question or request for clarification arising from his or her report.

In certain circumstances, the court may order the production of a second expert opinion.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

Intellectual property rights can be disputed either by opposition (in the administrative stage of the registration procedure) or by an annulment lawsuit.

Within the period of publication of the disclosure notice, until the date of granting of the patent, any third party may file a written opposition to the DSE regarding the patentability of the patent in question.

At the end of this period and once granted, industrial property rights can only be cancelled

by the competent courts of Macau (ie, the Court of First Instance) if granted contrary to any of the provisions of the Legal Regime of Industrial Property, and/or contrary to public policy or to accepted principles of morality.

The main grounds for dispute are:

- if the invention's title and its subject matter are not related;
- if the invention's abstract has not been described in an adequately clear and thorough fashion, so as to allow an expert to implement it;
- if the invention's subject matter is extended beyond the content of the initial application; and/or
- if the subject matter of the patent is not new or does not involve an inventive step.

The annulment proceedings may be started by any interested party.

Intellectual property rights may also be cancelled on grounds of expiry (eg, by virtue of reaching the end of respective term, lack of payment of annual fees, or waiver by respective title-holder), which can be argued by any interested party.

### 4.2 Partial Revocation/Cancellation

If the grounds for dispute concern only parts of the patent, a partial annulment lawsuit is possible, which may result in a partially valid patent, as long as the remaining claims constitute patentable subject matter in themselves.

### 4.3 Amendments in Revocation/Cancellation Proceedings

Patent holders are allowed to submit a limited number of requests for amendments, including:

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- until the request for the examination of the patent application is submitted or until DSE receives it;
- following the submission or receipt of the examination report; or
- if submitting a divisional application.

Patent holders may only submit such a request once in each of the above-mentioned situations.

This amendment includes the means to modify the patent's title and/or abstract, as well as introducing a short commentary, however neither should exceed the original contents of the patent application nor extend its original scope of protection.

#### 4.4 Revocation/Cancellation and Infringement

Revocation or cancellation and infringement cases are not heard together. As mentioned in **4.1 Reasons and Remedies for Revocation/Cancellation**, patent cancellation may only be issued by the competent courts of Macau, and therefore should be filed before the Court of First Instance, which does not hear applications for infringement.

Under Macau SAR Law, patent infringement entails a criminal offence, and thus such a claim should be reported to the body responsible for public prosecution (ie, the *Ministério Público*), who will open an investigation. Please see **3.1 Necessary Parties to an Action for Infringement** for more information.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

Currently, there are no special procedural provisions for intellectual property rights proceedings.

### 5.2 Decision-Makers

As intellectual property matters fall under the jurisdiction of civil courts, there are currently no technical or intellectual property-specialised judges in Macau. The parties have no influence on who is the decision-maker and trial by jury is not provided for in the law. However, both the court and any of the parties may request that expert opinion or guidance be provided in regard to highly specialised issues, for the purpose of which one or more experts will be appointed to deliver a report and provide testimony.

### 5.3 Settling the Case

Provided they are in agreement, the parties may choose to settle their dispute at any time, before the judge or privately (in which case they must notify the court of the execution of the settlement and discontinue the proceedings). In any event, it is necessary for the judge to endorse the settlement by confirming each of the parties' capacity to settle and the matter's availability for settlement.

As criminal prosecution regarding the infringement of IP rights is of a public nature (ie, irrespective of claim by respective title-holder), settlement between the parties does not entail the termination of related criminal proceedings.

### 5.4 Other Court Proceedings

Two (or more) proceedings, including arbitration, dealing with the same intellectual property matters cannot be held simultaneously within the jurisdiction of Macau SAR. Should the

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court receive notice of action with regard to an instance of pendency, the opposing party will be acquitted and tried in the proceedings where it was summoned first, although this acquittal is understood as a mere formality and not as *res judicata*.

## 6. Remedies

### 6.1 Remedies for the Patentee

In Macau SAR, the main remedies available to the patentee in an infringement lawsuit consist of search and seizure orders, restraining orders and other types of injunctions, plus damages. Upon receiving an injunction request, the judge has discretion to order different or additional injunctions.

When it comes to damages, the patent holder must prove their existence, namely in the form of actual damages and loss of profits.

If the defendant still does not comply with the remedies after the court decision becomes enforceable, the patentee can choose to initiate an enforcement procedure by petitioning the court to coercively enforce the judgment.

### 6.2 Rights of Prevailing Defendants

A prevailing defendant (ie, where the court rejects the infringement claim) may be entitled to receive court fees and other expenses incurred during the case, which include lawyers' fees (with limitations), costs of experts (if any) and court fees.

Additionally, the defendant may also claim for compensation for damages should the court accept the defendant's claim that the counterparty commenced litigation in bad faith (*litigância de má-fé*).

### 6.3 Types of Remedies

In Macau, the aforementioned remedies, in **6.1 Remedies for the Patentee**, are available for all kinds of intellectual property rights, regardless of type.

### 6.4 Injunctions Pending Appeal

If a patent is found to be valid and infringed in the first instance only for the infringer to appeal, the decision of the lower court is preliminarily enforceable. A stay of injunction is only possible under exceptional circumstances, resulting in the frequent rejection of such requests.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

The applicant, the holder of the industrial property right, and any person who has been directly affected, may appeal to the Court of First Instance against the decisions issued by the DSE regarding the grant or refusal of an industrial property right, as well as in respect of the transfer, licensing or any other decisions that affect, modify or extinguish the industrial property right.

The appeal shall be filed within one month counting from the publication date of the decision, or from the date of the respective certificate. Please also see **1.8 Remedies against Refusal to Grant an Intellectual Property Right**.

The DSE is not considered as the defendant, but it shall be notified of the appeal to provide the details of the administrative proceedings to the court. Opposing parties shall be summoned by the court to present their opposition within one month, if desired.

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If the appeal involves any technical issue which requires further information the court may, at any stage, order that the expert from the DSE, on whose expert report the DSE's decision was based, provide oral clarification.

The decision rendered by the Court of First Instance is not final and may be subject to appeal pursuant to the general rules of civil proceedings.

## 7.2 Type of Review

An appeal filed to both the Court of First Instance and the Court of Second Instance may imply a review of the facts of the case as well as a legal review.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

In Macau, there are no specific extra-judicial procedures that a party to an intellectual property matter is supposed to take. In spite of that, according to the usual practices, costs may arise from legal consultancy services, warning letters to the potential IP infringer, opposition to new IP applications with the Economic Bureau, and expert opinion in cases of patent infringement.

### 8.2 Calculation of Court Fees

Pursuant to Article 6, Section 1, r) of Decree-Law 63/99/M (Court Fee Regulation), the court fee for appeal proceedings, referred to in **7. Appeal**, is calculated based on the value of the dispute, which is determined by the court according to the economic repercussions of the proceedings for the party responsible for the court fee or, failing that, the economic situation of this party, but is never less than MOP91,000.

### 8.3 Responsibility for Paying the Costs of Litigation

Under Macau law, the losing party is responsible for the costs of litigation, including court fees, expert fees, and any other expenses arising from the proceedings, as well as for the payment of an amount arbitrated by the court in favour of the prevailing party considering the value of the proceedings and complexity of the case, which may be understood as partial reimbursement of the attorneys' fees.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

The parties may engage in mediation, conciliation or arbitration as alternative ways to settle an intellectual property dispute. The new Arbitration Law (Law No 19/2019), which follows closely the UNCITRAL Model Law on International Commercial Arbitration, came into force on 3 May 2020. However, the mentioned alternative dispute resolutions are not commonly used for intellectual property infringement cases in Macau.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

With regard to assigning an industrial property right, Article 11 of the Legal Regime of Industrial Property stipulates that industrial property rights may be assigned, totally or partially, free of charge or for consideration. The same article regulates that an assignment inter vivos shall be in writing, failing which the assignment shall be null and void. The same provision shall apply to rights deriving from applications for the granting



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of industrial property rights. No special restrictions, beyond what is established by general rules, apply to assignments. According to Article 402 of the Civil Code, the assignment can be finished by a contract or any other legal instrument allowed by law.

## 10.2 Procedure for Assigning an Intellectual Property Right

Pursuant to Article 11 of the Legal Regime of Industrial Property, there is no additional requirement further to the general rules on assignment of rights and contractual positions. Article 57 of the Legal Regime of Industrial Property stipulates that, after the contract assignment, there is a burden of registration of the fact of assignment to better protect the right of the one who acquires (ex vi Article 57, Section 2).

## 10.3 Requirements or Restrictions to License an Intellectual Property Right

Pursuant to Article 12 of the Legal Regime of Industry Property, except where there is express legal limitation, industrial property rights may, with or without consideration, be licensed for exploitation in whole or part and, when for a limited duration, for all or part of that duration. The same provision should apply to rights deriving from industrial property right applications, but a refusal to grant such rights shall imply the forfeiture of the licence. The exploitation contract licence shall be in writing, falling which the assignment is null and void (ex vi Article 212 of the Civil Code).

As for assignments, there are no special requirements for licensing. Article 13 of the Legal Regime of Industry Property stipulates some restrictions of the licensee. Unless otherwise provided in the licence/contract, the exploita-

tion licence shall be deemed non-exclusive. This means that the owner of the industrial property right does not forswear the right to grant any other exploitation licences for the rights to which the licence refers.

Article 13 also provides that, except where there is a stipulation to the contrary, it is presumed that:

- the granting of an exclusive exploitation licence shall not preclude the owner from also directly exploiting the industrial property right covered by the licence;
- the right obtained through the exploitation licence may not be assigned without the written consent of the industrial property right owner; and
- no sub-licences may be granted without the written authorisation of the of industrial property right owner.

## 10.4 Procedure for Licensing an Intellectual Property Right

The Legal Regime of Industry Property does not foresee a special procedure for licensing an industrial property right.

However, the parties shall request the DSE-registration of the grant of a licence, pursuant to Article 57 of that Regime, which is recorded in the IP title.



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Riquito Advogados provides legal services to a diverse range of clients in various industries, but has a particular focus on corporate clients. The firm has five qualified lawyers and offices in Macau SAR and Lisbon, Portugal, with key

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## Trends and Developments

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### The POSITA Position – Ordinary Person or Ordinary Skill?

Renowned English jurist Sir Edward Coke once said that “you should trust any man in his own art provided he is skilled in it”. He might not have anticipated the remarkable weight his words would have in the context of patent law. In a practice area involving inventions and innovations of a technical nature surpassing the understanding of most legal practitioners, the assistance of a skilled tradesperson in the relevant industry has been recognised and acknowledged to be of great necessity in aiding lawyers and judges alike in their understanding of the invention or innovation.

#### *The person having ordinary skill in the art*

Patents are uniquely technical in nature and are generally only understood by and applicable to a relatively small class of persons, who could be considered to be “persons having ordinary skill in the art” (POSITAs). These are essentially persons to whom a patent document is directed – ie, those with a practical interest in the subject matter of the patent. A POSITA assists the court in determining various crucial issues arising in patent litigation, including claim construction in validity and/or infringement issues, as well as (non-)obviousness, (in)sufficiency and industrial (in)applicability of the patentee’s invention. The involvement of a POSITA is therefore an indispensable part of patent proceedings.

#### *The attributes of a POSITA*

The identification of a POSITA is of significant importance in the patent scene, given their role(s). Needless to say, the choosing of a person who does not fulfil the requisites of a POSITA would be highly detrimental not only to the court’s understanding of the relevant patent in question, but also to the proper administration of justice. It also goes without saying that a POSITA taking on the role of an expert witness should provide evidence in an objective and unbiased manner.

What then are the prerequisites of a POSITA? Broadly, a POSITA is taken to possess the common general knowledge (ie, background technical knowledge) as well as the skills and qualifications relevant to the technical field in issue. A POSITA should be familiar with the workshop technique and literature in relation to the relevant field of art. They should also be able to absorb the contents of a myriad of specifications. That being said, a POSITA should be unimaginative and devoid of any inventive capacity; such were the attributes enumerated in the English case of *Rockwater v Technip* [2004] RPC 46 (“Technip case”), which have since been adopted by the Malaysian courts.

This POSITA can be either a single person or a team of persons that embodies all of the above characteristics. In instances where the relevant patent is interdisciplinary and no single person would have the requisite skills in all the technical fields, a combination of minds and their com-

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posite skills would be the most appropriate. At the end of the day, the POSITA is a legal creation of a notional person who is faultless and ideal, and understands all languages (see *Lilly ICOS LLC v Pfizer Ltd* [2001] IP & T 190), so it is hardly ever possible for any one expert to fulfil all of these requisites.

The acronym “POSITA” is frequently used, albeit in a loose context. It is understood that experts can hardly emulate all the characteristics of a POSITA. The contention is, of course, the threshold of a POSITA that an expert or a team of experts is expected to meet or, put another way, the extent to which an expert may deviate from the ideal notional person yet still be acknowledged as a POSITA.

### *Common general knowledge*

Perhaps it is important to first delve into the sub-topic of common general knowledge that a POSITA is imputed to have, for that lends much context to the deliberation later on – ie, how far is an expert expected to approximate to a POSITA? Common general knowledge can be appropriately summarised as being “derived from a common sense approach to the practical question of what would in fact be known to an appropriately skilled addressee – the sort of man, good at his job, that could be found in real life” (see *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457).

### *Approximating a POSITA*

In recognition of this ideal and in driving home the point that an expert need not embody all the attributes of a POSITA, Jacob LJ aptly captured this sentiment in the *Technip* case:

“11. None of the above is controversial. However, sometimes the requirement that the skilled man be uninventive is used by counsel for a pat-

entee in an attempt to downgrade or dismiss the evidence of an expert called to say that a patent is obvious – “my witness is more nerdlike than his” is the general theme. I do not find this a helpful approach. It is frequently invoked and Mr Waugh QC invoked it in this case in an effort to downgrade Rockwater’s expert evidence on obviousness given by Professor Witz. Mr Waugh said his witness, Mr Nash, was more appropriately qualified than Professor Witz, and that the latter, because he had patents in his name, “was of an inventive turn of mind”.

“12. I must explain why I think the attempt to approximate real people to the notional man is not helpful. It is to do with the function of expert witnesses in patent actions. Their primary function is to educate the court in the technology – they come as teachers, as makers of the mantle for the court to don. For that purpose it does not matter whether they do not approximate to the skilled man. What matters is how good they are at explaining things.”

The last two sentences above have gained prominence in the local legal scene, following their citation by the Federal Court in *SKB Shutters Manufacturing Sdn Bhd v Seng Kong Shutter Industries Sdn Bhd & Anor* [2011] 2 MLJ 78 (the “SKB Shutters case”). In the SKB Shutters case, the relevant question of law that was posed to the apex court was on the permissive presence or level of inventiveness of an expert as a POSITA. The leave question reads as follows:

“Upon finding that the expert witnesses could hardly be described as ‘the unimaginative skilled addressee’ in determining if there is inventive step in the appellant’s invention or otherwise, whether it is permissible for the Court to refer to the evidence of such experts to make a find-

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ing that the concept embodied in the appellant's patent is common general knowledge in the field of mechanical engineering which would be obvious to a normally skilled but unimaginative addressee in the art."

In answering the above question, the Federal Court stated that it did not matter that neither Defendant Witness 3 nor Plaintiff Witness 1 were not unimaginative skilled addressees. The court also held that the lower appellate court (ie, the Court of Appeal) was perfectly entitled to rely on the evidence of both these witnesses in determining whether the patent was obvious. The Federal Court further explained that the role of a POSITA was to educate the court on the technology, the technical terms and the common general knowledge surrounding the invention. It was in this context that the Federal Court cited the case of *Technip* in support of its decision that a POSITA need not approximate to the notional addressee.

In respect of this particular issue, the court held that an expert witness fulfilling the role of a POSITA in the real, physical world (ie, not being a legal construct) would not need to be completely unimaginative and devoid of inventive faculty. In fact, it would be an impossible and unjust standard to impose upon an expert witness. After all, courts have been known to make certain allowances for an "imperfect" POSITA. A skilled person inevitably possesses preferences or dislikes, but these must be objectively characteristic of real workers in the field and not merely idiosyncratic in nature. The above, considered in totality, illustrates the great difficulty in approximating the skilled person to a notional POSITA in the context of unimaginativeness and a lack of inventive faculty.

The question remains, however, as to whether this notion of non-approximation extends to other attributes a POSITA is supposed to embody.

### *An "expert" from another field of the art – the "ordinary person"*

Whilst the courts and patent litigants alike have come to accept that an expert may include someone with a certain degree of imagination or inventiveness, it remains true that these experts should still exhibit objectivity in their reading of the patent documents and assessment of the relevant issues at hand.

Despite this, it is hard to imagine courts accepting testimony from an "expert" who is not an expert in the relevant field of the art, regardless of how useful their explanation might be. After all, the position on the requirement for technical knowledge and standing of an expert or a team of experts in the relevant field or art has remained intact and unaffected by the finding in the *SKB Shutters* case. While possessing imagination or inventiveness, experts must still reside within the realm of the much-required relevant field of expertise where the patent has been called to issue.

The subject matter of inventions could range from a relatively simple shoe, for example, to genome sequencing. No judgment better illustrates this notion than that of *Pumfrey J* in the case of *Glaxo Group's Patent* [2004] RPC 843, at paragraph 24:

"There are technologies where no great knowledge is to be attributed to the skilled man, and others (such as genetic engineering) where to attribute an unrealistically low level of attainment to the skilled man would prejudice industrial development."

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The appropriate level of skill must be imputed according to the technology involved. In some instances, such as in genetic engineering, it may be the case that highly trained researchers with notable academic qualifications would form the notional team required, whereas in other instances formal education may not be strictly necessary, and practical experience in the field may suffice.

Where this becomes problematic is when the assistance of an expert is required in relation to a particular field but said expert does not have experience within the relevant industry. This alternative interpretation that a person need not be an expert with knowledge or practical experience in the relevant industry (or the ordinary persons) came about, presumably, following the confusion surrounding certain quoted phrases from Technip in the SKB Shutters case – that an expert (or to be more precise, any person) can assist the court regardless of the industry in which they are involved, which is permissible as long as they are able to “educate the court in the technology” and “explain things”. This was clearly taken out of context as one would recall the preceding sentences in Technip.

When viewed singly without the benefit of the preceding sentences in Technip (see above), the requirement that experts only need to “explain things” and that “it does not matter whether an expert approximates to the notional person” have been misunderstood by a few to mean that experts need not have the relevant knowledge or experience in the field of the invention. In the larger scheme of the attributes that are intrinsic in a POSITA, this cannot be right. Surely, the ability to explain things must be tied to the presence of the knowledge of the art, and no other.

The above notwithstanding, and not at least until the case of Spind Malaysia Sdn Bhd v Justrade Marketing Sdn Bhd & Anor [2018] 4 MLJ 34 (“Spind case”), a reader of the judgment of the SKB Shutters case viewed without an appreciation of the context laid out in Technip, might be led to this unfortunate “alternative interpretation” that it is equally permissible to call on someone who is not an expert in the field of the art, so long as they are able to explain the invention with cogent reasons. Using Laddie J’s analogy in Inhale Therapeutic Systems Inc. v Quadrant Healthcare plc [2002] RPC 21, it is hard to imagine an expert in the field of baking appearing in a court of law to assist the court in the field of internal combustion engines:

“For example, in theory a notional skilled person engaged in trying to improve the operation of an internal combustion engine is assumed to know, have read and assimilated the contents of all published material including those, say, in the baking field. It may be that a document in the latter field discloses something which, if applied to the internal combustion art, would produce a marked improvement in performance.”

This rationale that an expert need only explain things to the court, without regard being paid to their knowledge or experience, certainly does not sit well with the need for a team of experts, each in the relevant field or art of the patent. How well an expert explains the intricacies, complexities or nuances presupposes that an expert already possesses certain requisite levels of knowledge (common general knowledge).

Even with published books or articles as supporting evidence, an expert is expected to sift through them and be able to extract knowledge that forms part of the common general knowledge, effectively discarding the general knowl-

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edge disclosed to the public that may not necessarily be common general knowledge. It is hard to imagine someone who is not a player in the arena at all fulfilling the task that an expert in the relevant field is capable of performing. The ability to explain must thus entail an expert possessing certain requisite knowledge in order to be able to explain and educate the court.

This supposition finds support in various cases, including *Catnic Components Ltd & Anor v Hill & Smith Ltd* [1982] RPC 183, wherein the House of Lords held that a POSITA should have experience in the invention in question in addition to the requisite practical interest and common general knowledge. This position has also been reflected in the lowest and highest courts in Malaysia, in the cases of *Mohammad Mubde Absi & Ors v Hyat Collections Sdn Bhd & Ors* [2020] 10 MLJ 503 (“*Mohammad Mubde case*”) and *Spind*, respectively.

In *Spind*, the Federal Court rejected evidence of a supposed expert who, by his own admission, did not have any hands-on or practical experience at all in the design, handling and installation of plumbing and sanitary systems. In fact, the apex court went as far as to say that the witness in question cannot be considered an expert as defined by the relevant Evidence Act 1950, and accordingly, his personal opinion on the inventiveness or otherwise of the subject patent in question is not admissible. A similar position was taken by the High Court in the case of *Mohammad Mubde*.

Even on a superficial level, the above findings are intelligible for the sole reason that, having been conferred the appreciable role of educating the court on the relevant technology, its technical terms and the prevailing common general knowledge, POSITAs would have to invariably

draw upon their own stock of knowledge and experience in the relevant industry in order to do so. This is certainly not a task to be taken on by all and sundry, regardless of how well the technology may be explained by a person outside the realm of the art. In the words of Clauson J in *British Celanese Ltd v Courtaulds Ltd* (1933) 50 RPC 63, such an expert is to be “a man properly informed in the art”. The mantle that is crafted by the POSITA must be from “what he has acquired in his ordinary practice as a man engaged in the art”.

In any event, a person not engaged in the relevant art or not having practical experience in the art would not be a person to whom the patent would be directed anyway, having no practical interest in the subject matter. Premised on this rationale, it may be argued that a person could not possibly be considered as a POSITA if they do not have an inherent interest in the patent.

It is therefore plain and obvious that, despite not approximating to the ideals of a notional skilled individual, a person should at the very least still possess the knowledge or practical experience in the relevant art that would enable them to explain the patented technology and other related aspects to the court.

### *Conclusion*

“You should trust any man in his own art provided he is skilled in it.”

The words of Sir Edward Coke continue to ring true and remain pertinent in the patent world, if not arguably more so. A “man in his own art” and “skill” are two intertwined concepts such that one cannot be said to exist without the other. The danger with the alternative interpretation lies in the appeal that it had garnered, despite its



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inability to be reconciled with the basic tenets of patent law as already discussed above.

The quest for a person with the ordinary necessary skill should not be compromised and overlooked merely because it is difficult. The credentials of the experts should be the foremost order of the day. The donning of the mantle of a POSITA and the convincing argument must be won over by those skilled in the art, not by any other ordinary person. In a battle of wits, clearly, the person with “ordinary skill” should and must unequivocally prevail.

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Shearn Delamore & Co. was established in 1905 and is one of the leading law firms in Malaysia. With more than 100 lawyers and 230 staff, the firm has the resources to run and manage the most complex projects, transactions and matters, including co-ordinating and managing cross-border transactions together with the foreign and international law firms with which it continuously works. By combining diverse experience and interdisciplinary collaborations, the firm is able to provide a comple-

mentary range of skills. It maintains extensive global network links with foreign law firms and multilateral agencies, including the World Law Group (WLG), the World Services Group (WSG) and the Employment Law Alliance (ELA). Shearn Delamore & Co. formed an alliance with Drew & Napier LLC from Singapore, Martinez Vergara & Gonzalez Sociedad from the Philippines, and Makarim & Taira S. from Indonesia, to launch a formidable blue-chip legal network named Drew Network Asia (DNA).

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## MALAYSIA TRENDS AND DEVELOPMENTS

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

In Mexico, inventions can be protected through patent rights, utility models, designs, layout designs (topographies) of integrated circuits and vegetal varieties. These intellectual property rights are based on statutory law. Specifically, they are included in the new Federal Law for Protection of Industrial Property (FLPIP).

### 1.2 Grant Procedure

A right arises for a granted patent/registration through the filing of a patent application with the Mexican Institute of Industrial Property (*Instituto Mexicano de la Propiedad Industrial*, or IMPI). The application must contain all the information regarding the inventor and, if the right has been assigned, the information of the assignee. It must also contain formal documents such as the assignment and the power of attorney document. The inventor or the applicant may file the application themselves or through an agent. In addition, it is possible to claim priority from a previous application filed in a different country that is a member of the Paris Convention for the Protection of Industrial Property, if the claim is made within the 12-month term provided for such effect. A certified copy of the priority application must be filed within three months from the filing date, and it must include its full Spanish translation.

The application may also be filed as a National Phase Patent Cooperation Treaty (PCT) Patent Application, for which Mexico is a 30-month term country. If the information regarding the inventors, applicants and priority applications is the same as the information found in the international application's publication, the assignment and priority document are not required, as

they are in Paris Convention applications. The application is studied by a formal examiner at IMPI, who will determine if there are any formal documents missing and if all documents are in good order. The application must contain the invention's specification, claims and drawings, in Spanish. However, it is possible to file the application in a different language, in order to avoid missing the filing due date.

The examiner requests a Spanish translation during the formal examination. The application must be published in the Mexican Industrial Property Gazette as soon as possible following the expiration of a period of 18 months from the national filing date, provided that all formalities are deemed complete. After the publication has taken place, the application is studied as soon as possible by a technical examiner at IMPI and, if deemed necessary, an official action is issued, requesting clarification or changes to the application. Up to four official actions can be issued and, if the examiner determines that the application complies with all requirements, a notice of allowance is issued, granting a four-month term to pay the grant fees and five annuities, which include the year of grant and four additional years. If this is not done, the application is denied. Please note that the annuity payment is not required during the prosecution of the application.

### 1.3 Timeline for Grant Procedure

The grant procedure currently takes four to five years from the filing date, depending on the number of official actions issued by the technical examination department of IMPI and the complexity of the invention.

In Mexico, either the inventor or the owner of the patent, if it has been assigned by the inventor, may personally initiate the grant proceedings,

meaning that they sign the application form, or they may appoint an agent, who does not need to be a patent lawyer, but only needs to have an address in the Mexican territory.

The costs of a grant can vary widely since they depend on a series of factors, such as the complexity of the invention, the number of priorities, the number of claims or the number of official communications issued by IMPI. However, for an average application with 20 pages of 30 lines in English, two priorities and ten claims, the cost would be around USD8,000–9,000.

## 1.4 Term of Each Intellectual Property Right

The term of a patent right is 20 years; that of a utility model is 15 years; that of an industrial design, five years (renewable each five years up to a maximum of 25 years), and that of layout designs (topographies) of integrated circuits, ten years from the filing or legal date, which is the national filing date for Paris Convention applications, or the international filing date for National Phase PCT applications. The FLPIP provides for a compensation procedure although, it is yet to be seen how such a procedure will actually develop.

### Term Extensions

When, during the prosecution of a patent application, there was an unreasonable delay attributable to IMPI, a supplementary certificate can be sought for IMPI to adjust the term of the patent if it is established that the procedure for granting a patent exceeded five years from the Mexican filing date and the date on which the application was approved for grant.

Within the period of five years, no account shall be taken of the time engaged in resolving the examination of form, the actions or omissions of

the applicant tending to delay the procedure or those which are beyond the control of IMPI, as well as the periods attributable to force majeure.

The application for a certificate must be made at the time of payment of the final fees for granting the patent and may be requested only once.

It should be noted that the supplementary certificate is unfair, as it arbitrarily provides for compensatory time to offset the time lost in the patent process, by allowing one day of compensation for every two days of delay. It is reasonable to ask what the logic behind the rule of one day of compensatory time for every two days of delay is. Would it not have been better if the formula allowed one day of compensatory time for one day of delay? In other words, if a statutory rule does not have a logical underlying rationale, it is likely that such a rule would be considered unconstitutional.

### USMCA

According to the former North American Free Trade Agreement (NAFTA), now replaced by the United States-Mexico-Canada Agreement (USMCA), the owner of a patent could seek compensation for lost patent term time if IMPI took more than three years to grant the patent. The NAFTA treaty is enforced on all patent applications filed before 1 July 2020. In this regard, the authors' firm has successfully obtained a favourable decision in which, according to NAFTA, the lost enforceable time of a patent filed before 1 July 2020 was compensated with three additional years. This new precedent has already been published in the Official Gazette dated 8 January 2021 as a relevant case entitled: "Patents. When there are delays attributable to the administrative authority in a patent's approval, its validity may not be less than 17 years counted from the date of its granting." The precedent was issued by



the Supreme Court of Justice in the Bayer case and is in full force and effect for all patents filed before 1 July 2020.

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

The patent holder has the right to an injunction and may claim damages from third parties even if the illegitimate use of their patent was made before granting, provided that the application had already been published.

If the subject matter of the patent is a product, the patentee has the right to prevent others from making, using, selling, offering for sale or importing the patented product without their consent.

If the subject matter of the patent is a process, the patentee has the right to prevent others from using that process and from using, selling, offering for sale or importing a product obtained directly by that process, without their consent.

### Obligations

The owner must use the patent in the Mexican territory, within three years of the grant date or four years from the filing date, whichever comes later, in order to avoid a third party requesting a compulsory licence before IMPI.

### Public Information Listing Applicable Patents

Information and clinical data related to an IP right is classified information and therefore privileged and confidential; as a result, it is not accessible to third parties, including applicants for generics, according to international treaties such as Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights and Articles 20.48 to 20.51 of the USMCA (formerly NAFTA), and in accordance with domestic legislation. Namely, pursuant to:

- the Federal Commission against Sanitary Risks Guideline (COFEPRIS Guides for Data Exclusivity, published on 19 June 2012);
- Article 168 of the Federal Law for Protection of the Industrial Property; and
- Article 116 of the General Law of Transparency and Access to the Public Information.

## 1.6 Further Protection After Lapse of the Maximum Term

No further means of protection are currently available under the FLPIP for patented inventions after their 20-year term has lapsed. If the patent application took more than five years to be granted, a litigation strategy could request compensation for the time lost because of the administrative delay, based on NAFTA/USMCA. No further protection after lapse is provided (ie, there is no clinical data protection, although same are currently treated as industrial and/or business secrets).

## 1.7 Third-Party Rights to Participate in Grant Proceedings

According to Mexican patent law, third-party observations can be made within two months of the patent application being published. The observations may or may not be taken into consideration for the examination of the patent, depending on the examiner's criteria.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

Against a refusal to grant a patent, two actions may be used. The first is a reconsideration appeal, which is filed before IMPI, and the second is an appeal filed before the federal courts.

## 1.9 Consequences of Failure to Pay Annual Fees

The failure to pay annuities will result in the loss of the patent right. The maintenance fees are

paid every five years after the grant of the patent and must be paid five years in advance. If the inventor is also the applicant, they may pay one annuity at a time. The first five annuities are paid together with the grant fee. The annuity payment must be done in the anniversary month that corresponds to the filing or legal date. There is a six-month grace period to pay the annuities. If the annuities are not paid during the regular term or the grace period, there will be an additional six-month term to file a reinstatement request.

The current costs of annuities are:

- a professional fee of USD250 every five years;
- an official fee for patent annuities from the first to the fifth year of USD80 each year;
- an official fee for patent annuities from the sixth to the tenth year of USD92 each year; and
- an official fee for patent annuities from the 11th to the 19th year of USD105 each year.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

As mentioned, a post-grant proceeding include the following:

- a supplementary certificate – akin to the EU's supplementary protection certificate – to adjust the term of the patent is established for cases in which the procedure for granting a patent exceeds five years from the filing date, where this is directly attributable to IMPI due to unreasonable delays;
- a licence agreement; and
- the payment of annuities to keep the patent in force.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

Infringement actions and temporary restraining orders are available.

#### Damages

A rights-holder may claim damages through two different procedures: directly before the judiciary (either federal or state), by means of a civil or commercial action and without the need to obtain a definite infringement ruling to make the claim, or through IMPI, through a motion.

If a counterclaim for the annulment of the respective patent, registration or publication is filed, the court shall suspend the procedure until the respective judgment is entered.

To warrant the damages before the judiciary or IMPI, it is necessary to demonstrate wrongful conduct, the harm caused and a direct causal relationship between the two.

#### Criminal Actions

Criminal action is also an option when there are trade marks or trade secrets. Repeated administrative infringements of the Law are no longer a crime; a definition of trade mark forgery and a test to demonstrate such crime have been included. Crimes related to industrial secrets have been modified.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

There are two potential remedies available to third parties. They may:

- file a counterclaim requesting the cancellation of the intellectual property rights; and/or

- post a counterbond to neutralise the injunction filed against the defendant.

In some specific cases, a compulsory licence could be an option.

## 2.3 Courts With Jurisdiction

Jurisdiction in intellectual property matters is as follows:

- first instance at IMPI;
- second instance at IMPI and/or the federal courts (the Specialised Intellectual Property Chamber);
- third instance at the Circuit Court of Appeals; and
- exceptionally, a fourth instance before the Supreme Court of Justice (SCJ) in case of an unconstitutional provision of the FLPIP.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

The first instance of dispute resolution is IMPI and the second is a court specialised in intellectual property matters called the Specialised Intellectual Property Chamber. The third instance is a constitutional court which is not specialised in the field of intellectual property.

## 2.5 Prerequisites to Filing a Lawsuit

When a lawsuit is filed, it must be accompanied by a power of attorney, the payment of government fees, intellectual property rights and evidence. The owner and/or its licensee is able to file the lawsuit as long as the licence agreement is recorded with IMPI, unless the parties have agreed otherwise. In the latter case, only the patent holder can bring the legal action.

## 2.6 Legal Representation

The documents can be signed by the company's representative directly. Even in legal proceed-

ings before the courts, writs can be signed by the company's representative; however, if the company does wish to be represented by somebody else in court, that person must be a lawyer whose licence is duly recorded at the court.

## 2.7 Interim Injunctions

The infringement of an IP right gives the right to request an injunction. The injunction will be granted by IMPI if the plaintiff proves:

- the existence of an intellectual property right;
- the infringement of the intellectual property right;
- the posting of a bond; and
- the public existence of an intellectual property right ("recordal").

## 2.8 Protection for Potential Opponents

The opponent may post a counterbond to release the seizure of products. However, if the defendant loses the case, the plaintiff may collect the counterbond.

## 2.9 Special Limitation Provisions

The periods that limit the exercise of legal actions against the infringer of a patent are those in which the patent continues to be a published patent application without having yet been granted. As long as it is a patent application, rights cannot be exercised. If granted, it will, however, become retroactively effective on the date on which the infringement was verified while there was already a published patent application (Article 56, FLPIP).

The foregoing implies that a patent application is not the same as a granted patent and, therefore, the delay in granting a patent directly affects the duration of the patent and legal actions that may be brought against third parties.

It should be noted that according to the new FLPIP, damages can be requested before a civil court directly, without first obtaining the declaration of an infringement by IMPI, which can save time; however, in the event of a counterclaim for invalidation, the damages proceeding will be suspended until the counterclaim is resolved, which can take up to four years. Therefore, the potential time-saving benefit disappears by suspending the procedure instead of solving everything in one procedure.

## 2.10 Mechanisms to Obtain Evidence and Information

The FLPIP establishes a legal mechanism for the parties to request that IMPI gather information and data that is owned by third parties. If the request is related to the merits of the case, IMPI can request information or data to resolve the case. The plaintiff and/or defendant are able to request the support of third parties that have evidence proving the facts of their action or exception. IMPI may order third parties to produce said evidence, subject, if necessary, to conditions that guarantee the protection of confidential information. The evidence issued by third parties must be requested with the filing of the legal action or in the response.

## 2.11 Initial Pleading Standards

The preparation of a lawsuit requires an account of facts that put the case into context. Each statement must be proved, except when it is made under oath. Negative facts are not subject to proof; only positive facts or negative facts with positive effects are subject to proof. Once the lawsuit, or the response to it, is filed, allegations follow. At that point details may be added to the case. The procedures for tangible and intangible (eg, intellectual property, privacy and data protection) claims are different. Tangible cases (eg, property rights) are resolved before

civil courts and intangible matters are resolved before administrative courts.

Once the legal action has been filed, the defendant will have a one-month term within which to respond to the legal action, which may include a counterclaim requesting the nullity or expiration of the plaintiff's IP right. Subsequently, IMPI will grant a three-day term for the objection of evidence, and ten days for final pleadings. It should be noted that these terms of three and ten days are not regulated by the FLPIP, but by the Federal Law of Administrative Procedure and the Federal Code of Civil Procedure, which IMPI applies in a supplementary manner.

## 2.12 Representative or Collective Action

Collective actions are not allowed for intellectual property matters.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

The right conferred by a patent does not have effect against:

- any third party who is engaged in the private or academic sphere and not for purposes of profit;
- a third party that uses, manufactures, offers for sale or imports a product with a valid patent, exclusively to generate tests, information and experimental production necessary to obtain medical permits ("registrations");
- any person who markets, acquires or uses a patented product or a product obtained through a patented process after that product has been lawfully introduced into commerce;
- any person who has used the patented process, manufactured the patented product or initiated preparations necessary to carry out said use or manufacture prior to the date of

filing of the patent application or an application for acknowledged priority;

- employment of the corresponding invention in transport vehicles of other countries, or forming a part thereof, when such vehicles are in transit in national territory;
- any third party who, with regard to patents relating to living matter, uses the patented product as an initial source of variation or propagation for the obtainment of other products, unless said use is in a reiterated manner; or
- any third party who, in respect of patents relating to products consisting of live matter, uses, places in circulation or markets the patented product for purposes other than multiplication or propagation, and after the product has been lawfully introduced into commerce by the patent holder or by a licence of the latter.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

In accordance with the FLPIP, an infringement action may be initiated *ex officio* or *ex parte*. In the latter case, any party with legal standing and a founded claim may file the infringement action.

Therefore, an infringement action may only be filed by the owner of the intellectual property right, or any other person who may be authorised to carry out actions to protect it on the owner's behalf (including a licensee authorised to do so), or initiated by IMPI.

However, the law also allows for any third party to inform IMPI of circumstances that may constitute patent infringement, and such allegations

may be considered by IMPI in its decision to initiate a proceeding.

### 3.2 Direct and Indirect Infringement

The FLPIP does not differentiate between direct and indirect patent infringement.

### 3.3 Process Patents

The infringement procedure must be started once the patent has been granted. However, if there was an infringement prior to the granting of the patent, pursuant to the new FLPIP, a retroactive claim can be made for the use of the patent without the proper authorisation, which could have a defect of unconstitutionality due to retroactive application.

### 3.4 Scope of Protection for an Intellectual Property Right Patent Owner Prerogatives

In accordance with the FLPIP, the scope of protection of a patent is limited to its claims – ie, only the subject matter of the granted patent. The owner holds exclusive rights to exploit its patent's claims, or to authorise third parties to exploit them. These exclusive rights carry the prerogatives of preventing unauthorised parties from exploiting a patented process or invention, as follows:

- if the subject matter is a product, the owner may prevent third parties from making, using, offering for sale, selling, distributing or importing the patented product; and
- if the subject matter is a process, the owner may prevent third parties from using the patented process or from making, using, offering for sale, selling or importing the resulting product of a patented process.

The owner's prerogatives are further detailed by the FLPIP as the following specific forms of patent infringement:

- the unauthorised manufacturing of products covered by a patent;
- offering for sale or selling products covered by a patent, knowing that they were manufactured without authorisation by the patent holder;
- using patented processes, without the authorisation of the patent owner; and
- offering for sale products resulting from the use of patented processes, knowing that they were used without the patent owner's consent.

In addition to these specific patent infringement hypotheses, the FLPIP sets forth a broader premise for infringement, consisting of any acts that go against traditions and customs in industry and commerce that involve unfair competition and are linked to industrial property rights.

In deciding a patent infringement action, IMPI will analyse the circumstances brought before it and must then determine whether any of the above hypotheses is met. To do this, IMPI will evaluate whether the whole patent or any of its independent claims is identifiable in the activity that has been brought to IMPI's attention.

### Equivalents

The general rule that applies in the field of intellectual property is the strict application of the rule – ie, the literal application of the content of the legal precept. For example, the doctrine of equivalents is not expressly regulated in Mexican legislation and, therefore, theoretically an action based on that doctrine could not be successful. However, Section 33 of Article 386 of the FLPIP opens the possibility of seeking other

grounds for infringement (constituting a generic “catch-all” ground) contained in other legal provisions, which could be an action other than those mentioned in Article 386 of the FLPIP. In respect of the doctrine of equivalents, there was a legal decision, in 2016, that could be applied to legal actions involving the same, regardless of the fact that the statutory provisions do not include such provisions.

### 3.5 Defences Against Infringement

Defences might focus on the following.

- A third party that carries out purely experimental scientific or technological research, testing or teaching activities, in the private or academic spheres and for non-commercial purposes, and for this, manufactures, imports or uses the patented invention.
- A third party that uses, manufactures, offers for sale or imports a product with a valid patent, exclusively to generate test results, information and experimental production necessary to obtain a sanitary permit of medicines for human health.
- Any person who commercialises, acquires or uses the patented invention, after the invention has been lawfully introduced into commerce in Mexico.
- Any person who has initiated the use or manufacture of the invention, the necessary preparations to carry out its use or manufacture, or uses or manufactures the patented invention, prior to the filing date of the patent application or, where appropriate, the date of recognised priority.
- The use of the invention in transport vehicles registered in other countries, when they are in transit in Mexican national territory.
- A third party who, in the case of patents related to living matter, uses the patented invention as an initial source of variation or



propagation to obtain other products, unless said use is made repeatedly.

- A third party who, in the case of patents related to products consisting of living matter, uses, puts into circulation or commercialises the patented invention, for purposes other than multiplication or propagation, after it has been lawfully introduced in commerce by the owner of the patent, or a person who has been granted a licence.

Defendants will also usually seek to counterclaim the invalidation of the patent that has allegedly been infringed, through claims of lack of novelty, non-patentable subject matter or any other argument that may lead to the revocation/cancellation of the patent, and/or neutralise a potential injunction by posting a counter-bond with which the precautionary measure is suspended, releasing the seized merchandise or allowing the manufacture of products to continue.

### 3.6 Role of Experts

When one of the parties in a trial appoints an expert to render their own expert opinion as evidence, the other party may also offer expert evidence on the point to be resolved. If the counterpart is IMPI, their opinion has the importance of an expert; however, when there is a contradiction in the expert opinions, the judge can appoint a third expert to have a final opinion to resolve the disagreement, if any.

Parties may offer expert opinions as evidence; in which case they must provide IMPI with the name and qualifications of their designated expert. In turn, the opposing party may designate their own expert, and IMPI will designate a third expert. Each expert must clarify their position before IMPI in order to participate in the proceedings.

Each expert submits a report based on questionnaires submitted by the parties (as opposed to live examination and cross-examination in other jurisdictions). The reports are then added to the evidence to be judged by the appointed officials.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

The claims are interpreted on the basis of the specification, the technical terms and the working examples. The technical terms must be clear and provide for a (relevant in the context) antecedent. The claims must be fully supported in the specification, which must be sufficiently detailed to allow third parties to avoid additional undue experimentation when the invention is in the public domain. The claims are always interpreted literally and narrowly, in the sense of the wording of the claims and in view of the specification.

The claims of a patent can be limited through voluntary limitation.

### 3.8 Procedure for Third-Party Opinions

Under the Mexican legal system, it is possible to file an amicus brief in court; however, said opinion is not binding on the judge.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

Revocation/cancellation actions are available and may be initiated ex officio or ex parte. Any third party or a federal public prosecutor (where there are federal interests involved) may bring an action before IMPI.



A patent shall be revoked/cancelled if:

- the patent was granted in violation of specifications and requirements regarding patentability;
- the patent was granted in violation of the Mexican industrial property law in force when the patent was granted;
- the application was abandoned during prosecution; or
- the patent was granted by mistake or inadvertently, or was granted in favour of someone who has no right to have it.

## 4.2 Partial Revocation/Cancellation

When the revocation/cancellation only affects one or some of the claims, or a part of a claim, the revocation/cancellation will be declared solely for the affected claim or claims. Thus, the revocation/cancellation will be declared in the form of a limitation concerning the revoked/cancelled claims.

## 4.3 Amendments in Revocation/Cancellation Proceedings

Generally, applicants are only allowed to make amendments before the patent is granted. However, claims may be limited at any time, including during revocation/cancellation proceedings. This could happen if the owner of the patent subject to revocation/cancellation voluntarily limits the claims.

## 4.4 Revocation/Cancellation and Infringement

It is possible for revocation/cancellation actions and infringement actions to be decided together. This may happen when, for example, an infringement action is counterclaimed with a revocation/cancellation action seeking to invalidate the patent that is claimed to have been infringed. To successfully link the two actions, the counter-

claimant will argue the revocation/cancellation of the patent as an exemption against the infringement action (forcing IMPI to analyse the revocation/cancellation action before going forth to the substantive analysis in the infringement action).

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

From the first instance at IMPI to the final one before a circuit court and/or the Supreme Court of Justice a legal proceeding might take from four to six years.

The evidence and pleadings are filed in writing, except when the case is filed before a district court. In this case there is a trial hearing.

Fact witnesses and expert evidence can be filed before IMPI but in this instance a list of witnesses must be filed in a document; however, at second instance before a federal court, the evidence of witnesses and experts can be offered through a questionnaire to be answered by them.

There is no cross-examination at the first instance before IMPI but only before federal and district courts.

There are remedies before civil courts pursuant to the new FLPIP. Infringement actions can now be filed before a civil court to seek the declaration of infringement and damages in just one decision; however, if the defendant requests the cancellation of the patent, the legal proceeding shall be suspended until IMPI resolves the cancellation proceeding, which neutralises the benefit of resolving the infringement and damages in just one decision. In this regard, the lawmakers

have produced, in the new law, a legal absurdity that does not generate any advantage.

The most important special procedural provisions for intellectual property rights proceedings are as follows.

- intellectual property rights proceedings are heard by a specialised branch of IMPI;
- intellectual property rights proceedings in Mexico may be initiated ex officio;
- it is not possible to offer testimonials (regarding the actions of other individuals or entities) or confessions (regarding one's own actions) as evidence in intellectual property rights proceedings in Mexico;
- expert opinions are presented in writing, answering the questions submitted by the parties, and not in direct examination or cross-examination, as is the case in other jurisdictions;
- Mexican law makes no distinction between cancellation, revocation or invalidity actions, so a single action may contain claims attributable to revocation and invalidity actions; and
- there is a specific proceeding to request the supplementary certificate (see **1.4 Term of Each Intellectual Property Right**).

## 5.2 Decision-Makers

A case is determined by officials appointed by IMPI in the first instance. Such officials have a legal background and are supported by people with a technical and scientific background and knowledge. The parties have no say about who will be the decision-maker.

At the second instance, there is a federal court specialising in intellectual property, through which parties are able to challenge IMPI's decisions. Also, parties are able to challenge a federal court's decision before a constitutional court

named the Circuit Court of Appeals through an Amparo action; however, there is no specialised circuit court in IP.

Exceptionally, cases can be resolved in the Supreme Court of Justice when the unconstitutionality of a provision of the law is challenged, or when a case raises a question regarding the interpretation of the Mexican Constitution.

## 5.3 Settling the Case

The parties may reach an agreement at any time before a final and conclusive decision is made. IMPI may also suggest and/or assist the parties in finding an amicable solution to a contentious matter through a conciliation procedure as provided for in the FLPIP.

## 5.4 Other Court Proceedings

In an absolute contradiction of their intentions, Mexican lawmakers, on the one hand, wished to obtain, in a single resolution, the declaration of infringement and the payment of damages, which is very good; however, in an incredibly absurd way, it has allowed said procedure before a civil judge to be suspended by means of a counterclaim for the invalidity of the patent before IMPI, which neutralises any benefit of promptness and procedural logic. This is one of the most absurd and unconstitutional aspects of the new FLPIP.

A proceeding may be stayed when its procedural matters or substance are subject to the resolution of a different proceeding. For example, if the legal standing of the plaintiff in a specific infringement action depends on a patent, and the patent is subject to the resolution of a revocation/cancellation proceeding, the infringement action will be stayed until the revocation/cancellation action has been solved.

## 6. Remedies

### 6.1 Remedies for the Patentee

A patent holder may claim damages through two different procedures: (i) directly before the judiciary (either federal or state), by means of a civil or commercial action and without the need to obtain a definite infringement ruling to make the claim; or (ii) through a motion before IMPI.

If a counterclaim for the annulment of the respective patent, registration or publication is filed, the court shall suspend the procedure until the respective judgment is entered.

To warrant the damages before the judiciary or IMPI, it is necessary to demonstrate wrongful conduct, harm as well as a direct causal relationship between the two.

### 6.2 Rights of Prevailing Defendants

If the plaintiff does not prove the damages in the lawsuit, the defendant may request the payment of legal expenses incurred by the matter being taken to trial without good cause.

### 6.3 Types of Remedies

The remedies are the same for all technical intellectual property rights. Usually, remedies apply to damages proceedings. In the administrative courts, IMPI is able to impose sanctions and fines.

### 6.4 Injunctions Pending Appeal

The injunction is enforceable by posting a bond. If the injunction is appealed before a district court, the judge will request the appellant post a bond to suspend the injunction, which may be neutralised by posting a counter-bond. The counter-bond will allow the owner of the patent to enforce the injunction even when it is challenged by the infringer.

If the patent is valid and infringed by the defendant, IMPI will impose a fine on the defendant and order the infringement to be suspended, unless the defendant appeals and requests the suspension of IMPI's decision before a federal court. In this case, the defendant must post a bond to suspend the execution of the payment of the infringement and may continue using the patent until a final decision is issued by a federal or circuit court.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

Appeals challenging IMPI's decisions are regulated in a generic form in another law that applies to a variety of subjects, including intellectual property.

### 7.2 Type of Review

The appeal is limited to the arguments made by the appellant. Therefore, if they do not challenge a specific issue or illegality identified in the decision, IMPI and/or the relevant federal court – depending on the type of challenge – are not bound to resolve it. As a result, the facts, articles or interpretations of articles not contested by the appellant are interpreted as having been consented to.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

The estimated cost for filing a cancellation or infringement action, or for responding to either, is approximately USD10,500. Preparing and sending a cease and desist letter costs USD500. The estimated costs for preparing and filing pleadings are USD3,500.

## 8.2 Calculation of Court Fees

Government fees are paid only at the first instance before IMPI; no government fees apply for the rest of the litigation until the final instance.

## 8.3 Responsibility for Paying the Costs of Litigation

The plaintiff may claim compensation in civil proceedings for damages and legal expenses. If the legal procedure is not raised in civil proceedings, neither of the parties can claim payment of legal expenses, and each party will pay their own expenses without the possibility of reimbursement.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

It is not common but, if the parties agree, alternative dispute resolution may be implemented through a mediator or arbitrator.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

An assignment of an intellectual property right must be recorded at IMPI, by filing the assignment document, duly signed by both parties, bearing original signatures or a copy duly certified and authenticated with the Hague Convention apostille, or by a Mexican Consulate. If an authorised agent makes a request for the recording of the assignment, that request must include the corresponding power of attorney document.

### 10.2 Procedure for Assigning an Intellectual Property Right

The recording of the assignment is requested in writing by the agent authorised by either of the parties, including the respective power of attorney document to confirm the authorisation. IMPI reviews the documents and issues either an acceptance or an official requirement, if anything is missing, within three to four weeks of the date the request is filed. The official action informing that the recording of the assignment has taken place indicates the recording date and the name of the new owner of the intellectual property.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

The licensing of an intellectual property right must be recorded at IMPI, by filing the licence document, duly signed by both parties, bearing original signatures or a copy duly certified and authenticated with the Hague Convention apostille, or by a Mexican Consulate. If an authorised agent makes a request for the recording of the assignment, that request must include the corresponding power of attorney document.

### 10.4 Procedure for Licensing an Intellectual Property Right

The authorised agent of either of the parties requests the recording of the licence in writing, including the respective power of attorney document to confirm the authorisation. IMPI reviews the documents and issues an acceptance or an official requirement, if anything is missing, within three to four weeks of the date the request is filed. The official action announcing that the recording of the licence has taken place indicates the recording date and the name of the licensee of the intellectual property.

**Basham, Ringe y Correa S.C.** has a patent litigation team consisting of 14 professional lawyers and engineers who work together to litigate complex issues concerning the infringement and nullity of patents and strategies created by the firm and accepted by the Supreme Court of Justice to compensate for lost time in the granting of patents. In addition, the firm has a strong

practice defending rights and challenging the constitutionality of laws and treaties before Mexican federal courts and the Supreme Court of Justice. The firm's engineers are specialised in subjects such as chemistry, biology, biotechnology, pharmaceuticals, physics, mechanics and electronics.

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His work includes patents, trade mark and copyright litigation; privacy and data protection litigation; and administrative litigation. Together with his litigation team, he developed a legal strategy to standardise the validity of patents in Mexico, which ended with the recognition of a historical criterion (2020–2021) in terms of patents by the Supreme Court of Justice, and which establishes that patents cannot be valid for less than 17 years from their granting. He is a member of the Barra Mexicana Colegio de Abogados (BMA), the Asociación Mexicana para la Protección de la Propiedad Intelectual (AMPPI) and the International Association for the Protection of Intellectual Property (AIPPI).



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## Trends and Developments

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### Mexico and its Megadiversity Regarding Patents and Traditional Knowledge

About two thirds of the world's biodiversity is distributed in a group of countries known as megadiverse countries. Mexico is one of them.

Being the fourth nation in terms of plurality of species and being characterised by a historical interaction between biodiversity, culture and tradition, its abundance in genetic resources (GRR) gives the country the opportunity to position itself as a provider of genetic wealth for its use.

Having numerous indigenous and local communities, it became necessary to consolidate a legal framework that allows the development of their autonomy, the respect for their self-determination rules and the protection of their human rights in the face of procedures for access to GRR, associated traditional knowledge (ATK) and the effective income derived from their use.

Thus, the Indigenous legal frame of Mexico (like others with similar characteristics) gained relevance in the construction of the regulatory system addressed to guarantee the appropriate access to these resources.

Mexico participates in the development of appropriate legal schemes that respond to the confluence of these realities.

The first step was the adhesion to the Nagoya Protocol, the next one, the grounding of an

internal framework legislation on access to the GRR and the ATK.

For this reason, Mexico is focusing its efforts on achieving legal harmonisation that privileges the attention and regulatory understanding of the issue for authorities, users and resource providers.

These efforts involve the inclusion of a vision of the country as megadiverse and pluricultural, under a human rights approach, that vindicates indigenous communities and contemplates Biocultural Community Protocols (BCPs) for the protection of their resources.

The process of consolidating an indigenous legal framework is a base for building a legal system that allows appropriate access to GRRs and ATKs to be addressed, and that, when necessary, addresses the phenomena of misappropriation.

The input of GRR is frequent in industries such as pharmaceuticals and cosmetics, increasing commercial interests and making necessary the clarity of regulations on patents and biodiversity that guarantee, on one hand, the protection of the knowledge of traditional communities and, on the other, the regulation of co-existence with entities that seek to obtain patents on inventions from traditional knowledge.

It is no secret that there is currently work to be done to create specialised secondary legislation, therefore, the growing interest in the subject and



the willingness of the involved entities will benefit all the involved participants.

### *The Nagoya Protocol*

The Convention on Biological Diversity (CBD) represents the meeting of minds for the global protection of biological diversity, implemented through the Nagoya Protocol, an obligatory reference for Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from the Utilisation of Biological Diversity.

This specialised treaty is in full force and effect for Mexico as of 12 October 2014, and provides guidelines for the appropriate access to genetic resources and associated traditional knowledge.

The Nagoya Protocol is a complementary treaty to the CBD, whose objective is the fair and equitable sharing of benefits arising from appropriate access to, and use of, TACs and RRGs, contributing to the conservation of biological diversity – or biodiversity – and the sustainable use of its components.

It also seeks to avoid so-called biopiracy and protect genetic resources and biodiversity of native communities.

The treaty provides international standards of prior informed consent and mutually agreed terms between users and providers of such resources, and imposes certain requirements.

Therefore, Mexico is working to establish conditions of legal certainty so that the activities carried out in the national jurisdiction, which involve access to the GGRR and/or ATK, observe the legal standards of this treaty.

The implementation of crystal-clear procedures will enable the development of messages of

credibility and legality of operations linked to the legal frame of access in which the Mexican State participates.

These conditions of legal certainty must consider that many of the GGRRs are located within the territory of indigenous communities and that the ATKs belong to them by *ius soli*.

In the First Interim National Report on the Implementation of the Nagoya Protocol, Mexico reported the need to continue working on implementation activities that mature into a secondary law(s) on the subject and that contribute to reducing the split of legal regulations in different laws.

Thus, Mexico focuses its efforts on the creation of secondary national legislation that makes this legal framework effective.

### *The legal framework in Mexico*

The Mexican Nation is unique and indivisible on the outside, whereas on the inside it has a multicultural composition originally based on its indigenous communities who retain their own social, economic, cultural and political institutions.

The Mexican authorities are already working on two fronts; on one side, to avoid the dispersion of the relevant norms and, on the other, to ensure that the current provisions can incorporate the legal figures and rules that clearly implement the treaty.

The challenge arises when it is seen that secondary legal systems have not undergone modifications to adopt and adapt the international standards from the Nagoya Protocol, particularly in specific issues such as scientific collection,

extractive exploitation and access to GRR in regulatory processes.

The Mexican Constitution provides that international treaties shall be supreme law of the entire Union. In this sense, for the Mexican State, its exercise is imperative. Under this premise, Mexico must generate value in the processes and products resulting from the utilisation of genetic resources.

This process must take place along the research and development chain to promote the protection of intangibles through Industrial Property.

Thus, it is interesting to highlight specific points on which it will be necessary to build bridges between the Federal Law on the Protection of Industrial Property (LFPPI) and the Nagoya Protocol.

The application of the LFPPI should harmonise the object and purpose of the Nagoya Protocol and particularly in the processing of patents.

Currently, the law does not provide for a system that considers the history of access to, and use of, genetic resources, as well as a system of prevention (or even refusal) of the granting of any of the rights, when they are contrary to any legal provision. These are issues that some specialists have highlighted.

In other words, if a genetic resource was improperly accessed for the development of a product or process in violation of the standards derived from the Nagoya Protocol.

In view of the foregoing, it has been recommended in various forums that provisions be included in this regard, as well as others related to the drafting standards of a patent involving a genetic

resource, making it necessary to observe whether the descriptive sufficiency of the invention indicates if the resource was properly accessed. In terms of the international treaty, the patent applicant should indicate or exhibit the permit issued by the Competent National Authority of the Protocol.

### *Biopiracy*

“Biopiracy” is the term coined when there is an appropriation of biodiversity where, paradoxically, the vehicle of its materialisation is a right obtained through a procedure established by law.

In this scenario, it is closer to the concept of abuse of law by using a lawful venue (that of accessing a patent) for an illicit purpose (misappropriation of biodiversity).

Now, beyond the discussion about the suitability of the term, the country is facing a reality in which patents under this hypothesis are known as biopatents and their detractors argue that they affect the natural genetic resources of living organisms and the traditional knowledge of indigenous communities associated with these resources.

Considering the above, there are two opportunities:

- the first is to strengthen the current legal system to include the reference to traditional knowledge within the previous stages of patentability analysis; and
- the second, that of simplifying the governmental framework where (i) there are too many authorities that are involved in the protection of biopiracy by applying dispersed legal norms, diluting the sense of leadership in the national agenda of the issue

and (ii) where none of these authorities is competent in matters of Industrial Property, as the IMPI is (Mexican Institute of Industrial Property).

Mexican law is clear that biological and genetic material is not considered an invention, however, the final part of section VII of Article 47 seems to open the door for discussion around the concept of “... as found in nature...”.

Thus, it seems legitimate to patent an innovation where substances extracted from animals or plants are part of a product or a process for obtaining a product, without even questioning whether these substances had already been used by people belonging to a traditional community.

The action of the examiner of the patent authority that receives a patent application could be lawful, it could be legal, but not necessarily complete and global, and here lies the challenge, as said examiner cannot use laws and regulations from other competent authorities, even when they are related on its subject.

Moreover, if the prohibition concerns biological and genetic material as found in nature, the logical question will relate to genetic material not found in nature, for example material genetically manipulated to develop a new material that is the result of inventive step and capable of industrial application.

At this point, the inventive step and genetic manipulation would be conditioned first to access the genetic resource or material to be analysed and/or manipulated and it is at this point where the Mexican authority finds an area of opportunity following the guideline of the Nagoya Protocol.

Empowering examiners to identify genetic material and requiring compliance with the Nagoya Protocol prior to the grant of a patent seems an alternative.

However, this means moving from a system that qualifies an invention by elimination where approval proceeds if in the State of the Art there are no reports on the intended invention.

In light of the above, this leads to a reflection on whether the way in which the State of the Art has been understood makes its application effective, because in Mexican Law, Article 45 fraction II, it is established that it is part of “... the body of technical knowledge which has been made accessible to the public by means of an oral description...”.

The reality is that in a legal system where the documentary support of information is privileged, traditional knowledge transmitted orally has a flimsy umbrella and even more so if one considers that its quality of “technical” also languishes before its management and dissemination by members of a community whose members do not have recognised a “technical” preparation.

The question then arises as to whether traditional knowledge should be explicitly regulated as an exception to the universality of legal norms where one again steps on the thin ice that assumes that what is not regulated, is allowed.

There are efforts in other countries where a bet has already been made. Peru has a National Commission against biopiracy that is also linked to the National Institute for the Defence of Competition and Protection of Intellectual Property (INDECOPI).

Patent cases involving genetic resources from that country have already been identified, where approximately one third have been ruled in favour of indigenous communities. Is one third a satisfactory or sufficient ratio? It's hard to say, but it is certainly better than zero.

Thus, it seems that one of the underlying messages is related to making indigenous communities feel a true, accessible and effective closeness to the industrial property authority.

However, this ideal also poses other challenges such as how to make this approach effective; some jurisdictions have opted for the creation of catalogues that record the knowledge of traditional communities associated with biological resources.

Is cataloguing a real and effective solution? The creation of a registry of traditional knowledge involving biodiversity and that complements laws for the protection of indigenous knowledge over biological resources and the right to prior consultation of communities when there are measures that directly affect them, is an area where Peru has taken the lead.

In contrast, Brazil, for example, has a law protecting traditional knowledge but does not have a catalogue.

Other countries have legislation to protect their communities' traditional biodiversity knowledge, such as Colombia, Ecuador, Bolivia and Costa Rica.

Thus, the adoption of the CBD and the 2014 Nagoya Protocol serves as a fair counterweight to the patent system, enabling positive interactions between biodiversity and intellectual property regimes through mutually reinforcing synergies.

### *Conclusion*

Although Mexico already had several provisions with indigenous and rural content prior to the entry into force of the Protocol, it is in a scenario where progress is being made in the procurement of a specialised framework that allows an efficient application of the treaty at the operational level, for which the authorities, users and providers of the GGRR and/or ATK must continue with the work of making the applicable legal systems affordable and that allow a proper interpretation of existing and transitional legal norms.

The BCPs recently published by the government of Mexico in the Access and Benefit-Sharing Clearing-House constitute a significant effort by communities to contribute to the effective implementation of the treaty by incorporating the vision of indigenous communities and local communities in Mexico into this national process.

With BCPs in hand, the Mexican State can have a significant, timely and harmonious impact on legislative processes so that the elements embodied in them comply with their objectives and are able to prevent violations of indigenous rights.

# MEXICO TRENDS AND DEVELOPMENTS

Contributed by: Elías Ríos, Karen Covarrubias, Citlali Carlos and Luisa Arias, **Vila Attorneys at Law**

**Vila Attorneys at Law** is an important firm on Mexico's west coast, and maintains a boutique seal that has allowed a close relationship and communication with clients. The firm comprises 25 professionals, including expert attorneys in diverse areas, as well as engineers, among others. Every case handled by the firm is personally managed by partners and associates, who directly interact with clients instead of delegating their work into large structures. Vila's special-

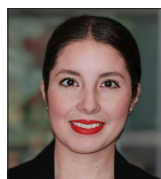
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# MEXICO TRENDS AND DEVELOPMENTS

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

The Portuguese legal system foresees the protection of inventions through patents and utility models. Naturally, in certain circumstances, an invention may also be protected by trade secrets and there is a new regime, in force since the start of 2019, for this type of protection. This article will focus, however, on the first two intellectual property rights.

Various types of patents can be protected in Portugal. It is possible to protect an invention through a national patent, a European patent (as granted by the European Patent Office (EPO)) and also an international (Patent Cooperation Treaty, or PCT) patent application designating Portugal. The prohibition against double protection was eliminated in 2018 and, therefore, it is even possible to have a Portuguese patent and European patent covering the same invention and co-existing in the Portuguese territory.

Provisional patent applications are also foreseen under Portuguese law and were created so as to assist with urgent filings or situations where the applicant wishes to have more time to assess the advantages of filing a definitive patent application.

The unitary patent and a unified patent court system was approved in the Portuguese parliament by Resolution No 108/2015 of 10 April 2015 and ratified by the Portuguese President of the Republic through Presidential Decree No 90/2015, published on 6 August 2015. Consequently, when the unitary patent and the unified patent court become realities, they will be applicable in Portugal.

Patents and utility models in force in Portugal may be searched in both national and international patent databases. However, in Portugal, there is no equivalent to an Orange Book that lists applicable patents in relation to certain products or processes (eg, in the pharmaceutical sector).

The entire system in Portugal is based on statutory law. Case law can assist in interpreting the statutory law. European Union directives may also be invoked for purposes of interpretation, when the national legislation does not seem to conform with mandatory EU directive provisions.

This chapter seeks to describe what is foreseen in Portuguese law, and the latter is focused, by and large, on Portuguese patents. It will therefore abstain from describing provisions that are foreseen in international treaties such as the European Patent Convention (EPC) or the PCT.

### 1.2 Grant Procedure Process

The process for the grant of a Portuguese patent is similar to that of a Portuguese utility model.

The process begins with the filing of an application. To receive a filing date, the application must contain at least the identification of the applicant and a document that describes the invention and the scope of the application in such a way as to be executed by an expert in the field. As in other jurisdictions, for the application to be considered complete, it should contain a description, claims, drawings and an abstract. If invoking a priority, the previous application should also be identified.

Once the application is complete, there is an examination regarding the formal requirements. Unless early publication is requested, the appli-

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cation will be published 18 months from the application date or priority date. This opens up a two-month opposition period. After this opposition stage is closed, the application enters the phase of examination on patentability requirements. If there are objections to the grant, the applicant will be invited to adjust the text of the application. This may happen more than once. At the end of the process, the *Instituto Nacional da Propriedade Industrial* (Portuguese Patent and Trademark Office, or PTO) will issue a decision to grant or will refuse the application.

## Representation

The applicant does not necessarily need to be represented by a lawyer or patent attorney. However, if the applicant is a non-resident of Portugal, it must indicate an address in this country, as well as a fax number or an email address.

## Costs

The Portuguese government seeks to promote the filing of Portuguese patent applications by applying low official fees. The cost of filing a Portuguese patent application, including examination, is currently EUR109.07.

If the applicant files a provisional patent application, the cost is currently EUR10.91 for filing, EUR54.54 for the search report and EUR76.36 to convert the application into a regular Portuguese patent application.

## 1.3 Timeline for Grant Procedure

The time to process a Portuguese patent application and examine the invention depends heavily on the size of the description and number of claims, the complexity of the invention, the technical field and the quality of the documentation submitted.

On average, the time taken between the filing and the decision to grant is around three to four years, although one should bear in mind that the application is normally only published 18 months after filing and only begins to be examined in full at around 20 months after filing.

The maximum durations assume annual renewals to keep the IP right in force.

## 1.4 Term of Each Intellectual Property Right

A granted patent will be valid for a term of 20 years, counting from the date of application. A supplementary protection certificate (SPC) can extend the life of a patent in the pharmaceutical field for a maximum of five years (an additional six-month extension is possible for paediatric medicines).

With respect to utility models, they are valid for an initial period of six years, but can be renewed a maximum of two times, for periods of two years. Consequently, a utility model can remain in force for a maximum of ten years counting from the application date.

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

### Pre-grant

After the publication of the patent application, the patentee acquires some provisional protection (Article 5 of the Portuguese Industrial Property Code, or PIPC), namely for purposes of calculation of damages if infringement is confirmed in the future.

As regards obligations at the pre-grant stage, the payment of annual renewal fees is an obligation that does not depend on the grant of the patent.

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Indeed, if the annual renewal fees are not paid, the patent application or the granted patent will lapse.

## Post-grant

The grant of the patent is the moment when the patentee obtains the full breadth of the rights foreseen in the law. Pursuant to Article 102 of the PIPC, the patent owner has the exclusive right to exploit the invention in any part of the territory of Portugal and also to prohibit third parties from manufacturing, offering for sale, storing, placing on the market, importing, possessing or using a product or process covered by a patent.

Naturally, if these exclusive rights are infringed, the patent owner is entitled to redress; namely, to obtain a court decision ordering that the infringement cease and the payment of an indemnification. Supplementary measures may also be decreed, such as the seizing of equipment, materials and closing of the premises used for carrying out the infringing activities.

In addition to rights, the patent owner also has some obligations. Aside from the need to renew the patent annually, as mentioned above, the patent owner has the obligation to put the patented invention to use in the territory.

Article 107 of the PIPC states that the patent owner must exploit the patented invention directly or indirectly and commercialise the results so as to satisfy the needs of the national market. This must be done within four years of filing the patent application or three years after the grant of the patent, whichever occurs later. The consequence for not putting the invention to use is the possible compulsory licensing of the technology to satisfy national needs. These provisions regarding compulsory licensing are rarely put into practice.

## 1.6 Further Protection After Lapse of the Maximum Term

SPCs that serve as an extension to a patent right are governed by EU regulation and can be obtained in Portugal. They apply to specific pharmaceutical and plant protection products that have been authorised by regulatory authorities.

For an SPC to be granted, it is necessary to comply with a variety of administrative requirements and the pharmaceutical product or plant protection product must be foreseen in the base patent.

An SPC can extend a patent right for a maximum of five years. A six-month additional extension is available in accordance with Regulation (EC) No 1901/2006 if the SPC relates to a medicinal product for children for which data has been submitted according to a paediatric investigation plan (PIP). PIPs are required to support the authorisation of medicines for children.

## 1.7 Third-Party Rights to Participate in Grant Proceedings

In Portuguese patent grant proceedings, third-party oppositions can be filed within two months from the publication date. These oppositions are filed with the PTO either in paper format or through the PTO's electronic platform. There are no third-party observations in Portuguese patent grant proceedings as there are in other jurisdictions.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

Under Portuguese law, the applicant of a patent or utility model may appeal a decision that refuses to grant said industrial property right to the Intellectual Property Court or, alternatively,

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to the Intellectual Property Arbitration Centre (ARBITRARE).

There is also an administrative proceeding to react to a refusal decision, whereby the applicant requests the reassessment of the decision to someone hierarchically superior to the director of Patents and Trademarks Department at the PTO. In practice, this is almost always the Directive Board of the PTO. Furthermore, it is understood that this mechanism should only be used when there are new facts or arguments not considered by the initial decision-maker.

## 1.9 Consequences of Failure to Pay Annual Fees

If a patent or utility model is not renewed within the normal deadline, the renewal fee can still be paid within an additional six months, subject to the payment of a surcharge. Failure to renew within this supplementary period leads to the lapse of the right and the publication of a notice in the IP Bulletin. The patent or utility model may still be revalidated within a period of one year following the publication, subject to the payment of triple the normal renewal fees.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

Pursuant to Article 102(8) of the PIPC, the owner of a patent may limit its scope by modifying the claims. A submission with the new set of claims must be filed with the PTO and a fee is due for this proceeding. The patent examiner will assess the amendments and, if in conformity with the law, approve the new claims.

It is also possible to request the limitation of patent claims in response to a judicial action seeking the invalidation of the patent (Article 115(2), PIPC). This provision is also applicable to utility models.

In short, the general rule is that the patent owner may limit the scope of the granted right, but it is forbidden to broaden the scope.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

When confronted with the infringement of a patent or utility model in Portugal, the owner of the right is presented with a series of possible responses.

First and foremost, patent infringement is a crime under Portuguese law (Article 318, PIPC) and, consequently, it is possible to file a criminal complaint against the infringer so that the situation is investigated by the Public Prosecutor's Office to determine if a criminal accusation can be brought against the infringer.

The patent owner may also file a civil action against the infringer, notably at the Intellectual Property Court, requesting the resolution of the dispute.

If the owner requires urgent relief, the grant of a preliminary injunction may also be requested from the Intellectual Property Court.

Finally, under Portuguese law, the patent owner may propose to the suspected infringer that the dispute be submitted to voluntary arbitration. This is expressly foreseen in Law No 62/2011 (as amended) for pharmaceutical patent disputes.

The voluntary arbitration may be "ad hoc" or institutional arbitration governed by the rules of an institutional arbitration centre. In Portugal, there is an arbitration centre specialising in intellectual property disputes called "ARBITRARE".

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It is also possible for patent owners to request customs border actions so as to detect and prevent the importation of patent infringing products into Portuguese territory. Customs border actions are governed by Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003, and also Law-Decree No 360/2007, of 2 November 2007.

## 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

A third party wishing to use commercially a patented invention in Portugal without the consent of the patent owner has a range of options depending on whether it believes the intellectual property right to be valid or not.

### Actions Seeking the Invalidity of the Patent

As mentioned in 1.7 **Third-Party Rights to Participate in Grant Proceedings**, under Portuguese law, opposition proceedings can be initiated during the administrative phase, before the patent application undergoes the examination on patentability requirements. In this way, third parties have the opportunity to try and prevent the granting of the patent right in the first place.

If the opposition is unsuccessful or if no opposition is filed, a third party may always respond to the decision to grant by filing an appeal within two months (see 1.8 **Remedies against Refusal to Grant an Intellectual Property Right**, *mutatis mutandis*).

A third party may also file a judicial action to invalidate, totally or partially, a granted patent. Invalidation may take the form of a nullity action or an annullability action.

A nullity action may be filed at any time and is reserved for cases where (i) the object of the protection cannot be patented under the law, (ii) there were significant failings in the administrative process, or (iii) public order provisions were infringed. The overwhelming majority of patent nullity actions in Portugal are based on the lack of novelty of the invention or the lack of inventive step.

An annullability action is reserved for situations where the right has been attributed incorrectly to the wrong person or entity.

### Actions That do Not Seek the Invalidity of the Patent

Although extremely rare, it is possible for a third party to file a judicial action aimed at obtaining a judgment declaring that a product or process does not infringe a patent (declaration of non-infringement).

Equally rare are compulsory licences. These are based on statutory law and are foreseen for the following situations: (i) public interest reasons, (ii) lack of use of the invention in the Portuguese territory, or (iii) in situations of dependency between patents.

Patents may also be expropriated by the state in situations where this is essential for the public interest, subject to the payment of just compensation. There are no known cases of patent expropriation in the last decades.

Irrespective of the action, the third party must, as a general rule, show legitimate interest and standing. These requirements are met by showing that the third party has genuine and lawful grounds for seeking and obtaining the legal remedy.

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## 2.3 Courts With Jurisdiction

In Portugal, there is a specialised first instance court for patent litigation: the Intellectual Property Court. This judicial court is competent for most intellectual property civil disputes (ie, criminal disputes fall under the jurisdiction of other courts).

Appeals of decisions of the Intellectual Property Court are assigned to a specialised section of the Second Instance Court of Lisbon, which deals with intellectual property cases.

There is no specialised section at the Supreme Court for intellectual property matters, but this highest court can rule on cases related to points of intellectual property law.

Likewise, the Constitutional Court is sometimes called upon to assess the constitutionality of some legal provisions in Portuguese intellectual property law.

It should be noted that Portugal also has a separate structure for administrative courts. Although it is now rare for these administrative courts to deal with patent matters, there was a time (approximately 2006–11) in which they were heavily involved in patent-linkage cases in the pharmaceutical sector.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

As mentioned in 2.3 Courts with Jurisdiction, Portugal has a specialised first instance judicial court for civil disputes related to intellectual property matters. The Intellectual Property Court was created by Law No 46/2011, of 24 June 2011, and installed pursuant to Ordinance No 84/2012, of 29 March 2012. This Court's scope is currently defined in Article 111 of Law

No 62/2013, of 26 August 2013 (in its current version).

As also mentioned at 2.3 Courts with Jurisdiction, the Second Instance Court of Lisbon also has a section specialised in intellectual property, as foreseen in Law No 55/2019, of 5 August 2019.

In addition to these judicial bodies, Portugal also has, since 2008, a fixed arbitration centre specialising in intellectual property matters called ARBITRARE (Dispatch No 28519/2008, of 22 October 2008). The PTO and the Institute for Registries and Notaries are bound to this arbitration centre, which means that interested parties can refer cases to it and the aforementioned public entities must accept the competence of ARBITRARE (Ordinance No 1046/2009, of 15 September 2009).

Finally, it is worth noting that Lisbon (the capital of Portugal) has been proposed as a host city for one of the patent mediation and arbitration centres under the Unified Patent Court system. This has not yet become definitive.

## 2.5 Prerequisites to Filing a Lawsuit

There is no requirement to issue a formal demand letter or a warning letter in Portugal prior to filing a lawsuit. However, given the time and costs associated with litigation, it is always logical to explore the possibility of reaching an extra-judicial resolution before initiating judicial or arbitration proceedings.

In pharmaceutical patent disputes under Law No 62/2011 (as amended), the patent owner must react to a marketing authorisation (MA) application or registration by initiating proceedings against the applicant within 30 days. This does not always give much time to the patent owner



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to contact the MA applicant and seek an amicable resolution to the dispute.

If the patent owner is the claimant, the patent registry should be checked to ensure the patent is correctly recorded with the name of the patent owner. This is important for purposes of legitimacy and standing. Likewise, the recordal of a patent licence is important if the claimant seeks to claim damages suffered by the licensee.

If the lawsuit is to be filed by the licensee, it is also required that the licence be recorded at the PTO.

## 2.6 Legal Representation

As a general rule, the majority of lawsuits related to patent matters will require each party to retain legal counsel.

A few theoretical cases may fall outside this general rule if the value of the case is very low and no possibility of appeal would apply. In any case, given the complex and technical nature of the proceedings, even in these exceptional cases, professional legal representation is advised.

## 2.7 Interim Injunctions

Portuguese judicial courts are able to grant interim injunctions on an *inter partes* or *ex parte* basis. It should be noted that such an injunction needs to be linked to a main action. The interim injunctions can be requested prior to the filing of the main action or during its pendency.

The general criteria for an *ex parte* interim injunction are *fumus boni iuris* (prima facie evidence of the existence and validity of the right) and *periculum in mora* (irreparable harm or at least harm that could only be repaired with great difficulty unless urgent relief was given). The applicant must also convince the court that notification

of the alleged infringer before the measures are enforced would run a serious risk of rendering them useless.

*Inter partes* interim injunctions are also possible and far more common. The criteria of *fumus boni iuris* and *periculum in mora* mentioned above are applicable for situations where the infringement is imminent, but not yet occurring. In cases where infringement is ongoing, the applicant need only show the existence of *fumus boni iuris*.

## 2.8 Protection for Potential Opponents

Protective briefs are not foreseen under Portuguese law. However, a bond can indeed be required to be posted by the patent owner/applicant of the interim injunction as a condition for the granting of the interim measure.

Often, the best course of action for the defendant to preventively protect itself against the risk of an interim injunction being granted against it is to file a pre-emptive invalidity action so as to weaken the *fumus boni iuris* criterion, assuming there are grounds for this.

An action to obtain a declaration of non-infringement could have the same purpose, but it is a strategy that is rarely adopted and carries with it several risks.

## 2.9 Special Limitation Provisions

A judicial action that seeks to stop an imminent or ongoing infringement of a patent may be filed at any time while the industrial property right is in force. Likewise, injunctive relief may also be requested at any time. Under Portuguese law, it would be required to show *periculum in mora* in situations where the patent infringement is imminent, which would impose the filing of the interim injunction on an urgent basis, although not with-

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in a defined period of time. This requirement of *periculum in mora* does not need to be shown in cases where the infringement is ongoing.

If a judicial action seeks indemnification for damages suffered as a result of the infringement of a right, the limitation period is three years counting from the date when the injured party became aware of the right to indemnification.

If the infringement may also qualify as a crime – which would be the case in patent infringement – the limitation period will be defined under criminal law. Article 118 of the Portuguese Criminal Code sets the limitation period at five years for crimes that may imply prison sentences of over one year but less than five years.

## 2.10 Mechanisms to Obtain Evidence and Information

Evidence gathering procedures have been foreseen in Portuguese intellectual property law since the transposition of the Enforcement Directive (Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights) in 2008. These measures aim at obtaining evidence in the possession of the counterparty or from another party not connected to the case and can be requested prior to the filing of the court action or while it is ongoing (during the appropriate phase of the proceedings).

For patent infringement cases, these measures are foreseen in Articles 339 and 344 of the PIPC.

In general terms, the procedure is commenced with an application to the competent court. In said application, the court must be provided with an indication of the specific evidence that the applicant wishes to obtain and the likelihood that it exists and is in the possession of the counter-

party. It is also necessary to show the existence or threat of infringement of the patent right. In order to obtain financial and accounting documentation, the applicant must also show that the alleged infringement is occurring on a commercial level. In other words, the infringing acts have a direct or indirect commercial or economic goal.

## 2.11 Initial Pleading Standards

The Portuguese civil procedure system is front-loaded, which means that the plaintiff will need to provide in detail all the facts that substantiate its claim and also attach all the documentary evidence with the initial pleadings. Article 552 of the Civil Procedure Code sets out a series of formal requirements in order for the initial pleadings to be considered correctly drafted and accepted by the secretariat of the court.

There are no special provisions for patent cases, with the exception of the indication of the competent court which, in cases of patent infringement or invalidation, will be the Intellectual Property Court. In relation to the rest, the plaintiff must follow the general rules of the Civil Procedure Code.

Although the proceedings are front-loaded, there are some (limited) opportunities for the parties to file additional submissions and documents at other stages of the proceedings, although with the risk of these being disregarded or being admitted subject to the payment of a fine.

If the defendant files a counterclaim, the plaintiff will be entitled to submitting a reply (“*replica*”).

## 2.12 Representative or Collective Action

Representative or collective actions (such as class actions) exist under Portuguese law and have been initiated in situations involving public health, quality of life, consumer protection, etc.

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Nothing is expressly foreseen in the class action law for intellectual property matters and there is no precedent of this type of action being used for patent cases.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

The PIPC foresees a plethora of situations that limit or restrict the enforcement of a patent right, for example, private acts with no commercial purposes (Article 103, PIPC). Portuguese law also foresees the exhaustion of patent rights after the first authorised sale on the market (Article 104, PIPC).

A patent is also not considered to be enforceable against a third party that, in good faith, had reached the invention independently before the priority date of the patent and was using the invention or making serious preparations to do so (Article 105, PIPC).

Other legal defences, such as abuse of a right, are also generally foreseen under the law and may be invoked by a defendant in order to try and prevent a conviction for infringement.

Finally, the enforceability of patent rights must also co-exist with Portuguese and EU competition law. It is beyond the scope of this chapter to detail the aspects in which patent right enforcement may be incompatible with competition law, however, the same issues faced in other European jurisdictions would also be relevant in Portugal (eg, “pay for delay”).

Likewise, the matter of standard-essential patents (SEPs) and their licensing on fair, reasonable and non-discriminatory (FRAND) terms is also relevant in a discussion related to the enforcement restrictions faced by a patent owner in Portugal.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

In a civil patent infringement action, there must be at least a plaintiff and a defendant. These are the necessary parties to file the infringement action. In criminal proceedings related to patent infringement, it is possible to file a complaint against unknown parties and it will be the Public Prosecution Office’s role to investigate and determine the suspected infringers.

Pursuant to Article 338 of the PIPC, a licensee is entitled to file an action for infringement, as well as to request interim measures and evidence gathering measures in patent infringement cases, unless the licence agreement stipulates otherwise. The licence agreement should, however, be recorded with the PTO.

### 3.2 Direct and Indirect Infringement

The reform of the PIPC in 2018 clarified the issue of direct and indirect patent infringement, a topic which had raised curiosity amongst some patent law scholars.

Direct infringement is a situation in which the alleged infringer, without authorisation from the patent owner, carries out one of the infringing acts foreseen in the law (eg, manufacturing, offering for sale, storage, placement on the market or importation of a product or process that infringes a patent).

Indirect infringement covers cases in which a third party offers or makes available to another person the means for the latter to execute the invention. Article 102(3) makes it clear that this contributory infringer must know or should know that the means made available are suitable and aimed at the execution of the invention. A theo-

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retical scenario would be if an entity prepared assembly kits with all the individual parts necessary to assemble an infringing product and sold them to a distributor. The kit itself does not fall in the scope of the patent claims, but the actions clearly contribute to the infringement by another party.

The remedies for direct and indirect infringement are those described in **1.5 Rights and Obligations of Owners of Intellectual Property Rights**.

### 3.3 Process Patents

In accordance with Article 99 of the PIPC, if the patent covers a process for producing a new product, there is a reversal of the burden of proof, and the same product produced by third parties will be presumed to have been made through the patented process. This is a particularity of patent infringement proceedings.

The issue of parts of an allegedly infringing process being practised outside Portugal is an interesting one, since, as is well known, infringement will only occur when all the integers of the independent claims are present. Therefore, only when the various parts of the patented process are put together in Portugal will there be an infringement situation.

### 3.4 Scope of Protection for an Intellectual Property Right

Similar to what occurs in other European jurisdictions, the scope of a patent under Portuguese law is defined by the patent claims, which should be interpreted, in the event of a lack of clarity, based on the content of the patent description and drawings.

Portuguese courts and other dispute resolution bodies (ie, arbitration tribunals) tend to follow the teachings of the Protocol on the Interpretation of

Article 69 of the EPC, and, therefore, the doctrine of equivalence is accepted in Portuguese case law.

The role of the prosecution history may also be relevant in many cases, notably in terms of verification of added matter and the search for contradictory statements made by the applicant. However, it does not have the same weight as in some other jurisdictions, such as in US case law.

### 3.5 Defences Against Infringement

The most common defences in a patent infringement case are (i) arguments of non-infringement (ie, that the product or process does not fall in the scope of the patent), and (ii) the invalidity of the patent itself.

In some cases, there are other formal procedural defences also, such as lack of standing, statute of limitations, and incomprehensible pleadings.

Other patent specific defences – such as exhaustion of rights, compulsory licensing, FRAND licensing – are possible in certain cases but there is not much case law regarding these defences.

### 3.6 Role of Experts

In complex patent cases, experts are frequently called upon to explain the scope of the invention and the technical aspects behind it. Expert reports are often prepared and filed regarding infringement, but also regarding issues such as novelty and inventive step.

The perspective of these experts is often important to provide the court with the opinion of a person skilled in the art.

It is more common for the parties to appoint experts to provide testimony as (expert) wit-

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nesses. However, the courts frequently appoint experts as well, when requested by the parties or when the court feels that it is essential to have a clear understanding of the technical matters being discussed.

Some judges also appoint a technical assistant to advise them directly.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

There is no separate procedure for construing the terms of the patent's claims. The claims are interpreted in the context of the judicial proceedings and in accordance with the normal reasoning described in 3.4 Scope of Protection for an Intellectual Property Right.

### 3.8 Procedure for Third-Party Opinions

In Portuguese patent cases, the court may request an expert opinion or seek specific information from private or public entities (such as the PTO). However, this information and evidence is assessed freely by the court and the court will not seek a third-party opinion of what the judgment should be. Indeed, it is the court's function to administer justice and this cannot be delegated to third parties.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

A patent revocation action may be initiated as a reaction to a concrete infringement claim or it may be motivated by a wish to reduce the risk of such an infringement in the future (ie, to clear the path). In the first scenario, it is common for the revocation of the patent to be requested as a counterclaim in the infringement proceedings.

In order to request the revocation of a patent right, the requestor must demonstrate some legitimate interest in order to have standing. However, this legitimate interest need not be personal. Indeed, it would be possible, for example, for a software association to request the revocation of a software patent if it was believed that it was meritless and stifled competition in the sector as a whole.

### 4.2 Partial Revocation/Cancellation

Partial revocation of a patent or utility model is possible in situations where some claims are invalid and others remain patentable. Article 115(1) and (3) of the PIPC confirms this possibility.

Another scenario where it would be possible to obtain a partial revocation or cancellation would be if the invention is the result of the work of more than one person or entity and there is a dispute as to the ownership of the content included in the patent. The court may cancel some claims in these cases.

### 4.3 Amendments in Revocation/Cancellation Proceedings

The amendment of a patent's claims is possible in revocation proceedings, in accordance with Article 115(2) of the PIPC, provided the scope of protection is limited and not broadened.

The amendment request can be submitted directly to the court handling the case or, alternatively, pursuant to Article 102(8) of the PIPC, the patent owner may request the amendment to the PTO and then communicate said limitation to the court.

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## 4.4 Revocation/Cancellation and Infringement

Unlike the German system, the Portuguese system concentrates patent revocation and infringement issues in the same proceedings and the same trial (assuming, however, that the revocation is raised as a counterclaim).

If the revocation of the patent is raised in separate proceedings before or at roughly the same time as the infringement action, the revocation action is generally seen as a preliminary matter that must be resolved before infringement can be assessed. Consequently, the infringement proceedings will typically be stayed until such time as the revocation action is definitively resolved.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

Cases involving patent rights in civil, criminal and administrative proceedings follow the same general procedural rules that are applicable to other matters. By way of example, in civil proceedings, there will be an initial stage where the parties exchange briefs. This is followed by a preliminary hearing to deal with exception defence arguments and organise the trial.

There will be a single trial hearing (typically lasting for more than one day) where all the evidence will be produced and discussed. All parties will have the opportunity to produce witnesses to prove facts alleged by them and the witnesses will be subject to cross-examination. The witnesses may be technical experts or other witnesses that are relevant for providing evidence on other issues (eg, regarding damages).

The trial is concluded with final statements from the attorneys and the court will then typically adjourn and issue a written decision.

Similar to what occurs in civil proceedings involving other matters, if the damages cannot be determined at the same time as the decision on merits, there is the possibility of determining the precise amount of damages in a subsequent phase, known as the “*liquidação*” phase.

Notwithstanding the above, there are a few particularities that are specific to intellectual property cases, detailed below.

### Evidence Gathering

One of the areas where there are specific procedural provisions in intellectual property cases is evidence gathering. These specific measures are a result of the transposition of the Enforcement Directive and take into consideration the specificities of intellectual property rights and the difficulties in obtaining and preserving evidence of infringement.

### Preservation of Trade Secrets

Portuguese intellectual property law also contains specific procedural provisions aimed at preserving trade secrets in court proceedings and during trial. These consist, for example, in limiting the access to documents containing trade secrets, restricting the attendance of trials by third parties or access to transcripts and the redaction of judgments.

### Preliminary Injunctions

Unlike the general civil procedure rules for the granting of a preliminary injunction, namely showing *fumus boni iuris* and *periculum in mora*, intellectual property infringement cases are special since there are specific provisions and there is no need to demonstrate *periculum in mora*



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when the infringement is ongoing. This facilitates the granting of interim measures to stop a patent infringement that is occurring at the time.

## 5.2 Decision-Makers

Patent related cases are decided by legal judges, although these may sometimes request to be assisted by a technical expert/assistant. A case heard at a first instance court (eg, the Intellectual Property Court) will be managed and directed by a single judge. If an appeal is filed to a second instance court, the judgment will be typically taken by three legal judges and that will also be the norm at the Supreme Court. In certain cases, it is possible to involve additional judges in the decision-making process.

Trial by jury only exists in very limited situations in criminal cases and is not applicable to patent infringement cases.

It should also be noted that the judges are selected randomly in accordance with the court system's procedures. Consequently, it is not possible to influence who the decision-maker will be.

Forum-shopping is also not a possibility in Portugal since the Intellectual Property Court has jurisdiction over the entire territory.

## 5.3 Settling the Case

Civil proceedings, including patent infringement civil proceedings, may always terminate as a result of a settlement amongst the parties.

At the preliminary hearing, the court will ask the parties if any settlement is possible as part of normal procedure. There are often situations where the court is informed that settlement is very likely and, consequently, at the request of

the parties, suspends the proceedings until such time as the parties conclude their settlement.

There are mediation services in Portugal that litigating parties can resort to, albeit they are infrequently used.

## 5.4 Other Court Proceedings

The vast majority of patents that are in force in Portugal are European patents. Consequently, when litigation arises, it is not unusual for the disputes to be pan-European.

The existence of other court or patent office proceedings may, naturally, have an impact on current proceedings. The classic example in patent cases is the suspension of a patent infringement case while the revocation of the patent is being discussed in another proceeding. In Portugal, the staying of the infringement case may occur if the invalidation of the patent is being discussed in another Portuguese court or, in the case of European patents, if there are ongoing opposition proceedings at the EPO. As Portuguese courts are not bound to the decisions of other foreign courts, invalidation proceedings in other countries will not have the same impact, but the decisions may have some influence on the judge, particularly from experienced and well-respected courts in Germany, Netherlands and the UK.

Anti-suit injunctions in patent litigation, that have been popular in recent times in other jurisdictions, have not yet been tried and tested in Portugal and, therefore, it is unclear how a Portuguese court would react to such a request.



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## 6. Remedies

### 6.1 Remedies for the Patentee

The Enforcement Directive was transposed into Portuguese law in 2008 and, therefore, the remedies that exist for the patentee in a patent infringement case are largely harmonised with those that exist in other EU jurisdictions.

In addition to the right to obtain a decision to cease the infringement, the patentee will typically be entitled to be indemnified for damages suffered. In civil procedures, these damages are determined in a main action and not in a preliminary injunction.

The general rule under Portuguese patent law is that the injured party is entitled to damages equivalent to the losses suffered and the patentee has the burden of proof in relation to those losses. The court should take into consideration the profit obtained by the infringer, the damages that resulted from the infringement, the lost profits suffered by the right-holder, as well as the expenses borne by the right-holder related to the protection of the IP right and the investigation and termination of the infringing activity. The court should also consider the moral damages to the injured party.

In the event that it is not possible to determine the value of the damages suffered by the injured party, the court may – provided the right-holder does not oppose such an approach – establish an equitable amount that takes into consideration, at least, (i) the income that the IP holder would have gained had the infringer requested a licence to use the intellectual property right, and (ii) the expenses incurred by the IP holder related to the protection of the IP right and the investigation and termination of the infringing activity.

Enhanced damages for wilful or repeated infringement are also foreseen in Article 347(6) of the PIPC. In this situation, the court may sum up all the different types of damages foreseen in the previous paragraphs of Article 347.

Although the provisions mentioned above do give the judge more flexibility than that which exists in many other types of civil proceedings, the fact remains that the judge does not have discretion in ordering remedies. Indeed, these must be requested by the plaintiff and the latter still has the burden of proof. Even in a regime of compensation through reasonable licence royalties, the plaintiff must consent to the judge applying such a methodology.

In addition to damages, the injured party may request auxiliary remedies/sanctions such as the seizure of equipment or the closure of premises.

### 6.2 Rights of Prevailing Defendants

A prevailing defendant in Portugal does not have many rights in comparison to other European jurisdictions. The prevailing defendant will be entitled to the reimbursement of court fees and expenses and a small compensation to cover attorneys' fees.

If the issue of bad-faith litigation is raised by the defendant, it is possible that the plaintiff will be ordered to indemnify the former for some additional expenses.

In the specific context of preliminary injunctions, the plaintiff may be ordered to pay compensation for the damages caused to the prevailing defendant in the event that the injunction is ultimately found to be unjustified or ceases to have effect as a result of the plaintiff's conduct, or when it transpires that no infringement has occurred or if the risk of suffering irreparable or

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hardly reparable damage is considered unfounded, in all cases when the plaintiff acted with fault or abusively.

## 6.3 Types of Remedies

The types of remedies that are available in Portuguese patent law are the same as those that exist for other intellectual property rights, irrespective of whether they are technical IP rights.

## 6.4 Injunctions Pending Appeal

A preliminary injunction may be requested at any time, including before the initiation of a main action. If a patent is found valid and infringed at first instance, the appeal of that decision will not normally have suspensive effect unless the losing party requests such a suspension and offers up a bond. It will be up to the court to assess the viability of staying the enforcement of the decision, pending appeal.

It is not common to request a preliminary injunction after the first instance decision confirming the validity of the patent and its infringement. When no suspensive effect is granted to the appeal and the defendant does not voluntarily comply with the first instance orders, it is more frequent for the patent owner to initiate proceedings aimed at enforcing those orders (“*processo executivo*”).

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

There are no special provisions concerning the appellate procedure for patent infringement and validity proceedings. It should be noted, however, that Article 45(3) of the PIPC stipulates that in appeals related to decisions of the PTO, it is not possible to appeal against second instance

court judgments (save in exceptional cases where such appeals are always possible).

### 7.2 Type of Review

An appeal to the second instance court will generally imply a full review of the facts of the case (although the scope of the appeal is defined by the parties) and, on occasion, this court will order the first instance court to repeat part of the trial in order to produce additional evidence.

The Supreme Court of Justice is reserved for legal reviews and the Constitutional Court will only assess the constitutionality of legal provisions.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

As described in 2.5 Prerequisites to Filing a Lawsuit, there are no requirements in Portugal regarding warning letters, protective briefs and other such measures. However, it is fairly common to send one or more cease and desist letters through lawyers and this will, evidently, have some costs.

Furthermore, the investigation and preparation of the lawsuit also represents costs for the plaintiff. Often, this is one of the most expensive stages of the proceedings, since it is necessary to collect, analyse and organise a great deal of evidence. Portuguese proceedings are front-loaded and, therefore, a considerable amount of time and effort is dedicated to the phase prior to filing a lawsuit.

### 8.2 Calculation of Court Fees

The court fees that must be paid for commencing proceedings are based on the value of the case (eg, on the amount of damages being claimed).

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Portuguese procedural law stipulates that the value of intangible rights, for civil law cases, is fixed at EUR30,000.01 when no other criteria is applicable. This value allows the case to be appealable to the higher courts.

In a patent revocation case and other proceedings not related to the indemnification of damages, it will be customary to use this amount as the value of the case.

The court fees that must be paid to file the lawsuit are determined in accordance with the provisions of the Regulation on Procedural Costs (*Regulamento de Custas Processuais*).

### 8.3 Responsibility for Paying the Costs of Litigation

In a judicial court scenario, the winning party is entitled to recoup the court costs and other expenses, as well as a contribution towards its legal fees (ie, attorneys' fees).

This contribution is calculated based on the outcome of the litigation (if it was a full victory or a partial one) and the amount of court costs that were paid by the parties. In practice, the contribution tends to be a fairly symbolic amount compared to the actual legal costs that each party has to bear with the litigation.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

The use of alternative dispute resolution proceedings to settle patent disputes (particularly, arbitration proceedings) is no longer common in Portugal, after a period (2012–18) in which it was mandatory for pharmaceutical patent infringe-

ment cases, pursuant to Law No 62/2011 of 12 December 2011.

Currently, arbitration is only mandatory for disputes between employee-inventors and the employer, in order to determine the remuneration due for the invention assigned automatically to the employer.

As mentioned in **1.8 Remedies against Refusal to Grant an Intellectual Property Right**, Portugal has a fixed arbitration centre specialised in intellectual property matters called ARBITRARE which was established in 2008. The PTO is bound to this arbitration centre.

In terms of patents, ARBITRARE is used more frequently by parties wishing to appeal decisions of the PTO, including the refusal of patent applications. The applicant must file the appeal against the decision within two months of the publication of said decision in the IP Bulletin. Following this, typically a single arbitrator is appointed to conduct the proceedings in accordance with a pre-established arbitration centre regulation. The decision of the arbitrator has the same value as that of a first instance court.

With the exception of the disputes above, solely between the PTO and a private entity, all other disputes that involve other opposing parties require the consent of all for the arbitration to be valid and to proceed.

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## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

Under Portuguese law, the assignment of a patent must be subject to a written agreement that identifies the parties (assignor and assignee), the patent, whether the assignment is total or partial and whether it is for a consideration or not.

In order for the assignment to be applicable vis-à-vis third parties, it must be recorded at the PTO. If the agreement is not in Portuguese, a translation must also be submitted.

If the recordal of the assignment is requested by the assignor, there must be documentary proof of the acceptance of the assignment by the assignee.

The PTO will assess if all the requirements are met and, if so, will approve and publish the recordal.

### 10.2 Procedure for Assigning an Intellectual Property Right

The procedure for assigning a patent or utility model in Portugal is fairly straightforward. Please see **10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights** regarding the requirements of the assignment agreement.

Once the assignment agreement has been executed, and, if applicable, a translation has been prepared, the interested party must file a recordal application with the PTO and pay the respective fees.

Upon approval, the PTO will publish a notice of the assignment and send the applicant a confirmation letter.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

Under Portuguese law, the licensing of a patent or utility model must also be subject to a written agreement (under pain of being considered invalid) and should identify if the rights granted are total or partial, if the licence is for consideration or not, what geographic territories are covered and if it is for the duration of the IP right or another time frame.

The licence should also deal with the issue of exclusivity. Under Portuguese law, if the agreement is silent regarding exclusivity, it will be assumed that the licence is non-exclusive. If the parties agree to absolute full exclusivity, in the sense that even the patent owner is excluded from using the patented rights, then that circumstance should be expressly foreseen. Finally, if sublicensing is permitted, then this should also be expressly contemplated in the agreement.

A licence agreement may not be assigned to a third party without the written consent of the patent owner.

The licensing of a patent application is possible under Portuguese law, with the caveat that, in the event that the application is refused, the licence will automatically lapse.

### 10.4 Procedure for Licensing an Intellectual Property Right

The procedure for recording a patent or utility model licence in Portugal is similar to that described in **10.2 Procedure for Assigning an Intellectual Property Right**.

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Once the licence agreement has been executed, and, if applicable, a translation has been prepared, the interested party must file a recordal application with the Portuguese PTO and pay the respective fees.

Upon approval, the Portuguese PTO will publish a notice of the licence in the IP Bulletin and send the applicant a confirmation letter.

# PORTUGAL LAW AND PRACTICE

Contributed by: Ricardo do Nascimento Ferreira and Vasco Stilwell d'Andrade, Morais Leitão, Galvão Teles, Soares da Silva & Associados (Morais Leitão)

**Morais Leitão, Galvão Teles, Soares da Silva & Associados (Morais Leitão)** is a leading full-service law firm in Portugal, with decades of litigation experience. Broadly recognised, Morais Leitão's reputation amongst both peers and clients stems from the excellence of the legal services provided in a variety of sectors. The firm's work is characterised by a technical expertise, combined with a distinctive approach and cutting-edge solutions that often challenge

conventional practice. With over 250 lawyers at a client's disposal, Morais Leitão is headquartered in Lisbon with additional offices in Porto and Funchal. Due to its network of associations and alliances with local firms and the creation of the Morais Leitão Legal Circle in 2010, the firm can also offer support through offices in Angola (ALC Advogados), Mozambique (MDR Advogados) and Cabo Verde (VPQ Advogados).

## Authors



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## Trends and Developments

### Contributed by:

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### Introduction

The year 2022 was a challenging one regarding patent litigation, despite the fact that, as in 2021, the number of judicial and arbitration cases was not that high. In fact, contrary to 2012-2017 – where hundreds of arbitral actions were filed and judged – and since Law 62/2011 of 12 December was amended by the current Industrial Property Code (2018), the number of patent cases has significantly decreased.

The reason is quite simple: there was a mandatory arbitration system in place, which established that in disputes between pharmaceutical patents and generic drugs, the publication of a marketing authorisation application for a generic medicine triggered a legal term of 30 days for the patent holder to file an arbitration proceeding. Of course this caused a massive surge in patent litigation in Portugal until the end of 2017.

The amendment of Law 62/2011 saw the establishment of voluntary arbitration instead of mandatory arbitration. Since January 2018, the triggering of the 30-day legal term to file a voluntary arbitration proceeding implies the agreement of the parties to submit the dispute before an arbitral tribunal – or in a case where there is no agreement on that question, the patent holder must file a legal action before the Intellectual Property (IP) Court. Considering that usually there is no agreement between the parties to follow the arbitration route, patent litigation cases are filed in the Estate Court and this means a decrease in patent litigation cases in Portugal in pharma and biotech patents and generic medicines.

It is also noted that the law change has meant a considerable number of agreements between pharma originator companies (patent holders) and generic companies, with a view to avoiding the costs and slowness of legal proceedings.

In relation to other patents – eg, mechanical patents or utility models – the number of cases in Portugal during 2022 was also not significant.

What follows is an analysis of (i) patent litigation cases, (ii) Supplementary Protection Certificates (SPCs) and (iii) the trends in Information Technology (IT) and trade secrets litigation.

### Patent Cases

Although, as mentioned previously, the number of patent litigation cases was not high in 2022, there were a couple of interesting proceedings regarding the enforcement of pharma and biotech patents, as well as cases related to patented medical devices.

Specifically, Abreu Advogados represented pharma companies in legal proceedings where the discussion of classical matters like literal infringement, infringement by equivalence, novelty, inventiveness and sufficiency took place.

There is a tendency of the IP Court to assess sufficiency in a much more in-depth way than it did in previous years.

The judgments on infringement by equivalence are also increasingly addressed with a much better technical approach.

In addition, the IP Court is increasing the assessment of infringement and validity within expert evidence, which is normally requested by the parties or ordered by the court on an ex officio basis.

Abreu Advogados has also been involved in very interesting cases dealing with patented medical devices, one of which is still pending.

In these cases, the discussions on the inventiveness of the enforced patents are concentrated on the problem/solution approach following the European Patent Office's (EPO's) Boards of Appeal case law.

Appeals before the Court of Appeal of Lisbon regarding decisions of the IP Court are also being argued, and some of them are still pending.

In two different rulings, the courts declared that if the second active principle is directly identified or is identified under a functional formula in the claims of the basic patent, then Article 3(c) of the EU Regulation No 469/2009 should be interpreted in the sense that the combined product is eligible for a second SPC. This is because the new combined product defined under Articles 1(b) and (c), resulting from the association of two active principles, is protected in the basic patent and has not yet per se benefitted from an SPC.

As for the rest, the IP Court still usually dismisses legal actions based on the view that a marketing authorisation application, and even the grant of a marketing authorisation to a generic company for a product whose origin is patent-protected, does not represent patent infringement.

In preliminary injunctions, if there is no actual launch onto the market of a generic product that

infringes a patent, the patent holder must evidence irreparable harm within the legal concept of periculum in mora.

On the contrary, if the generic is launched onto the market, the patent holder should only evidence the existence of the patent right and the infringement, which is what the Enforcement Directive expressly states.

As for the mandatory legal action before the IP Court under Law 62/2011 – if no voluntary arbitration is agreed by the parties – the jurisprudence of the Court of Appeal of Lisbon remains stable regarding the legal standing and procedural interest of a patent holder in filing such action. In other words, there is an explicit procedural interest of the patent holder in filing this specific legal action to legitimately enforce its patent rights.

In a decision rendered by the Court of Appeal of Lisbon on 18 May 2022, the court was very clear:

*“In the light of the ratio legis of Law No 62/2011, that provision must be interpreted in the sense that it does not prevent the filing of a lawsuit against a generics manufacturer based on an imminent or current violation of an industrial property right after the period set therein has elapsed, provided that the patent is in force. Otherwise, a new patent expiry date would have been created in the Portuguese legal order, which neither the Industrial Property Code nor the international conventions to which Portugal is bound in this matter to provide or consent; and which would, moreover, be of strongly questionable compatibility with the provisions of Articles 42 and 62 of the Constitution, which protect, respectively, intellectual rights and private property.*

[..]

*The submission of an application for authorisation to market a generic medicinal product is, therefore, sufficient for holders of intellectual property rights (eg, patents) on the active substance of the medicinal product to have an interest in acting, requesting that the applicant for authorisation is ordered to refrain from manufacturing, marketing, storing or exporting medicinal products.*

*And so, it is concluded that the general criterion for assessing the procedural interest – the violation of a right or the existence of a dispute – is derogated by Article 3 of Law No 62/2011, of 12 December – namely, in the wording of Decree-Law No 110/2018, of 10 September – in derogation from the general rules, the holders of [intellectual property] rights do not need to justify resorting to action based on an infringement, current or imminent, or to demonstrate an interest in acting.*

*It is, therefore, sufficient ‘the publication, on the Infarmed website, of a request for [marketing authorisation] (or registration) for a generic medicine’ so that the holders of the patents of the reference medicines can propose the action.*

In addition, a recent decision from the Supreme Court of Justice on 15 September 2022, should be highlighted, which is a very comprehensive decision regarding all the issues that have been discussed in relation to the matters at stake.

*“Regarding the question that matters to be considered, we have that this Supreme Court of Justice (SCJ) has taken a consistent orientation in the sense of recognising the interest in acting to the plaintiffs with recognised industrial property rights, resulting from a patent, in the face of a request for a marketing authorisation, however publicised, from which we will closely follow a*

*recent statement that, in a clear and well-structured way, highlights the jurisprudential orientation adopted.*

*Thus, in the judgment of this SCJ, handed down on 21 April 2022, within the scope of Process No 40/20.3YHLSB.L1.S1, it was understood, and this Collective Court supports, that the holders of IP may propose the special action provided for in Article 3 of Law No 62/2011, of 12 December, in the wording of Decree-Law No 110/2018, of 10 September, in view of the publication of a simple request for a marketing authorisation, gleaned from this paragraph: ‘As for the matter of the defendants’ appeal involving the assumption of procedural interest, even if this is not included in the Code of Civil Procedure, it is admitted and recognised by case law’.*

[...]

*This requirement of interest in acting being fulfilled when, in relation to the plaintiff, ‘the situation of need, in which he finds himself, requires the intervention of the courts [...] hand of the process or to make the action proceed – but no more than that’ – Antunes Varela/José Miguel Bezerra/Sampaio e Nora, op. cit. p.180 and 181 – it follows from this that the claimant of a conviction action will only have a procedural interest as long as he alleges the violation of his right – cfr Manuel de Andrade, Elementary notions of civil procedure, p.80 or by Antunes Varela/José Miguel Bezerra/Sampaio e Nora, op. cit. p.182.*

[...]

*Law No 62/2011, of 12-12, when introducing amendments to the Medicines Statute, also added an Article 23-A, in which it is expressly stated that the request that aims to obtain inclusion of the medicine in the co-payment cannot*

*be rejected based on the existence of any industrial property rights, and that the decision to be taken on the inclusion or exclusion of medication in the reimbursement is not intended to assess the existence of any industrial property rights.*

[...]

*In tune with this understanding also the decision of the SCJ of 5-17-2018, in proc. 889/17.4YRLSB.S1 repeats that '[the] grant of [a marketing authorisation] for a generic does not constitute, in itself, a violation of the industrial property right arising from the patent of the reference medicine, not being included, for therefore, in none of the actions prohibited by the provisions of Article 101.º, No 2, of the Industrial Property Code' (text of Article 102 of the new Industrial Property Code, approved by Decree-Law No 110/2018).*

[...]

*As already stated – in the decision of SCJ of 8-4-2021 in proc. 219/19.0YHLSB.L1.S1 of which the here rapporteur was a subscriber and whose understanding was replicated in ac. STJ of 9 December 2021, in proc. 225/20.2YHLSB-A.S1, of which the rapporteur here was rapporteur there – being a condemnation action at stake, such as the one proposed by the plaintiffs against the defendants, the question that arises as an alternative is to know whether 'the presentation of a marketing authorisation application for a generic medicine is sufficient for the holders of intellectual property rights (eg, patents) on the active substance of the medicine to have an interest in acting, requesting that the authorisation applicant is condemned to abstain from the manufacture, marketing, storage or export of medicinal products' or if 'the presentation of an application for authorisation to market a generic*

*medicinal product is not sufficient for holders of intellectual property rights to on the active substance of the medicine are interested in acting, making it necessary that the applicant has started or is about to start manufacturing, marketing, storage to, or the export of medicines.*

*In this context, the important thing is to find out whether the general criterion for assessing the procedural interest mentioned above is derogated by Article 3 of Law No 62/2011, of 12 December, in the wording of Decree-Law No 110/2018, of 10 September.*

[...]

*In this regard, it is enunciated in decision of the SCJ of 8-4-2021 that we follow [The] text of Article 3 of Law No 62/2011, of 12 December, in the wording of Decree-Law No 110/2018, of 10 September, is compatible with two interpretations: the first in the sense that it prevents holders to invoke their IP rights after the expiry of a period of 30 days counting from the publication on the Infarmed website of the application for authorisation to market a generic medicine; the second in the sense that it does not prevent or, in any case, does not absolutely prevent holders from invoking their rights after the 30-day period has elapsed.*

*The preference for the first interpretation would determine one of two things – either that the procedural interest would be waived or, even if the procedural interest was not waived, that the application for a marketing authorisation would have as an automatic, immediate and necessary effect the 'need reasonable, justified, well-founded, to resort to the process'.*

*In any case, the first interpretation, in the absolute, rigid terms in which it is stated, would cause*

*insurmountable or almost insurmountable difficulties – as they concluded; eg, the judgment of the Constitutional Court No 123/2015, of 7 July 2015[11], the judgment of the SCJ of 7 December 2016, handed down in case No 554/15.7YRLSB.L1.S1 or the judgments of the Constitutional Court No 187/2018, of 10 April 2018, and No 496/2018, of 10 October 2018.*

*Concretising: the decision of Constitutional Court No 123/2015 deemed ‘unconstitutional the normative dimension resulting from Article 3, paragraph 1, in conjunction with Article 2 of Law No 62/2011, of 12 December, according to which the holder of an industrial property right may not sue the holder of the marketing authorisation or the applicant for a marketing authorisation beyond the period of 30 days, counting from the publication by Infarmed referred to in Article 9, paragraph 3, of the same Law, for violation of Article 20, paragraphs 1 and 5, of the Constitution of the Portuguese Republic.*

[...]

*On the other hand, the preference for the second interpretation, which does not prevent or does not at all prevent holders from invoking their rights after the 30-day period has elapsed is compatible with two solutions: the first in the sense that the special action provided for in Article 3 of Law No 62/2011 may be proposed as long as an application for authorisation to market a generic drug is published on the Infarmed website – advocated Evaristo Mendes, ‘Patents for medicines. Arbitration required. Jurisprudence commentary. Precedent of Law No 62/2011’, in: *Intellectual Properties*, No 4-2015.*

*In favour of the second term of the alternative, it is argued that holders of intellectual property rights need – continue to need – to justify recourse*

*to action based on an infringement, current or imminent, and to demonstrate an interest in taking action. The presumption of interest in bringing an action could not be fulfilled by the allegation by the plaintiff that there is, on the part of the defendant, the intention to market the drugs for which he requested marketing authorisations, above all, ‘when the court is faced with the peremptory assertion of the defendant, who has not challenged the claimant’s right nor has he been accused of having violated it, that he does not intend to commercialise the generic in question before the expiry or invalidation of the patent’.*

*Violation, or the threat of violation, of the applicant’s IP rights would always be necessary because the non-existence of the legal obligation to initiate an arbitration action – whenever the application for marketing authorisation for a generic drug is publicised and because the mere formulation of such a request does not, in itself, generate any infringement or threat of infringement of the patent relating to a pharmaceutical compound used in the production of medicines – it would determine that there is no interest in acting by the holder of that patent in an action in which the abstention of infringement is petitioned of the rights arising from the same and the prohibition of alienation of the marketing authorisation to third parties, to the exclusion of other circumstances that point to the likelihood of the prediction of the violation of a right.*

[...]

*Having exposed the issue in its argumentative terms and consequences, we accept, as we have already done in the transcribed judgment and in the one of 9 December 2021 – in proc. 225/20.2YHLSB-A.S1 of which the rapporteur here was rapporteur there – that Article 3 of Law No 62/2011, of 12 December, is essentially*



*in favour of holders of IP rights not needing to justify recourse to action based on an infringement, current or imminent, or to demonstrate an interest to act, being sufficient to publish, on the Infarmed website, a request for marketing authorisation (or registration) for a generic drug. It is not required that the interested party who intends to invoke his industrial property right under the terms of the previous article must do so before the IP Court, being able to do so there (at the IP Court) but also before an institutionalised arbitral tribunal or before a non-institutionalised arbitral tribunal.*

[...]

*In short, the process provided for in Article 3 of Law No 62/2011, of 12 December, sets up a special process for settling rights that is likely to be triggered by the publication of a simple application for marketing authorisation (at which time there will be no in principle, any infringement or imminent threat of infringement of industrial property rights), allows the holders of rights to establish it or not, depending on their interest in it. And can such a procedure be initiated within a period of one month from this publication, because this fits the logic of a quick process, intended to end, ideally, before there is an Infarmed decision on the application for marketing authorisation.*

[...]

*It was decided and an attempt was made to explain that the general criterion for assessing the procedural interest, dependent on the concrete allegation of violation of the invoked right, is derogated by Article 3 of Law No 62/2011 (in the wording of Decree-Law No 110/2018, of 10 September) which accepts the exceptional possibility that holders of IP rights do not need to justify*

*the recourse to action based on an infringement, current or imminent, it being sufficient to publish, on the Infarmed website, an application for marketing authorisation (or registration) for a generic drug. However, this understanding, in deviation from the aforementioned general rule, is admitted because, in the absence of any concrete violation of the authors' rights, the existence/publication of the marketing authorisation application comprises, in the interpretative economy of the observed precepts, relevant objective reasons for, even in this case, grant protection of interest to the claim of the plaintiffs. Even if there is no violation of the invoked right, there is an marketing authorisation publication request and it is this existence and what it means that determines the configuration of the interest in acting."*

## **SPC Cases**

In what concerns SPC litigation, the pending cases are still focused on the fulfilment of the legal requirements established by Article 3(a) and (c) of EU Regulation No 469/2009.

In this regard, the tendency of the IP Court and Court of Appeal of Lisbon remains to follow the European Court of Justice (ECJ).

The IP Court has decided that a product protected by an SPC is protected in the basic patent (i) where the active principle is claimed in the basic patent and (ii) where the active principle is not directly claimed in the basic patent, but the functional definition formulae of the claims, interpreted in light of the description of the basic patent, implicitly contain and necessarily identify the active principle in a specific form.

In addition, a very important decision from the Court of Appeal of Lisbon granted an SPC based on the following assumptions:

*“If it is demonstrated that a non-active principle (excipient) – combined with an active principle – produces a pharmacologic, immunologic or metabolic effect per se covered by the therapeutic indications contained in the marketing authorisation.*

*An excipient can be included in the definition of the product established by Articles 1(b) and 3(a) of EU Regulation 469/2009 in the case that the excipient of a pharmaceutical product per se has therapeutic efficacy on its own covered in the marketing authorisation.”*

This is a landmark judgment not only because it overturned the refusal to grant an SPC decision from the Patent Office and the IP Court decision rendered in an appeal, but also because it is believed that it was the first grant of an SPC in the EU in the particular circumstances.

## **The Trend of IT and Trade Secrets Litigation**

In Portugal, there has been an increase in litigation regarding patents in the field of telecommunications and IT.

Furthermore, so-called computer-implemented inventions are also subject to a large number of litigation cases, also involving copyright issues.

Software in general is not patentable in Portugal, however if the software has a technical contribu-

tion which is novel, inventive and has industrial applicability, it can be protected by a patent. The computer-implemented inventions are thus software patents and this area is being quite well developed in Portugal, notably through a large number of start-ups.

Following this notable development, it is inevitable that disputes over software patents are increasing.

Trade secrets is also an area where there are some legal disputes and it is believed that these will increase.

## **Outlook for 2023**

It is expected that the trend of more judicial litigation regarding (i) patented medical devices, (ii) IT, TMT patents and computer-implemented inventions and (iii) trade secrets, will continue in 2023.

Legal questions related to the scope and extension of protection through SPCs shall also be ongoing.

Substantial changes to the technical and legal approach are not expected from the IP Court and Court of Appeal of Lisbon.

The impact of the Unified Patent Court is crucial to be assessed.



# PORTUGAL TRENDS AND DEVELOPMENTS

Contributed by: António Andrade, Manuel Durães Rocha and Ricardo Henriques, **Abreu Advogados**

**Abreu Advogados** is an independent law firm with over 28 years of experience in the Portuguese market, and is present in ten locations. As a full-service law firm, Abreu is one of the largest law firms in Portugal, working with the most prestigious law firms in the world in cross-border projects. Universally recognised as market leaders in IP (notably in patent and trade mark litigation), Abreu's team has a comprehensive approach to the clients' commercial requirements, including industrial property

rights, copyright protection, enforcement (ie, administrative and court litigation), arbitration, as well as drafting and revision of IP licensing and contracts. Abreu has represented world-renowned pharmaceutical companies on lawsuits related to patent and SPC infringement and invalidity, as well as judicial appeals before the IP Court and Court of Appeals against the refusal of SPCs. The team is also experienced in trade mark and designs litigation, notably for famous and well-known brands.

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## PORTUGAL TRENDS AND DEVELOPMENTS

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

Slovak law allows for the protection of various forms of intellectual property (IP) through a number of means, all of which are based on written legislation, ie, statute. Case law cannot create new ways of protecting inventions, but it helps to shape and define the statutory provisions.

#### National Patent

For true inventions, formal protection through a patent is available. Patents can be obtained through a number of routes.

A national patent lasting up to 20 years can be obtained from the Industrial Property Office (IPO) following a full examination of patentability of the applied-for invention. National patent applications can be extended to result in patents through the Patent Cooperation Treaty (PCT) – more than 150 countries are members.

#### European Patent

European Patents can be obtained from the European Patent Office (EPO), provided that they designate the Slovak Republic and are validated after grant. European patents can be based on national applications or result from the PCT international procedure. Their effect is identical to that of national patents.

#### SPC (Supplementary Protection Certificate)

In certain fields of technology (human or veterinary medicaments and chemical plant protection products) supplementary protection certificates may be obtained from the IPO. These extend the term of protection of a patent by up to five years.

#### Utility Models

Utility model protection is available for technical innovations where the benefit of full term of protection of a patent is not needed and/or where rapid formal protection without examination is desirable. Their term of protection is ten years, but a utility model grants in roughly six to 12 months. Utility models cannot protect some methods/processes or uses, such as biological products and processes of the preparation, processes for the manufacture of chemical or pharmaceutical substances or medical use of substances.

#### Trade Secrets

Trade secrets protection can be relied on to protect technology and general know-how if these can be kept secret. Any information or fact which has commercial value, is identifiable and is being kept secret can be protected from being disclosed or acquired without the owner's permission.

#### Unfair Competition

The prohibition of unfair competition, ie, conduct in commerce which is capable of harming competitors and at odds with good morals of competition, protects technical innovations even where they are not otherwise protectable through one of the formal routes, such as patents or utility models and may even extend the duration of formal rights to a certain extent if the court is of the opinion that the nature of competition is undesirable. It particularly protects against "slavish imitation" of existing products. Case law plays an important role in unfair competition.

### 1.2 Grant Procedure

Some IP rights require that the technical innovation is registered prior to it being granted protection by the law. Trade secrets and unfair

competition do not require any formal steps to be undertaken.

## National Patent

National patents result from the filing of a national patent application with the Industrial Property Office. The first to file an application can obtain a patent, although if it is proven in court that the applicant had no right to file for the protection of the invention, the patent application or granted patent can be assigned to the rightful inventor or its legal successor. The patent application has to be published no later than 18 months from the date of priority. The IPO subjects the application to a preliminary examination to prevent publication of clearly unsuitable applications. The patent applicant must request full examination of the patent within a certain deadline. Should the IPO then find that the application fulfils all statutory requirements, in particular that the invention is new and inventive over the prior state of the technology, that it is clear and industrially applicable, it will grant the patent. The patent is enforceable upon publication of its grant in the official journal.

## European Patent

European patents can be obtained through the filing of a European Patent application with the IPO or EPO. The key steps of the procedure are the same as described above for national patents, but different timelines apply. A granted European Patent designating the Slovak Republic is effective upon publication in the EPO journal. However, if it is not validated within six months, through the filing of a translation and payment of appropriate fees with the IPO, it is deemed to have never been effective in the Slovak Republic.

## SPC (Supplementary Protection Certificate)

Supplementary protection certificates must be applied for with the IPO within six months of the grant of the patent or the registration of the product. The IPO then examines whether a certificate can be granted, and if all conditions are satisfied it issues the certificate. The SPC becomes effective once the patent expires.

## Utility Model

Utility models are granted by the IPO following an examination of formalities of the application. Substantive examination of novelty and innovative level are not carried out. If the formal requirements are met the IPO carries out a prior art search and publishes the utility model application with the search report. Within three months of this publication anyone can oppose the grant of the utility model, where lack of novelty and inventive step can be grounds for opposition. The utility model is enforceable upon the publication of its grant in the official journal.

## Trade Secrets

Trade secrets and know-how are protected without any need or in fact possibility for formal registration. The courts will examine whether something is a trade secret once the owner seeks to enforce it. Trade secret protection applies to identifiable information or facts which have commercial value and are being kept secret.

## Unfair Competition

Unfair competition conduct is again declared to be such by the courts when the person claiming to be entitled to protection from it files the claim in court. No prior formal registration is available or necessary. Unfair competition is defined as “conduct in commerce which is capable of harming customers or competitors and is at odds with good morals of competition”. Unfair competition conduct is prohibited by law.

## 1.3 Timeline for Grant Procedure

The length of the registration procedure varies between rights. Trade secret and unfair competition protection applies automatically.

### National Patent

The national patent registration procedure before the IPO usually lasts one to five years. However, if the application is complex or if the applicant so requests, it can take significantly longer. There is no requirement for the patent applicant to be represented, although this is very strongly advised. The official fees for the full procedure usually range between EUR500 and EUR1,000. The costs of representation (from preparation of patent application, up to grant) usually costs significantly more, with EUR5,000 to EUR10,000 being a realistic expectation. In very simple cases EUR1,000 to EUR5,000 can be expected.

### European Patent

European patent applications usually proceed to grant within three to five years, but in complex matters this can be much longer. The applicant does not have to be represented, unless they are not from one of the states where the European patent can have effect. In that case they must appoint an official representative who is on the official list or is a legal representative under the national laws of a member state. The official fees are circa EUR6,600. A realistic expectation of the costs of representation is between EUR5,000 and EUR15,000.

### SPC

Supplementary protection certificate proceedings usually last one to two years. The official fees are circa EUR200. The cost of representation is usually between EUR1,000 and EUR3,000.

### Utility Model

Utility model applications usually result in grant within six to 12 months, longer if an opposition is filed. The official fees are circa EUR100. The cost of legal representation varies; however, EUR1,000 to EUR5,000 can be expected.

## 1.4 Term of Each Intellectual Property Right

The duration of each type of right varies. In some cases it is strictly defined by statute. In the case of trade secrets and unfair competition the duration is potentially unlimited; however, the judges in each case decide whether protection still applies or whether it ever came into existence.

### Patents

Patents have a maximum term of protection of 20 years from the date of the filing of the patent application. This applies for both national patents and European patents. Maintenance fees have to be paid every year to keep a granted patent valid.

### SPC

Supplementary Protection Certificates have a maximum term of protection of five years from the date of expiry of the patent on which they are based. An additional “paediatric extension” of six months may also become available. Calculation of an SPC’s actual duration is determined by the method described in **1.6 Further Protection After Lapse of the Maximum Term**.

### Utility Model

Utility models have a maximum term of protection of ten years from the date of application, or, if branched off from a patent application, ten years from the patent’s application date. Utility models initially provide four years of protection, and can be extended on application twice, each



time by three years. The extensions are subject to an official fee.

## Trade Secret

Trade secret protection has no maximum term of protection and can potentially last indefinitely. While the information remains secret and useful, no one may use it without the owner's permission.

## Unfair Competition

Protection from unfair competition also has no maximum term of protection. However, protection should not significantly outlast the term of protection of a patent or utility model: ie, at some point even slavish imitation may become permissible. The courts in each case decide whether protection still exists or in fact whether it existed at all.

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

Each right has a specific set of rights that it creates for the owner and a set of obligations that the owner must abide by to maintain it.

### Obligations

To maintain a national or European Patent or an SPC an annual maintenance fee must be paid. If this is not paid, the right shall lapse. Grace periods for late payments apply.

A utility model's term extensions have to be applied for within the last year of the utility model's current duration.

In the case of trade secrets, the owner has to take reasonable steps to keep the secret protected from discovery or disclosure.

The person seeking protection from unfair competition should not itself be acting in unfair competition.

### Rights

A valid right generally enables the owner to exclude others from using the protected technical solution, meaning that no person may manufacture, use, offer, introduce onto the market, or store, import or otherwise deal with a product which falls within the scope of protection of the right, if the patent owner did not grant permission for such conduct. The use and offering of protected methods is similarly restricted.

A patent, SPC or utility model is enforceable if it is formally placed on the relevant register, which is maintained by the IPO. No further requirements apply. The register is accessible for free to all.

If infringement of the rights occurs the right-holder, or a registered licensee, can enforce the right in court. In such a case an injunction can be ordered against the infringing conduct, prohibiting it. In addition, the withdrawal of the product from the market and destruction of goods can be ordered by the court. Similarly, the offering and use of infringing methods can be prohibited.

Restoration of the status quo, or otherwise remedying the situation caused by infringement of rights can be ordered. This applies to trade secrets and unfair competition generally. Infringement of patents, SPCs or utility models automatically amounts to unfair competition conduct so they also benefit.

Customs may be relied on to physically seize goods infringing patents, SPCs or utility models.

The right-holder can also demand access to information about the scale of infringement of its patents, SPCs or utility models and, if it is not provided voluntarily, a court can order its disclosure.

### *Damages*

Damages are available for infringement of rights. Damages amount to compensation of actual damage as well as lost profit. In addition, a surrender of unjustified enrichment by the infringer can be demanded. Reasonable compensation for immaterial harm, ie, non-economic harm, can be obtained as well. Such monetary compensation has to be proved exactly. However, in the case of breach of a patent, SPC or a utility model, compensation can be sought in the form of a lump sum amounting to at least a fictitious licence that would have authorised the infringement.

Publication of an apology at the infringer's expense can be obtained.

Publication of the judgment can be authorised by the court.

### **1.6 Further Protection After Lapse of the Maximum Term**

Additional protection extending past the maximum term of protection of a patent is provided by the SPC.

SPCs have a maximum term of protection of five years from the date of expiry of the patent on which they are based. Their actual duration is determined based on when a patent application was filed and when the product was approved for marketing. If the product's marketing approval or registration took place later than five years from the date of patent application, then for every day over those five years, one day of pro-

tection is provided under the certificate – up to the maximum of five years. Under the “paediatric extension” an additional six months of protection can be obtained in the case of pharmaceuticals, where the product is tested for safety and efficacy in the paediatric population.

Unfair competition can slightly extend the protection of patents, and utility models in particular in relation to slavish imitation. The court will in each case separately determine whether, given the totality of the circumstances, a technical solution should still be protected from the particular conduct or not.

### **1.7 Third-Party Rights to Participate in Grant Proceedings**

Anyone can submit observations on the patentability of a patent, before it is granted. Such a person does not have full rights in the patent application proceedings. The IPO or EPO will generally ask the patent applicant to respond and take all such information into account when deciding whether to grant a patent.

Theoretically the same applies to SPCs, although it rarely happens in practice.

Once a utility model application is published by the IPO anyone can, within three months, file an opposition to its grant. In the ensuing proceedings the parties exchange submissions at the end of which the IPO decides to either grant the utility model or not. The opponent has full procedural rights.

### **1.8 Remedies Against Refusal to Grant an Intellectual Property Right**

If a national patent or a utility model application is not granted, the applicant can appeal the first instance decision of the IPO to the President of the IPO. The appeal has to be filed within

one month. The appeal usually lasts one to two years.

The decision of the President of the IPO can then be subjected to judicial review proceedings before the administrative courts. This is in principle a full review process, where issues of law and fact can be raised. The first instance decision of the Regional Court Banská Bystrica can be appealed to the Supreme Court. The first instance proceedings take one to two years and the appeal a further one to two years.

Theoretically, a constitutional complaint can be lodged with the Constitutional Court if a breach of fundamental rights occurs.

In SPC matters, a preliminary question may be referred by the courts to the Court of Justice of the European Union (CJEU). The IPO cannot make a CJEU referral.

At the EPO, a refusal to grant a patent can be challenged through an appeal to the Boards of Appeal.

## 1.9 Consequences of Failure to Pay Annual Fees

To maintain patents and SPCs and to extend the duration of utility models fees have to be paid.

Failure to pay a patent or SPC annual maintenance fees on time results in the right lapsing. A six-month grace period for payment of the maintenance fee applies; however, the fee is doubled.

Failure to request an extension of a utility model and pay the extension fee results in the utility model expiring. A six-month grace period for payment of the extension fee applies; however, the fee is doubled.

A party that missed a deadline can apply to have it reinstated, if it does so within two months of finding out, and no more than one year has passed since the deadline. An application has to be lodged and accompanied by the fee payment and the IPO has to issue a decision reinstating the time limit and thus the right. An appeal to the President of the IPO and judicial review as described in **1.8 Remedies Against Refusal to Grant an Intellectual Property Right**, are available. Again, third parties may continue to carry on with conduct which was begun before the reinstatement took place – because the patent, SPC or utility model is not effective against them.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

Once a patent, SPC or utility model is granted and published, the owner cannot amend the right otherwise than through an application for its revocation. Thus, while partial surrenders are not possible, the IPO does not review the reasons for the partial revocation application of the owner.

In the case of European patents, the owner is in addition entitled to submit a correction of the validation translation at any time, subject to payment of the appropriate fees.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

In case of infringement of a right there are a number of means of resolving the dispute open to the owner of the right.

#### Negotiation

The right-holder can seek to negotiate with the infringing party, before taking formal steps or at

any time while these are pending or even after they conclude. A negotiated settlement agreement provides the parties with relative certainty about their future relations. The negotiated settlement can go beyond that which the court can order, and can thus provide a complex business solution to the dispute. Negotiation is often begun with a warning letter.

## Mediation

Mediation is available to resolve an infringement dispute as well. Slovak Republic has a system of registered mediators, who are specially trained. A mediator aims to bring the parties to settle the matter amicably. Mediators aim to outline their legal and practical view of the aspects of the dispute and the relative positions of the parties, so as to encourage them to settle. Mediation can be undertaken at any time: before, during and possibly even after litigation concludes. A mediator's finding is not binding.

A court can advise the parties to attend mediation, before litigation proceedings begin. While this is not very common in industrial property disputes, it can occur.

## Arbitration

Parties may agree to have the dispute decided by an arbitrator or a panel of arbitrators of their choosing. The arbitrator's award is final, binding and enforceable. However, in certain cases it can be overturned by the courts.

## Litigation

The right-holder can apply to the courts to seek protection from infringement – enforce their right to a patent, SPC, utility model, trade secret or the right to be free from unfair competition. The courts can order preliminary/interim injunctions before full proceedings are even begun.

## Customs

The right-holder can apply to customs for a market watch, under which the customs aim to seize product suspected of infringing the patent, SPC or utility model. An external market watch aims to target products not on the EU market (imports) and the internal market watch can target products already on the market. Targeted inspections of premises are available. A customs seizure either results in voluntary destruction of the seized product or litigation aimed to determine whether the product infringes – if it does it is destroyed.

## 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

A third party that is convinced that it does not infringe a right can either maintain that the right is not in law valid or the product/method or that its conduct does not amount to infringement of the valid right.

A national patent, SPC and utility model can be challenged at the IPO by any person through an invalidity action. A legal interest does not have to be shown unless the right has already expired.

A European patent can be challenged at the EPO through an opposition filed within nine months of the publication of grant of the patent by any person without the need to show a legal interest. After that date an assumed infringer, ie, a person being sued by the patent owner, can challenge the patent if opposition proceedings are pending. Once the opposition window closes and if no opposition is pending, the European patent can be challenged before the IPO through an invalidity, as if it were a national patent.

A compulsory licence can be obtained from the IPO in relation to a patent or utility model where the invention is not being used at all or insuffi-

ciently, and at least four years have passed from the application's date or three years from the grant date. Compulsory licences are extremely rare. They are only effective once granted and shown on the register of patents.

If the product or process does not technically correspond to that which is the subject of the patent, SPC or utility model an action for determination of non-infringement can be filed with the IPO. The applicant must have a legal interest in the determination, which is present if it genuinely intends to use or market the product or process. The IPO then decides whether the product or process, as it is described by the applicant, falls within the scope of protection of the patent, SPC or utility model.

While the law in principle allows for declaratory judgments on invalidity or non-infringement, these are only permissible where there is an urgent legal need for them. The courts have so far always ruled that there is no urgent legal need in determining whether a patent, SPC or utility model is infringed or valid.

### 2.3 Courts With Jurisdiction

The District Court Banska Bystrica has sole jurisdiction in industrial property matter at first instance. The Regional Court Banska Bystrica hears appeals.

In trade secrets or unfair competition litigation, either the District Court Banska Bystrica, District Court Bratislava I, or District Court Kosiceľ has jurisdiction depending on the location of the defendant. The respective regional courts hear appeals.

The Supreme Court hears admissible extraordinary appeals.

In matters where the final decisions of the IPO or customs are being challenged through judicial review, the Regional Court Banska Bystrica administrative branch has jurisdiction. The appeal is decided by the Supreme Court.

The Constitutional Court hears constitutional complaints of the parties, or referrals by any of the courts.

A preliminary question may be referred to the CJEU on issues of EU law, by any of the courts.

### 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

Several permanent arbitration and permanent mediation centres operate in Slovakia.

### 2.5 Prerequisites to Filing a Lawsuit

If the patent, SPC or utility model is shown as valid on the official register maintained by the IPO, it can be enforced without any further prerequisites by the owner.

A licensee must have its licence registered with the IPO to be able to enforce it against infringers.

No prerequisites apply to enforcement of trade secrets or unfair competition.

### 2.6 Legal Representation

In IP and unfair competition conduct matters, the parties must be represented by either an attorney-at-law or a patent attorney.

### 2.7 Interim Injunctions

Interim (preliminary) injunctions (PIs) are available before and during proceedings.

To succeed with a PI request, the PI applicant has to prove that:

- it has a valid right;
- this right is likely infringed by the defendant's conduct;
- the preliminary order sought is necessary given the general circumstances of the case; and
- the benefit of the PI order to the applicant is not exceeded by the detriment caused to the defendant.

Validity of the right, or rather the lack thereof, cannot be a reason for the court refusing a preliminary injunction.

By law, the court must decide immediately and not later than within 30 days. The defendant is not informed of the PI application, or a decision rejecting/refusing the PI application. In practice almost all cases are decided on an *ex parte* basis as a result.

The PI applicant has strict and unlimited liability for damage caused by the PI, if the PI fails otherwise than through the applicant's success in the action on merits. The effect of EU law, the CJEU decision in Bayer C688/17, which appears to prohibit this form of liability, is so far unclear.

A bond can be requested by the court when ordering the PI, but this is rare.

## 2.8 Protection for Potential Opponents

Defending against a PI application is notoriously difficult, given that the defendant is not informed of the PI application being filed and the court decides relatively quickly in *de facto ex parte* proceedings. In addition, no new evidence should be presented on appeal. An application to revoke a PI then does not assist the defendant as the courts have refused to entertain the rerunning of the appeal argumentation on whether the PI should have been granted. An order PI is

thus difficult to get rid of for years and defending against it through any means is the only option.

One means of defence is aiming to submit a defensive brief with the court in the hope that the court will look at it when deciding on the PI application. Defensive briefs are not anticipated by the law, but they are not prohibited by the law either. They are increasingly being used. Their effect appears to be minimal, however, as the courts have no system of searching for them. The existence of a single court of jurisdiction for patent, SPC and utility model matters assists, as only one defensive brief needs to be sent out. In an ideal scenario, the court would search its database when it obtains a PI, and study the defensive brief and attached evidence, before deciding or at least make the brief part of the court file, so that the defendant can rely on it even on appeal. More often than not, the briefs simply never play any role and remain on the court's files indefinitely.

Another alternative is to call the court regularly and aim to submit a written defence once the PI application is filed in the PI application proceedings directly. This should ensure that arguments and evidence can be relied on by the first instance court and on appeal.

## 2.9 Special Limitation Provisions

The right-holder can obtain an injunction if the infringing conduct is taking place or is threatened when the court issues the first instance decision. For the action on merit, it is not relevant when the infringement began. A PI cannot be ordered if it is not urgently needed: ie, if the right-holder suffers infringement for too long, a PI will no longer be available.

In the case of damages and other monetary claims a limitation period of three years applies.



The moment at which the owner found out about who caused the damage/harm and the level thereof is decisive.

The right to non-monetary remedies such as the right to an apology is not limited in time.

## 2.10 Mechanisms to Obtain Evidence and Information

The right-holder can generally request that the court seizes or otherwise acquires evidence which may not be available later, or only with great difficulty. This can be done even before action on merit proceedings begin.

It is possible to request preliminary seizure of a sample of allegedly infringing product and related documents before proceedings begin, or after they begin. The proceedings are the same as in interim injunction proceedings (see 2.7 Interim Injunctions).

Third parties must generally disclose any evidence they have available in court, if the court so requests, unless they would themselves admit infringement. The defendant can refuse to testify. The defendant has to produce evidence clearly identified by the court in an order.

Information about scope of infringement can be sought from the defendant, however, not in a preliminary manner: ie, only once infringement is ruled upon will the court order the defendant to disclose such information.

## 2.11 Initial Pleading Standards

The infringement proceedings are generally front-loaded in that all arguments should be contained in the initial pleadings and all evidence attached or identified. However, for tactical or practical reasons it is also possible to state the absolute bare minimum in the initial claim, and

supplement arguments and evidence and make evidence requests later, as it is possible to do so until the end of the first oral hearing and with the court's permission even later. IP proceedings do not differ from other litigation.

## 2.12 Representative or Collective Action

Representative or collective actions are not available in industrial property disputes.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

Even if a lawsuit is clearly unfounded, there is no sanction under Slovak law for bringing it, other than the obligation to pay the defendant's costs.

Certain conduct could amount to unfair competition, such as dragging customers into the IP dispute with another supplier by accusing the competitor of infringing rights.

# 3. Infringement

## 3.1 Necessary Parties to an Action for Infringement

The owner of the right can enforce it in their own right.

A licensee can enforce the right once it is registered in the patent, SPC, or utility model register and if it is expressly authorised to do so under the licence, if it informs the owner of its intent to enforce, and the owner does not bring proceedings itself within 30 days of such notification.

## 3.2 Direct and Indirect Infringement

The right-holder can seek protection from both direct infringement, and from indirect infringement of a patent.

Direct infringement of a patent or utility model is:



- the manufacture, use, offering, introduction of a patent-protected product onto the market, or its storage, import or other dealing with it for such purposes;
- the use of a patented method/process or offering it; and
- dealing with a product made through a patented process.

There is a presumption of infringement of a process if the defendant's product is identical to that made by the patented method, where it is most likely the protected process was used and the owner could not access evidence about the process.

Indirect infringement is such conduct where the defendant does not practice the invention, but supplies a key element of the invention to another or offers to do so, and the key element is not readily available on the market for a legitimate use. The supplier of the key element cannot benefit from the exemptions to patent/utility model law in particular under the non-commercial use, experimental use exemption.

The same applies to SPCs, although minor differences exist.

Other conduct, such as that aimed at assisting infringement (sometimes called secondary patent infringement), can be caught under the prohibition of unfair competition as it is not moral to assist others in infringing patents, SPCs or utility models.

### 3.3 Process Patents

In the case of process or method patents the process or method must be practised within the territory of the Slovak Republic. However, since the offering of a process is infringing conduct in its own right, in such a case it is not relevant

where in the world the process is carried out if the offer is made in the jurisdiction. The injunction would then only be directed to offering, and not the practising of the protected process.

### 3.4 Scope of Protection for an Intellectual Property Right

The scope of protection of patents, SPCs and utility models is determined by first looking to their claims, which are interpreted literally. In this process the description and drawings are relied on as well. It is examined whether all the technical features of the claim as they would be identified by the person skilled in the art are present in the product or process under examination. If all technical features are present the product or process falls within the scope of the claim. If a technical feature of the claim is missing in the product or process under examination, it must be determined whether the missing feature is in fact essential to the invention and can thus be disregarded or whether it is not in fact present as a permissible technical equivalent in the product or process under examination.

The right-holder has to prove that the feature, despite being in the claim, is in fact not essential. The patent grant procedure may have resulted in superfluous technical features, which are in fact not necessary to exercise the invention, and which should be disregarded.

The right-holder has to prove that an equivalent feature is present in the product or process, and that even with the substitution the patented invention is still realised. There is still very limited case law on the issue of equivalents.

There is no rule stating that prosecution history cannot be taken into account.

The courts carry out the analysis themselves. However, as all judges are legally trained only, they extensively rely on experts, especially those listed in the field of “Patents and Inventions/Industrial Property”, to interpret claims. The court, in proceedings before it, can also instruct the IPO to determine whether a product or process falls within the scope of protection of a patent, SPC or utility model.

Anyone can apply to the IPO for a determination of non-infringement, where the IPO determines whether the product or process described in the application (ie, a product as such cannot be presented for examination) falls within the scope of protection of a patent, SPCs or utility model.

An expert admitted with the Ministry of Justice in the field of “Industrial Property” can be approached to prepare an expert report on whether a product falls within the scope of protection of a patent, SPC or utility model.

### 3.5 Defences Against Infringement

The defendant can raise a number of defences to infringement.

First it can claim that it is a prior user of the right. In such a case the right is not effective against it. The exact scope of such right remains unexplored, eg, it is unclear whether use must be continual, whether improvements extinguish the right and how it can be assigned, if at all.

Second, patent rights could have been exhausted, as once the right-holder places the product onto the market in the EU or EEA, the patent can no longer be enforced in relation to that product. This permits free movement of goods within the EU and EEA.

A compulsory licence can allow an infringer to use the right, but only after such compulsory licence is granted by the IPO.

There is still no local case law on reasonable and non-discriminatory (FRAND) agreements in standard essential patents, and whether injunctions are unavailable if the right-holder does not engage in genuine negotiations. Given that existing EU case law has not created hard rules, it is difficult to know whether a right-holder will be unable to seek an injunction in such cases, if it does not engage in genuine negotiations.

### 3.6 Role of Experts

The judges are all legally trained and as a result the courts rely on experts or the IPO to resolve technical issues. The parties can present expert reports prepared by Slovak experts, and these have the same weight as those presented by experts appointed by the courts.

The courts maintain a list of appointed experts, and one of the fields of expertise is “Industrial Property”. Such experts are often retired officers of the IPO or patent attorneys. Such experts are often called on and permitted by the courts to interpret patent or utility model claims, ie, to determine whether a certain product or process falls within the scope of protection of the patent, SPC or utility model.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

There is no distinct procedure for interpreting patent claims; the court carries out patent interpretation itself when weighing the case as a whole, with the parties presenting the competing position. The courts often rely on the above-described experts to interpret the claims for them through an expert report.

The court can also request an opinion from the IPO as to whether a product or process falls within the scope of a patent or utility model. As part of that exercise, the IPO has to interpret the claims.

### 3.8 Procedure for Third-Party Opinions

There is no system for the court to seek third-party opinions. However, an affected third party can seek to intervene in court proceedings. Such intervening party has near full rights in the proceedings, ie, it joins the side of the dispute on the success of which it has a legal interest and it presents its own argumentation and evidence. However, it cannot act adverse to the party on whose side it joined, and it cannot settle, withdraw, amend the main claim or appeal, etc.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

A registered right can be revoked on application to the IPO. Any person can seek to revoke a registered right. Revocation proceedings can be begun even after a right has expired; however, in that case the applicant has to show a valid legal interest in doing so.

The courts cannot revoke a patent. The courts have ruled that they cannot address patent validity issues.

Patent revocation can be based on the argument that:

- the conditions for patentability were never present (lack of novelty or inventiveness over the prior art, lack of industrial applicability, the subject matter is not patentable for lack of

technical nature or excluded from patentability – eg, surgical or medical treatment);

- the invention is not described so fully or clearly to enable the person skilled in the art to practise it;
- the patent contains added matter over the scope of the application; and
- the patent owner is not the inventor or legal successor.

Utility models can be revoked for similar reasons.

SPCs can be revoked for reasons specified in the respective EU regulations. Generally, this is because the protected product to which the SPC applies was in fact not properly supported/anticipated by the basic patent, the product was already protected through a certificate, or some other error occurred in the granting process.

### 4.2 Partial Revocation/Cancellation

The right can be revoked only partially, where the reasons for revocation apply only to its part.

This does not apply to SPCs, which can only be revoked as a whole or not at all.

### 4.3 Amendments in Revocation/Cancellation Proceedings

To avoid full revocation of a right, the owner can almost at any time make auxiliary requests that amend the original wording of the right. This does not apply to SPCs.

Technical features can be taken from the description.

### 4.4 Revocation/Cancellation and Infringement

Infringement is ruled on by the courts. The courts can theoretically address the issue of whether a

patent, SPC or utility model is valid, but they have so far refused to accept this. In such a case the court would refuse to provide protection to the right or its invalid part; it cannot order its removal from the register.

To fully revoke a right and have it removed from the register, an application must be filed with the IPO.

The court can wait for the IPO decision on validity, but not in all circumstances and never in preliminary injunction proceedings. The court can theoretically decide to resolve the validity issue itself.

The validity proceedings and infringement proceedings proceed at their own pace – the system is bifurcated. If a final infringement decision is made in favour of the right-holder and the patent is later revoked, the infringement proceedings can be reopened.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

Ordinary rules of procedure apply to industrial property and unfair competition litigation.

In cases involving trade secrets or unfair competition, one of the three district courts (District Court Banská Bystrica, District Court Bratislava I, District Court Košice I) in whose jurisdiction the defendant is located has jurisdiction.

Cases involving patents, SPCs and utility models are heard by an IP specialised judge at the District Court Banská Bystrica, which is the only court of jurisdiction.

First instance proceedings take one to two years to reach judgment, depending on complexity. The first hearing takes place three to nine months after a claim is filed. Usually two, and sometimes three, hearings are necessary. Each lasts a maximum of one day, usually only a few hours. There is no upper limit on the number of oral hearings.

The first hearing is often organisational and generally results in the court admitting most of the evidence presented in the matter so far and deciding to appoint an expert. At the second hearing the expert is heard, or experts are heard, and the court decides, or adjourns to fully consider the expert's evidence, or to have it reviewed by another expert.

All witnesses and experts can be cross-examined: although formally it is the court that asks the questions, in practice this often dispensed with and parties address their questions to the witness or expert directly.

The judgment can either address infringement and damages, or the court can issue an interim judgment on infringement and reserve its judgment on damages until after the appeal on infringement is heard. Damages claims are not common; most cases proceed as pure infringement cases seeking an injunction. Damages are then claimed at a later date through separate proceedings – limitation periods must be kept in mind.

### 5.2 Decision-Makers

Industrial property cases are decided by a single judge at the District Court Banská Bystrica and a panel of three judges at the Regional Court Banská Bystrica who specialise in industrial property. All judges are legally trained and have no formal technical education.

The parties cannot influence where and who hears their case.

In the case of unfair competition or trade secrets a certain level of forum shopping may be available as there are three courts with jurisdiction (District Court Banská Bystrica, District Court Bratislava I, District Court Košice I) and while the location of the defendant is decisive, it can be argued that the place of infringement can determine jurisdiction as well.

### 5.3 Settling the Case

The court has to encourage parties to settle. The court does so before beginning proceedings and throughout the proceedings. The court can invite parties to attend mediation. However, the defendant cannot force a case to be settled as it is the plaintiff who is ultimately in charge of the litigation.

### 5.4 Other Court Proceedings

If invalidity/revocation proceedings are pending before the IPO or EPO, the infringement court can decide to stay and await the decision. It should only do so where it is advantageous to do so given the circumstances, ie, it should not do so when the other decision is far away.

Otherwise, there would be no expectation of any delay; in particular, no anti-injunction proceedings are available and foreign decisions or proceedings play no tangible role.

## 6. Remedies

### 6.1 Remedies for the Patentee

The right-holder can demand that:

- the infringing conduct stops, eg, product is not made, offered, used, disposed of, stored, imported or otherwise dealt with;
- the infringing state of affairs is remedied, ie, any product is withdrawn from the market, and is destroyed;
- an apology is made at the expense of the defendant;
- the damage caused is compensated (including lost profit);
- the unjustified enrichment of the infringer is surrendered;
- reasonable compensation for immaterial harm is paid;
- a court judgment is published at the expense of the defendant;
- information about infringement is provided by the defendant; and
- it receives costs, ie, actual reasonable expenses incurred in the proceedings and legal expenses at statutory levels (see 6.2 Rights of Prevailing Defendants).

The court does not have to order the destruction of goods. The court decides on the wording and scope of publication of an apology, based on what it thinks is appropriate.

### 6.2 Rights of Prevailing Defendants

The successful defendant can seek costs, which include actual, reasonably incurred expenses (primarily the court fee, cost of acquisition of evidence, notary public fees, translation and expert cost) and cost of legal representation. Legal representation costs are recoverable at statutory levels, which means that in cases where no damages are sought the recovery is circa EUR1,000 per instance per defendant.

If a party has partial success it can usually only recover costs in part.

## 6.3 Types of Remedies

The remedies for the various industrial property rights are in practice the same. However, only in the case of patents, SPCs and utility models can the plaintiff demand that the monetary compensation for damage, unjustified enrichment and reasonable compensation for immaterial (non-economic) harm is paid in the form of a lump sum equal to at least the licence fee that would have authorised the infringement. This is not available in unfair competition cases, where the pecuniary compensation must be precisely calculated and proven.

## 6.4 Injunctions Pending Appeal

The first instance judgment is not effective or enforceable if it is appealed. All orders are thus ineffective until the appeal court decides. This does not apply to the preliminary injunction which may continue past the first instance judgment.

A fresh interim injunction could also be sought to provide protection pending the appeal.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

Appeals in industrial property matters proceed under ordinary rules of procedure.

In the case of patent, SPC and utility model appeals, the Regional Court Banská Bystrica has exclusive jurisdiction and sits in three-member panels/senates. All judges are legally trained and specialise in intellectual property.

### 7.2 Type of Review

The appeal proceedings allow for a review of both fact and law. However, new evidence can-

not be presented as a general rule, unless it can be shown that one of the exceptions, such as the evidence did not exist at the time of first instance judgment, or to undermine the credibility of evidence relied on in the judgment, or to prove errors of procedure.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

No costs have to be incurred before a lawsuit is initiated.

Preparing a warning letter generally costs between circa EUR500 and EUR1,500 depending on case complexity.

For the defendant, preparing a protective brief can cost between EUR3,000 and EUR7,000, depending on case complexity. Daily monitoring of court can cost circa EUR1,000 per month.

### 8.2 Calculation of Court Fees

The court fee, where no financial claims are made, is circa EUR100. For PI applications the court fee is circa EUR35.

Where damages are sought, the court fee is 6% of the sum sought with a maximum of EUR16,596.50, or possibly EUR33,193.50.

### 8.3 Responsibility for Paying the Costs of Litigation

Each party bears its own costs of sustaining the proceedings, ie, costs of legal counsel, acquisition of evidence, notary public fees, translation fees, expert fees.

The plaintiff has to pay the court fees and the PI bond (if demanded). The defendant pays the court fee only if counterclaiming.

The court pays the costs of steps it undertakes including the acquisition of evidence, commissioning of expert reports and translations. The court can demand an advance payment from the parties.

The losing party is ordered to compensate the successful party's expenses, and the state/court's costs as described in **6.2 Rights of Prevailing Defendants**. In the case of only partial success in the matter, costs are awarded in part.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

Alternative dispute resolution is not common in intellectual property disputes.

Negotiation, mediation and arbitration are available if the parties agree.

The benefit of alternative dispute resolution is that it can be much quicker than litigation.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

Industrial property rights placed on a register must be assigned in writing and the assignment recorded with the IPO.

### 10.2 Procedure for Assigning an Intellectual Property Right

The assignment must be in writing and an application must be lodged with the IPO for its registration, which usually takes a few weeks to a few months.

This does not apply to trade secrets or unfair competition.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

A licence to registered industrial property has to be in writing.

A licence to a registered right is only effective once it is registered by the IPO.

### 10.4 Procedure for Licensing an Intellectual Property Right

A licence must specify:

- the scope of the licence;
- the duration;
- the territory to which it applies; and
- what financial compensation is due to the licensor.

A licence must be in writing.



Contributed by: Petr Kusý, Čermák a spol

Čermák a spol is a law and patent office; a boutique firm specialising in intellectual property and related fields. It is active in the prosecution of patents, where through its patent attorneys before the Czech Industrial Property Office, the EPO and other patent offices, and after the grant of a patent, it is able to both defend against validity challenges to the patent, and enforce the patent against infringers through its attorneys-at-law. With over 40 employees and

numerous external assistants, Čermák a spol is one of the largest IP firms in the country. It has a dedicated partner office in Slovakia and established contacts around the world. Given the firm's long-term presence on the market, dating back to 1990, the firm has represented most of the key players in all fields of technology, including most of the leading companies in the pharmaceutical, chemical, telecommunications or mechanical engineering sectors.

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## Law and Practice

### Contributed by:

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

In Sweden, inventions may be protected through a patent that gives the patentee an exclusive right to exploit the invention (a “negative right”).

Information concerning an invention that has not yet been patented, or which for some reason cannot enjoy patent protection, or is not appropriate for patent protection, can enjoy protection as a trade secret. In order to be protected as a trade secret, the information concerning the invention must fulfil certain criteria, including being kept secret and being deemed as important to the company’s business such that it would be detrimental to the company if the information were disclosed.

Protection for inventions and trade secrets is primarily governed by statute, although the details of protection conferred have been developed through case law.

### 1.2 Grant Procedure Patents

The exclusive right for an invention arises through a patent being granted and thereby registered. A patent application can be made:

- nationally;
- throughout Europe, pursuant to the European Patent Convention (EPC); or
- internationally, pursuant to the Patent Cooperation Treaty (PCT).

For the two latter options, the application is made to the European Patent Office (EPO) or the World Intellectual Property Organization (WIPO) and, following an initial examination, the applicant may choose to designate Sweden as

one protected country. The application is then transferred to the national regulatory authority for the necessary steps to move the application forward. The application authority in Sweden is the Swedish Intellectual Property Office (*Patent- och registreringsverket*, or PRV), for both national and foreign applications. Irrespective of the form in which the application is made, a granted patent results in a national Swedish patent registration.

#### *Swedish patent grant procedure*

The national application procedure includes a formal and a technical examination; the same also applies to EPC applications, where the application is processed by the EPO.

The initial, formal examination is based upon whether the application is complete and whether the application fee has been paid. Any deficiencies in these respects must be rectified before the technical examination of the invention can be commenced. The subsequent technical examination is based upon whether the invention is patentable – ie, whether it is novel, may be subject to industrial application and involves an inventive step. Inventions whose commercial exploitation would violate public order or morality, such as inventions relating to the cloning of human beings, are not patentable. In this context it may be noted that Swedish authorities and courts follow the case law of the EPO.

The person responsible for the subsequent technical examination must be a qualified patent engineer who possesses knowledge of the area in question for the relevant invention. This part of the examination leads either to a technical order or to a final order. In a technical order, the applicant is given the opportunity to address any impediments towards the grant of the patent that the examiner has identified. If the PRV

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considers that a patent can be granted, a final order is issued whereby the applicant is given the opportunity to perform minor adjustments and review the application documents. After the applicant has paid a basic fee for publication, the PRV publishes its decision and the patent is thereby deemed to be granted.

A final decision concerning the rejection of the application is taken by the technical administrator in consultation with a separate and experienced patent expert. A decision to reject an application can be appealed to the Patent and Market Court.

Certain information in an application becomes public as a result of the filing of the application (eg, the applicant's name). Other information becomes public within a period of 18 months from the date of filing or the priority date or, alternatively, in connection with the grant of the patent if this occurs earlier and the applicant has not requested that the PRV postpones the grant. If the application is rejected, withdrawn or discontinued prior to the expiry of the 18-month period, it is not published. Accordingly, the applicant can withdraw the application during the prosecution phase if they believe that the patent will not be granted and wish to keep the invention secret.

## Trade Secrets

Information regarding an invention can also be protected as a trade secret. There is no registration procedure regarding trade secrets; instead, protection is acquired automatically, provided that certain criteria are fulfilled (see **1.1 Types of Intellectual Property Rights**).

## 1.3 Timeline for Grant Procedure

If an application meets the formal requirements, then the PRV will issue a technical, or final,

notice within approximately seven months. The time limits for a final decision vary, depending on whether or not there is an obstacle to granting the patent. The final decision is generally rendered within two years from the filing date.

There is no requirement according to Swedish law concerning representation (authorised or other) for a patent applicant. However, statistics show that applications by professional patent attorneys are granted to a much higher extent.

The average application costs to grant a national patent are relatively low. The general application fee is SEK3,000 and the publication fee is SEK2,500. Additional fees may apply; eg, if the sought patent has more than ten patent claims. The average costs in addition to the formal fees amount to approximately SEK40,000.

## 1.4 Term of Each Intellectual Property Right

A patent remains in force for a maximum term of 20 years from the application date. However, medicinal and plant protection products can be granted an extended term of protection for a maximum of five years. Also, medical products authorised for the treatment of children may be granted an additional protection term of six months (5.5 years in total).

If an invention is protected as a trade secret, it will remain protected for as long as it fulfils the requirements for being a trade secret.

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights Patents

The exclusive right of a patent is set forth in statutory law and allows the holder, inter alia, to stop others from using the protected invention commercially. The patentee may obtain an injunction,

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under penalty of a fine, against an infringer or anybody who participates in the infringement. In order to stop an ongoing infringement, it is also possible to apply for an interim injunction. A patentee can also apply for other measures, such as an order to provide information regarding the origin and distribution network of the infringing goods. The patentee is entitled to reasonable compensation for infringed use and damages caused by the infringement. The different options made available to the patentee in the Swedish Patents Act are based mainly on EU Directive 2004/48 on the enforcement of intellectual property rights (IPRED).

The scope of the exclusive right conferred by patent protection also includes the right to assign, license or pledge the patent.

There is no obligation to make use of the invention, although a court may, under certain circumstances, grant a compulsory licence to a third party if it is not used.

A patentee is obliged to pay annual fees in order to maintain the patent. The annual fee increases each year the patent is maintained, and ranges between SEK1,400 and SEK8,400. This obligation also applies during the application procedure.

There are no public information listings of certain products or processes which are protected by a patent in Sweden.

## Trade Secrets

Trade secret protection arises automatically (see 1.1 Types of Intellectual Property Rights). Therefore, the owner of a trade secret is not obliged to pay any fees. Protection conferred by a trade secret includes protection against different kinds of misappropriation; eg, when secret

information is obtained, exploited or disclosed without permission. Misappropriation of a trade secret may result in an injunction and entitle the holder of the trade secret to damages.

## 1.6 Further Protection After Lapse of the Maximum Term

A patent can be maintained for a maximum term of 20 years from the application date. However, medicinal and plant protection products can be granted a Supplementary Protection Certificate (SPC) in accordance with EC Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (SPC Regulation). According to the SPC Regulation, the term of protection is extended to a maximum of an additional five years. Medical products authorised for the treatment of children may be granted an additional protection term of six months (five and a half years in total).

The SPC application has to be filed within six months from the first marketing authorisation. The patentee has to pay an application fee as well as annual fees, and a decision to grant an SPC can be challenged by third parties. A decision to deny an application for an SPC can be appealed to the Patent and Market Court.

## 1.7 Third-Party Rights to Participate in Grant Proceedings

Third-party observations can be filed during the application procedure. An observation may refer to any aspect that affects the decision on whether a patent should be granted. The person who files an observation is not a party to the proceedings in a formal sense. However, the third party shall receive a notice if the patent application is granted.

A third party may also file a written opposition within nine months of a patent being granted.

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The opposition procedure includes an exchange of submissions between the patentee and the opponent, after which the PRV decides whether to revoke the patent, maintain it with an amended wording, or reject the opposition. The patent shall be revoked if:

- it was granted despite not being capable of industrial application, or it not being novel over the prior art, or it not meeting the requirement of inventive step;
- it includes something that was not evident from the application when it was filed; or
- it pertains to an invention that is not described with sufficient clarity to enable a person skilled in the art to carry it out with the guidance of the description.

The patent shall be maintained with an amended wording if the patentee modifies it during the opposition procedure in order to overcome the obstacles in question. The final decision in an opposition procedure may be appealed by the patentee or the objecting party to the Patent and Market Court within two months of the date of the decision.

## Entitlement Claims

A third party may also file a claim for transfer of ownership based on the party's title to an invention pending patent registration (a "better right" or "entitlement" claim). At the request of the claimant, the PRV may transfer the patent application or register the claimant as the inventor (or co-inventor). If it cannot be determined who has the better right to the invention, the PRV can order the claimant to initiate court proceedings. The PRV will disregard the claim unless the claimant initiates court proceedings within a certain time. A decision to reject a request for transfer may be appealed by the claimant.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

An applicant who is not granted a patent may appeal the decision of the PRV. Likewise, final decisions in opposition proceedings may be appealed by the losing party. An appeal has to be made within two months of the date of the PRV's decision. The appeal is to be lodged with the PRV, which may reconsider its decision unless there is a party opposing it. If the PRV stands by its decision, or if there is an opposing party, the appeal is submitted to the Patent and Market Court.

## 1.9 Consequences of Failure to Pay Annual Fees

Failure to pay the annual fees of a patent application will lead to a dismissal of the application. This situation is unusual, since payment for the first three years is due in the third year. Where a patent has been granted, failure to pay the fees will lead to the annulment of the patent. A delay in payment can be remedied if an additional fee of 20% of the due amount is paid within six months. In exceptional cases, where a patentee has suffered a loss of rights due to failure of payment despite having observed all due care required, the patentee can complete payment within two months after annulment of the patent and file for a declaration that such payment has been made in due time.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

Once a patent has been granted there are two possible ways for a patentee to amend its granted patent.

### Patentee-Proposed Amendments

The patentee may file a request to the PRV consisting of proposed amendments to one or several of the granted patent claims and, where



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necessary, also amendments to the description. The proposed amendments must limit the scope of the patent compared to the granted rights. Furthermore, the description needs to be sufficiently clear in order to enable a person skilled in the art to utilise the invention. In addition, the amendments may not cover subject matter which did not appear in the application as filed (ie, added matter).

The PRV may not, without the consent of any applicable rights-holders, grant a request to amend an already granted patent if the patent is subject to seizure, charged with a lien, claimed through attachment or part of a pending dispute concerning the transfer of the patent. Furthermore, if the patent is subject to opposition proceedings before the EPO or part of an invalidity action, at the time the request for amending the patent is made, that request shall be denied.

### Amendments During Revocation Proceedings

A patentee may also file one or several claims (auxiliary requests) to the court during the course of a revocation action in order to amend the patent claims. Such auxiliary requests also need to comply with the above-mentioned requirements for the procedure before the PRV. In addition, the court needs to assess whether the amended patent claims in the auxiliary requests contain the definitive information concerning what is sought to be protected by the patent. The court will, if the patent as granted is found to be invalid, assess whether such auxiliary requests presented by the patent holder mean that the patent, in its amended wording, should be deemed valid. Furthermore, if a patent holder seeks to amend its patent during ongoing revocation proceedings, such proposed amendments must fall within the scope of the revocation action requested by the plaintiff.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

A patentee (or licensee) is entitled to apply for an injunction against imminent or ongoing infringements. An injunction can be obtained against the infringer, or against anybody who participates in the infringement, and the infringer can be subject to a fine. When it is considered urgent to stop an ongoing infringement, the patentee may request the court to issue an interim injunction.

Patent infringement can also be prosecuted as a criminal offence. However, in order for a prosecutor to initiate a criminal action, there must be a public interest in doing so. Furthermore, Swedish Customs can be contacted in order to seize suspected infringing goods.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property Remedies

There are several remedies for third parties who wish to challenge the exclusive right of a patent. Third parties can:

- file a third-party observation during the application procedure with the PRV;
- file a request for the transfer of ownership based on title to the invention during the application procedure with the PRV;
- file an opposition with the PRV within a certain time from the patent being granted; or
- initiate court proceedings with an action for better right/entitlement to the invention, a revocation action, a declaratory action for non-infringement or an action for a compulsory licence.

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## Procedure

To initiate court actions, certain formal rules apply.

Only a person claiming entitlement to a patent can initiate an action for a transfer of ownership. Such an action can be brought within one year from the date on which such a person learned of the grant of the patent. If the patentee was acting in good faith regarding their right to the invention when the patent was granted, or when it was assigned to them, an action must be brought within three years from the date on which the patent was granted.

A third party may bring a revocation action if a patent is deemed to be detrimental to them.

A declaratory action for non-infringement requires the claimant to have a specific interest in a clarification of whether there has been an infringement. This may be the case, for example, if someone deems that they are prevented from using a method or product in their business because it is uncertain whether the exclusive right of the patent protects that method or product.

Any third party who may be presumed to have the ability to exploit the invention in an acceptable manner may seek a compulsory licence. The applicant must demonstrate that they have unsuccessfully attempted to obtain a licence on reasonable terms from the patent owner. Furthermore, a patentee may seek a compulsory licence to use an invention protected by another patent, where the use of the aforementioned patent is dependent on a patent owned by another party (in such cases the applicant must demonstrate that their invention constitutes significant technical progress of considerable economic interest in relation to the other invention). It is very rare

for an application for a compulsory licence to be granted by Swedish courts.

In addition, anyone who was commercially exploiting an invention at the time a patent application covering the invention was filed may continue to use the invention notwithstanding the patent. However, such prior-use right requires that the exploitation did not entail clear abuse in relation to the applicant for the patent or any predecessor in title.

## 2.3 Courts With Jurisdiction

The Patent and Market Court is a specialist court which forms part of the Stockholm District Court, with exclusive jurisdiction in matters concerning Swedish patents, or the Swedish part of a European patent. It also hosts the seat of the Regional Nordic-Baltic division of the Unified Patent Court.

Appeals are made to the Patent and Market Court of Appeal within the Svea Court of Appeal in Stockholm. A leave to appeal is required in order for the court to try a case.

Judgments and decisions from the Patent and Market Court of Appeal are, as a rule, not appealable. However, the court may allow an appeal to the Supreme Court if a case involves an important issue of legal principle. However, such an appeal is still subject to a leave to appeal from the Supreme Court.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

There are no specialised bodies or organisations for the resolution of disputes related to patents or trade secrets.

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## 2.5 Prerequisites to Filing a Lawsuit

There are no statutory prerequisites to filing a lawsuit. However, the ethical rules of the Swedish Bar Association require its members (*advokater*) to give an opponent reasonable time to consider a claim before taking legal action. Furthermore, a party who initiates an unnecessary action is liable to pay the counterparty's litigation costs, even if they win the case. Cease-and-desist letters are thus used in almost all cases, unless there are particular (urgent) reasons not to do so (eg, interim injunctions).

Anyone who wants to initiate court proceedings in relation to the validity of a patent must notify the PRV and inform everyone who has a licence or a pledge for the patent, according to the PRV's register.

## 2.6 Legal Representation

The parties in patent proceedings do not need to be represented by a lawyer. In theory, anyone may be appointed and act as a party's representative, or a party may simply choose to represent themselves. However, due to the technical and complex nature of patent litigation, a legal counsel is almost always chosen to act as the party's representative.

## 2.7 Interim Injunctions

A patentee or a licensee may request an interim injunction

An interim injunction may be granted if the following conditions are fulfilled;

- the applicant must show probable cause for an infringement of the patent (or imminent infringement);
- there must be reasons to believe that, by continuing to infringe or to contribute to the

infringement, the defendant diminishes the value of the exclusive right in the patent;

- the measure must not entail inconvenience or injury to the defendant that is disproportionate to the reasons in favour of an interim injunction; and
- the applicant must provide sufficient security for any loss which the defendant might incur as a result of the injunction.

Where the claimant does not have the ability to lodge the security, the court may discharge them from the obligation. The security is normally a bank guarantee that may be used by the defendant.

The purpose of an interim injunction is to preserve the value of an exclusive right until the case has been conclusively adjudicated or the court has reverted the interim injunction decision (eg, following the inclusion of new evidence). If the defendant has filed a counterclaim for revocation, the court will also take into consideration whether it is probable that the patent will be invalidated. However, there is presumption that a granted patent is valid in interim procedures. This presumption may be overturned if the defendant can show that it is probable that the patent will be declared invalid. In this regard, the defendant would need to rely on either (i) new circumstances or new evidence not taken into account during the examination proceedings or (ii) deficiencies or inaccuracies in the examining authority's decision. According to recent case law from the Swedish Patent and Market Court of Appeal, the validity presumption needs to be assessed on a case-by-case basis, however, the validity presumption is not necessarily affected by the fact that the relevant patent has been held invalid in interim injunction proceedings in other jurisdictions.

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Interim injunctions are normally decided following written correspondence between the parties without any oral hearing. It is very unusual to make use of the possibility of holding an interim oral hearing.

An injunction may be issued without notifying the defendant before the decision is rendered if a delay would entail a risk of loss (an *ex parte* decision). Swedish courts are, in general, reluctant to issue such injunctions. It would require extraordinary circumstances in patent cases.

How long it takes before a preliminary injunction may be granted varies, depending on the complexity of the case. In normal cases, one can expect to have a decision within three to six months.

## 2.8 Protection for Potential Opponents

There are no particular protective measures, such as protective briefs, for a potential opponent. However, in order to challenge a claimant's request for an interim injunction, the defendant may, apart from arguing non-infringement, argue that the security provided by the claimant contains deficiencies or ambiguities (eg, regarding the amount or the wording of a bank guarantee or the authority on which it is based).

A potential opponent may file a declaratory action for non-infringement, or commence invalidity proceedings.

## 2.9 Special Limitation Provisions

The Swedish Patents Act contains several special limitation provisions.

The right to damages in infringement proceedings is limited to damages incurred during the five years preceding the date on which an action is brought.

An action regarding damages pertaining to the application period up until the grant of a patent must be brought no later than one year after the expiry of term for opposition or, where an opposition has been brought, no later than one year after a ruling by the patent authority that the patent shall be maintained.

An invalidity action that is based on the fact that a patent has been granted to someone who is not entitled to the patent must be brought within one year from the date on which the party claiming to have such entitlement learned of the grant of the patent. If the patentee was acting in good faith regarding their right to the invention when the patent was granted, or when it was assigned to them, an action must be brought within three years after the patent was granted.

The same limitation provision applies to an action for transfer of ownership based on entitlement to an invention. It may be noted that the one-year period applies regardless of whether or not the patentee was acting in bad faith.

There is no special limitation provision in the Swedish Patents Act governing actions for permanent or interim injunctions. The court may grant an injunction even if the infringer has ceased the infringing activity. As regards interim injunctions, the granting thereof requires the claimant to show that there is a risk that continuation of the infringing act diminishes the value of the exclusive right granted by the patent. As such, any action where an interim injunction is requested, would need to be filed within a relatively short time frame from the claimant's discovery of the infringing act (ie, probably within a few months).

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## 2.10 Mechanisms to Obtain Evidence and Information

There are several mechanisms by which a party can obtain information from an opposing party or a third party.

As a general option, a court may, upon request from any party, issue an order for the production of written documents according to general provisions in the Code of Judicial Procedure (1942:740). Anybody holding a written document that can be assumed to be of importance as evidence in a court case is obliged to produce it. Certain types of documents/information are privileged (eg, correspondence between an attorney and their client, or between relatives). An order for production of written documents can refer to documents in the other party's possession, or in a third party's possession.

### Orders for the Production of Information

A patentee or licensee can also obtain an order for the production of information regarding the origin and distribution network of infringing goods or services. The court may order an infringer or certain third parties involved in an infringement to provide such information under penalty of a fine.

An order for the production of information may be issued under the condition that the applicant shows probable cause for patent infringement, and that the requested information can be deemed to facilitate the investigation of infringement. It may only be issued if the reasons for the measure outweigh the inconvenience or injury it entails for the person subject to the order or any other opposing interest.

### Infringement Investigations

Furthermore, a patentee or licensee may obtain an order for an infringement investigation. Where

it can reasonably be assumed that someone has committed, or contributed to, an infringement of a patent (or an attempted infringement or preparation to infringe), the court may order an investigation in order to search for objects or documents that can be assumed to be of importance for the inquiry into the infringement. The applicant must provide sufficient security for any damage that may be caused to the subject of the investigation.

A request for an infringement investigation can be made during infringement proceedings or prior to the initiation of such proceedings. The applicant must, however, initiate main proceedings within one month from the finalising of the investigation if a request is made separately.

## 2.11 Initial Pleading Standards General Pleading Standards

The initial pleading standard is determined by the general provisions in the Code of Judicial Procedure (1942:740). The summons application must include:

- detailed contact information for the claimant and defendant;
- a precise request for relief;
- a detailed description of the circumstances relied upon; and
- an interim statement of evidence, including the evidentiary theme for each piece of evidence.

### Patent Litigation Pleading Standards

In a general sense, the procedural rules are the same as in other civil law matters.

In practice, the summons application in main proceedings is normally quite extensive. The summons application shall include a preliminary schedule of evidence. However, it is possible to

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elaborate an argument and invoke new or different evidence during the entire preparatory stage. Negligence on one party's side (ie, submitting new arguments and evidence late in the proceedings) may, however, be reflected in their liability to pay the opposing party's legal costs.

## 2.12 Representative or Collective Action

The Swedish legal system does not permit representative or collective actions in patent cases.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

The patentee is restricted from asserting their right against others in breach of Swedish competition law (eg, anti-competitive agreements and abuse of dominant position). Anti-competitive agreements are invalid and cannot be enforced.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

The patentee or a licensee (exclusive or non-exclusive) may bring an infringement action.

It is not possible for third parties such as distributors or sales agencies to initiate an action for infringement.

Both legal entities and/or their representing individuals can be sued for patent infringement.

### 3.2 Direct and Indirect Infringement

#### Direct Infringement

Statutory law provides that any of the following actions constitutes direct infringement.

- manufacturing, offering, placing on the market or using a product protected by the

patent, or importing or possessing such a product for any of these purposes;

- using a process that is protected by the patent or knowing – or where it is clear from the circumstances – that the process cannot be used without the consent of the holder of the patent, and offering the process for use in Sweden; and
- offering, placing on the market, or using a product prepared by a process protected by the patent, or importing or possessing the product for any of these purposes.

#### Indirect Infringement

Indirect infringement, on the other hand, requires an act that contributes to a direct infringement. Indirect infringement occurs if:

- a third party, without the consent of the patentee, exploits the invention by offering or supplying a means to a person who is not entitled to exploit the invention to use it in Sweden;
- the means relate to an essential element of the invention; and
- the party offering or supplying the means knows, or it is obvious from the circumstances, that those means are suited and intended for use in conjunction with use of the invention.

A patentee is entitled to the same remedies in both cases: to request an injunction or a declaratory judgment against the infringer and to seek compensation for damages.

### 3.3 Process Patents

Direct infringement in a process patent may be established either by the infringer using the infringing process in Sweden or by the infringer offering the process for use in Sweden. The latter is dependent on the fact that the infringer



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knows – or that it is, in the light of the circumstances in the individual case, clear – that the process may not be used in Sweden without the consent of the patent holder.

Direct infringement in a process patent can also be established in cases where an allegedly infringing process is practised outside of Sweden, but where the product of that process is placed on the market, used, imported or possessed in Sweden. This is referred to as the indirect product protection (*indirekt produktskydd*).

The main rule as regards patent infringement is that the burden of proof lies with the patent holder, who must show infringement. According to case law, in certain cases concerning process patents the burden of proof of infringement may shift to the alleged infringer if the patent holder shows that it is probable that the alleged infringer uses a process which infringes the process patent.

### 3.4 Scope of Protection for an Intellectual Property Right

The scope of patent protection is determined by the patent claims. When construing the patent claims, the description may serve as a guide.

Further principles of how to assess the scope of protection have been elaborated in case law. In general, Swedish courts follow the principles of Article 69 of the EPC and the Protocol on the Interpretation of Article 69. Equivalents are deemed to be protected under Swedish law provided that certain criteria – which have been developed in case law – are fulfilled.

According to established case law, the following criteria are decisive in the assessment of equivalents.

- the inventive idea must have been utilised completely;
- the subject matter of infringement must achieve the same technical result as the invention pursuant to the patent, despite differences in relation to the patent claims;
- the differences may be deemed to be obvious (*närliggande*) to the skilled person; and
- the solution leads to a result that is equal to the result obtained by the patent-protected solution.

If these criteria are fulfilled, there may be factors in the specific case that still exclude an application of the doctrine of equivalents. For example, if the invention is of a simple nature, if the difference between the wording of the patent claim and the supposed infringing object relates to a central feature of the patented invention crucial for its patentability, or if the equivalent feature has been subject to amendments during the prosecution. However, according to case law from the Patent and Market Court, amendments made during the prosecution not related to issues of novelty or inventive step, do not constitute a bar against applying the doctrine of equivalents.

### 3.5 Defences Against Infringement

An alleged infringer will try to exclude infringement of the patent enforced by stating that the act does not fall within the patent's scope of protection. However, there are other defences that are commonly used depending on the specific situation. The defendant may:

- argue prior-use rights;
- apply for a compulsory licence;
- argue exhaustion of rights; or
- argue that the alleged infringing acts have been conducted for non-commercial purposes.



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es or for experimental purposes, or that the Bolar exemption applies.

In the special case of standard-essential patents, it may be argued that the patentee has failed to offer a licence on fair, reasonable and non-discriminatory (FRAND) terms before seeking injunctive relief against a potential infringer.

### 3.6 Role of Experts

Experts appointed by parties have an important role in Swedish patent proceedings. They are frequently consulted and relied upon in order to provide the court with information concerning one or several technical issues. The court can also appoint an expert, although this right is rarely exercised.

The expert must provide a written expert opinion during the preparatory stages of the proceedings. The expert is also examined during the main hearing, and the opposing party has a right to cross-examine the expert.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

There is no separate procedure for construing the terms of the patent's claims. The patent claims are inevitably construed in the infringement or invalidity proceedings.

### 3.8 Procedure for Third-Party Opinions

According to the Swedish Code of Judicial Procedure, a Swedish court may request a third-party opinion on matters of fact in relation to a case. However, in civil cases and even more so in patent cases, this is rarely exercised.

In the case of third-party opinions on legal matters, the general principle applicable to Swedish courts is the "jura novit curia" principle; ie, the court knows the law. However, if a question

should be determined in accordance with foreign law, the court may demand that the party invoking such foreign law should provide evidence thereof.

It is possible to submit amicus briefs (or amicus curiae) to a court in order to try to influence the court in its decision; however, such third-party opinions are very rarely seen.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

#### Pre-grant Opposition

Before the relevant authority grants a patent application, third parties have two possible options to oppose the registration of the patent. First, a third party may object to the granting of the patent. Secondly, a third party is able to claim entitlement to an invention. However, a claim for a transfer of ownership to an invention entails the burden of proof of such title lying with the party making the claim.

#### Post-grant Opposition and Subsequent Revocation Action

When a patent application is granted, third parties have the right to file a written opposition regarding the granting of the patent, within nine months. Such an opposition must include the grounds on which the third party bases the opposition, and it is tried by the PRV.

The decision taken by the PRV regarding an opposition filed by a third party may be appealed to the Patent and Market Court within two months from the decision.

Furthermore, there are no standing to sue requirements according to Swedish law in terms

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of initiating an opposition against a granted patent within nine months from the date a patent application has been granted.

A revocation action may also be initiated in court proceedings, either as an independent action or as a counteraction in an ongoing infringement action.

According to Swedish law, there are several grounds that may result in the revocation/cancellation of the patent granted: lack of novelty, lack of inventive step, insufficient disclosure, added subject matter and a third party having a better right to the invention.

As a main rule under Swedish law, it is only required that a granted patent is detrimental to a party in order for such party to have a standing to sue for revocation of the granted patent.

## 4.2 Partial Revocation/Cancellation

A patentee is able to request a patent limitation (eg, in order to limit the scope of the claims in a patent). This course of action may be taken to avoid revocation/cancellation proceedings. The PRV reviews a patent limitation request and, if it is rejected, the decision to reject may be appealed to the Patent and Market Court.

In court proceedings, the claimant may contend that only certain claims in a disputed patent should be declared invalid, and thus, if such a claim is successful, the result will be a partial revocation/cancellation of the registered patent.

## 4.3 Amendments in Revocation/Cancellation Proceedings

In court proceedings regarding the invalidity of a patent, the patentee may propose that the patent claims in question shall be amended in order to maintain a limited scope of protection for the

invention and prevent the allegedly invalid patent from being revoked or cancelled. The court then reviews whether the amended patent claims meet the requirements for patentability, and that the amendment de facto entails a limitation of the scope of the patent protection.

## 4.4 Revocation/Cancellation and Infringement

The Patent and Market Court has exclusive jurisdiction in cases regarding patent infringement and patent revocation/cancellation. Since the two separate cases are brought before the same court, the rule is that they are joined and heard together if it is beneficial for the conduct of the proceedings.

# 5. Trial and Settlement

## 5.1 Special Procedural Provisions for Intellectual Property Rights

There are some special procedural provisions in the Patents Act (eg, regarding the competent court) and the Patent and Market Courts Act (eg, regarding the panel of judges and restrictions on the possibility of appeal). However, the procedure in patent proceedings is very similar to other civil court proceedings. Most procedural provisions are found in general provisions in either the Code of Judicial Procedure or the Court Matters Act.

The Patent and Market Court (the first instance court) aims to render a judgment within one year from the summons application.

The typical timeline in patent proceedings is that the statement of defence is ordered to be submitted within one month from the serving of the summons. Thereafter, the parties exchange a couple of submissions before the court sched-

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ules a case management meeting. After the case management meeting there will be some additional exchanges of submissions until a certain date set by the court where the parties must submit their respective final statement of evidence. The cases are normally declared closed (ie, the point after which no new evidence or circumstances shall be invoked) one to two months prior to the hearing.

As regards the Patent and Market Court of Appeal (second instance) the timeline is also approximately one year in normal cases; ie, one year from appeal to the main hearing in the appeal court.

In very rare situations, a patent case can be tried by Supreme Court of Sweden (see **2.3 Courts With Jurisdiction**). The timeline for a case in the Supreme Court varies, but, as a main rule, it will be concluded by the court within a year.

The court proceedings consist of one main hearing in each respective instance. During the main hearing in the first instance both fact witnesses and experts are typically heard both by direct examination and cross-examination.

If a case is appealed, the main rule is that the examinations are reviewed by the appeal court by looking at video recordings of the examinations in the court of first instance.

All remedies requested in an action are, as a main rule, decided on in the same judgment. It is, however, quite common in patent infringement cases that the claimant seeks a declaratory judgment in relation to damages; ie, a request that the court shall declare that the defendant is liable for damages resulting from an infringement (without substantiating the amount of damages suffered as a result of the infringement). The

amount of such damages will then need to be decided in subsequent proceeding.

## 5.2 Decision-Makers

In Sweden, the Patent and Market Court and the Patent and Market Court of Appeal are specialised IP and competition courts, so the appointed judges are specialised in intellectual property law, competition law and marketing law.

The composition of the court depends on the specific decision in question and in which instance the proceedings are pending. As a rule, both legal judges and technical judges determine decisions on the merits of a case.

The parties may not affect the court's decision on whether a legal or technical judge should determine the case. However, the parties are informed about the choice of technical judge/judges, and can then make an objection that there is an apparent conflict of interest (the same applies to legal judges).

## 5.3 Settling the Case

There are no formal mechanisms for settling a case. The parties may settle a case either without third-party involvement or with assistance from the court (through non-mandatory settlement conferences or court mediation). The case can be settled until the day of the judgment. It may be noted that the court is obliged to investigate the possibility of a settlement during the preparatory stage of the proceedings.

If the parties reach a settlement, they may choose either to have the settlement confirmed in a judgment by the court or, should they prefer to keep it confidential, to withdraw the case jointly.

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## 5.4 Other Court Proceedings

The court decides whether a case should be stayed pending the resolution of other proceedings. Parallel proceedings, such as revocation proceedings and/or anti-suit injunctions, do not influence the current proceedings as a starting point. However, if it is clear that the validity of a patent will be determined in the near future, the court will likely stay ongoing infringement proceedings.

## 6. Remedies

### 6.1 Remedies for the Patentee

#### Injunctions

A patentee can file a request at the court for an injunction subject to a default fine, pursuant to the terms of which the alleged infringer is enjoined from continuing its allegedly infringing conduct. Such an injunction is available both as a permanent injunction and as an interim injunction. For an interim injunction to be granted, the patentee must show that there is probable cause for infringement. It must also be reasonably assumed that the continuation of the infringing act diminishes the value of the exclusive right in the patent. Finally, the patentee must provide security for the potential loss of the alleged infringer.

#### Damages

If an infringer has not acted with intent or negligence, damages are limited to reasonable compensation for the use of the invention subject to the patent. If an infringer has acted with intent or negligence, the patentee also has the right to additional compensation for the additional loss resulting from the infringement. When determining the amount of additional compensation, the court will consider in particular:

- lost profits;
- profits realised by the party committing the infringement;
- damage to the reputation of the invention;
- non-pecuniary loss; and
- the patentee's interest in preventing infringement from taking place.

Punitive and provisional damages are not available under Swedish law.

#### Other Remedies

The patentee may also request an alleged infringer to provide, under penalty of a fine, information regarding the origin and distribution network for the goods and services to which the infringement pertains and/or an infringement investigation (see **2.10 Mechanisms to Obtain Evidence and Information**).

The court may also, at the request of the patentee, order that goods that infringe an exclusive right to a patent must be withdrawn from the market, destroyed, modified, etc, and that an infringer bear the costs pertaining to the patentee's publication and spreading of information regarding the judgment on patent infringement.

The court has no discretion regarding the choice of remedies stated above.

#### Enforcement of the Remedies Available

If an infringing party does not comply with an award granted by the court, the patent holder may file a request with the Swedish Enforcement Authority to enforce the remedies awarded.

As regards injunctions subject to the penalty of a fine, if an infringer is non-compliant in regard to such injunction, the patent holder must bring an action to the court to enforce the injunction. If the injunction is found to have been breached,

the court will order the infringer to pay the fine set out in the injunction to the Swedish state.

## 6.2 Rights of Prevailing Defendants

Generally, the prevailing party has the right to be reimbursed by the losing party for reasonable litigation costs and lawyers' fees. However, this may vary, depending on whether the prevailing party has succeeded with all claims tried by the court.

## 6.3 Types of Remedies

The types of remedies for technical intellectual property rights do not differ from one another.

## 6.4 Injunctions Pending Appeal

A request for an injunction will normally be granted if the claimant has proven patent infringement. Where the defendant appeals the judgment of the first instance court, in most cases effects pertaining to such a granted injunction will be suspended until the case is conclusively adjudicated. However, the court may order that an injunction shall enter into force instantly and last until the decision has become legally binding or the court decides otherwise. If the defendant appeals the decision to the appeal court, the defendant may request an inhibition of the injunction until the appeal court has assessed the case in its entirety.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

The appellate procedure is, in principle, the same as in proceedings not related to intellectual property rights. However, the Patents Act and the Patent and Market Courts Act include special provisions regarding the appellate pro-

cedure in patent proceedings (see **2.3 Courts With Jurisdiction**).

## 7.2 Type of Review

An appeal implies a full review of the facts of the case. The appellant can, however, limit the scope of review to certain questions. The parties can exchange submissions and, thereafter, an oral hearing takes place. Oral evidence invoked in the first-instance proceedings is, however, normally video-recorded, and the Patent and Market Court of Appeal will review the recordings instead of having the witnesses testify again. It should also be noted that new facts or evidence are not allowed in the appeal proceedings, except under certain circumstances.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

The costs arising before a lawsuit are typically related to:

- warning letters;
- the gathering of evidence;
- research on technical and legal questions;
- drafting the summons application;
- arranging a bank guarantee when necessary; and
- efforts to settle the dispute.

### 8.2 Calculation of Court Fees

Depending on the type of case and the value of the claim, the court fee for commencing proceedings is fixed at either SEK900 or SEK2,800.

### 8.3 Responsibility for Paying the Costs of Litigation

The losing party is required to reimburse the prevailing party for their reasonable litigation costs. This applies to lawyers' fees, court fees, costs

for evidence, etc. The litigation costs can also be divided between the parties if both have prevailed in different matters. However, exemptions apply if a party has acted negligently or initiated an unnecessary trial.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

Alternative dispute resolution is not normal practice when settling a patent case. However, licensing agreements and other contractual issues related to patents are often submitted to arbitration. Patent infringement disputes are sometimes submitted to arbitration, but the possibility of obtaining an interim injunction subject to a default fine at the Patent and Market Court is probably the reason why this option is not used more often. It is not possible to submit an invalidity action with an in rem effect in an arbitration procedure. However, it is possible to submit an inter partes invalidity action in an arbitration procedure. It is also possible to use mediation, although this is rare.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

There are no formal requirements or restrictions for assigning a Swedish patent or patent application.

### 10.2 Procedure for Assigning an Intellectual Property Right

There is no formal procedure for assigning a patent right. The patentee or assignee may request that the assignment is registered in the patent register administrated by the PRV. This procedure requires, inter alia, a written and signed request from the patentee or the assignee. In general, proof of the assignment is not required for the registration.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

There are no formal requirements or restrictions to licensing a patent right. The patentee is free to license their right by way of an agreement. However, where the patentee has granted a licence, the licensee may assign their right to others only if an agreement has been made to that effect.

### 10.4 Procedure for Licensing an Intellectual Property Right

There is no formal procedure for licensing a patent right, and it is rare, although possible, for patent licences to be registered in the patent register.

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Advokatfirman Vinge KB is unique in the Swedish market in providing a genuine full-service IP offering within three key areas: contentious, non-contentious and prosecution (patent prosecution in collaboration with patent agency firms). Patent litigation is one of the key practice areas and involves disputes within the telecoms, pharmaceutical, med-tech, chemical and mechanical areas. Vinge's IP team consists of approximately 25 lawyers based in Stockholm, Gothenburg and Malmö, and is engaged in infringement and invalidity disputes, often with

an international character. Vinge is often involved in large pan-European litigations where the members of the team work closely with internationally eminent patent law experts. The team is also experienced in disputes relating to patent title, compensation to inventors and disputes arising from patent-related commercial contracts (arbitration and litigation). The firm's full-service concept often results in the IP team working closely with Vinge's experts in EU and competition law, dispute resolution and life sciences.

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## SWEDEN LAW AND PRACTICE

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# VINGE

# SWITZERLAND

## Law and Practice

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

In Switzerland, inventions are primarily protected by patents. A patent with effect for the territory of Switzerland can either be applied for and granted as a Swiss national patent under the Swiss Patents Act (PatA) or as a European patent under the European Patent Convention (EPC) with the designation of Switzerland. According to the PatA and Swiss judicial practice, certain inventions are excluded from patentability, such as gene sequences, methods of medical treatment or mere computer programs.

Under Swiss law, protection of an invention as a utility model is not available and the Federal Council (the Swiss government) recently abandoned its plan to introduce a utility model as part of the partial revision of the PatA that is currently underway. See **1.2 Grant Procedure** and **1.7 Third-Party Rights to Participate in Grant Proceedings** for details of this revision.

Undisclosed inventions may qualify as trade secrets and are then protected by law against unlawful use and disclosure, which may qualify as an act of unfair competition (Article 6, Act against Unfair Competition) or a criminal act (Article 162, Penal Code). In addition, trade secrets can be protected through contractual means. The Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) is not directly applicable in Switzerland, which is not an EU country, nor has any analogous law been adopted in Switzerland. Overall, the Swiss provisions on trade secret protection are less detailed than the legal framework in the European Union, but they provide effective protection that meets the requirements of Article 39, paragraph 2 of the

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

### 1.2 Grant Procedure

A Swiss national patent is granted pursuant to the PatA upon application to the Swiss Federal Institute of Intellectual Property (*Institut Fédéral de la Propriété Intellectuelle*, or IPI). European patent applications with protection for Switzerland may be filed with the European Patent Office (EPO) pursuant to the EPC.

European patent applications have the same effect in Switzerland as national patent applications filed with the IPI (Article 110, PatA) and are recorded in the Swiss register once granted by the EPO.

The IPI currently examines national patent applications only with respect to formal requirements and selected legal requirements, such as the technical nature of the invention, whether the invention is contrary to public policy or morality, the clarity and uniformity of the claims and added matter. In contrast to the examination procedure of European patents by the EPO, the IPI does not examine the material requirements of novelty and non-obviousness before granting the patent (Article 59 paragraph 4, PatA).

However, it should be noted that the PatA is currently undergoing a partial revision, which aims at introducing the option of requesting a full examination of a patent application, including with respect to novelty and inventive step. As a result, inventors should soon have the choice between applying for an “unexamined” or a “fully examined” national patent with the IPI. Pursuant to the proposed bill, the examination for novelty and inventive step can not only be requested by the applicant, but also by third parties. As an additional innovation, in each case a pub-

lic state of the art search report would be prepared, which is intended to give at least preliminary indications as to the novelty and inventive step of the claimed invention. The new law will be debated in parliament this year and it is not expected to enter into force before mid-2024 or even 2025.

Trade secret protection is granted by law, without any examination or registration by any authority, provided that the undisclosed invention meets the conditions for protection, such as confidentiality and an interest in such confidentiality.

### 1.3 Timeline for Grant Procedure

Currently, patent examination by the IPI for granting a national patent may last between one and two years or even longer, depending on whether the IPI is asked to provide a report on the state of the art or arrange an international-type search (Article 59 paragraph 5, PatA). Patent granting proceedings by the EPO usually take longer, as the examination of the novelty and obviousness requirements takes time. The European patent grant procedure generally takes about three to five years from the date the application is filed, but in certain cases it can last considerably longer depending on the complexity of the file.

The average costs for the grant of a patent by the IPI amount to approximately EUR700 (without any fees for optional searches). To take a patent application through to the grant stage before the EPO, one may expect costs of around EUR5,000. These costs do not include the fees for consultancy services of a patent attorney.

Swiss residents do not need to be represented by a patent attorney before the IPI, but applicants (natural or legal persons) who have neither residence nor a place of business in Switzerland are obliged to be represented by a local pro-

fessional representative. Similar rules apply for residents of non-contracting states in front of the EPO.

### 1.4 Term of Each Intellectual Property Right

For both Swiss national patents and European patents with protection for Switzerland, the term of protection is 20 years from the filing date of the patent application (Article 14, PatA).

Inventions that qualify as trade secrets are protected by law as long as the invention meets the conditions for protection – ie, as long as the invention remains confidential and the inventor has an interest in its confidentiality.

### 1.5 Rights and Obligations of Owners of Intellectual Property Rights

#### Obligations

In order to maintain both Swiss national patents and Swiss parts of European patents, once granted, the patent owner's primary obligation is to timely pay the registration and annual renewal fees. The amount of the renewal fees is progressive based on the years of protection.

#### Rights

Both Swiss national patents and European patents with protection for Switzerland, confer on their owners the right to prohibit others from commercially using the invention (Article 8, PatA). It is the responsibility of the patent owner to enforce their exclusivity rights. Possible civil legal actions include:

- an action for permanent injunction or remedy of the unlawful situation (Article 72, PatA);
- an action for monetary relief, including damages such as lost profits, accounts of the infringer's profits and surrender of the

unjust enrichment in the form of a reasonable licence fee (Article 73, PatA); and

- an action for declaratory judgment on the existence or non-existence of a circumstance or right governed by the PatA (Article 74, PatA).

Actions for injunction or remedy can also be requested as preliminary measures (Article 77, PatA). Moreover, in order to establish infringements, patent owners may request as a preliminary measure that the court carries out a so-called precise description of the allegedly unlawful process or product (Article 77, PatA).

Besides the initiation of civil actions, the patent owner may file a complaint in order to start criminal proceedings against the infringer of their patent rights (Articles 81 et seq, PatA). The PatA also provides for custom measures (Articles 86a et seq, PatA). If the patent owner has clear indications that goods infringing their patent may imminently be imported into or exported out of Swiss customs territory, they may request the Customs Administration to refuse the release of the goods. The Customs Administration may withhold the goods for a maximum period of ten working days, so that the applicant may obtain preliminary measures.

Inventions that are only protected as trade secrets enjoy protection either under Swiss criminal law (Article 162, Penal Code), under unfair competition law (Article 6, Act against Unfair Competition) or by contractual means. Unfair competition law provides for civil injunctions, remedies and monetary relief actions as well as for criminal sanctions.

## 1.6 Further Protection After Lapse of the Maximum Term

Upon an application by the owner of a Swiss national patent or a European patent with protection for Switzerland, the IPI may grant a supplementary protection certificate (SPC) for the active ingredients or a combination of the active ingredients of medicinal products or plant protection products (Articles 140a et seq, PatA). An SPC can only be granted on the basis of a valid patent and a granted marketing authorisation for the medicinal product.

The period of protection for the SPC begins as soon as patent protection expires and is valid for a maximum period of five years. This term may be extended for a further six months if paediatric studies have been carried out and the results are reflected in the product information of the respective medicinal product (paediatric extension).

For situations where the patent owner is not eligible to apply for an ordinary SPC, which could be prolonged through a paediatric extension, the PatA also provides the possibility of a paediatric SPC that is directly linked to the patent and not to the ordinary SPC.

## 1.7 Third-Party Rights to Participate in Grant Proceedings

Third parties currently do not have any right to participate in the grant proceedings for a Swiss national patent or an SPC – eg, by filing third party observations. However, any person may file an opposition against a Swiss national patent once it is granted by the IPI. Due to the currently limited scope of the examination by the IPI, the national opposition proceedings system was never used. Hence, with the current revision of the PatA, which aims at introducing the option to request a full examination of the patent

application (see **1.2 Grant Procedure**), opposition proceedings will be abolished. Instead, third parties will have the possibility to file an appeal to the Federal Patent Court (and subsequently to the Federal Supreme Court), whose specialised judges will also be competent to review the patent for novelty and inventive step, if a full examination had been requested. The current opposition deadline of nine months will be shortened to an appeal deadline of four months for third parties.

The grant of an SPC can be challenged by appeal if the appealing party can show a legal interest in the outcome of the proceedings.

In proceedings before the EPO, third parties can file observations concerning the patentability of the invention (third-party observations) in order to try to prevent a patent from being granted. However, third parties cannot take part in the grant proceedings as a formal party. Any person may, however, file an opposition against a European patent once it is granted by the EPO.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

Against a refusal to grant patent protection or an SPC by the IPI, an appeal can be filed with the Swiss Federal Administrative Court and thereafter to the Swiss Federal Supreme Court.

A decision of the EPO refusing to grant a European patent may be appealed with the EPO's Boards of Appeal.

## 1.9 Consequences of Failure to Pay Annual Fees

A patent registered in the Swiss patent register is cancelled (and the patent protection terminates with effect *ex nunc*) if the annual renewal fees are not paid on time.

Where the patent owner provides prima facie evidence of having been prevented, through no fault on their part, from observing a time limit, the IPI may grant, on request, the re-establishment of their rights (Article 47, PatA). Acceptance of the request has the effect of restoring the situation that would have resulted from carrying out the act in good time. However, due to the quite strict practice on the no-fault requirement, Article 47 of the PatA is often not applicable.

Alternatively, the patent owner may file a request for further processing with the IPI (Article 46a, PatA). The request must be made within two months after receiving notification of the missed time limit or within six months after the time limit has expired. Within this time, the action that has been omitted must be executed. If the request for further processing is approved, the situation that would have resulted from executing the act on time will be restored.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

Once the patent has been granted (and the opposition period has expired), the patent owner may file with the IPI a request for a declaration of partial surrender of a Swiss national patent or the Swiss part of a European patent in order to:

- surrender a patent claim;
- limit an independent claim by combining one or more patent claims, which are dependent on it; or
- limit an independent claim in some other way – in such cases, the limited claim must refer to the same invention and define an embodiment that is included in the specification of the published patent and in the version of the patent application that determined the date of filing.



The partial surrender may not be used to file new patent claims or to make up for something else that was overlooked in the granting procedure.

On the occasion of registration of a partial surrender, the patent owner may, within a three-month period, file an application for the establishment of one or more new patents to cover the dropped patent claims; such new patents are given the filing date of the original patent.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

Under Swiss law, civil legal actions include:

- actions for permanent injunction or remedy of the unlawful situation (which may also be requested as preliminary measures);
- actions for monetary relief; and
- declaratory judgment actions.

Moreover, the patent owner may also initiate criminal proceedings or apply for customs measures.

Please see **1.5 Rights and Obligations of Owners of Intellectual Property Rights** for more detail.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property Opposition Proceedings

Pursuant to the current law, within nine months of publication, any third party, without the need to demonstrate a proven interest, may file an opposition against a Swiss national patent granted by the IPI or against a European patent granted by the EPO.

Grounds for opposition against a Swiss national patent are rather limited. The opposing party may claim that the patent contains inventions that are excluded from patentability because:

- the invention relates to the human body or its elements;
- the invention relates to naturally occurring sequences or partial sequences of genes; or
- the invention's exploitation is contrary to human dignity or disregards the integrity of living organisms, or is in any other way contrary to public policy or morality according to Article 2 of the PatA.

It should be noted that the ongoing revision of the PatA will abolish this opposition system and replace it with an appeal option to the Federal Patent Court with a four-month appeal deadline for third parties. The grounds for appeal will be expanded to include a review for novelty and inventive step. See **1.2 Grant Procedure** and **1.7 Third-Party Rights to Participate in Grant Proceedings** for details of this revision.

The EPC allows for more grounds for opposition. In addition to similar opposition grounds allowed under Swiss law, a third party may also claim that:

- the invention is not new;
- the invention does not involve an inventive step;
- the invention is not susceptible to industrial application;
- the invention is not disclosed clearly and completely enough for a person skilled in the art to carry it out; or
- the patent's subject-matter extends beyond the content of the application as filed.

## Civil Proceedings

Third parties, with a proven interest, may also initiate civil proceedings in order to claim the invalidity or partial invalidity of a Swiss national patent or of the Swiss part of a European patent if the invention is excluded from patentability, is obvious, not novel or not disclosed in a way that a person skilled in the art could carry it out, or if matter was added after the filing date (Articles 26 et seq, PatA).

In addition, when the patent has been filed by an applicant who was not entitled to that patent, the entitled person may apply for assignment of the patent application or, if the patent has already been granted, of the patent itself (Article 29, PatA).

## Compulsory Licensing

Under Swiss law, third parties with a legitimate interest may, under certain conditions, also initiate actions for the grant of compulsory licences (Articles 36 et seq, PatA), if:

- a patent cannot be used without infringing a prior patent, provided that the invention represents an important technical advance of considerable economic significance in relation to the invention that is the subject matter of the prior patent;
- a patent is not sufficiently exploited in Switzerland, and where such a failure to exploit cannot be justified;
- the public interest so requires;
- a licence to patents in the field of semiconductor technology is required to remedy a practice held to be anti-competitive; or
- a licence to use a patented biotechnological invention is required for research purposes.

Requests for the grant of compulsory licences are rare and to date no compulsory licence

appears to have ever been granted by a court in Switzerland.

## 2.3 Courts With Jurisdiction

The Swiss Federal Patent Court rules on civil actions concerning patents at first instance. Pursuant to Article 26 of the Patent Court Act (PCA), it has exclusive jurisdiction over civil patent litigation concerning patent validity as well as patent infringement, compulsory licence actions, requests for preliminary measures and enforcement of judgments made under its exclusive jurisdiction.

The Federal Patent Court also has jurisdiction in other civil actions that have a connection to patents, in particular those concerning contractual rights to patents (ownership and licensing) or their assignment. In such cases, the jurisdiction of the Federal Patent Court does not preclude the jurisdiction of the cantonal courts. For such disputes, the claimant may choose whether to bring an action before the Federal Patent Court or the relevant cantonal court.

An appeal against the decision of the Federal Patent Court or of a cantonal court can only be lodged with the Federal Supreme Court directly as second instance. The decision of the Federal Supreme Court is final. The Federal Supreme Court can, however, remand the case back to the Federal Patent Court for new consideration of certain aspects. In such event, the Federal Patent Court's second decision can again be appealed to the Federal Supreme Court.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

The Federal Patent Court is a specialised court for patent matters. It comprises judges with legal training and judges with a technical qualification.

Besides the Federal Patent Court and cantonal courts, arbitral tribunals may also be competent to resolve disputes related to patents. According to Swiss case law, all aspects of intellectual property disputes are arbitrable, including contractual issues related to patents as well as disputes over the validity of patents. Although arbitral awards on the validity of patents are recognised and enforced in Switzerland, arbitration proceedings related to mere validity disputes are rather rare, because of the multi-jurisdictional nature of most arbitral proceedings and hence possible enforcement issues with respect to certain jurisdictions. However, contractual disputes in connection with patents, such as licensing disputes, are often submitted to arbitral tribunals.

No other (non-statutory) specialised organisations exist in Switzerland to rule on patent disputes.

## 2.5 Prerequisites to Filing a Lawsuit

There are no special prerequisites for filing a patent action in Switzerland. Civil actions relating to intellectual property rights can be filed with the competent court without any need to attempt conciliation in front of a conciliation authority.

The issuance of warning letters is also not required, although mostly recommended to consolidate the legitimate interest of the claimant and to support the attribution of the procedural costs to the defendant. Sometimes litigation costs can even be avoided following settlement discussions or voluntary undertakings triggered by warning letters.

If patent infringement proceedings are commenced by an entitled licensee (see **3.1 Necessary Parties to an Action for Infringement**), it is

not required that the licence is registered in the patent register.

## 2.6 Legal Representation

Parties may decide, but do not have any obligation, to be represented by an attorney at law in intellectual property matters. If a party decides to be represented in front of a Swiss court, the representative must be a qualified attorney at law. In proceedings concerning the validity of a patent in front of the Federal Patent Court, the parties may also be represented by a qualified and admitted patent attorney (Article 29, PCA).

## 2.7 Interim Injunctions

Measures for interim relief are available under Swiss law if the applicant can provide prima facie evidence that the following requirements are met:

- the right to which they are entitled has been infringed or an infringement is imminent;
- such infringement threatens to cause not easily reparable harm;
- the requested relief is relatively urgent; and
- the requested relief is proportionate to the harm caused by the alleged infringement (Articles 261 et seq, Civil Procedure Code, CPC).

Note that urgency is not a strict requirement for granting interim relief. However, interim relief will not be granted if the applicant has waited for a substantial period of time (according to current practice, for more than 14 months) before requesting measures for interim relief.

In cases of special urgency, and in particular where there is a risk that the enforcement of the measure will be frustrated, the court may order the interim measure immediately and without hearing the opposing party (*ex parte interim*

measures) (Article 265, CPC). The *ex parte* interim measures must subsequently be confirmed in *inter partes* proceedings granting the opposing party its right to be heard.

In addition, all interim relief proceedings require confirmation in main proceedings. In an interim judgment, the Federal Patent Court will set a deadline for the commencement of main proceedings, whereby the injunction lapses if the applicant does not initiate main proceedings, in which case the applicant is liable for any damages caused to the defendant.

In interim relief proceedings the applicant can request:

- an injunction;
- an order to remedy an unlawful situation;
- an order to a registering authority or to a third party; or
- performance in kind.

## 2.8 Protection for Potential Opponents

Any person who has reason to believe that an *ex parte* interim measure will be applied against them, may set out their position in advance by filing a protective letter (Article 270, CPC).

Protective letters must be filed with the Federal Patent Court and/or the cantonal courts that are likely to have jurisdiction for ordering the *ex parte* interim measures in the case at hand. The other party will be served with the protective letter only if they actually initiate the respective proceedings. The protective letter becomes ineffective six months after it was filed.

## 2.9 Special Limitation Provisions Statute of Limitation

Monetary claims in patent infringement proceedings are time-barred after three years from the

date on which the injured party became aware of the loss or damage and of the identity of the person liable for them, but in any event ten years after the date on which the loss or damage was caused. If the action for damages is derived from an offence for which criminal law envisages a longer limitation period, that longer period also applies to the civil claim.

Claims for injunctive and declaratory relief are in principle not time-barred, but rather remain available as long as there is a legitimate interest in obtaining such a relief.

## Forfeiture

The enforcement of rights might be limited due to their forfeiture based on Article 2 of the Swiss Civil Code, which requires every person to act in good faith in the exercise of their rights. If a person waits too long before initiating enforcement proceedings, their rights may be forfeited if the court determines, taking into account all relevant circumstances, that the claimant acted against good faith. As an example, the right to apply for interim measures is considered forfeited 14 months after the patent owner actually learned, or should have learned, of the infringement unless there are special circumstances (see 2.7 Interim Injunctions). With regard to main proceedings, forfeiture is likely to occur after approximately eight years. Based on Swiss case law, urgent status will not be granted by the courts if the patent owner has waited so long.

## 2.10 Mechanisms to Obtain Evidence and Information

Swiss procedural law does not provide any procedural mechanisms for far reaching US-style fishing expeditions in order to obtain all evidence from the opposing party that might be relevant. However, there exist certain mechanisms allowing a party to obtain specific evidence.

## Swiss Patents Act

Based on the Swiss Patents Act, a patent owner with a legitimate interest – ie, providing prima facie evidence that their patent has been infringed or an infringement is suspected – may request that the Federal Patent Court order as an interim measure:

- the securing of evidence; and/or
- a precise description to be made of the allegedly unlawful processes used and/or of the allegedly unlawful products manufactured, as well as the means used to manufacture them (Article 77, PatA).

The procedure for making the description is typically carried out by a technically trained judge and a clerk at the location where the alleged infringement takes place. Upon the request of an opposing party, the court will take necessary measures to safeguard business and trade secrets and might exclude the applicant (but not its representatives) from taking part in the inspection. The court will draft a written report describing the product or process and before the applicant receives the report, the opposing party is given the opportunity to comment (Article 77, PatA).

Under Swiss law there is no limitation as to how the evidence obtained through a description can be used, which means that a Swiss description can also be used to support proceedings abroad.

## Swiss Civil Procedure Code

The Swiss Civil Procedure Code also allows a more general right to ensure preliminary taking of evidence without any need to start civil litigation (Article 158, CPC). Similar evidence as during a pending litigation on the merits can be the subject of such a preliminary taking of evidence – ie,

the party may request witness hearings, the production of specifically identified documents, the inspection of goods or places or the drafting of a court-appointed expert's report. The questioning of the parties, however, can only be part of the proceedings on the merits.

In general, the parties to the case, and third parties, have a duty to co-operate in the taking of evidence (Article 160, CPC). However, the court cannot enforce its order, if a party to the proceedings does not produce the required evidence. But the court will take such conduct into account when assessing the evidence and the facts of the dispute.

## 2.11 Initial Pleading Standards

Under Swiss procedural law, the statement of claim must contain:

- the prayers for relief;
- a statement of the value in dispute;
- the allegations of fact;
- a notice of the evidence offered for each allegation of fact; and
- the date and signature.

It is not required by law to state the legal arguments (since the court must know the law), but it is common practice to do so and some courts expressly expect the parties to briefly state on which grounds their actions are based.

In general, in main proceedings, each party is entitled to two submissions during which it may provide new facts and evidence, amend its prayers for relief and limit the patent claims at stake; either inter partes or through a limitation request at the IPI. After the second submission, new facts and new evidence are admissible only if presented immediately after they become known and (i) if they occurred after the second

submission (proper nova), or (ii) if they existed before but could not have been submitted despite reasonable diligence (improper nova). At such stage, a limitation of the patent claims at stake will only be considered if it were triggered by new arguments or evidence brought forward in the rejoinder. In any case, new facts and new evidence are admitted only until the court begins its deliberations.

## 2.12 Representative or Collective Action

Under Swiss law, no class actions or other collective actions are permitted. However, joinder of parties in civil proceedings is admissible.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

Restrictions on the assertion of patent rights may apply from the law against unfair competition and antitrust law, in particular with respect to restrictions against parallel imports which are not justified (Article 9a, PatA and Article 5, Swiss Cartel Act) and unlawful practices by market-dominant undertakings or undertakings with relative market power (Article 7, Swiss Cartel Act).

Furthermore, a patent owner might be restricted in the enforcement of their rights due to their forfeiture based on Article 2 of the Swiss Civil Code (acting in good faith), in particular if they were to wait too long before initiating enforcement proceedings (see 2.9 Special Limitation Provisions).

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

#### Civil Actions

The patent owner who has their rights infringed, or is threatened with an infringement, may initiate

a civil action. The exclusive licensee, irrespective of the registration of the licence in the patent register, may also bring an infringement action independently, provided this is not expressly excluded by the licence agreement (Article 75, PatA). Non-exclusive licensees, however, may only join the infringement proceedings filed by the patent owner or the exclusive licensee in order to claim their own losses or damages.

An infringement action can be raised against any person:

- who uses a patented invention unlawfully;
- who refuses to notify the authority concerned of the origin and quantity of products in their possession which are unlawfully manufactured or placed on the market, and to name the recipients and disclose the extent of any distribution to commercial and industrial customers;
- who removes the patent mark from products or their packaging without authorisation from the proprietor of the patent or the licensees; and
- who abets any of the said offences, participates in them, or aids or facilitates the performance of any of these acts (Article 66, PatA).

If there are several infringers, the claimant is not obliged to initiate the infringement action against all potential infringers.

#### Criminal Proceedings

Criminal proceedings can be initiated against the same persons provided that they wilfully committed the patent infringement, on complaint by the patent owner or ex officio if the infringer acts for commercial gain (Article 81, PatA).



## 3.2 Direct and Indirect Infringement

Swiss law does not explicitly know a doctrine distinguishing between direct and indirect patent infringement. Whoever commits an infringement act as described in Article 66 of the PatA may be held liable under Swiss civil and criminal law.

However, the PatA implicitly distinguishes between direct infringement (Article 66 litterae a, b and c, PatA) and contributory infringement (Article 66 littera d, PatA), according to which any person who abets, participates in, aids or facilitates the performance of any (direct) infringement may also be held liable under civil and criminal law. According to case law of the Swiss Federal Supreme Court, a contributory infringement is accessory to a direct infringement, meaning that an unlawful principal act is required for a contributor infringement, whereby it is sufficient for a claim for injunctive relief against the contributory infringer that a direct infringement is imminent.

With regard to its application in an international context, the “accessoriness” has the effect that the contributory infringer, acting in Switzerland but contributing to a direct infringement abroad, cannot be held liable under Swiss law. On the other hand, if the direct infringement takes place in Switzerland, a contributory infringer contributing to that infringement may be liable irrespective of whether the contributory acts are performed in Switzerland or abroad.

Regarding the supply of (non-infringing) materials or parts to a customer who uses these parts or materials for the manufacture of goods infringing a patent, the Swiss Federal Supreme Court has clarified that the supplier is liable as contributory infringer if they knew or should have known that the means supplied were suitable for,

and intended to be used by the customer for use in the infringing goods.

## 3.3 Process Patents

The most important particularity of process patent infringement proceedings concerns the burden of proof. In general, the claimant carries the burden of proof in infringement proceedings. However, the burden of proof may be reversed if the patent in question is a process patent. If an invention concerns a process for the manufacture of a new product, every product of the same composition is presumed to have been made by the patented process until proof to the contrary has been provided (Article 67 paragraph 1, PatA). The same applies by analogy to a process for the manufacture of a known product if the patent owner provides prima facie evidence of an infringement of the patent (Article 67 paragraph 2, PatA).

Regarding the territorial scope of a process patent infringement, the general rules apply, meaning that a direct infringement must occur in Switzerland in order for Swiss law to apply. Accordingly, the Swiss Federal Supreme Court held in a case that if a device intended for carrying out a patented process is manufactured in Switzerland, but the process itself is only carried out abroad, the process patent is not infringed in Switzerland.

## 3.4 Scope of Protection for an Intellectual Property Right

### Literal Infringements

The patent claims determine the scope of protection of a patent (Article 51 paragraph 2, PatA). According to established practice, the patent claims must be interpreted from the viewpoint of a skilled person, starting with the claim language but also taking into account the description and



the drawings. General technical knowledge is also accepted as a means of interpretation.

The Swiss Federal Supreme Court held that the prosecution history of a patent is, in general, not decisive for the interpretation of the patent claims. Waivers and limitations made by the patent applicant during prosecution are to be taken into account only to the extent that they are ultimately reflected in the patent claims and/or the description.

### Equivalent Infringements

The PatA explicitly holds that an imitation is also deemed to constitute a use (Article 66 littera e, PatA) and, hence, not only literal infringements but also equivalent infringements are known under Swiss law. The Swiss Federal Supreme Court and the Federal Patent Court have elaborated in several decisions, taking into account other European courts' practice, a standard test for the assessment of an equivalent infringement based on three main steps.

- Equal effect – the modified feature must objectively fulfil the same technical function as the corresponding feature of the patent claim.
- Accessibility – the modified feature must be obvious to the skilled person in light of the teaching of the patent; the Federal Patent Court has clarified that the starting point for the assessment of accessibility is not the general prior art, but the patent at issue, as this step should not be confused with the assessment of the inventive step.
- Equality – the skilled person must consider the modified feature as an equivalent solution taking into account the claim language and the description.

If all three requirements are fulfilled, an equivalent patent infringement exists according to Swiss practice.

### 3.5 Defences Against Infringement

Within Swiss patent infringement proceedings, the defendant may attack the validity of the claimant's patent or raise non-infringement arguments.

#### Validity Defences

The defendant may plead the invalidity of the patent as a defence in the form of an objection or as a formal counterclaim. If the defendant raises the invalidity as an objection and the court determines that the patent is in fact invalid, that decision has only a direct effect between the parties – ie, the infringement action is rejected but the patent is not revoked from the patent register. If the defendant decides to file a counterclaim, this has the same effect as a standalone invalidity action – ie, if the invalidity of the patent is confirmed by the court, the infringement action is rejected and the patent is also declared invalid and formally revoked.

#### Lawful Use Defences

Alternatively, or additionally, defendants may also claim to have lawfully used the allegedly infringed patent. Defendants may argue the following.

- That they have been granted a valid licence right.
- That they can rely on a statutory exception as per Article 9 of the PatA, including the exceptions of:
  - (a) private use for non-commercial purpose;
  - (b) use for research or experimental purposes (in order to obtain knowledge about the subject-matter of the invention);
  - (c) use for teaching purposes, use for obtain-

- ing marketing authorisation for a medicinal product (Bolar-type exemption);
  - (d) use by a medicinal professional for an individual person (medical prescription exemption); or
  - (e) use for a direct individual preparation of a medicinal product in a pharmacy (pharmacists' exemption).
- That the patent owner's rights were exhausted (Article 9a paragraph 1, PatA); whereas in general EEA-wide exhaustion applies, but if the patent is of subordinate importance for the functional characteristics of the goods, global exhaustion applies, and if the price of the patented goods is fixed by the state (such as with medicinal products), national exhaustion applies.
  - That they have a prior use right (ie, have commercially used the invention in good faith in Switzerland or have made special preparations for that purpose prior to the filing or priority date of the patent application (Article 35, PatA)); in this case, the defendant might have to pay the patent owner appropriate compensation (Article 48, PatA).
  - That the patent in question is a standard essential patent and defendants rely on a FRAND (fair, reasonable and non-discriminatory) licence; so far, no case law in this respect has been established in Switzerland since all FRAND cases in front of the Federal Patent Court have been settled.

### 3.6 Role of Experts

As a general rule, the Federal Patent Court makes its decisions as a three or five-member body (panel), of whom at least one member must possess technical training. One of the technically trained judges will issue a written opinion (the "Technical Opinion") covering all technical aspects of the case and the parties are given the opportunity to comment. Such Technical Opin-

ions do not bind the other judges, although in many instances they will be largely followed in the judgment.

Additional technical know-how, at the request of a party or ex officio, may be obtained by an opinion from one or more external experts appointed by the court ad hoc (Article 183, CPC). However, external expert opinions basically do not play a role in patent proceedings, since the Federal Patent Court has technically trained judges with expertise in all relevant fields of science.

The parties may submit written expert statements. However, these are considered as assertions of the parties only.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

All arguments against the infringement of patent claims must be raised within the same proceedings. There is no separate procedure for construing patent claims.

### 3.8 Procedure for Third-Party Opinions

Swiss law does not provide for a mechanism where a third party that is not a party to the patent proceedings may file, on its own, any kind of amicus brief to the court.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

There are several reasons for a revocation or cancellation of a patent.

Often, a patent registered in the Swiss patent register is cancelled because the renewal fees are not paid on time.

Swiss national patents or Swiss parts of European patents are also cancelled, and removed from the Swiss patent register, if an action for invalidity of the patent has been successful. The cancellation is done by the IPI upon the provision of full official copies of the final judgments. Any person with a proven interest may bring an invalidity action if the invention is excluded from patentability (eg, human body), is obvious, not novel, not disclosed in a way that a person skilled in the art could carry it out or if the application has been unduly amended (Articles 26 et seq, PatA). The requirements for the interest to be demonstrated by the claimant are rather low. The only exception is an invalidity action based on the allegation that the patent owner has no right to the grant of the patent. This particular ground for invalidity can only be asserted by the person claiming to actually be entitled to the patent.

An action for the cancellation of a patent could also be brought by a person with a demonstrated interest if the grant of licences does not suffice to meet the demand of the domestic market after a period of two years from the grant of the first compulsory licence (Article 38, PatA). Such actions are very rare and to date no patent appears to have ever been cancelled based on such action in Switzerland.

Finally, based on the prohibition against double patenting, a Swiss patent is revoked in favour of a European patent for one and the same invention with effect in Switzerland and granted to the same inventor or to their successor in title with the same filing or priority date (Article 125 paragraph 1, PatA).

## 4.2 Partial Revocation/Cancellation

Partial cancellation is possible if the successful invalidity action relates to certain patent claims only (Article 27, PatA).

## 4.3 Amendments in Revocation/Cancellation Proceedings

A patent owner may amend a patent by surrendering a patent claim, limiting an independent claim by combining one or more patent claims which are dependent on it or limiting an independent claim in some other way (see **1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights**).

A patent may also be amended during invalidity or infringement proceedings. However, the patent owner is only able to rely on the amended patent up to a certain stage of the proceedings.

The Swiss Federal Supreme Court has clarified that if the patent owner amends the patent through the IPI during pending infringement proceedings, this has an *ex tunc* effect and thus the original patent that is the subject of the infringement proceedings no longer exists. If the introduction of new facts (ie, the amended patent) is no longer admissible at the stage of the proceedings in question, the infringement proceedings must be dismissed. This is generally the case if the patent is limited after the second pleading, at which stage new facts and new evidence are admissible only under very strict circumstances (see **2.11 Initial Pleading Standards**). Hence, if the patent owner wants to proceed against the alleged infringer based on the amended version of the patent, they must commence new infringement proceedings.

## 4.4 Revocation/Cancellation and Infringement

The Swiss patent litigation system is not bifurcated. Where an invalidity claim is raised as a defence within patent infringement proceedings, that invalidity claim is heard at the same time and within the same proceedings.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights Procedural Provisions

The Swiss Federal Patent Court has exclusive jurisdiction in certain civil patent litigations. However, the proceedings before the Federal Patent Court are primarily based on the ordinary Swiss Civil Procedure Code, which applies to all civil proceedings. The Patent Court Act only contains a few provisions relating to the proceedings (eg, composition of the panel, jurisdiction and legal representatives).

#### Typical Steps of Infringement Proceedings

Ordinary infringement proceedings are initiated by filing a written statement of claim, followed by a written statement of defence in which the defendant usually asserts invalidity of the patent; either by way of a defence or by filing a counterclaim.

After the exchange of the first briefs, the parties are summoned to an instruction hearing in front of a delegation of the court, normally consisting of the court president, the leading technical judge and a court clerk. The instruction hearing consists of two parts. In a first part that is minuted, the court delegation can pose questions to the parties to seek specific clarifications or to get information with respect to parallel proceedings. The delegation will also mention if further

substantiation is required. This part is normally quite short. The second, informal part of the instruction hearing is not minuted. The delegation of the court will present a confidential preliminary assessment of the case and the parties may then engage in court-mediated settlement negotiations.

If no settlement is found, the proceedings continue and the parties will exchange their second briefs (ie, reply, rejoinder and comments on new invalidity arguments and evidence in the rejoinder). Thereafter, the technical judge will issue their written expert opinion, on which the parties may comment in writing. As a final step, the parties are summoned to the main hearing. After the parties' pleadings, the court can decide whether a court expert will be appointed, witnesses will be heard, or other evidence will be taken. In most cases the court closes the proceedings after the main hearing and renders its judgment in writing within four to six weeks.

Ordinary proceedings on the merits concerning infringement or the nullity of a patent generally take about 18 to 24 months.

#### Action by Stages

An infringement action is typically initiated as a so-called action by stages (*Stufenklage*). In the first stage, the Federal Patent Court renders a partial judgment on the validity of the patent (if contested), the infringement, injunctive relief and the disclosure of information for the calculation of monetary relief. In the second stage, the patent owner asserts the amount of its monetary relief claim based on the information received and the Federal Patent Court decides on the monetary relief.

## 5.2 Decision-Makers

The Federal Patent Court makes its decisions as a three-member (or occasionally a five-member) body (panel), of whom at least one member must possess technical training.

In the rare proceedings concerning patent matters that are ruled before civil cantonal courts (see **5.4 Other Court Proceedings**), external technical experts may be appointed to submit an expert opinion *ex officio* or at the request of a party (Article 183, CPC). However, the final decision remains with the judges also with regard to technical questions.

## 5.3 Settling the Case

Settlements may be agreed at any stage of civil proceedings. They may be discussed with the mediation of the court or upon separate negotiations among the parties only. Swiss courts often actively support the parties in order to find a settlement.

In front of the Swiss Federal Patent Court, the parties are summoned to an instruction hearing after the exchange of the first briefs (see **5.1 Special Procedural Provisions for Intellectual Property Rights**). During this hearing, the court will present a confidential preliminary assessment of the case, which should serve as a basis for settlement discussions. A considerable number of disputes are settled at this stage.

## 5.4 Other Court Proceedings

In respect of contractual rights related to patents, such as ownership and licence rights, legal actions may not only be filed with the Federal Patent Court but also with the cantonal courts (Article 26 paragraph 2, PCA). Where the invalidity or infringement of a patent is to be adjudicated in such proceedings as a preliminary question or on a defence basis, the cantonal court grants

the parties a reasonable period of time for filing the validity or infringement action before the Federal Patent Court, which has exclusive jurisdiction over this subject matter (see **2.3 Courts with Jurisdiction**). The cantonal court must then stay the proceedings until a final decision has been made by the Federal Patent Court. However, considering that actions before cantonal courts with regard to patents have become very rare since the establishment of the Federal Patent Court, the influence of cantonal proceedings on the others are, in practice, very limited.

If infringement proceedings before the Federal Patent Court relate to a European patent which is the subject of pending opposition or appeal proceedings before the EPO, the Federal Patent Court may stay its proceedings. In practice, however, this plays only a very limited role, since the Federal Patent Court emphasises that it only suspends its proceedings if a decision by the EPO can be expected in a short time. Instead, it is the Federal Patent Court's standard practice to submit an acceleration request to the EPO.

Parallel infringement proceedings in front of other European courts do not have a direct influence on proceedings before the Federal Patent Court. The Federal Patent Court, however, is generally interested in judgments of other European courts when parallel parts of European patents are involved, although such judgments do not bind the Swiss courts in any way.

Anti-suit injunctions of foreign courts are generally considered as inadmissible under Swiss law.

## 6. Remedies

### 6.1 Remedies for the Patentee

Civil remedies for patent owners include injunctions or reparatory remedies, damages (including legal costs), declaratory judgments, delivery up or destruction of infringing goods, a recall order and publication of the judgment. See **1.5 Rights and Obligations of Owners of Intellectual Property Rights** for further detail.

Permanent injunctions are the most common remedy sought in infringement proceedings and are generally granted if an infringement is affirmed. In order to enforce the injunction, the judgment provides for administrative fines (per day of violation) if the infringer does not comply with the injunction, and for criminal sanctions.

For past infringements, the patent owner may claim monetary remedies in the form of damages such as lost profits or, if the infringer acted in bad faith, account of the infringer's profit. Alternatively, the patent owner can choose to ask for surrender of the unjust enrichment in the form of a reasonable royalty rate. Swiss law does not provide for punitive or exemplary damages or the like.

Since the patent owner usually does not have all the necessary information to prove the amount of damages or the profit to be surrendered, Swiss law grants the patent owner a claim for the necessary information and the infringer may be ordered to render account on the sales and gross turnover made from the infringing activities. Such a claim is usually asserted in a so-called action by stages. See **5.1 Special Procedural Provisions for Intellectual Property Rights**.

The court is bound by the available civil remedies and the parties' prayers for relief and has no discretion in ordering other remedies.

### 6.2 Rights of Prevailing Defendants

According to Swiss civil procedure law, the losing party must bear the court costs and has to reimburse the prevailing party for its legal costs and expenses, including the costs for assisting patent attorneys. The compensation for legal costs is calculated based on tariffs depending on the value of the dispute. Such compensation will often not cover all the fees actually incurred.

If the defendant has incurred damages as a consequence of the proceedings, they may claim compensation for such damages. Within proceedings for interim measures, the court may make the interim measure conditional on the payment of a security deposit by the applicant, if it is anticipated that the measures may cause damage to the opposing party. An applicant for interim relief is liable for any damages caused in the event such measures are later found to be unjustified. If the applicant proves, however, that they applied for the measures in good faith, the court may reduce the damages or entirely release the applicant from liability (Article 264, CPC).

### 6.3 Types of Remedies

The same types of remedies are available for infringements relating to Swiss national patents and Swiss parts of European patents. Essentially, also the same types of remedies are available for civil proceedings involving inventions protected as trade secrets. See **1.5 Rights and Obligations of Owners of Intellectual Property Rights** for further detail.



## 6.4 Injunctions Pending Appeal

An appeal to the Swiss Federal Supreme Court does not have suspensive effect and, accordingly, injunctions granted at first instance are enforceable during the appeal proceedings. Upon request, the Federal Supreme Court may grant suspensive effect, but this is quite rare.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

Appeals to the Swiss Federal Supreme Court against decisions of the Federal Patent Court or the civil cantonal courts as sole instance follow the same rules as appeals in civil matters.

### 7.2 Type of Review

The Swiss Federal Supreme Court's discretion when reviewing final decisions of prior instances on the merits is limited to legal questions. In a recent judgment the Swiss Federal Supreme Court decided that the construction of patent claims is a legal question. In addition, the assessment of invalidity grounds is also a legal question. In contrast, a review of the facts is only possible in a very limited manner by ascertaining an abuse of law by the prior instance in arbitrarily determining the facts (Article 97, Supreme Court Act, SCA).

With regard to decisions on interim measures, the discretion of the Swiss Federal Supreme Court is narrower and limited to a review of a violation of constitutional rights (Article 98, SCA).

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

Prior to filing a patent lawsuit, there may be significant costs associated with the technical assessment of a patent's validity (as the defendant's usual defence will be to bring an invalidity action against the patent) and the assessment of the potential infringement of said patent by the allegedly violating goods of the counterparty. Additional costs may arise for the issuance of warning letters or the preparation and filling of protective briefs.

### 8.2 Calculation of Court Fees

Upon filing an action, the claimant is requested to advance part of the court costs. In proceedings before the Federal Patent Court, the advance payment is usually half of the expected court costs, which corresponds to the expected court costs up to and including the instruction hearing.

### 8.3 Responsibility for Paying the Costs of Litigation

As a principle, the losing party must bear the court costs and has to reimburse the prevailing party for its legal costs. A proportionate allocation in relation to the outcome is also possible. Both, court costs and the compensation for legal costs, are calculated based on tariffs depending on the value of the dispute.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

In Switzerland, alternative dispute resolution (ADR), or more specifically arbitration, is an important means of resolving intellectual prop-



erty disputes, particularly in international cases where a single decision is advantageous.

ADR in Switzerland is attractive for patent disputes as Switzerland provides for arbitration experts in most fields of technology and Switzerland has a liberal regime regarding the recognition and enforcement of arbitral awards.

According to Swiss case law, all aspects of intellectual property disputes are arbitrable, including contractual issues related to patents as well as disputes over the validity of patents. Whereas arbitration proceedings related to mere validity disputes are rather rare, contractual disputes are often the subject of arbitration proceedings (see **2.4 Specialised Bodies/Organisations for the Resolution of Disputes**).

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

Under Swiss law, the assignment of intellectual property rights consists of the undertaking to assign the right and the actual disposition of the right. While the undertaking to assign the right is not required to fulfil specific formal requirements, the actual transfer of the patent or patent application rights must be made in writing (Article 33 paragraph 2bis, PatA).

In order to validly assign and transfer the patent or patent application rights neither the approval of the IPI nor its recording in the Swiss patent register is required. However, if the assignment

is not recorded, it is invalid against persons who have acquired in good faith rights to the patent from the registered patent owner.

For the recording of the assignment of the patent or patent application rights, the IPI requests the written consent of both the assignor and the assignee.

### 10.2 Procedure for Assigning an Intellectual Property Right

See **10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights**.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

Under Swiss law, there are no specific formal requirements for licence agreements. Licence agreements can even be concluded orally and no approval of the IPI is required. However, where the patent application or the patent is owned by two or more persons, a licence grant requires the consent of all co-owners.

Licences may be recorded in the Swiss patent register, but this is not required for their validity between the contractual parties. However, if the licence is not recorded, it is invalid against persons who have acquired the patent in good faith (Article 34 paragraph 4, PatA).

For the recording of the licence rights, the IPI requests the written consent of the licensor.

### 10.4 Procedure for Licensing an Intellectual Property Right

See **10.3 Requirements or Restrictions to License an Intellectual Property Right**.

Contributed by: Lara Dorigo and Thomas Legler, **Pestalozzi**

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## Trends and Developments

### Contributed by:

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### The Next Ten Years for the Swiss Federal Patent Court

On 1 January 2022, the Swiss Federal Patent Court had its tenth anniversary! In the [Swiss Trends & Developments](#) chapter of the 2022 Patent Litigation Global Practice Guide, we took this as an opportunity to look back and reflect upon the last ten years for a moment – and this year we want to give an outlook on how the Swiss Federal Patent Court could further establish and position itself in the second decade after its foundation. If one looks at the most recent case law of the past year, one clearly notices that the Swiss Federal Patent Court renders its judgments with both the necessary pragmatism and a sense of proportion, making it an increasingly attractive forum for any patent owner to enforce their patent rights.

In the first years after its foundation, quite a number of cases dealt with procedural questions and were decided on the basis of Swiss procedural law. Depending on whether one sympathised more with the plaintiff or the defendant, one was happy or not with the result – but a true patent litigator is jubilant only when the case is argued and decided on the merits, not when a case is won because the filing of amended patent claims after having obtained the Court's preliminary opinion is deemed too late (which is the case in Swiss proceedings and often a pain for patent owners). The possibility of still amending the patent in infringement proceedings has been unnecessarily limited in recent years by the Federal Supreme Court and should again be handled more pragmatically in the authors' view.

Like other courts, the Swiss Federal Patent Court always tries to find a compromise between time, costs and quality. It is immediately clear that these aspects are contrary to each other and that, especially in patent litigation, the highest quality can hardly be achieved quickly and, at the same time, at low cost. But since the Swiss are well-known for reaching good compromises, it seems clear that the Swiss Federal Patent Court is on a very promising path. In particular, a look at some recent decisions in summary proceedings shows that the Federal Patent Court is taking a quick and pragmatic and, at the same time, well-founded approach, which – from a neutral and restrained perspective – could be called patentee-friendly. To illustrate this rather patentee-friendly approach, this article highlights three cases which the Swiss Federal Patent Court decided last year. Some of these judgments were made in awareness of – and in contrast to – rulings in parallel proceedings by well-established courts in the United Kingdom, Germany, or the Netherlands.

#### *The “Fingolimod Case” (S2022\_002)*

In a dispute spreading across numerous European countries, Novartis sought to enforce its second medical use patent EP 2 959 894 (EP 894). The patent covers a 0.5mg per day dosage of active ingredient fingolimod, which forms the basis of Novartis' drug Gilenya. The product is used to treat relapsing-remitting multiple sclerosis.

The dilemma Novartis faced was that the extended market exclusivity for Gilenya expired

in March 2022, but EP 894 had not yet been officially granted by that time. However, the patent grant was imminent, as the European Patent Office (EPO), in the form of the Board of Appeal, had already given the green light to the granting of EP 894.

In light of Article 67 of the European Patent Convention (EPC), the EPC member states have different regimes as to what rights a patent application confers. In Switzerland, injunctive relief generally requires a granted patent. The same applies, for example, in Germany.

In the meantime, some generic manufacturers in Europe took advantage of the gap between the end of Novartis's market exclusivity and the official granting of the patent to sell their own generic products in various markets. Therefore, Novartis initiated patent infringement proceedings against these generic manufacturers, including Mepha Pharma AG in Switzerland, even though Novartis did not yet have a granted patent.

Several courts, including the Düsseldorf Regional Court, dismissed Novartis's application for preliminary injunctions on the grounds that injunctive relief is only available for a granted patent while financial compensation can also be claimed based on a published patent application.

So, what did the Swiss Federal Patent Court do?

The Swiss Federal Patent Court neither dismissed nor suspended the case.

It was undisputed between the parties and acknowledged by the Court that a published European patent application does not grant the applicant the protection provided for in Article 64

of the EPC in Switzerland and that preliminary injunctive relief requires a granted patent. However, in Switzerland, it is sufficient for the issuance of preliminary measures if, at the time of the judgment, the plaintiff is entitled to a claim that has been infringed or that is likely to be infringed. If an application for a preliminary injunction is filed while the application is still pending and the patent is granted only during the course of the proceedings, this defect is deemed to be "cured" because, according to general principles of Swiss civil procedure, the facts at the time of the judgment (rather than at the time of filing) are decisive. Therefore, a patentee can file a request for preliminary measures as soon as the grant of the patent is only a question of time and the claims have been established. In the present case, the fact that the defendant was not aware of the reasoning of the EPO Board of Appeal was not considered to cause any significant disadvantage. Firstly, the applicant was not aware of the reasoning either. Secondly, and crucially, the defendant must allege and establish the lack of validity in the present proceedings and respond to the relevant counterarguments of the applicant presented in those proceedings. The Board of Appeal's reasoning is not binding on the Swiss Federal Patent Court in any case.

Likewise, the defendant's request to suspend the preliminary injunction proceedings was dismissed immediately. The Court pointed out that summary proceedings serve the purpose of granting quick and provisional legal protection if the relevant prerequisites are met. Accordingly, preliminary injunction proceedings should be suspended only with extreme caution. In the present case, the grant of the patent was foreseeable and, according to general experience, would take place before the summary proceedings were ready for judgment. If this were not the case, the judgment would have to be suspended

until the patent were granted. However, the proceedings should not be stayed immediately, as this would violate the applicant's constitutional right to have its case decided within a reasonable time.

### *The "Sorafenib Tosylate Case" (S2021\_006)*

In this case, also spreading across Europe, Bayer HealthCare sought preliminary injunctive relief against the generic product Sorafenib Zentiva of Helvepharm, the Swiss branch of Zentiva. More specifically, Bayer HealthCare sought to enforce the compound claim 12 of EP 2 305 255 B1 (EP 255), claiming the tosylate salt of sorafenib as such. Sorafenib tosylate is the active ingredient in Bayer's medicament Nexavar, which is, inter alia, authorised for the treatment of primary kidney cancer and advanced primary liver cancer.

This case has attracted attention because it was litigated simultaneously in a number of European countries. For example, EP 255 was held to be invalid in Germany, UK and in the Netherlands.

So, what did the Swiss Federal Patent Court decide?

While the Technical Judge in his written Preliminary Opinion provisionally regarded claim 12 of EP 255 as invalid due to lack of inventive step, similar to the positions taken, for example, in the UK and Germany; the applicant convinced the court to decide that claim 12 was valid and a preliminary injunction was granted accordingly.

Even though the defendant referred to the entire range of grounds for invalidity to defend itself, namely Article 123(2) of the EPC, invalid priority, lack of novelty and lack of inventive step, in the end, the case depended mainly on the assessment of inventive step.

With respect to the examination of priority, attention should be paid to one important aspect where Swiss case law might differ from the case law of other European jurisdiction. The Swiss Federal Patent Court pointed out that according to the case law of the Swiss Federal Patent Court, it was sufficient for a valid priority claim if at least one of the applicants of the earlier application and one of the applicants of the later application were identical. Since in the present case, the defendant did not dispute that at least the eight inventors/applicants for whom copies of the signed "Bayer Corporation Agreements" were filed were identical during the relevant period, the priority claim was considered valid. Thus, in a case where validity is dependent on the priority claim and where the priority claim might be disputed because not all applicants of the earlier application and the later application are identical, it could still be advisable for a patent owner to enforce the patent in Switzerland.

Regarding inventive step, the judgment discussed the questions as to whether the skilled person would have considered the tosylate salt at all as a target compound for the development of a sorafenib medicament and, if so, whether and at which stage the skilled person would have given up in view of discouraging results obtained in pre-formulation studies. The judgment of the Swiss Federal Patent Court came to the conclusion that the skilled person could not have determined promising properties of sorafenib tosylate – ie, by measuring the dissolution rate of sorafenib tosylate – with routine methods at the priority date. The Court concluded that the skilled person would not have realised that sorafenib tosylate had a surprisingly high dissolution rate, despite its low solubility.

As mentioned above, an inventive step was acknowledged by the Swiss Federal Patent Court, and a preliminary injunction was granted.

### *The “Deferasirox Case” (S2021\_005)*

In this case, Novartis and Mepha Pharma again faced each other, and Novartis AG sued Mepha Pharma AG for the alleged infringement of the Swiss parts of EP 2 964 202 (EP 202) and EP 3 124 018 (EP 018).

Both patents concern formulations of deferasirox which is an active ingredient from the group of iron chelators and used to treat iron overload caused by frequent blood transfusions.

The patents require, according to the independent claims, that deferasirox or a pharmaceutically acceptable salt thereof is present in the claimed film-coated tablet for oral administration in an amount from 45% to 60% by weight based on the total weight of the tablet. The issue in dispute was, in particular, whether the alleged infringing product “Deferasirox Mepha® 90 mg, 180 mg and 360 mg” containing deferasirox in an amount of 64.3% by weight met this essential feature. Or, in other words, the Federal Patent Court considered the question whether a tablet with a higher amount of the active ingredient – ie, a tablet containing 64.3% by weight of that active ingredient – may fall within the protective scope of a patent wherein the weight range of the active ingredient is defined as 45% to 60% by weight.

Interestingly, in a parallel case, the High Court of England and Wales recently invalidated the two patents following revocation action proceedings brought by Teva. The presiding judge found that Novartis’ claim relating to the amount of deferasirox within the tablet was an obvious modification over the two previous examples of prior

art. While the precise figures for Teva DFX were confidential in the UK proceedings, the judge also found that Teva did not infringe the claims of the patents.

So, what did the Swiss Federal Patent Court decide in this case?

The Swiss Federal Patent Court decided that Deferasirox Mepha® did not literally infringe the patents. So far so good. However, the Swiss Federal Patent Court also concluded that Deferasirox Mepha® 90 mg, 180 mg and 360 mg containing 64.3% Deferasirox by weight realised the feature “a Deferasirox content in the range of 45% and 60% by weight” by equivalent means.

In this case, the Court – for the first time, by the way – dealt with the question of how numerical ranges in a patent claim are to be construed, especially against the background of a product allegedly infringing the patent claim despite a feature deviating from this numerical range.

When assessing the question of infringement under the doctrine of equivalence, the Swiss Federal Patent Court basically applied the three-step-test known as “*Schneidmesser’s*” (cutting knife) questions, developed by the German Federal Supreme Court (BGH, judgment X ZR 168/00 dated 12 March 2003 “*Schneidmesser I*”; see the Swiss decision S2013\_001 of 21 March 2013, cons. 17.2 “*Drospirenon I*”). However, the relevant questions are not formulated completely identically by the Swiss courts, as is shown below. According to Swiss practice, the first two questions must be answered in the affirmative and the last in the negative for a patent infringement to exist.

- Does the modified feature, in combination with the other technical features of the patent



claim, objectively perform the same function as the claimed feature? Known as “same effect.”

- Is the equal effect obvious to the person skilled in the art when viewed objectively, considering the teaching of the patent, if the features are interchanged? Known as “accessibility.”
- Does an objective reading of the patent specification lead the skilled person to the conclusion that the patent owner has formulated the claim – for whatever reasons – so narrowly that it does not claim protection for an accessible embodiment having the same effect?

In the case at hand, the Federal Patent Court affirmed the “same effect”, mainly because the tablet with 64.3% by weight of deferasirox was bioequivalent to Novartis’ tablet. The bioequivalence was confirmed by the fact that the generic tablet was approved by the Swiss Agency of Therapeutic Products (Swissmedic) in a drug application procedure to which bioequivalence is a prerequisite.

The second question – ie, “accessibility” – was also answered in the affirmative for the reason that the patents did not require explicit compliance with the upper limit of the claimed range. Rather, it was allegedly clear from the patents that the intention was to increase the proportion of active ingredient in the tablet. According to the Court, an increase of the portion of the active ingredient of up to 10% would still be considered safe and effective.

In a third step, the Federal Patent Court assessed whether the skilled person when reading the patent specification would conclude that the patentee had deliberately formulated the claim so narrowly that they thereby waived protection for

an embodiment with an equal technical effect that would have been accessible to the skilled person. In assessing this question, the Court particularly considered accepted tolerances for pharmaceutical formulations. In doing so, the Court took into consideration both the accepted tolerance for active ingredient weight and for the total weight of the tablet. That, in practice, much smaller deviations from the target weight can actually be achieved today than are considered acceptable by the cited references, was not relevant. What was decisive, according to the Court, was that these generous tolerances are apparently accepted in the technical field in question. Therefore, the skilled person would assume that a drug which is within these tolerances is effective and safe.

With an active ingredient content of 64.3% by weight of deferasirox, the challenged embodiments were considered to be within the tolerance generally accepted in the relevant technical field, which is 66% for the upper value of the relative active ingredient content, based on the total weight of the tablet.

As a result, the Federal Patent Court considered that Deferasirox Mepha® 90 mg, 180 mg and 360 mg containing 64.3% Deferasirox by weight fulfil the feature “a Deferasirox content in the range of 45% and 60% by weight” by equivalent means.

This case shows that even numerical ranges in patent claims, the scope of protection of which is normally strictly determined by their literal sense, are certainly amenable to the doctrine of equivalence and that differences that are much more than mere rounding differences can still fall within the scope of protection under the doctrine of equivalence.

Contributed by: Simon Holzer, Ulrike Ciesla, Louisa Galbraith and Simon Reuter, **MLL Legal**

The latter two cases – ie, the Sorafenib Tosylate Case and the Deferasirox Case – are currently being litigated in ordinary proceedings on the merits and it remains exciting to see whether the Court will confirm the preliminary rulings.

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In closing, with a look to the future, we would like to quote the President of the Federal Patent Court, Mark Schweizer. In a very recent interview, the President answered the question of where he sees the Federal Patent Court in 2032 as follows: “When I became president four years ago, I said that we wanted to become the best patent court in Europe. In ten years, that goal shall be realised.”

We think the Court is on its way to achieving this ambitious goal.

Contributed by: Simon Holzer, Ulrike Ciesla, Louisa Galbraith and Simon Reuter, **MLL Legal**

**MLL Legal** has an IP team that unites Switzerland's leading consultants and representatives for patent law. Led by Simon Holzer, MLL's patent team includes four partners and four associates. The firm handles an impressive amount of litigation in the Swiss life sciences and hi-tech areas and it is many global pharmaceutical originators' first choice. The team covers a wide range of industries, including pharmaceuticals, medical devices, software, telecommunications, and foodstuffs. It has also taken centre stage in Switzerland's first FRAND battle. MLL's

patent team has particular expertise in the field of supplementary protection certificates and achieved two landmark Swiss Federal Supreme Court decisions on behalf of Gilead Sciences Inc. (*Gilead v Mepha Pharma AG*), which affirmed the validity and infringement of Gilead's SPC for the combination product Truvada. Measured by published decisions, there is no other firm that has represented as many clients before the Swiss Federal Patent Court as the MLL Legal patent team.

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# SWITZERLAND TRENDS AND DEVELOPMENTS

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

Patent rights are provided in Taiwan to protect inventions. If a design is considered as an invention, its invention patent rights and utility model patent rights are based on statutory law. The Plant Variety and Plant Seed Act applies if plant varieties are regarded as inventions.

### 1.2 Grant Procedure

An invention patent needs to pass a formal examination and a substantive examination before being granted. Only a formal examination is needed for a utility model patent.

### 1.3 Timeline for Grant Procedure

For an invention patent application, the pending period is one to three years. The average cost (excluding the translation of the specification) for ten claims before proceeding to grant, after one response to an office action with cited reference(s), is around TWD70,000.

For a utility model patent application, the pending period is one year. The average cost (excluding the translation of the specification) before grant is around TWD30,000.

Representation is required for a foreign applicant.

### 1.4 Term of Each Intellectual Property Right

The term of an invention patent expires 20 years after its local or actual filing date. The term of a utility model patent expires ten years after its local or actual filing date.

### 1.5 Rights and Obligations of Owners of Intellectual Property Rights

The rights of an owner include:

- preliminary injunctions;
- permanent injunctions;
- prohibition of continuous or future infringement;
- damages for post-grant/post-acquirement infringement;
- court fees and reasonable costs incurred for stopping a patent infringement;
- up to treble damages for an intentional infringement; and
- reasonable fees for pre-grant use, between the patent grant date and publication date or the date on which a defendant was notified of the patent application and its contents (available only for invention patents).

The obligations of an owner include:

- annual renewal fees;
- that, before exercising the right of a utility model patent, the patentee shall not make a warning without presenting the utility model technical report in advance; and
- that, in addition to registration, the patent owner has the obligation to mark the patent certificate number on a patented article – if such a mark cannot be fixed to the patented article, the patentee may mark the labels or packaging, or make the mark in a distinct way that is sufficient to draw people's attention.

The public information regarding patents includes:

- English patent-related [information](#) issued by the TIPO; and
- the Taiwanese patent search [system](#) maintained by the TIPO.



## 1.6 Further Protection After Lapse of the Maximum Term

Generally, there is no further protection for technical intellectual property rights after their maximum term has lapsed, except for a pharmaceutical patent where the patent can be petitioned to be extended for two to five years if the regulatory approval costs the patentee the petitioned period.

## 1.7 Third-Party Rights to Participate in Grant Proceedings

A third party can submit its observations for consideration by an examiner during prosecution. A written statement accompanied by relevant evidence is enough for third-party submission.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

An applicant may first appeal a refusal decision to the Petitions and Appeals Committee (PAC) in the Ministry of Economic Affairs (MOEA). If the applicant is not satisfied with the PAC's decision, it can further appeal to the Intellectual Property and Commercial Court (IPC Court). There are two possible outcomes before the IPC Court. If the applicant is dissatisfied with the IPC Court's decision, it can further appeal to the Supreme Administrative Court (SA Court) to pursue a final decision.

## 1.9 Consequences of Failure to Pay Annual Fees

If the annuity is not paid within the specified time period, a late payment can be made within six months of the original due date, with a specified percentage addition.

The additional amount shall be calculated according to the length of time that has elapsed from the original due date. For every month that lapses, an additional fee at a rate of 20% must

be paid; the maximum additional fee shall be the same as the amount originally due. The elapsed time from one day to one month shall be calculated as one month.

In addition, a patentee who unintentionally fails to pay a patent annuity within the aforementioned time period for late payment may apply for reinstatement of the patent rights within one year after the expiration of the time period of late payment by paying triple the amount originally due.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

The patentee filing a request for amending the description, claim(s) or drawing(s) of a granted invention or utility model patent may only do so to:

- delete claim(s);
- narrow down the scope of claim(s);
- correct errors or translation errors; and
- clarify ambiguous statement(s).

Except for correction of translation errors, a post-grant amendment shall not extend beyond the scope of content disclosed in the description, claim(s), or drawing(s) as filed.

In addition, the post-grant amendment shall not substantially enlarge or alter the scope of the claim(s) as published.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

Sending a warning or cease and desist letter in order to develop a licensing relationship, seek a settlement/mediation or initiate a lawsuit

before the IPC Court are actions available to the owner of a technical intellectual property right against infringement. Injunctions or cross-border measures are also available. For trade mark and copyright infringements, criminal offences are involved.

## 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property Invalidation

Under Taiwan's patent practices, any third party can petition for an invalidation proceeding against the validity of a patent at the Taiwan Intellectual Property Office (TIPO), and the losing party can subsequently appeal before the PAC, IPC Court and SA Court. There is generally no particular admissibility/standing requirement.

### Compulsory Licensing

In response to a national emergency or other circumstances of extreme urgency, the TIPO will – in accordance with an emergency order or after notice from the central government authorities in charge of the business – grant compulsory licensing for a patent and notify the patentee as soon as reasonably practicable.

The TIPO may, upon request, grant compulsory licensing for a patent where:

- a patented invention is to be exploited non-commercially for the enhancement of the public interest;
- a later invention or utility model patent cannot be exploited without infringing upon a prior invention or utility model patent, and where the later invention or utility model patent involves an important technical advancement of considerable economic significance in relation to the prior invention or utility model patent; or

- a patentee has committed acts restricting competition or has committed unfair anti-competitive acts, for which a judgment has been made by a court of law or a decision has been rendered by the Fair Trade Commission of the Executive Yuan.

## 2.3 Courts With Jurisdiction

For civil or criminal infringement actions, the IPC Court has jurisdiction in the first instance, and the IPC Court has exclusive jurisdiction for some cases in the second instance, while the Supreme Court (SC) has jurisdiction in the third instance.

For prosecution or administrative matters, the IPC Court has jurisdiction in the first instance while the SA Court has jurisdiction over the second or final instance.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

There is no specialised body or organisation, other than the IPC Court, for the resolution of intellectual property disputes.

## 2.5 Prerequisites to Filing a Lawsuit

Other than recording the patent with the TIPO, there is no prerequisite to filing a lawsuit, but generally the plaintiff will issue warning letters before filing the lawsuit.

## 2.6 Legal Representation

It is unnecessary for the parties in intellectual property matters to be represented by a lawyer, but hiring a lawyer is always recommended. Furthermore, a civil court action before the SC or an administrative court action before the SA Court needs legal representation, as does a private prosecution before a criminal court or an oral debate before an SC criminal panel.

## 2.7 Interim Injunctions

### Provisional Attachment and Injunction

A creditor or claimant may apply for a provisional attachment and an injunction with regard, respectively, to monetary and non-monetary claims for the purposes of securing the satisfaction of specific performance or compulsory execution. A provisional injunction or measure will not be granted unless it can be shown that it is impossible or extremely difficult to satisfy a claim by specific performance or compulsory execution in the future.

A plaintiff must explain why it is necessary to apply for provisional attachment or injunction through such a motion. The courts may dismiss the motion if the explanation is insufficient. Even when the grounds of motion for an attachment or injunction are sufficient, the court may still order an applicant to provide a security for granting the attachment or injunction.

### Temporary Status Quo

A plaintiff can move for an injunction maintaining the temporary status quo before infringement proceedings. The plaintiff must explain why it is necessary to prevent material harm or imminent danger, or other similar circumstances, through such a motion. The practical standards may be understood as similar to those implemented in the USA, such as:

- there being a likelihood of irreparable harm with no adequate remedy at law;
- the balance of harm favouring the movant;
- there being a likelihood of success on the merits of the case; and
- the public interest favouring the granting of an injunction.

The courts may dismiss a motion if the explanation is insufficient. Even when the grounds of

motion for an injunction maintaining the temporary status quo are sufficient, the courts may still order an applicant to provide a security for granting the injunction.

## 2.8 Protection for Potential Opponents

The potential opponent can do the following to protect itself.

Try to submit a protective brief, though this is not statutory and there is no precedent, as far as is known.

- Investigate whether the patent rights term has expired.
- Investigate whether the annuity was duly paid.
- Investigate whether the patent rights are invalid or whether the patent rights are subject to an unfavourable invalidation decision or vulnerable to invalidation.
- Investigate whether the patent rights have been limited by law; eg:
  - (a) whether the suspect products are subject to a non-infringement statutory exemption;
  - (b) whether the suspect products are subject to compulsory licensing;
  - (c) whether the scope of the claims of the invention or utility model patent is limited by prosecution history estoppels; or
  - (d) whether the suspect products are merely an implementation of the prior art and a prior art defence is available.
- Investigate whether the time limit for actions has expired.

## 2.9 Special Limitation Provisions

There is no limitation period for claiming injunctive relief before the expiration of the infringed patent. For claiming damages, an infringement action shall be initiated within two years of the

date on which the owner knows of it, and within ten years of the date on which the action is made. Furthermore, the patent rights shall not extend to:

- actions for private and non-commercial purposes;
- actions for research or experimental purposes;
- prior use before the patent filing date;
- the seizure of vehicles merely passing through the territory of Taiwan;
- a false patent applicant's prior use before invalidation by the actual patentee; and
- use under the international exhaustion doctrine.

## 2.10 Mechanisms to Obtain Evidence and Information

When a document or object (hereinafter document) is in the possession of an opposing party or third party, a party can move that the courts order that opposing party or third party to produce that document. When the courts find that the disputed fact is material and that the motion is justified, they may order the opposing party or third party to produce the document through a ruling.

In addition, a party has the duty to produce:

- documents to which such party has made reference in the course of a litigation proceeding;
- documents of which the opposing party may require the delivery, production or an inspection, pursuant to the applicable laws;
- documents which are created in the interests of the opposing party;
- commercial account books; and
- documents which are created regarding matters relating to the action.

## 2.11 Initial Pleading Standards

There is generally no special provision for lawsuits in intellectual property proceedings that differs from non-intellectual property proceedings. However, for a patent infringement lawsuit, a plaintiff is required to demonstrate why there is a patent infringement, or to submit a patent infringement evaluation report. Therefore, it seems that the initial pleading standard for a complaint is, at least, plausibility.

After service of the complaint, the plaintiff may not amend its claim or raise additional claims, except where:

- the defendant agrees;
- the amendment or addition of the claim is based on the same transaction or occurrence;
- only the demand for judgment for the relief sought is expanded or reduced;
- a change of circumstances makes it necessary to replace the original claim with another claim;
- the claim shall be adjudicated jointly with regard to several persons and one or several such persons who are not parties are joined as parties;
- the existence or non-existence of a certain legal relation, based upon which the case shall be decided, becomes disputed in the course of the proceeding and an additional claim for a declaratory judgment confirming such legal relation against the defendant is raised; or
- it would neither severely obstruct the defendant's defence nor delay litigation.

In addition, supplementing or rectifying factual or legal statements supporting rather than changing the claim may always be submitted by closure of the oral debate.

## 2.12 Representative or Collective Action

Multiple parties with common interests may appoint one or more persons from among themselves to sue or be sued on behalf of the appointing parties and the appointed parties. In addition, multiple parties with common interests who are members of the same incorporated charitable association may appoint such an association as an appointed party to sue or be sued on behalf of them, to the extent permitted by said association's purpose as prescribed in its bylaws.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

It is impermissible to collect royalties on unpatented products or an expired or impracticable patent; otherwise, the patent is unenforceable because of patent misuse/abuse.

A patentee may not commit acts that restrict competition or acts of unfair competition. Furthermore, upon request, the TIPO may grant a compulsory licence for a patent when a patentee has committed acts restricting competition or has committed unfair competition acts, for which a judgment has been made by a court of law or a decision has been rendered by the Fair Trade Commission of the Executive Yuan. A compulsory licence will also be granted when there is a non-profit use in a national emergency or public interest improvement. A compulsory licence is also possible when a re-invention represents economic significance. Please see **2.2 Third-Party Remedies to Remove the Effects of Intellectual Property** for further detail.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

A patent owner and an infringer are the necessary parties to an action for infringement. An exclusive licensee, however, may also file an action for infringement at any time, unless otherwise provided for in the licensing agreement.

### 3.2 Direct and Indirect Infringement

#### Direct Infringement

Direct infringement is the act of making, offering for sale, selling, using or importing an infringing product for the aforementioned purposes, or using an infringing process, or using, offering for sale, selling or importing for the aforementioned purposes the product obtained directly by the infringing process.

#### Indirect Infringement

Indirect infringement can be described in Taiwan as an infringement done by an accessory or abettor, and can only arise when the accused indirect infringer has at least some knowledge of the patent and intends to help in its infringement. If, however, there is no direct infringement, there cannot be indirect infringement either. Inducing or contributory infringers are joint tortfeasors to be jointly liable for the damages arising therefrom. The remedies for direct and indirect infringement are basically the same and include:

- preliminary injunctions;
- permanent injunctions;
- prohibition of continuous or future infringement;
- damages for post-grant/post-acquirement infringement;
- court fees and reasonable costs incurred for stopping a patent infringement;

- up to treble damages for an intentional infringement; and
- reasonable fees for pre-grant use, between the patent grant date and publication date or the date on which a defendant was notified of the patent application and its contents (available only for invention patents).

### 3.3 Process Patents

The patentee of a process patent has an exclusive right to prevent others from exploiting the invention, without their consent, where the exploiting means:

- using the process; and
- using, offering for sale, selling or importing for these purposes the product obtained directly by that process.

If an article produced following a manufacturing process that is still unknown within and outside of Taiwan before the filing of a patent application for that manufacturing process, another article identical thereto made by another person shall be presumed to have been produced following the said manufacturing process.

Under the current laws, if parts of the allegedly infringing process are practised outside Taiwan, it will be very difficult for the patentee to claim infringement. However, if there is a direct infringement in Taiwan (eg, an infringing product manufactured abroad according to a process patent was sold in Taiwan), the patentee may make a case to claim indirect infringement against the foreign manufacturer under the Taiwan Civil Act. Note that the Taiwan Patent Act does not provide rules regarding indirect infringement and that court cases in Taiwan are divided over whether to apply indirect infringement under the Taiwan Civil Act.

### 3.4 Scope of Protection for an Intellectual Property Right

Claims delineate the exact periphery, or metes and bounds, of the conferred protection, and the scope of protection is based on the construction of the plain meanings of a claim. In addition, the courts may be conservative in applying the doctrine of equivalents. In general, the courts may adopt any doctrine or principle that is prevalent in a major jurisdiction.

### 3.5 Defences Against Infringement

The defences available against a claim for infringement can be summarised as follows.

- The patent rights are invalid.
- Non-infringement.
- The patent rights have been limited by law, such as:
  - (a) the suspected products are subject to a non-infringement statutory exemption, such as prior use rights;
  - (b) the suspected products are subject to a compulsory licence;
  - (c) the scope of the claims of the invention or utility model patent is to be interpreted in terms of the prosecution history estoppel; and
  - (d) the suspected products are merely an implementation of the prior art, and a prior art defence is available.
- The right to claim patent infringement becomes extinguished if not exercised within two years of the patentee becoming aware of the damage; the rights to claim also become extinguished if not exercised within ten years of the time of infringement.
- Patent exhaustion.

### 3.6 Role of Experts

An expert may testify on behalf of a party or before the courts, and may assist a court to



understand or evaluate the technical or specific issues related to a case. An expert may also help to evaluate or spot any weaknesses in the technical credentials or testimony of an opposing party's expert witness.

Experts shall be appointed by the court and the number of experts shall also be determined by the court. However, before appointing an expert, the court may accord the parties an opportunity to be heard.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

There is no separate procedure for construing the terms of a patent's claims, but the IPC Court may order such a procedure.

### 3.8 Procedure for Third-Party Opinions

In general, the Taiwan Code of Civil Procedure provides that the person who has the special knowledge or experience needed for giving expert testimony, or who has been commissioned by a government agency to perform the function of giving expert opinion, is under a duty to give expert testimony in an action between others.

In addition, the Judicial Yuan (the highest judicial authority in Taiwan) regulates the Expert Consultation Guidelines for Courts, which state that for patent civil cases, when the court deems it necessary, it may exercise its powers for expert consultation.

There is no amicus brief system formally provided for in relevant laws or regulations. However, in practice, the IPC Court does seek opinions from third parties on some material legal issues met in certain cases, although it is quite rare for the IPC Court to do so.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

An invalidation proceeding may be sought against a patent before the TIPO after the patent is granted. Standing to sue is not required for a revocation or cancellation action.

An administrative appeal may be filed before the PAC against an unfavourable TIPO decision from the invalidation proceeding; an administrative appeal may be filed before the IPC Court against an unfavourable PAC decision; and an administrative appeal may be filed before the SA Court against the unfavourable IPC Court decision.

The most common reasons for invalidation include that:

- the claimed invention does not meet the definition of invention or utility model;
- the invention does not have industrial applicability, novelty or non-obviousness;
- the claimed invention belongs to a statutory subject matter exclusion;
- the specification does not meet the requirement of enablement or written description;
- the claims are indefinite, not concise or not supported by the specification;
- the claimed invention violates the first-to-file principle;
- the amendments/divisional application/corrections fall beyond the scope disclosed by the specification, claims or drawings as filed;
- the corrections substantively enlarge or alter the scope of the claims as published;
- the patent was not filed by the person who has the rights to file the patent application or by all joint owners of the rights to file the patent application; and



- the home country of the patentee does not accept patent applications filed by ROC nationals.

## 4.2 Partial Revocation/Cancellation

Partial invalidation is usually possible if only part of the claims violates the legal requirements and is subject to invalidation.

## 4.3 Amendments in Revocation/Cancellation Proceedings

Amendment is possible in invalidation proceedings. A patentee may amend or correct the patent when responding to the briefs of the invalidation petitioner. The patentee filing a request for correcting the description, claim(s) or drawing(s) of a granted invention patent, however, may only do so:

- to delete claim(s);
- to narrow the scope of claim(s);
- to correct errors or translation errors; and
- to clarify ambiguous statement(s).

In revocation/cancellation/invalidation proceedings, the patentee may amend the claims in light of the newly cited prior art and/or the attacking arguments. Certainly, the amendment shall not extend beyond the scope of the content disclosed in the description, claim(s) or drawing(s) as filed. It goes without saying that such amendments shall also not substantively enlarge or alter the scope of the claim(s) as filed or published.

## 4.4 Revocation/Cancellation and Infringement

If revocation/cancellation and infringement are instituted separately, they will not be heard together – ie, the infringement follows civil proceedings but the invalidation follows administrative proceedings. Nevertheless, the judges in civil proceedings may independently judge

whether the claimed invention is invalid or not, and do not need to wait for the results of the invalidation. The valid or invalid decision by the judges in an infringement proceeding, however, may bind the case at issue only, and may not bind any other parallel or associated cases in theory – ie, an invalidation case before the TIPO.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

Although the court procedures for patents are generally the same as those for common civil proceedings, civil actions for patents are filed before the IPC Court. There is a special act organising the IPC Court (Intellectual Property Court Organisation Act) and a special law (Intellectual Property Case Adjudication Act) providing how the IPC Court should try a case, although provisions in the special law largely adopt those of the Code of Civil Proceedings.

### 5.2 Decision-Makers

A case is determined by legal judges through the assistance of technical experts at the IPC Court. Some legal judges, however, claim technical experts have not really helped, while some technical experts complain that legal judges often ignore either their valuable technical opinions or their appraisals. The parties have no influence on who the decision-maker is.

### 5.3 Settling the Case

The courts may seek settlement at any time, irrespective of the phase the proceedings have reached. When both parties are close to agreeing to a settlement, they may ask the courts for a settlement proposal within the scope specified by the parties.

When the disputed subject price or value of a case is less than TWD100,000, the case shall be subject to mediation by the courts before the relevant action is initiated. However, a party may move for mediation before initiating the relevant action even though the disputed subject price or value of the case is more than TWD100,000.

## 5.4 Other Court Proceedings

It is possible for revocation and infringement proceedings to be respectively pending before two different courts if a separate revocation proceeding has been initiated before the TIPO prior to or during a civil action. For an infringement case in the civil courts, the case will not be suspended until the resolution of an invalidation proceeding at the TIPO, PAC, IPC Court or SA Court. If, however, the SA Court holds that the patent at issue is invalid, all the courts with pending related cases must follow the decision of the SA Court because the SA Court's validity decision is binding.

## 6. Remedies

### 6.1 Remedies for the Patentee

The remedies or rights an owner may claim include:

- preliminary injunctions;
- permanent injunctions;
- prohibition of continuous or future infringement;
- damages for post-grant/post-acquirement infringement;
- court fees and reasonable costs incurred for stopping the patent infringement;
- up to treble damages for an intentional infringement; and
- reasonable fees for pre-grant use, between the patent grant date and publication date or

the date on which a defendant was notified of the patent application and its contents (available only for invention patents).

All of the above remedies are subject to the discretion of a judge.

The remedies for injunctions are enforced through sanctions against non-compliant defendants. The enforcement court may impose a default surcharge of no less than TWD30,000 to no more than TWD300,000. If the non-compliant defendants still fail to comply with the court's order, the court may impose the default surcharge again or place them into custody.

The remedies for monetary compensation are generally enforced through property attachment carried out by the court.

### 6.2 Rights of Prevailing Defendants

A prevailing defendant has no rights but may petition before the SC to prescribe that a plaintiff shall bear a nominal or small sum – ie, TWD80,000 – for compensating the attorneys' fees it expends if the defendant eventually wins the case before the SC.

### 6.3 Types of Remedies

There are three kinds of patents: invention, utility model and design. Each kind of patent has the same, or full remedies, except that reasonable fees for pre-grant use by a defendant between the patent grant date and publication date, or the date on which the defendant was notified of the patent application and its contents, are available only for invention patents, and utility model patent rights can be enforced only after having an official positive technical report. Damages calculations for patents and trade marks are certainly different.

## 6.4 Injunctions Pending Appeal

If a patent is found to be valid and infringed at first instance, the injunction petition is much more likely to be granted and the injunction will be thus enforceable. As a matter of fact, some judges may grant the injunction as long as the patentee submits a bond. If the patent has been found to be valid and infringed, some judges may still require a plaintiff to submit a bond for granting the injunction. Once the injunction is granted, it will not be stayed by appeal by an infringer unless the infringer submits a counter-bond, which may be three times that of the initial bond submitted by the plaintiff.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

Appellate procedures for a civil proceeding for patents are identical to those of common civil proceedings. There are, however, two instances at the IPC Court, so a losing party in the first instance at the IPC Court can appeal before the IPC Court for a second instance judgment.

### 7.2 Type of Review

The second instance of the IPC Court may have a full review of the facts and legal issues of a case. The SC may, however, only review the legal issues of the case, including if the lower court's method or process of finding the facts violated the rules of logic and experience.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

Costs of warning letters, infringement evaluation reports, evidence investigation and collection, possible unsuccessful negotiations with the

potential opponent, etc, may arise before filing a lawsuit. Although hourly charges are preferred by attorneys in Taiwan, a flat fee or fee cap is possible.

### 8.2 Calculation of Court Fees

The method of calculating court fees for commencing proceedings depends on what kind of remedies the plaintiff claims. If the plaintiff claims for prohibition of continuous or future infringement, the court fee will generally be calculated on a per defendant basis. However, if the plaintiff claims for damages for post-grant/post-acquirement infringement or reasonable fees for pre-grant use, the court fee will generally be value dependent.

### 8.3 Responsibility for Paying the Costs of Litigation

Court fees are paid by the losing party; if the losing party is the defendant, reasonable costs incurred for stopping the patent infringement will be borne by the defendant as well. Each party must pay its own attorneys' fees, except the nominal attorneys' fees borne by the losing party in a third instance and decided by the SC.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

Parties to a dispute occurring at present or arising in the future may enter into an arbitration agreement assigning a single arbitrator or an odd number of arbitrators to constitute an arbitral tribunal to determine the dispute. However, disputes are limited to those that can be settled in accordance with the laws, and are very broad in coverage.

In addition, parties to an arbitration may explore settlement options to their dispute prior to the issuance of an arbitral award. If the parties reach a settlement prior to the conclusion of an arbitration, the arbitrator shall record the terms of settlement in a settlement agreement, which has the same effect as the arbitral award.

In the absence of any arbitration agreement to the contrary, the parties may also choose to submit their dispute for mediation and jointly appoint an arbitrator to conduct a mediation. Upon the successful conclusion of mediation between the parties, the arbitrator shall record the results of the mediation in a mediated agreement, which has the same effect as a settlement agreement in the preceding paragraph. As mentioned, it is possible to have a case before the court first, and to ask the court for mediation.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

A patent right owner may assign a patent right, and must record it with the TIPO. The requirements for recordal include a petition form submitted by the patentee or the assignee, and the relevant assignment or documents. In general, if the patent rights are jointly owned, they shall not be completely or partly assigned without the consent of all joint owners. The assignment shall have no locus standi against any third party unless it is recorded with the TIPO.

### 10.2 Procedure for Assigning an Intellectual Property Right

A patentee or assignee may submit the relevant assignment or documents with a petition form for assignment before the TIPO for assigning a patent. If a petitioner is foreign, a power of attorney is required.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

A patent right owner may license a patent right. The requirements for recordal include a petition form submitted by the patentee or the licensee, and the relevant licensing agreement or documents. In general, if the patent rights are jointly owned, they shall not be completely or partly licensed without the consent of all joint owners. The licensing agreement shall have no locus standi against any third party unless it is recorded with the TIPO.

An exclusive licensee may sub-license a third party to exploit the licensed patent, unless otherwise agreed upon by contract. A non-exclusive licensee is not allowed to sub-license a third party to exploit the licensed patent without the consent of the invention patentee or the exclusive licensee. The sub-licensing contract shall have no locus standi against any third party unless it is recorded with the TIPO.

### 10.4 Procedure for Licensing an Intellectual Property Right

A patentee or licensee may submit the relevant licensing agreement or documents with a petition form for licensing before the TIPO for licensing a patent. If a petitioner is foreign, a power of attorney is required.

**Deep & Far Attorneys-at-Law** has a litigation team comprising more than 40 attorneys. They include lawyers, patent attorneys, patent engineers and paralegals. Deep & Far specialises in patent litigation in Taiwan, China and Hong Kong. The firm deals with a broad range of legal issues, with a focus on the practice of all aspects of intellectual property rights, including patents, trade marks, copyrights, trade secrets,

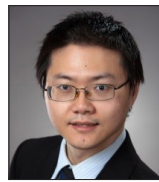
unfair competition, and/or the licensing, counselling, litigation and/or transaction thereof. Deep & Far also prosecutes worldwide patent matters for local clients. For international or foreign clients, Deep & Far prosecutes patent matters mainly in Taiwan, significantly in China and Hong Kong, and with minor representation in Macau, Singapore, Korea and Japan.

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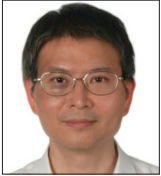
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## Trends and Developments

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### Patent Litigation Trends before the Taiwan IP Court

#### *Introduction*

One of the key ways to enforce patent rights is to initiate civil proceedings against a potential infringer in order to maintain the patentee's exclusive rights in the market. It is therefore critical for a patentee to know the legal environment in a given jurisdiction in advance to evaluate whether it is worth claiming the patent rights in that jurisdiction. There are some factors needing evaluation, such as the case success rate, the success rate in raising a patent invalidity defence, the success rate in moving for preliminary injunctions, and the success rate in moving for documentary evidence preservation in patent litigation civil cases.

This article deals with the statistics relating to these proceedings, makes some analyses, and gives some conclusions and suggestions.

#### *Success rate statistics at first instance for patent litigation civil cases before the Taiwan IP Court*

In 2019, the success rates for invention patents, utility model patents and design patents were, respectively, 11.11%, 13.51%, and 20.0%. The total success rate was 12.82%.

In 2020, the success rates for invention patents, utility model patents and design patents were, respectively, 20.00%, 21.43%, and 0.00%. The total success rate was 18.31%.

In 2021, the success rates for invention patents, utility model patents and design patents were,

respectively, 23.3%, 14.3%, and 28.6%. The total success rate was 21.9%.

In Q1 to Q3 of 2022, the success rates for invention patents, utility model patents and design patents were, respectively, 35.0%, 6.3%, and 33.33%. The total success rate was 24.4%.

#### *Success rate statistics in raising patent invalidity defences in patent litigation civil cases before the Taiwan IP Court*

In 2019, the rates of finding patent rights invalid, finding patent rights valid, and having no disposition were, respectively, 52.64%, 13.68%, and 33.82%. Therefore, the success rate in raising patent invalidity – found by ignoring the cases without any disposition – was 79.38%.

In 2020, the rates of finding patent rights invalid, finding patent rights valid, and having no disposition were, respectively, 40.91%, 16.21%, and 42.42%. Therefore, the success rate in raising patent invalidity – found by ignoring the cases without any disposition – was 71.05%.

In 2021, the rates of finding patent rights invalid, finding patent rights valid, and having no disposition were, respectively, 40.00%, 20.58%, and 39.42%. Therefore, the success rate in raising patent invalidity – found by ignoring the cases without any disposition – was 66.03%.

In Q1 to Q3 of 2022, the rates of finding patent rights invalid, finding patent rights valid, and having no disposition were, respectively, 33.13%, 27.81%, and 39.06%. Therefore, the success rate in raising patent invalidity – found



by ignoring the cases without any disposition – was 54.36%.

### *Success rate statistics in moving for injunctions maintaining the temporary status quo in patent litigation civil cases before the Taiwan IP Court*

- In 2019, the success rate was 30.77%.
- In 2020, the success rate was 42.86%.
- In 2021, the success rate was 30.43%.
- In Q1 to Q3 of 2022, the success rate was 15.00%.

### *Success rate statistics in moving for documentary evidence preservation in patent litigation civil cases before the Taiwan IP Court*

- In 2019, the success rate was 40.00%.
- In 2020, the success rate was 30.00%.
- In 2021, the success rate was 52.17%.
- In Q1 to Q3 of 2022, the success rate was 18.75%.

### *Analysis of patent litigation cases before the Taiwan IP Court*

It can be seen that the success rate statistics for patent litigation civil cases for invention and utility model patents, at first instance, are relatively low. Although the success rate of invention patents in 2022 seems to be more moderate, this is largely because there have been many permanent injunctions granted in relation to COVID-19 vaccine-related patents owned by drug manufacturers or distributors. It can be inferred that the gross success rate for functional product or process patents may be lower than 20%.

In particular, looking into the cases where the plaintiff won, the awarded damages were generally quite low and not especially beneficial in view of the costs sunk into the litigation. The higher success rate for design patents may justify this

analysis because, in general, the products falling into design patents are simple industrial product and would not generate high profits. Therefore, it seems that the IP Court is still taking a position unfavourable to the patentee and tends to protect or maintain the original market order.

In addition, in the author's observation, the IP Court usually interpreted the scope of a litigated patent in a very narrow way, so it is very difficult to apply the doctrine of equivalents.

From the statistics regarding raising patent invalidity defences in patent litigation civil cases, it seems clear that patents face a relatively disadvantageous situation when these are litigated before the IP Court. The gross success rate in raising patent invalidity is larger than 70%.

In addition, the IP Court often likes to broaden the scope of prior art disclosure or the common knowledge without a clear basis to justify its finding of motivation to combine the different prior arts. Therefore, it is doubtful that hindsight bias is commonplace in many cases.

From the statistics regarding moving for an injunction maintaining the temporary status quo in patent litigation civil cases, it seems that the IP Court might be less willing to grant the preliminary injunction against the potential infringer. However, IP right-holders should keep track of developments in the future. If the success rate in moving for preliminary injunctions cannot increase, it will further reduce the incentive of the patentee to pursue litigation and deploy more patents in Taiwan in the future.

From the statistics regarding moving for documentary evidence preservation in patent litigation civil cases, it seems that the IP Court is becoming less willing to grant documentary evidence

preservation against the potential infringer. This trend is also not helpful for the patentee to claim rights in Taiwan.

### *Conclusions and suggestions*

In conclusion, the factors that should be considered in pursuing patent litigation in Taiwan can be summarised as follows:

- the success rate is relatively low for functional product or process patents (ie, invention and utility model patents) and moderate for visual product patents (ie, design patents);
- winning cases are usually related to cases with lower damages and are not valuable for the patentees;
- the success rate in raising patent invalidity defences is quite high and disadvantageous to patentees;
- the success rate in moving for preliminary injunctions is decreasing and disadvantageous to patentees; and

- the success rate in moving for documentary evidence preservation is decreasing and disadvantageous to the patentees.

In view of the above, when a patentee evaluates whether it is worth claiming its patent rights in Taiwan, the author's suggestion is that the patentee should try its best to resolve the dispute through settlement in the early stages of the lawsuit, because in the early stages the defendant will be more willing to settle the dispute at a certain price. If it enters into the substantive trial proceedings, the defendant may no longer be open to considering settlement options and the trend in court practice is relatively unfavourable for the patentee.

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## Law and Practice

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**Moroğlu Arseven see p.438**



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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

The Turkish legal system provides for “patents” and “utility models” for the protection of inventions. Both of these forms of protection are based on statutory law, they are regulated in the Industrial Property Code (IPC).

### 1.2 Grant Procedure

#### Patents

After a patent application is duly and completely filed, the Turkish Patent and Trademark Office (TPTO) conducts a procedural examination.

A priority claim either can be made on first filing or two months from the application date.

If the TPTO determines that there is a deficiency in the application documents, the applicant is given two months to correct it.

The applicant must request the TPTO to undertake a standard state of the art search within 12 months from the application date and pay the necessary fee for the search. If the applicant does not request such a search within the permitted time period, the patent application will be deemed to be withdrawn.

The search report is the first step in deciding whether or not an invention is patentable. Once the search report is prepared, the TPTO notifies the applicant regarding the report and relevant documents.

After a total of 18 months, as of the application/priority date, the patent application is published in the Official Patent Bulletin. The applicant may file a request for an earlier publication.

If the applicant decides to proceed with the application, it is entitled to request the preparation of the examination report within three months from the notification of the search report.

If the TPTO concludes that the application meets the patentability criteria, the TPTO will issue the patent (on payment of the necessary fees).

If the TPTO concludes that the application does not meet the patentability criteria, the applicant is allowed three months to either amend its claims or object to the TPTO's report. Applicants are limited to three rounds of this notification, response and amendment process.

Third parties are entitled to submit oppositions to the patent within six months of the publication of grant. The applicant has the right to file a response to a third-party opposition within three months.

If there is no third-party opposition, the patent becomes final and the final decision of the TPTO is published in the Bulletin.

#### Utility Models

The grant procedure is shorter and easier for utility models.

After the procedural examination, if there is no deficiency or the deficiencies are corrected, the applicant is entitled to request a search report.

Once the search report is prepared by the TPTO, the applicant is notified in this regard.

The application is published in the Bulletin 18 months after the application date. The applicant may file a request for an earlier publication.

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Third parties are entitled to submit their opinions and the applicant is entitled to file an opposition against the publication within three months of publication.

The TPTO examines these opinions and oppositions. If the TPTO's examination decision is positive, the application matures to registration.

### 1.3 Timeline for Grant Procedure

Obtaining a patent takes approximately two to five years. Obtaining a utility model takes around two to three years.

Turkish citizens and Turkish residents do not need a representative to initiate grant proceedings; in other words, right-holders can file applications themselves. However, foreign applicants must assign a registered local patent attorney.

Official fees for granting a patent for 2022 can be found on the TPTO [website](#).

Official fees for granting utility models for 2022 can be found on the TPTO [website](#). Official fees for 2023 have also been published and are available at the TPTO's [website](#).

In a smooth-running proceeding, the cost will vary from EUR5,000–8,000 (including official and attorneys fees). These figures do not include the drafting of the patent application.

Since utility model registration procedures are shorter and less complex, the total cost of the whole registration procedure will vary from EUR3,000–6,000.

### 1.4 Term of Each Intellectual Property Right

Patent protection lasts for 20 years, whereas utility model protection lasts for 10 years as of the application date.

### 1.5 Rights and Obligations of Owners of Intellectual Property Rights

Patent and utility model holders are entitled to:

- prevent others from using their inventions;
- seek legal remedies (such as infringement actions and compensation claims) to protect their rights, including the right to an injunction; and
- assign their intellectual property rights, sign licence agreements, or put pledges on the patent or otherwise dispose of it.

Right-holders are obliged to pay the annual renewal fees.

The patent file submitted to and registered with the TPTO becomes publicly available and may be reviewed by any interested person. The TPTO's online system allows the public to conduct searches of its online database. One can conduct such searches for a patent based on its applicant, invention summary, invention headline, IPC class or Co-operative Patent Classification (CPC) class.

### 1.6 Further Protection After Lapse of the Maximum Term

There is no further protection after the expiration of protection dates.

### 1.7 Third-Party Rights to Participate in Grant Proceedings

Third parties are entitled to file third-party observations after the publication of the patent/utility model application. If these observations are



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filed before the preparation of the search report, they may be considered during the preparation of the report. Even so, the third party filing the observation does not become a party to the proceedings.

Third parties are entitled to oppose the patent within six months from the publication date of the grant of the patent. This post-grant opposition procedure is not available for utility models.

As for utility models, third parties are also entitled to submit observations and objections against the application within three months of the publication of the search report.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

Applicants are entitled to file actions within two months of the notification date of the decision before the first instance intellectual and industrial property rights civil courts of Ankara for the cancellation of a negative and finalised decision of the TPTO.

## 1.9 Consequences of Failure to Pay Annual Fees

The failure to pay annual fees results in loss of rights.

- If the intellectual property right is granted, failure to pay the annual fees results in the loss of the rights arising from the patent/utility model.
- If the application process is ongoing, it results in the invalidity of the application.

Annual fees must be paid every year on the date that the application was filed, starting two years after the application date (when the second year is completed, and the third year starts). It must be noted that right-holders must pay the annual

fees even if they are not notified in this regard. If the fee is not paid on this date, it is possible to pay within six months provided that an additional fee is paid.

Annual fees differ for patents and utility models, and also are updated every year. The fees can be found via the links provided in **1.3 Timeline for Grant Procedure**.

The IPC provides another option for patent holders and applicants, who are allowed to reinstitute rights by paying the relevant fees. The IPC allows patent holders to revive a patent which has lapsed due to failure to pay the annual maintenance fee in time. To revive such a patent, the right-holder must deposit the penalty fee within two months of the TPTO notifying them that the patent has lapsed. The patent will become valid again for a further year, running from the fee payment date.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

Article 99 of the IPC provides a post-grant opposition system, whereby third parties can oppose a patent within six months of the publication of the decision stating that the patent is granted. Upon the TPTO notifying the patent owner about an opposition, the patent owner can file a response or amendments to the patent within three months. If the Re-examination and Evaluation Board (the “Board”) examines the opposition and finds that the patent conforms with the IPC, it will refuse the opposition. If the Board concludes that the patent partially conforms to the law, it will confirm the partial validity. It will inform the patent owner accordingly, requesting the amendment of the patent in line with partial approval. If no amendments are filed (or the amendments are not approved), the patent will be invalidated.

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Otherwise, the claims of a Turkish patent cannot be amended by the patent holder after the grant of protection. However, Article 140 of the IPC states that the right-holder may restrict its right to the patent, either in full or partially, for one or more claims. The IPC allows for the cancellation of a whole claim; however, it does not provide the right to amend the claim. Where the patent is restricted in part, the patent remains in force for the claims which have not been cancelled.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

#### Settlement and Mediation

If the parties seem open to the discussion of a settlement, the right-holder may choose to contact the infringing party through a warning letter and may come to terms by signing a settlement agreement.

Moreover, under Turkish Law, mediation has recently become a prerequisite for filing lawsuits concerning commercial disputes with monetary claims, including IP-related disputes. If a lawsuit is filed without applying for mediation first, the case will be dismissed with respect to compensation claims ex officio on procedural grounds, without any further examination of the merits, and the examination will continue with respect to other claims such as elimination of the infringement and seizure of infringing items (if any).

Recently, the 11th Chamber of Court of Appeal, which is responsible for IP cases, ruled that there is no need to apply for an obligatory mediation if the action includes prevention of or elimination of the outcomes of the infringement request. Although the regulation does not foresee any exceptions on obligatory mediation, right-hold-

ers may initiate patent infringement actions, including compensation claims, without applying for mediation based on said decision of the Court of Appeal's respective chamber.

#### Court Proceedings

The most effective way for a patent owner to enforce their rights is to initiate an infringement action against the alleged infringers before the specialised intellectual and industrial property rights civil courts.

Such infringement actions are generally started with a preliminary injunction claim and the discovery and determination of evidence.

To obtain an injunction, the requesting party must prove that, if the injunction is not granted:

- irreparable harm will arise; or
- the outcome the requesting party seeks in its main action will be unlikely to be achieved.

The preliminary injunction procedure may be initiated with or before the main action. However, if the court accepts the preliminary injunction claim, the main action should be filed within two weeks.

The right-holder is also entitled to request the discovery of evidence before filing the main action. According to Article 400 of the Civil Procedural Law, any party is entitled to request the court to conduct a site visit or expert examination, or to hear a witness, on the condition that the requesting party will receive a legal benefit in filing such a request. The condition of the legal benefit is deemed to be met if the evidence will be lost or very difficult to collect unless it is immediately secured. The determination of evidence is a preliminary measure and is therefore conducted immediately. After the evidence

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is examined, an expert report is obtained. An important point is that, during the determination of evidence procedure, no evidence (eg, infringing products) is seized.

Infringement actions may be subject to alternative dispute resolution (ADR).

## 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

### Invalidation Actions

According to the IPC, “[p]ersons concerned, public prosecutors or the relevant public institutions and organisations may request the invalidity of patent”. Therefore, third parties may initiate invalidation actions. While initiating these actions, third parties may also request a preliminary injunction to prevent the right-holder enforcing their rights. However, the courts are generally reluctant to render such preliminary injunction decisions.

The IPC also introduced a post-grant opposition system, whereby third parties can oppose a patent within six months of publishing the decision stating that the patent is granted. Within this opposition, they may argue that:

- the patent does not meet the patentability criteria;
- the invention is not disclosed in a sufficient manner; or
- the patent exceeds the scope of the initial application.

### Non-infringement Decisions

Obtaining a declaratory judgment in which a court determines that infringement has not occurred (a “non-infringement determination”) is a key pre-emptive defensive measure. Sending a warning letter to the counterparty is not a prerequisite for filing the action, though the timing

is important. In general, for all cases, the plaintiff must have a legal benefit in filing the action at the time the action is filed. In pharma cases, the timing of the non-infringement action is especially important, because the settled practice of the courts underline that as long as the actions of the plaintiff fall within the Bolar exemption, the action is deemed untimely and refused on procedural grounds.

### Compulsory Licensing

The IPC sets certain conditions for granting a compulsory licence (CL) in Turkish practice and regulates the following CL request/grant proceedings, respectively.

- In the case of non-use arguments – the courts are entitled to handle these requests.
- In the case of interdependency of the subjects of the patents – the courts are entitled to handle these requests.
- In cases where plant breeders cannot develop a new type of plant without infringing on a preceding patent.
- In cases where patent holders engage in activities that prevent, distort or restrict competition while using the patent – the Turkish Competition Authority is entitled to handle these requests.
- To meet the requirements of the Doha Declaration (the export of pharmaceutical products to foreign countries experiencing public health problems) – the courts are entitled to handle these requests.
- In the interest of public order – Turkey’s Ministry of Health and the Ministry of National Defence are entitled to request these CLs and the President decides on the granting.

Even though actions for CLs are possible, in Turkey they are very rarely seen.

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## 2.3 Courts With Jurisdiction

### First Instance

All patent cases are handled by the specialised IP courts, which exist only in Istanbul, Ankara and Izmir. In other cities, the Third Civil Court of General Practice is authorised.

According to the general jurisdiction rules of the Civil Procedural Law No 6100 (CPL) and specific rules of the IP Law, several courts are authorised to handle disputes. These include:

- the court of the domicile of the defendant;
- the court of the domicile of the plaintiff;
- the court of the place where the infringing act was carried out; and
- the court of the place where the act of infringement produced its effects.

In addition, Article 156 of the IP Law determines the jurisdiction of the courts.

Accordingly, jurisdiction is determined on the following basis.

In actions which are initiated by the right-holder against third parties, if the plaintiff resides in Turkey, the courts in the following places have jurisdiction: the domicile of the plaintiff or the place where the infringement takes place (or the place where the infringing acts have their results).

Where the plaintiff is not domiciled in Turkey, the court of the place where the registered patent attorney resides has jurisdiction. If there is no registered attorney, the court where the TPTO is located has jurisdiction.

In actions initiated by third parties against the right-holders, if the defendant resides in Turkey, the courts where the defendant is domiciled have jurisdiction. If the defendant does not reside in

Turkey, the court of jurisdiction is the court in the location of the business of the plaintiff's agent. If the agent's record has been deleted from the registry, the court of jurisdiction is one of the specialised IP courts of Ankara, where the TPTO is located.

Generally, both the plaintiff and the defendant will prefer the dispute be handled by the IP courts – as long as the jurisdiction rules allow the action to be filed in Istanbul, Ankara or Izmir – since these courts have extensive knowledge of IP disputes.

### Second Instance

The first-instance courts' decisions can be challenged before the Regional High Court.

### Third Instance

The Court of Appeal is the third and final judicial authority.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

The parties are always entitled to settle the issue amicably at any stage of the proceedings. As to arbitration, it is widely accepted that the disputes regarding the invalidation of a patent cannot be subject to arbitration since the results of ADR are only binding on the parties, but such a dispute relates to the official registry and the TPTO is not a party to the invalidation action. However, it is accepted that a declaratory action for non-infringement, or infringement actions, may be subject to ADR. However, ADR is still not as effective as court proceedings.

Moreover, Turkey has recently adopted new legislation requiring an application to mandatory mediation for monetary claims arising from trade law disputes, including intellectual property disputes (see 2.1 Actions Available against

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Infringement for further detail). In addition, during the period between the application to the mediation bureau and the preparation of the final report by the mediator, the statute of limitations will be suspended.

The parties can apply to the Mediation Bureau within the jurisdiction of the competent court with regard to the subject of the dispute at hand.

## 2.5 Prerequisites to Filing a Lawsuit

As explained in 2.1 **Actions Available against Infringement**, mediation is a prerequisite for filing lawsuits concerning commercial disputes with monetary claims, including IP-related disputes. However, current court decisions rule that there is no need to apply for an obligatory mediation if the action also includes claims for determining and preventing an infringement.

## 2.6 Legal Representation

It is not obligatory to be represented by a lawyer in IP matters, parties can therefore represent themselves. However, although representation is not mandatory, it is common/advisable given the complexity of the matters involved and the unique procedural law principles.

## 2.7 Interim Injunctions

Interim injunctions are available in Turkish Law.

As intellectual property rights can be irreparably and irrecoverably damaged by third-party acts, injunctions play a significant role in litigation. Injunctions are effective tools in patent litigation to preserve the results which plaintiffs hope to achieve.

The legal framework and criteria for injunctions in Turkey are outlined by the CPL and the IPC.

Injunctions can be obtained before or during a trial. To obtain an injunction, the requesting party must prove to the court's satisfaction that:

- irreparable harm will arise if the injunction is not granted; or
- the outcome which the requesting party seeks in its main action will be unlikely to be achieved unless the injunction is granted.

The IP courts are conservative in rendering preliminary injunction decisions, especially in the lack of an expert report, as such decisions generally lead to the restriction of property rights and/or commercial activities.

### Procedure

In patent litigation, upon receipt of a preliminary injunction request, a common approach for a court is to handle the preliminary injunction procedure as follows.

- Even though it is left to the discretion of the judge to conduct the preliminary injunction proceedings *ex parte* or *inter partes*, the judges generally determine a hearing date to hear both parties' arguments on the injunction; the hearing is generally scheduled within a month of the request.
- At the hearing, the judge generally decides to send the file for expert examination, as the merits of patent litigation generally involve technical issues; the report is prepared within one to two months.
- The judges generally grant their decision in line with the report in return for payment of a guarantee; this guarantee will be between EUR7,000–100,000, or more depending on the value of the patent and the parties' economic situation.
- The expert report is notified to the parties, who then have two weeks to file objections.

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These steps generally take around one to three months.

## 2.8 Protection for Potential Opponents

There are no options provided to a potential opponent. However, under Article 159/2-c of the IPC, the court may require the defendant to deposit a guarantee for the possible losses to the plaintiff from a preliminary injunction. Which type of preliminary injunction shall be applied is left to the sole discretion of the judge.

## 2.9 Special Limitation Provisions

There are no special limitation provisions for patent infringement actions. The general rules apply.

As for a patent invalidation action, the action can be filed during the patent protection term and up to five years afterwards.

As for patent infringement actions, these actions can only be filed following the publication of the patent. However, if the defendant has been informed about the patent and its scope, the action may be filed before the application date. The limitation period for infringement actions, including compensation claims, is two years as of the date on which the infringement and the infringer are discovered, and a maximum of ten years as of the infringing action(s). As long as the infringing actions continue, the limitation period does not start running.

## 2.10 Mechanisms to Obtain Evidence and Information

### Evidence Determination

Article 400 of the CPL describes the procedures concerning determination of evidence. According to these, any party is entitled to request the court to conduct a site visit or expert examination, or to hear a witness, on the condition that

the requesting party will receive a legal benefit in filing such a request. The condition of the legal benefit is deemed to be met if the evidence may be lost or very difficult to set forth unless it is immediately secured.

The determination of evidence should be requested through a petition, either before filing or during the action. If the request is filed before filing the action, it should be filed before the competent court of jurisdiction to handle the main action. As to the timeline, the determination of evidence is a preliminary measure and is therefore conducted immediately. The counterparty has the right to oppose the determination of evidence decision of the court within one week as of the notification date. If the counterparty does not oppose it, the determination of evidence is performed one week after the request.

### Expert Reports, Evidence Seizure and Other Issues

Generally, judges allow the expert around one month to prepare their report. The report should not include any conclusions as to the merits of the case, but the report should simply assess the existing situation or secure the evidence. It is important to underline that during the determination of evidence procedure, no evidence, such as infringing products, are seized.

In order to seize the evidence, a preliminary injunction decision should be granted by the court, as such a seizure directly affects property rights.

Additionally, under Article 288 of the CPL, the judge may decide that discovery should be conducted ex officio or upon the claim of one of the parties in the courts or in the place of the dispute. Within the scope of discovery, the



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judge can also decide to have expert assistance regarding the technical aspects of the dispute.

## Compensation

Moreover, according to Article 150/3 of the IPC, the right-holder may ask the court to order the person responsible for compensation to submit to the court the documentation related to the use of the industrial property right:

- before instituting a legal proceeding for compensation related to infringement of an industrial property right, in order to determine the evidence; or
- if a legal proceeding for compensation has been instituted, in order to determine the amount of damages.

## 2.11 Initial Pleading Standards

The procedures for intellectual property lawsuits are regulated in the CPL; therefore, no special provisions apply to pleading standards in patent litigation.

The parties must submit all arguments and list the evidence that support these arguments during the exchange of petitions phase, which includes two petitions per party. Then, as the court invites the parties to the preliminary examination hearing, the court grants the parties two weeks' peremptory additional time as of the receipt of the notification to submit missing evidence. According to the CPL, the parties can change their arguments during the exchange of petitions phase; otherwise, widening and amending of the claims or defence are not allowed.

Additionally, after this limited time frame, if a party explicitly consents to it, the other party may change its claims or arguments. If one of the parties is not present at the preliminary examination hearing without any valid excuse, then the

present party is permitted to change or extend their argument without seeking the counterparty's consent.

## 2.12 Representative or Collective Action

Turkey has no mechanisms for class or collective actions.

However, depending on the type of the action, plaintiffs and defendants may number more than one. For example, the plaintiffs may include the patent owner and the licensee and there may be multiple defendants.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

In principle, the enforcement of a patent does not constitute an antitrust violation, as using a legal right cannot be deemed to be unlawful according to the Turkish Constitution. However, there could be liability in the case of an abuse of a legal right causing an antitrust violation. In such a case, the antitrust issues should be separately examined. It must be noted that the Turkish Competition Authority (TCA) does not have any precedent for the enforcement of patent rights and its relationship with antitrust law.

The IP Law sets certain and exceptional conditions for granting compulsory licences, which are very rare. Such compulsory licence conditions may be interpreted as a restriction on IP rights.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

According to the IPC, the patent owner is entitled to file infringement claims. Unless otherwise agreed in the licence agreement, the exclusive



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licensee is entitled to file an infringement action on behalf of themselves.

For non-exclusive licence agreements, by default, the licensee does not have direct rights to file an infringement action. The non-exclusive licensee can ask the patent owner to file an action against a patent infringement, unless it is otherwise limited in the agreement. If the patent owner does not take the requested action within three months, the non-exclusive licensee can file the action themselves.

Distributors cannot file patent infringement actions, unless they are licensees.

No other party can file patent infringement actions.

## 3.2 Direct and Indirect Infringement

Indirect patent infringement is not explicitly set forth under the infringement rules in the IPC. Instead, according to Article 86 of the IPC titled “Prevention of the Indirect Use of the Invention”, the patentee is granted a right to prevent the factors or equipment regarding a part which makes the practice of the invention subject to a patent possible, and which constitute the essence of the invention, from being released by third parties to parties who do not have an authority to use the invention subject to a patent.

In this context, the conditions of indirect use of the invention are as follows.

- The element or the instrument supplied to the infringer must relate to a part that constitutes the essence of the invention.
- The supplier must be aware of the following, or these matters should be sufficiently clear:

(a) the elements or the instruments are suitable for the implementation of the invention; and

(b) such elements or instruments will be used for the implementation of the invention.

In cases of direct infringement, the infringing action should directly comply with the actions listed in the law and must include all features of the patent. In an infringement action, the defendant is the party who takes the mentioned infringing actions.

## 3.3 Process Patents

There are several provisions that the holder of a process patent can rely on during the proceedings.

According to Article 141/2 of the IPC, if the subject of a patent is related to a process for obtaining a product or material, the court may ask the defendant (instead of the plaintiff) to prove that the process used for obtaining the same product or material was different from the patented process.

Moreover, if the product obtained by using the patented method is new, it is deemed that the same product or material is produced by the patented method. Anyone who claims otherwise is obliged to prove it.

## 3.4 Scope of Protection for an Intellectual Property Right

The scope of protection of the patent is determined by its claims. The description and drawings are also taken into account when interpreting the claims. The claims are not interpreted word for word, but the scope of protection cannot be extended to the features that are obvious to an expert yet not clearly written in the claims.

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When determining the scope of protection, all elements equivalent to those defined in a claim are also considered. If an element performs the same function and provides the same result as that specified in a claim, that element is accepted as equivalent.

Moreover, to determine the scope of the patent, the statements of the patent owner made during the prosecution history and the validity term of the patent are also considered.

### 3.5 Defences Against Infringement Patent Cancellation

The most common strategic defence is to request the cancellation of the patent. Even though there is no bifurcated system in Turkey, cancellation proceedings still affect infringement actions. In other words, the court awaits the outcome of the cancellation action regarding the patent before deciding on the infringement.

#### Bolar Exemption

The Bolar exemption is another common defence, especially in pharma litigation. Pursuant to this exemption, the patent owner cannot prevent third parties' experimental activities. These activities include performing experiments with an invention subject to a patent, the licensing of pharmaceuticals, and performing all necessary tests and experiments. The Bolar exemption is widely accepted and applied in Turkey.

#### Exhaustion of Rights

Another defence might be the exhaustion of rights principle. Turkish law adopts the international exhaustion principle; that is, if a product is sold anywhere in the world, the right to first sell is exhausted, and the original product can be sold by anyone.

#### Personal Use

Personal or experimental use of the invention may be brought forward as a defence in an infringement action, as such actions are clearly excluded from the scope of protection of the patent.

#### Prior Use

According to Article 87 of the IPC, prior use may also be used as a defence against infringement claims. If third persons have been using the patent in Turkey or taken real and serious measures in good faith at or before the application date, the patent holder cannot prevent such activities. Such activities should always be proportionate and cannot be extended to harm the rights of the patentee.

#### Agricultural Defences

Additionally, farmers are allowed to use production materials resulting from production performed on land if they have themselves cultivated it with a patented product that is:

- sold by the patent owner;
- used with its permission; or
- obtained through other commercial means.

Farmers can also use patented breeding or other animal reproduction materials sold by the patent owner, or used with its permission, or obtained through other commercial means for agricultural purposes.

### 3.6 Role of Experts

The judges of the IP courts do not have a technical background and therefore appoint experts in order to understand the technical merits of a case. As a result, these expert witnesses play a significant role in patent disputes. It is reasonable to say that these reports determine the judge's decision in most cases.

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Experts submit their opinion in writing. If the judge deems it necessary, further questions may be addressed to the experts to shed light on the technical merits of the case or to clarify contradictions. Experts must attend the examination hearing if the judge orders them to do so and respond to questions put to them.

The experts are appointed by the court. However, if the parties agree to appoint experts, they may put their suggestions to the court for its approval.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

There is not a separate procedure for construing the terms of the patent's claims. In the case of an invalidation action, the patent's claims are examined by the court. Generally, the judges appoint experts to prepare a report in this regard.

### 3.8 Procedure for Third-Party Opinions

Expert witnesses play a significant role in patent disputes. Please see 3.6 Role of Experts.

Moreover, the CPL regulates that the parties to a lawsuit may obtain further information from an independent expert about the subject of the lawsuit. The judge, upon request or ex officio, may decide to invite and listen to the expert from whom this information is obtained.

Turkish law does not set forth amicus briefs. Only the parties to the action or parties duly invited to the action to defend or plead can submit opinions and statements. The parties, however, are entitled to submit private expert reports as stated in 3.6 Role of Experts.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

Under Article 138 of the IPC, a patent is declared invalid by the court if the:

- patentability requirements are not met;
- invention has not been described in a sufficiently explicit and comprehensive way to enable a person skilled in the concerned technical field to implement it;
- patent exceeds the scope of the application or is based on a divisional application and exceeds its scope;
- holder of a patent does not have the right to a patent; and
- patent exceeds the scope of its protection.

### 4.2 Partial Revocation/Cancellation

Under the IPC, a court can partially invalidate a patent for one or more claims. However, a single claim cannot be partially invalidated.

For partial invalidation of a patent, the remaining claims of the patent must fulfil the patentability requirements, which are novelty, inventive step and applicability to industry.

If an independent claim is invalidated, the dependent claims remain intact if they meet the patentability criteria.

### 4.3 Amendments in Revocation/Cancellation Proceedings

During the post-grant opposition proceedings before the TPTO, it is possible to amend claims.

During invalidity actions before courts, where the grounds for invalidity concern only part of a patent, a partial invalidity shall be ruled by cancellation of the claims pertaining to that part. An

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individual claim may not be partially invalidated. In other words, a claim may not be amended, but may be cancelled as a whole.

On the other hand, a European patent validated in Turkey may be limited by amending those claims in proceedings before the courts or authorities that relate to the validity of the European patent under Article 138/3 of the European Patent Convention. The patent, thus limited, shall form the basis of the proceedings. It should be noted that the practice of this Article and the precedents whereby such requests are accepted are very few.

#### 4.4 Revocation/Cancellation and Infringement

Turkey does not have a bifurcated system, and invalidity and infringement procedures are separated. Invalidation actions can be filed either separately or as a counterclaim within the timeframe to respond to the infringement claim in an infringement proceeding. If the invalidation is filed as a counterclaim, both the infringement and the invalidation claim are handled by the same court regardless of the jurisdiction rules. At the end of the case, the invalidation claim is concluded first since it is about the validity of the patent, which is also the basis of the infringement claim.

Even if the invalidation is filed separately, these actions are considered to be closely associated. The outcome of invalidation is awaited in the infringement action or the cases may be combined.

Generally, the proceedings before the first instance courts both for infringement and invalidation take around 18–24 months.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

The general procedural provisions are set out by the CPL and are the same for all civil proceedings.

Even though some steps may change based on the nature of the dispute, the phases of a civil action in general are as follows.

If there is a preliminary injunction request, such request is initially examined. The court will conduct such examination before or during a hearing.

Once the plaintiff's petition is duly served on the defendant, the defendant is obliged to submit a response within two weeks. Following the defence notification, the plaintiff is also obliged to respond within two weeks. Subsequently, the defendant can submit their second response to the plaintiff's counter-arguments within two weeks as of the receipt. The defendant's submission to the plaintiff's counter-statement concludes the exchange of petitions phase. The exchange of petition phase usually takes three months. After this phase, the judge determines a hearing date.

Upon the end of the exchange of the petition phase, the preliminary examination phase begins. In this phase, the court examines the conditions of the conflict between the parties. This examination is considered as a preparation for the analysis of the merits of the case. The parties should file their evidence and arguments within two weeks as of the receipt of the invitation to the preliminary examination hearing date. After that, new evidence and arguments

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may only be filed with the consent of the counterparty.

After the preliminary examination phase, the investigation phase begins. The court evaluates evidence submitted as well as investigating the accuracy of the facts alleged by the parties. In order to examine the submitted documents' accuracy, the court may decide to confer with an expert witness. After the expert witness report is delivered to the parties, the parties are entitled to file comments on or objections against the report. Prior to the decision, the court evaluates the report and comments. If the court finds the report adequate, it does not ask for an explanation and concludes the investigation phase. However, if the report is considered inadequate, further explanation can be requested from the expert, or another expert panel can be assigned. Expert examination is almost obligatory in patent cases due to case law, because of their technical nature. Expert reports are obtained in writing at investigation stage. The court is entitled to invite the experts to the hearing and, in such cases, the attorneys of the parties are entitled to pose questions to the experts directly. Generally, the judges prefer this route, including patent litigation, with very limited exceptions. If there is a request for compensation, the file is also conferred to an accounting expert for calculation.

Following the conclusion of the investigation phase, the judgment phase begins. In this final phase, the judge renders a decision after examining the accuracy of the claims. The judge then prepares the reasoned judgment, which is served to the parties upon request. According to the Turkish Procedural Law, the plaintiff bears the costs of the proceedings. Once a final verdict has been proclaimed by the court, the legal proceedings' official expenses are paid by the losing party to the adverse party. If there is a com-

penetration claim regarding damages caused by infringement, the case has to be referred to mandatory mediation before the case is filed. Generally, the proceedings before the first instance courts take around 18–24 months, after a series of hearings are conducted.

## 5.2 Decision-Makers

All patent cases are handled by the specialised IP courts, which exist only in Istanbul, Ankara and Izmir. In other cities, the Third Civil Court of General Practice is authorised. All first-instance courts, including the IP courts, consist of one judge. The parties are not allowed to choose the judge who will hear the case. Jury proceedings are not applicable under the Turkish legal system.

Regional courts and the Court of Appeals have a minimum of three judges.

While the judges in the specialised IP courts have a significant understanding of the Industrial Property Law, they do not have a technical background and commonly appoint experts to better understand the technical merits of a case.

## 5.3 Settling the Case

According to the CPL, during the preliminary hearing, the courts recommend settlement and mediation to the parties. In this regard, if the judge is of the opinion that the conflict could be resolved by settlement/mediation, the preliminary hearing will be postponed once.

For further detail regarding mandatory mediation, please see **2.1 Actions Available against Infringement**.

## 5.4 Other Court Proceedings

Please see **4.4 Revocation/Cancellation and Infringement** for discussion of the relationship

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between invalidation and infringement actions and how the outcome of one may affect the other.

The concept of the anti-suit injunction is not recognised in Turkish law, and courts are not obliged to consider foreign anti-suit injunctions. However, within the scope of patent invalidation or determination of non-infringement actions, the plaintiff can request the patent owner to be prevented from using its rights arising from the patent registration for itself or its clients as a preliminary injunction (PI). In the case of such a PI, the patent owner is restricted from filing an infringement action and a PI request. Otherwise, its actions shall be considered as breaching the granted PI. In any event, such PIs are quite exceptional and rarely granted.

## 6. Remedies

### 6.1 Remedies for the Patentee

Typical remedies granted to successful plaintiffs in main infringement actions include:

- compensation for damages (moral, material and reputational);
- the destruction of infringing products;
- the confiscation of manufacturing tools; and
- the publication of the judgment.

#### Damages

As per the IPL, “damages” means actual damage and lost profits. “Actual damage” is the net decrease in the requesting party’s assets. The requesting party may also ask for lost profits, which are calculated based on one of the following methods set out in the IPL:

- the income which the patent owner would have generated if the infringing party’s competition had not existed;
- the infringer’s income; and
- the amount that the infringer would have paid as an appropriate licence fee had the parties entered into a licensing relationship.

Generally, plaintiffs are reluctant to request compensation, as the calculation of the compensation may be problematic, considering the unrecorded nature of much of the economy and improperly kept trade books. It is common for plaintiffs to receive less compensation than they request. Thus, choosing the calculation method based on a licence fee is more common.

Punitive damages are not available under Turkish law. However, under Article 150/2 of the IPC, where the industrial property right is infringed, additional compensation may be claimed if the reputation of the industrial property right suffers damage because the products or services forming the subject of the right are used or produced in an inferior manner, or such products produced in this way are made available or launched to the market in an improper manner.

If losing party does not comply with the court order and pay compensation, it could be enforced through enforcement offices.

#### Other Remedies

The most common remedies accepted at the end of an action are the destruction of the infringing goods and the prevention of the counterparty from committing infringing actions.

While the confiscation of manufacturing tools is executed, it is important to be proportionate and not to prevent the defendant from continuing its



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trading activities with respect to non-infringing goods.

## Costs

Losing parties bear the costs, including the successful party's official attorneys' fees. The official attorneys' fees are determined in line with the annual tariff declared by the Turkish Bar Union and are updated every year. The official attorneys' fees are also collectable through enforcement offices.

## 6.2 Rights of Prevailing Defendants

The losing party bears the litigation costs and attorneys' fees.

## 6.3 Types of Remedies

There are not different types of remedy for patents and utility models. The same remedies are valid for both types of IP right.

## 6.4 Injunctions Pending Appeal

Decisions relating to intellectual and industrial property rights can only be enforced once they are finalised (after both stages of appeal).

Unless otherwise specified, the effect of the preliminary injunction continues until the decision regarding invalidity/infringement is finalised. According to the CPL, a preliminary injunction can be requested at any stage of the proceedings, and it can be re-evaluated if the conditions change. Thus, if the preliminary injunction was not accepted at the beginning of the action and then the action is accepted before the first instance, the plaintiff may request a preliminary injunction at the appeal stage. Nevertheless, the acceptance of preliminary injunction requests at the appeal stage is not common.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

There are no special provisions concerning the appellate procedure for intellectual property rights proceedings. It is regulated by the general provisions set out by the CPL.

### 7.2 Type of Review

Second instance appeals before the Regional High Court imply a full review, including the facts of the case as well as the legal review.

In third instance appeals against the Regional High Court's decisions before the Court of Appeal, the examination is limited to legal review.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

There are no protective briefs available in Turkish law.

If parties send notarised letters or conduct e-determination, notarisation costs will arise. However, these costs may vary depending on the evidence determined or on the pages of the letter.

The average cost of a notarised letter is TRY800–1,300, whereas average e-determination costs are around TRY1,000–2,000.

### 8.2 Calculation of Court Fees

At first instance, the official fees and expenses – excluding the expert fee for patent actions without claiming damages – are around TRY5,000.

If the case is referred to an expert body, the expert fee can be around TRY2,000–5,000 per



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expert. Considering these cases are generally examined by an expert committee consisting of three experts, the expert fee can be around TRY6,000–15,000. The minimum attorneys' fee determined in line with the annual tariff declared by the Turkish Bar Union is TRY15,000 in cases of invalidation actions and infringement actions without claims for damages. If there is a compensation claim, the official attorneys' fees are calculated in percentages depending on the amount requested.

Professional attorneys' fees may vary depending on the complexity of a case.

### 8.3 Responsibility for Paying the Costs of Litigation

In general, the plaintiff bears the litigation costs until the end. The losing party bears the official litigation fees and official attorneys' fees of the counterparty.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

Disputes regarding the invalidation of a patent cannot be subject to arbitration since the results of ADR are only binding for the parties. An invalidity dispute relates to the official registry and public policy.

However, negative declaratory and infringement actions may be subject to ADR.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

Assignment of patents and utility models must be in writing and notarised. Approval from the notary public is a validity condition for assignments. The recordal of the assignment to the registry is not compulsory, but rights arising from the assignments that are not recorded in the registry cannot be claimed against third parties acting in good faith. Therefore, it is highly recommended and good practice to have the assignments registered.

### 10.2 Procedure for Assigning an Intellectual Property Right

Initially, parties should execute an assignment agreement in writing.

The assignment agreement should be signed by the representatives of the parties and notarised.

After notarisation, the assignment is duly completed and valid.

As a rule, it is optional to record the assignment agreement with the TPTO. The recordal only has an explanatory effect.

If a party files a request and pays the fee, the assignment is recorded before the TPTO and published in the Official Bulletin.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

Licence agreements must be in writing. Notarisation or notification to the TPTO is not obligatory. Rights arising from licence agreements that are not registered in the registry may not be claimed against third parties acting in good

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faith. Therefore, it is highly recommended and good practice to register the licence agreement.

## 10.4 Procedure for Licensing an Intellectual Property Right

Initially, parties should execute a licence agreement in writing.

Notarisation or legalisation is not required for licensing.

As a rule, it is optional to record the licence agreement with the TPTO. The recordal only has an explanatory effect.

However, as with assignment agreements, it is advisable to record the licence agreement before the TPTO.

If a party files a request and pays the fee, licensing is recorded before the TPTO and published in the Official Bulletin.

Additionally, the patent applicant/patent owner can declare that they will issue a licence to anyone who wishes to use the invention subject to the patent with a written request to the TPTO. The TPTO publishes the licensing offer accordingly.

# TURKEY LAW AND PRACTICE

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**Moroğlu Arseven** is a full-service law firm, with broad expertise and experience in all aspects of business law. Established in 2000, the firm combines a new generation of experienced international business lawyers who have academic, judicial and practical experience in all aspects of private law. Its dynamic and dedicated team has a reputation for carefully analysing legal frameworks to provide flexible solutions for clients. The firm serves local clients in international markets, as well as international clients operating in Turkey. Moroğlu Arseven

operates across a wide range of industries, including manufacturing, retail, energy, banking and financial markets, construction and real estate, pharmaceuticals, life sciences, information technologies, telecoms, media, entertainment and sports. In-depth sector knowledge ensures seamless service across practice areas, enabling the firm to meet all a client's legal needs in Turkey. The firm's lawyers are capable of communicating in English, French, German and Turkish.

## Authors



**Işık Özdoğan** leads Moroğlu Arseven's intellectual property team. She is a prominent figure and thought leader in the global intellectual property sector. Her expertise spans every aspect of

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**Gökçe İzgi** specialises in assisting intellectual property owners to establish, manage, commercialise and protect their assets in Turkey, as well as helping them to understand and

deal with complex regulatory and compliance challenges. She concentrates primarily on patents and trade marks, along with a range of intellectual property issues which arise within heavily regulated industries. Gökçe has notable experience providing detailed and highly tailored advice in circumstances where legal rights, regulatory obligations and commercial practices intersect.

# TURKEY LAW AND PRACTICE

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**Merve Altınay Öztekin** supports clients with complex intellectual property disputes and litigation, as well as offering day-to-day advice on managing IP assets. She regularly assists clients in understanding and navigating local regulatory rules, such as those in the pharmaceutical sector or for advertising and product liability. Merve specialises in helping clients to protect, enforce and commercialise their trade marks, patents and designs. She has successfully represented many well-known brands and patents on both sides of high-stakes and complex IP lawsuits.

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## Trends and Developments

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### 2022 UK Patent Litigation

The UK patent litigation market has remained active in 2022, despite the challenging socio-political environment. A variety of patent cases have been heard and judgments delivered, with a focus on the life sciences and SEP/FRAND sectors. These cases have resulted in important legal and practice-related trends and developments, as well demonstrating the Patents Court's renewed focus on bringing patents cases to trial within 12 months of a claim being issued.

Looking forward to 2023, there is a significant pipeline of patent trials set to keep the Court and legal community busy for the year and beyond. In addition, the anticipated launch of the Unified Patent Court and the Unitary Patent in June 2023 will bring about the most significant changes to European patent litigation in a generation. 2022 has shown that the English Courts continue to position the UK as a jurisdiction that will be influential in the global and European markets; indeed, most of the decisions listed in this article were part of multi-jurisdictional disputes where the UK litigation played a key role in the global strategy. In delivering well-reasoned decisions on the most complex and technical IP issues as well as demonstrating a willingness to understand and engage with the complex economics that sit behind many of those cases, the English Courts will continue to position the UK as a leading jurisdiction and hold an important influential and strategic role in multinational disputes.

### Life Sciences

Litigation in the life sciences and pharmaceutical industries continues to be prevalent in the UK. The number of patent disputes remained steady throughout 2022, but they are becoming increasingly complex and high stakes. As set out below, two notable decisions from the Patents Court this year were the *Novartis v Teva* (fingolimod) and *Neurim v Teva* (melatonin) preliminary injunction decisions, in which in each case the Court denied injunctive relief sought by the patentee to prevent the launch of a generic version of a blockbuster small molecule drug. Other important developments included a decision involving the plausibility of a compound patent (*Sandoz v BMS*), which will be considered by the Court of Appeal in 2023.

In terms of other ongoing trends, as expected, biologics are now firmly established at the forefront of pharmaceutical litigation and comprise the vast majority of the current generation of blockbuster medicines. Further, the success of mRNA-based COVID vaccines has led to renewed focus on using mRNA-based vaccines and treatments for other diseases, as well as other next-generation technologies such as CRISPR gene editing. The complexity of these technologies, along with diverse ownership of IP, leads to conditions ripe for litigation and has led to an increase in litigation between key players in the field. The ongoing legal battle between Moderna and BioNTech/Pfizer is expected to garner further attention in 2023.

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The coming year may also see further developments in the law in relation to recovery of damages by the NHS and generic companies in pharmaceutical cases where a patentee obtained a preliminary injunction that was later deemed unjustified. This issue is currently being addressed in the damages phase of the litigation concerning Warner-Lambert's blockbuster medicine Lyrica (pregabalin), which is due to go to the first of a series of trials in 2023. The outcome is expected to reshape the consideration of damages in pharmaceutical cases in the UK, similar to the impact seen in recent cases in Australia. This is one of many cases before the Patents Court that demonstrates that the UK is, as a forum, willing to engage in highly complex economic analyses that other courts may seek to avoid.

### *Neurim Pharmaceuticals (1991) Limited and Anor v Teva UK Ltd [2022] EWHC 954 (Pat)*

In *Neurim v Teva*, the Court refused to grant a preliminary injunction restraining Teva from selling its generic melatonin product on the basis that damages would be an adequate remedy for Neurim if a preliminary injunction was not awarded. Traditionally in the UK, preliminary injunctions in patent cases have been rare outside of the pharmaceuticals sector. However, the Patents Court has previously been receptive to the argument that the downward price spiral that the generic launch would trigger was likely to cause irreparable harm to the patentee, justifying a preliminary injunction. In *Neurim v Teva*, the Court found that the loss Neurim would suffer was capable of being ascertained with a high degree of certainty. Notably the Court found that damages would not be an adequate remedy for the loss suffered by the generic party Teva if it was enjoined, as those damages were considered to be unquantifiable. Further, Teva's generic product had been on the market for eight months, so

preservation of the status quo favoured rejecting the injunction application.

### *Novartis AG and Anor v Teva UK Ltd and Others [2022] EWHC 959 (Ch)*

In *Novartis v Teva*, Novartis sought a preliminary injunction to prevent the launch of a generic version of its fingolimod product on the basis of a yet-to-be granted European patent application. The Court found that it had jurisdiction to grant a preliminary injunction on a patent yet to be formally granted but, on the facts of this case, would not do so. In refusing the injunction, the Court held that damages were an adequate remedy for Novartis. On the other hand, in assessing whether damages would be an adequate remedy for the generics, the Court found that their damages (individually or collectively) would be hard to quantify on an adequate basis. The Court did not make any detailed findings on the balance of convenience, given its conclusion that damages would be an adequate remedy for Novartis, but noted obiter that where a patentee has filed numerous divisional patents and amendments which result in the generics company being unable to clear the way, this will be considered as a factor in whether to grant a preliminary injunction.

These decisions mark a trend in the development of the Patents Court's approach to one less amenable to the grant of preliminary injunctions sought by the patentee. The Court now applies increasingly close scrutiny to patentees' claims of irreparable harm and the inadequacy of damages as a remedy whilst continuing to consider the potential damage suffered by generic or bio-similar parties to be unquantifiable.

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### *Sandoz Limited v Bristol-Meyers Squibb Holdings [2022] EWHC 822 (Pat)*

In *Sandoz v BMS*, the Court found BMS' patent in relation to apixaban invalid for lack of plausibility and for obviousness due to lack of technical contribution over the prior art. Lack of plausibility is not itself a ground of revocation but, as it was in this case, can be the foundation for an invalidity attack framed under the grounds of lack of inventive step and/or sufficiency. In its decision, the Court considered the reasoning in three prior cases regarding plausibility (*Agrevo*, *Fibrogen v Akebia* and *Warner-Lambert*) and found it was bound by the UK Supreme Court in *Warner-Lambert*. In summary, the specification must contain a contribution by the patentee and that contribution must be more than common general knowledge. BMS have appealed and the hearing will take place in the Court of Appeal in early 2023. The assessment of plausibility continues to become a more and more important element of life sciences patent disputes. In addition to *BMS v Sandoz* in the Court of Appeal, the Supreme Court will be hearing *Fibrogen v Akebia* on this issue in 2023 and the EPO's Enlarged Board of Appeal will give a decision in *Sumitomo (G2/21)*, all of which will likely provide important clarification on the law in this area.

### Technology

In the technology sector (not including SEP/FRAND licensing developments, which are considered below), the DABUS saga continues, with the Supreme Court granting permission to appeal the Court of Appeal's refusal to allow an AI-based machine to be an inventor of a patent; the appeal will be heard in March 2023. Further developments include guidance in relation to preparing expert evidence and the availability of the "Formstein defence" in UK patent disputes. Additionally, medical device and technology litigation has continued to be active in 2022, with

judgments issued in several important cases such as *Advanced Bionics v Med-El* and *Alcon v AMO Development*, and other cases pending for trial in 2023 (eg, *Abbott v Dexcom*). In the coming year, there is expected to be an increased focus on AI and automation, with a key judgment expected in the *Autostore v Ocado* dispute.

### *Alcon Eye Care Ltd v AMO Development LLC and Another [2022] EWHC 955 (Pat)*

In *Alcon v AMO*, the Court found two patents owned by AMO, relating to laser systems for cataract surgery, to be invalid for obviousness, and in the alternative, for insufficiency. Proceedings in Europe and the US are ongoing.

This case re-established the approach to establishing the identity and characteristics of the "skilled team" and illustrated a recent renewed focus on the issue of hindsight and the appropriate instruction of experts in UK patent actions. The parties agreed that a team of at least two experts was necessary, a skilled ophthalmologist (SO) and a skilled engineer (SE) but disagreed as to the mindset and approach of the skilled team. The judgment reflected that where there are real teams operating in an established field, experts who are able to speak to (and from) practical experience in the relevant field will be of greater assistance than those whose evidence is based solely on a theoretical analysis, particularly in relation to establishing the common general knowledge. Further, the judge noted that where a skilled team is involved in which the members would have had to collaborate closely, such interactions between experts should be reflected in the process of the development of the experts' evidence.



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## *Vernacare Limited v Moulded Fibre Products Limited [2022] EWHC 2197 (IPEC)*

*Vernacare v Moulded Fibre* concerned the alleged infringement of two patents relating to the shape and composition of a disposable washbowl made of moulded paper pulp. The Court held the first patent valid but not infringed and the second patent valid and infringed. Notably, in relation to the assertion of infringement under the doctrine of equivalents with respect to the first patent, the Court applied the Formstein defence (a concept developed from the UK's Gillette defence with a name borrowed from German case law) finding that the allegedly infringing immaterial variant would have been obvious at the priority date and, accordingly, if the patent was infringed it was invalid. This case marked a significant development in the law in 2022, as it was the first instance where the Formstein defence was determinative of the issues, thereby confirming its availability in the English Courts.

Following *Actavis v Lilly* in 2017 it is clear that the doctrine of equivalence has become firmly entrenched as an important part of UK patent litigation; decisions such as *Vernacare* show that the Court will continue to refine its scope, bringing more certainty to the issue of infringement.

## SEP/FRAND

The surge in SEP and FRAND litigation globally has continued and the UK remained a prominent jurisdiction in 2022. The key issue in these disputes is the "FRAND licence" and specifically, what constitutes FRAND licence rates. Following on from *Unwired Planet v Huawei*, the first trials since *Unwired Planet* in which the Court will determine the FRAND terms for a global SEP licence were heard in 2022 (*InterDigital v Lenovo* and *Optis v Apple*), with judgments in both expected in 2023.

Other key matters reconsidered by the Court in 2022 included the form of undertaking required to avoid a FRAND injunction following a finding of infringement and validity of an asserted SEP (*Optis v Apple*), and the appropriate fora for determining FRAND rates (*Nokia v OnePlus*). Although the UK has become a favoured jurisdiction for SEP holders, more recently implementers have also asked the Court to determine FRAND rates (*Kigen v Thales*); this trend is expected to continue and increase in 2023 and beyond. Another area expected to develop is the resolution of SEP/FRAND disputes through arbitration or mediation. Courts globally appear to be in support of this trend and the Court of Appeal recently advocated for legally enforceable arbitration (*Optis v Apple*). The UPC Patent Mediation and Arbitration Centre will also be launching in June 2023 and, although it is still unclear exactly how this will operate in practice, given the likelihood that SEP holders will be some of the first adopters of the UPC, there is potential scope for streamlining future SEP/FRAND disputes through UPC arbitration.

## *Optis Cellular Technology LLC & Others v Apple Retail UK Ltd & Others [2022] EWCA Civ 1411*

This decision is part of the ongoing *Optis v Apple* proceedings, in which *Optis* seeks the determination of a global FRAND licence in respect of its portfolio of telecommunications patents. The FRAND trial was heard in June 2022 and judgment is expected in 2023.

The Court of Appeal confirmed that a party found to infringe a valid and essential patent will be considered unwilling (and not permitted to rely on the SEP Holder's ETSI undertaking) if it fails, after judgment in the technical trial, to give an undertaking to take whatever licence the Court determines to be FRAND (notwithstanding

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that the precise form of those terms has yet to be set). The consequence of failing to give the undertaking would be the imposition of a FRAND injunction after the relevant technical trial.

The Court of Appeal also addressed the proper interpretation of Clause 6.1 of the ETSI IPR Policy, which requires an SEP-owner to give an irrevocable undertaking to grant licences on FRAND terms. The Court of Appeal confirmed that an implementer does not permanently lose its right to rely on Clause 6.1 if it does not commit to enter into a court-determined licence either as soon as the SEP owner indicates that it is willing to do so or when there is a finding of validity and infringement of an SEP (and noted that such an interpretation would promote hold-up). The Court also confirmed that the irrevocable nature of the undertaking means it should be open to an implementer to enforce it at any time, regardless of whether the implementer has previously decided not to do so.

The Court of Appeal also dismissed Optis' cross-appeal against the High Court's dismissal of its request for an unqualified injunction (as opposed to the FRAND injunction the High Court considered appropriate). In the postscript to the judgment, Lord Justice Arnold shared his personal views on the appropriate mechanism for the resolution of rate setting disputes, which advocated for legally enforceable arbitration to be incorporated as a dispute resolution mechanism in the IPR policies of standards-development organisations like ETSI.

*Nokia Technologies OY & Another v OnePlus Technology (Shenzhen) Co., Ltd & Others*  
[2022] EWCA Civ 947

This decision is part of the Nokia v OnePlus proceedings, in which Nokia seeks inter alia a declaration that three of its UK patents are essential

to the relevant standards, that they are valid and infringed by the Defendants (OPPO), and a declaration that the terms of a global licence it has offered are FRAND. In this decision, the Court of Appeal reconsidered OPPO's request for a stay of the proceedings on jurisdictional and/or case management grounds, which was dismissed at first instance.

The Court of Appeal dismissed OPPO's appeal. On jurisdiction, the Court of Appeal agreed that the dispute was correctly characterised as a claim relating to the infringement of UK patents, in line with the position affirmed by the UK Supreme Court in *Unwired Planet and Conversant*, and as such the English Court is the appropriate forum to determine the dispute. If the dispute was purely related to the terms of a global FRAND licence, then the Chongqing Court in China where OPPO had commenced parallel global FRAND rate determination proceedings would have been an alternative forum.

The stay on case management grounds was also refused; the Court found that OPPO wanted the FRAND issues to be determined in the forum of their choice, having commenced duplicative proceedings in China, rather than to save time/costs. The Court also noted that if OPPO really wanted an expeditious FRAND determination and to save money on legal costs, they could have achieved this by dispensing with their invalidity and non-essentiality challenges in the UK, and in essence going "straight to FRAND".

The Supreme Court refused OPPO's application for permission to appeal. This decision follows the trend of recent case law confirming the difficulties in successfully challenging jurisdiction or seeking stays of proceedings on global case management grounds in SEP/FRAND cases in the UK since *Unwired Planet/Conversant*.

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### *Kigen v Thales [2022] EWHC 2846 (Pat)*

*Kigen v Thales* marked an important development in the English Court's acceptance that "free-standing" claims for FRAND determination can be brought by implementers.

Following failed negotiations initiated by Thales, Kigen brought a claim in May 2022, seeking declarations that Thales' SEPs were invalid or not essential to the relevant standards, a declaration that it is entitled to a FRAND licence to Thales' Essential IPR, and a determination of those terms.

Thales subsequently brought an application in June 2022 that there was no jurisdiction to grant declaratory relief in respect of Thales' SEPs, because Kigen only sought declarations of invalidity and non-essentiality of the two patents in suit, and as such there was no issue before the Court giving it a jurisdictional basis to determine FRAND. Thales' application was later amended to add a request for a stay under CPR Part 3 on the basis that unless and until Kigen gives an unqualified commitment and undertaking to enter into any licence determined by the English Court to be FRAND, no further steps should be taken in the proceedings because such steps would be a disproportionate use of the Court's time. At a hearing in November, Thales argued further that Kigen's pleaded case as to FRAND was to seek a licence to Essential IPR (as defined in the GSMA Articles) and without an undertaking to match that case (or an amendment to its pleaded case), Kigen was essentially acting like an unwilling licensee by seeking a declaration from the English Court without committing to accept the terms of the declaration.

In the above decision, the Court accepted that Kigen's position was now equivalent to that of an unwilling licensee defendant, rather than a

claimant who asks for a licence of all essential IPR. Accordingly, the Court stayed the FRAND claim until Kigen amends its claim or (in order to remove doubt as to Kigen's willingness to take a licence) gives an undertaking that it will enter into a licence for all Thales' relevant Essential IPR. The Court held that it would be an abuse of process if Kigen did not either amend its claim or give an undertaking to clarify and reinforce its pleaded case.

### *InterDigital v Lenovo and Optis v Apple FRAND Determinations*

The world awaits what will be the second ever global FRAND determination judgment from the English Court in *InterDigital v Lenovo*, which is expected early in 2023. It remains to be seen what approach the Court will adopt in determining the terms of a FRAND licence, but the degree of transparency in this judgment will be important for those involved in FRAND disputes globally. Greater transparency and guidance from the Courts on how to arrive at FRAND rates could reduce the need to use up valuable Court and judicial time. The FRAND judgment in *Optis v Apple* is also expected in 2023, hopefully also providing further guidance on what constitutes FRAND rates.

### **Procedural Developments**

#### *Hearing format*

The COVID-19 pandemic brought about a fast and widespread use of remote and hybrid trials and hearings. In 2022, the majority of trials and hearings in the Patents Court were heard in person, however the Court retains the flexibility of being able to hear matters remotely or in a hybrid format (and to take witness evidence by videolink, as appropriate). The relevant court will decide whether a case is suitable to hold as a remote/hybrid hearing based on the interests of justice; in general, the shorter and simpler the

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matters in dispute at a hearing the more likely it is that that hearing may be heard fully remotely. From June 2022, in order to further the principle of open justice, courts and tribunals were granted new powers to allow reporters and other members of the public to observe hearings remotely.

### *Trial listing*

The Chancellor of the High Court released a new Practice Statement in February 2022, reiterating the Patents Court's goal to bring patent cases on for trial within 12 months of the claim being issued. The statement notes that it does not exclude the possibility of cases being expedited where warranted, or streamlined by other means – ie, the Shorter Trials Scheme.

In 2022, the trend of parties requesting early trial dates before the Case Management Conference (CMC) continued. *Nokia v OnePlus* [2021] EWHC 2746 confirmed that courts are willing to hear short (30 minute) listing applications in order to bring patent trials within 12 months of issue. *Pfizer v Amgen* [2022] EWHC 2296 (Pat) provided further guidance for these early trial listing hearings, emphasising the onus on the parties to provide as much detail as possible to the court regarding the trial to be listed.

To maintain the 12-month objective, trials and hearings are now being listed during the court vacation period in September with greater frequency. The Patents Court's recommitment to quick decisions and expedition where appropriate reinforces its global reputation for efficient and high-quality justice. This will be of increasing importance once the UPC launches this year, given the UPC's own ambitious timelines.

### *Interaction with foreign proceedings: expedition and stays*

The Patents Court has continued to seek to actively manage its listings in 2022 to ensure the Court's time is used effectively whilst avoiding prejudice to litigants. This is clearly seen in its decisions in relation to stays and expeditions in the face of parallel proceedings in other jurisdictions.

In relation to stays in light of parallel EPO proceedings, the Patents Court has continued to apply the Court of Appeal's guidance from *HTC v IPCOM* which broadly sets out that a stay of the UK proceedings is the default option, but identifies various factors relating to the parties' need for commercial certainty which mean that, in practice, in the majority of cases that "default" position is overridden.

Even for matters which do not directly involve a stay, the interplay with EPO proceedings will continue to be important. In *Neurim v Mylan* [2022] EWHC 109 (Pat), the Court reminded the parties of their duty to keep the Court apprised of parallel EPO proceedings, regardless of whether any application was to be made or it suited their strategy. The judge commented that "the Court might have wanted to make its own decision to put the UK trial a little later in case (as turned out) the EPO revoked the Patent and made it unnecessary".

As for expedition of cases, the position of the Patents Court remains that expedition is available where there is good reason for it. In the context of parallel foreign proceedings, expedition will only be granted where a foreign decision might have an impact on the UK market; the export value of a UK judgment is not enough.

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### *Declaratory relief*

The use of declaratory relief in UK patent litigation (specifically Arrow Declarations (declarations that an alleged infringement would have been obvious at a particular date) and Declarations of Non-Infringement (DNIs)) has become more prevalent. Both types of declarations can provide a useful means of establishing commercial certainty and protection against patent infringement. The availability of Arrow Declarations and DNIs highlights the English Court's willingness to provide creative solutions to legal disputes and deliver judgments that are commercially useful. Notwithstanding this, the Court of Appeal in *Teva UK Ltd and Another v Novartis AG* [2022] EWCA Civ 1617 confirmed that English Courts should not make declarations solely for the purpose of influencing a decision of a foreign court, on an issue governed by the law of the foreign court.

It remains to be seen how the UPC will impact the availability of declaratory relief in patent litigation disputes. Whilst the power of the English Courts to grant declaratory relief is primarily derived from statute, it is unclear whether the UPC will have the same levels of flexibility in granting declaratory relief. Nevertheless, at least for now, the English Courts will remain a desirable forum for parties seeking commercially important Arrow Declarations.

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Kirkland & Ellis International LLP has a patent litigation practice comprised of approximately 220 attorneys in London, Austin, Boston, Chicago, Houston, Los Angeles, New York, Palo Alto, Salt Lake City, San Francisco and Washington, DC. Nearly 75% of Kirkland's patent litigation attorneys are engineers and scientists, who are trained in a variety of technical disciplines. With decades of experience, Kirkland's IP litigation attorneys have achieved extraordinary results in patent, copyright, trade mark, trade secret misappropriation and advertising matters. They represent clients across a broad range of indus-

tries, including life sciences, technology, consumer products manufacturing, financial services, automotive, and food and beverage. Other areas of practice are pharmaceutical and biologics patent litigation, co-ordinating global IP enforcement/defence cases, SEPs and FRAND disputes, post-grant proceedings before the US Patent and Trademark Office's Patent Trial and Appeal Board, and appeals of high-stakes cases in the US Court of Appeals for the Federal Circuit and the US Supreme Court, as well as the Court of Appeal of England and Wales and the UK Supreme Court.

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## UK TRENDS AND DEVELOPMENTS

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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

According to the Law of Ukraine “On Protection of Rights to Inventions and Utility Models” (the “Patent Law”), an invention or utility model is a result of intellectual, creative human activity in any field of technology.

Intellectual property rights to either inventions or utility models are confirmed by patents in Ukraine. Legal protection is also provided to secret inventions or utility models that contain information classified as a state secret.

An invention is patentable, if it is (i) new, has (ii) an inventive step, and is (iii) industrially applicable. A utility model meets patentability criteria if it is merely (i) new and (ii) industrially applicable.

Inventions, including any technologies, may also be protected as commercial secrets.

### 1.2 Grant Procedure

Intellectual property rights to an invention or utility model arise once a respective patent, confirming the rights, is granted. A patent is granted upon examination of the invention or utility model by the state organisation, the Ukrainian National Office for Intellectual Property and Innovations (UA PTO).

If an object is patented under the Patent Cooperation Treaty, the international application is submitted to the International Bureau of the World Intellectual Property Organization that decides on its patentability.

Intellectual property rights to an invention protected as a commercial secret arise out of an agreement where the parties agreed to treat

information about the technology as a commercial secret.

### 1.3 Timeline for Grant Procedure

The average grant procedure term is around three years for inventions and one and a half to two years for utility models. However, each individual case depends on the complexity of the object, the volume of files involved and the number of office actions to be overcome. It should be noted that information about an application for an invention is published only 18 months after its submission if it has not been withdrawn; ie, an applicant receives an 18-month period during which the essence of the invention is not disclosed.

Ukrainian citizens and legal entities may act on their own behalf before the UA PTO or authorise a representative. The law does not set any restrictions on a person of representative in such a case. However, foreigners, stateless persons, foreign legal entities, and other persons who have permanent residence outside Ukraine may exercise most of their rights in their relations with the UA PTO through patent attorneys only.

The official cost associated with the granting procedure is established by the government. The average official cost is approximately USD400–700, excluding patent attorney’s fees.

### 1.4 Term of Each Intellectual Property Right

The term of intellectual property rights for an invention is 20 years as from the date of filing the application with the UA PTO or the date of filing the international application.

The term of intellectual property rights for a utility model is ten years as from the date of filing the application with the UA PTO.

A fee must be paid for maintaining a patent for each year of its validity. In addition, the law allows supplementary protection for some inventions, which should be confirmed by a Supplementary Protection Certificate and may not exceed five additional years.

The term of intellectual property rights for an invention protected as a commercial secret is set forth in the respective agreement.

The Martial Law imposed in Ukraine in 2022 caused a legal ambiguity regarding IP rights terms. Namely, according to the Law of Ukraine “On Protection of Interests of Persons in the Sphere of Intellectual Property during Martial Law Imposed in Connection with the Armed Aggression of the Russian Federation against Ukraine”, IP rights, the validity of which expires on the day of imposition of the Martial Law in Ukraine or during the Martial Law, shall remain valid until expiry or cancellation of the Martial Law. Upon expiry or cancellation of the Martial Law, the term of validity of IP rights may be extended in the manner envisaged by the regular IP law. In view of the main purpose of the above norm, and in combination with other provisions of the said Law, it may rather be interpreted as suspension of deadlines for renewal of IP rights and other prosecution terms only. However, to date in patent infringement cases involving the patents that have expired during the Martial Law, the first instance and appellate courts have been reluctant to close the proceedings since they deem such patents valid until the Martial Law expires/is terminated.

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

### Rights of Owners of Intellectual Property Rights

A patent holder has a right to use their invention/utility model at their own discretion, provided that such use complies with the law and does not infringe the rights of other patent holders.

The Patent Law lists the following actions as use of the invention/utility model:

- manufacturing a product using a patented invention/utility model, using such product, offering for sale, including via the internet, selling, importing and otherwise introducing into turnover or storing such product for the said purposes; and
- applying a process protected by a patent or offering it for use in Ukraine, if a person offering such process is aware that the use is prohibited without a patent holder’s consent or, given the circumstances, it is obvious.

A patent holder also has a right to prohibit or allow use of its invention/utility model, demand ceasing an infringement, and recover damages caused by an infringement.

### Obligations of Owners of Intellectual Property Rights

The Patent Law sets forth the following obligations of a patent holder:

- to pay the fees for maintaining validity of intellectual property rights for an invention/utility model; and
- to use its rights to an invention/utility model in good faith.

All patents are published in the respective state registers available online and constantly updated.

ed by the UA PTO. There are no separate registers of patents in specific areas (eg, medicinal products) in Ukraine.

A commercial secret owner has the right to use their commercial secret, and to prohibit or allow such use.

## 1.6 Further Protection After Lapse of the Maximum Term

Since 16 August 2020, supplementary protection certificates (SPCs) have been available in Ukraine.

A holder of a patent for (i) an active pharmaceutical ingredient of a medicinal product, the process for obtaining a medicinal product or application thereof; or (ii) an animal protection product or plant protection product, which require marketing authorisation in Ukraine, has the right to extend the term of validity of the intellectual property rights (supplementary protection), which is certified by the SPC.

An SPC is issued at the request of a patent holder. There is a fee for submitting the application.

The rights to supplementary protection shall be limited to products that received marketing authorisation in Ukraine under the Ukrainian law and their use as medicinal products, animal protection products or plant protection products within the scope of rights granted by a respective patent on the day of applying for the SPC.

Conditions to be complied with while applying for supplementary protection include that:

- a patent holder may obtain supplementary protection if a request for marketing authorisation in Ukraine was filed within one year as

from the date of submitting such a request for the first time in any country;

- the term of supplementary protection shall be equal to the period between filing the patent application with the UA PTO and the date of receipt by the patent holder of the first market authorisation in Ukraine, reduced by five years – generally, the term of supplementary protection may not exceed five years;
- for patents protecting the active pharmaceutical ingredient of a medicinal product intended to be used by children, which is indicated in the market authorisation file, the term of supplementary protection is additionally extended for another six months; and
- the UA PTO must receive a request for supplementary protection within six months either as from the date of publication of information on issuing a patent or as from the date of the first market authorisation in Ukraine (whichever is later).

Prior to 16 August 2020, right-holders could also obtain an extension of a patent in full, unlike an SPC that is limited to protection of a specific medicinal product.

Due to the significant change made to the Patent Law on 16 August 2020, there is currently a lacuna in the law because the holders of patents obtained long before the above date have, in fact, lost the right to obtain SPCs for their inventions. Court cases to restore the right to obtain an SPC are ongoing.

## 1.7 Third-Party Rights to Participate in Grant Proceedings

During examination of an application for invention, any person may submit a reasoned pre-grant opposition. Such pre-grant opposition shall be filed with the UA PTO within six months as from the application's publication date in the

Official Bulletin. This term may not be renewed or extended. An official fee should be paid for filing an opposition. The UA PTO sends an opposition to the patent applicant.

A patent applicant may file a response to such opposition within two months as from receiving the notification of opposition from the UA PTO. In addition, an applicant may either attempt to refute an opposition or amend/withdraw the patent application.

The results of consideration of an opposition are recorded in the motivated examiner's opinion on an application. The UA PTO sends its decision and the examiner's opinion to the person who filed the opposition.

After information regarding the patent application is published, any person may also file their observations on whether the invention complies with the patentability requirements. No filing fee is required for filing such observations. The UA PTO sends an observation to the applicant.

## 1.8 Remedies Against Refusal to Grant an Intellectual Property Right

An applicant may appeal refusal to grant a patent to the Chamber of Appeals of the UA PTO or to the courts within two months, either as from receipt of the refusal or as from receipt of copies of materials opposed to the application. The official fee shall be paid for filing an appeal. An applicant may also appeal a decision of the Chamber of Appeals to the courts within two months as from the decision date. Subsequently, a decision of a first instance court may be appealed to the Court of Appeals and, further, to the Court of Cassation.

## 1.9 Consequences of Failure to Pay Annual Fees

The intellectual property rights to an invention/utility model shall expire on the first day of the year for which the fee has not been paid. However, the Patent Law provides for a grace period of 12 months during which a patent holder may still pay the fee. In this case, the annual fee amount is increased by 50%. Upon payment of the fee, validity of intellectual property rights to an invention/utility model is restored.

## 1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights

After a patent is granted, a holder may at any time waive the rights confirmed by the patent in whole or in part within the published claims. For this purpose, a patent holder submits a respective request with the UA PTO.

A partial waiver may occur through, *inter alia*, introducing amendments to an independent claim. However, such amendment may only reduce rather than increase the scope of legal protection confirmed by a patent.

The UA PTO examines a new edition of claims for compliance with the requirements of the law. An official fee is paid for such examination.

Amendments to the claims take effect from the date of their official publication.

## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

A right-holder may use a variety of legal mechanisms to protect its intellectual property rights.

## Extrajudicial Remedies

Before filing a claim for protection of intellectual property rights with the court, a right-holder may send a cease and desist letter to an alleged infringer. Sending such a letter is not a prerequisite for filing a suit but can sometimes help to avoid litigation. The demands in the letter usually include ceasing the infringement, refraining from infringing the rights in the future, and/or recovering damages.

According to the Commercial Code of Ukraine, a recipient of such a letter must respond within one month. If a response is not received or its content does not satisfy the demands of a right-holder, the latter may send a repeated letter or file a lawsuit.

## Judicial Remedies

### *Preliminary injunction*

A patent holder may protect their rights by asking the court to apply a preliminary injunction (PI), which may include a variety of actions depending on the substance of an infringement. For example, the court may apply a PI by prohibiting the relevant authorities from granting a marketing authorisation for a potentially infringing product or introducing any changes into the pharmaceutical registration dossier.

In a motion for a PI, a patent owner should provide the court with sufficient evidence confirming that there are reasonable grounds to believe that infringement is taking place, and that failure to apply a PI will create obstacles in enforcing a court decision or make it impossible.

The court should consider a motion for a PI within two days as from its filing. Rulings on PIs enter into force immediately.

### *Court action*

A patent holder may file a claim demanding the termination of intellectual property rights infringement, withdraw from the turnover objects infringing intellectual property rights, recover damages/lost profits, etc.

Jurisdiction of the dispute depends on the parties: if individuals are involved as parties to the dispute, the civil courts shall consider the case; and if only legal entities are involved, the commercial courts will be appropriate.

### *Criminal proceedings*

The Criminal Code of Ukraine envisages criminal liability for infringement of rights to an invention/utility model if a suffering party incurs damages in an amount exceeding approximately USD670.

### *Customs detention*

A right-holder may record its patents with the Customs Register. If a customs officer reveals goods suspected of infringing intellectual property rights, customs clearance of such goods is suspended, and a right-holder shall be notified thereof. The latter may bring a court action for confiscation and destruction of such goods, and, before an enforceable court decision is taken, request a PI to suspend customs clearance.

### *Unfair competition proceedings*

Should technical information considered a commercial secret be unlawfully collected, disclosed and/or used, the owner of the commercial secret may file a complaint for protection from unfair competition with the Antimonopoly Committee of Ukraine to terminate an infringement and impose a fine thereon.



## 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

### Post-grant Oppositions

Post-grant oppositions are available with regard to patents in Ukraine. Such opposition may be filed with the Chamber of Appeals of the UA PTO within nine months as from the date of publication of a patent for an invention in the Official Bulletin or within the entire term of validity of a patent for utility model (or even after these rights are no longer valid).

Any person through a patent attorney may file a post-grant opposition. The respective official fee shall be paid. The proceedings before the Chamber of Appeals of the UA PTO are adversarial, and parties may submit evidence to substantiate their position. Post-grant opposition shall be considered within four months, which may be extended for another two months at a party's request if the extension fee is paid, and may also be stayed for no more than two months due to reasons envisaged by the law. The Chamber of Appeals' decision may be challenged through the court within two months as from its receipt by a party.

### Invalidation Action

Any interested person may apply to the court with a claim demanding to invalidate a patent on the grounds of its non-compliance with the patentability conditions or on another ground set forth by the law.

The litigation is adversarial, where, in addition to other evidence, parties or the court normally engage technical experts to opine on those matters requiring specific knowledge. Depending on whether participants are individuals or legal entities, a case may be heard in either civil or commercial court.

A legitimate interest should be proved to file an action. A statute of limitations that generally constitutes three years should not be missed. According to the Supreme Court, the statute of limitations period begins from the moment when a given conflict arose in the market rather than from the date of publication of the patent being challenged.

### Compulsory Licensing

The grounds for compulsory licensing established by the Patent Law are as follows.

- If a patent holder does not use, or does not use sufficiently, a patented invention for three consecutive years, the matter shall be decided by the court, and the burden of proof regarding adequate reasons for such non-use lies upon a patent holder; prior to filing the claim, a plaintiff shall approach a patent holder, and only after getting its refusal may the court action be commenced.
- In the case of dependent inventions – when a person seeking a licence holds a patented invention which is both (i) dependent on the other invention and (ii) may not be used without infringing the respective patent.
- The Ukrainian government may allow a compulsory licence to ensure public health, national security, environmental safety and other public interests.

## 2.3 Courts With Jurisdiction

The High Court of Intellectual Property was established in 2017 to consider IP cases and serve as both first and appeal instances. It has not started its operation yet due to ongoing judicial reform and IP cases are currently considered by the commercial, civil, administrative and criminal courts.

The commercial courts consider matters between legal entities, while cases involving individuals are normally considered by the civil courts. Administrative courts consider cases against state authorities. The venue of a dispute mostly depends on the defendant's location. Criminal IP cases are considered by the criminal courts.

The appellate court shall be in the region where a respective first instance court resolved an IP case.

The Supreme Court serves as a cassation instance; however, not every case may qualify for a cassation consideration because of "cassation filters" introduced by the procedural codes. This is decided on a case-by-case basis at the stage of commencing cassation proceedings.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

See 2.3 Courts with Jurisdiction for discussion of the High Court of Intellectual Property.

In addition, parties to a contract may agree to transfer their dispute for resolution by a particular arbitral tribunal, having a location either in Ukraine or abroad. That is, only patent disputes arising from contracts may be resolved by a dispute resolution body other than a court.

The Ukrainian arbitral body is the International Commercial Arbitration under the Ukrainian Chamber of Commerce and Industry, located in Kyiv.

## 2.5 Prerequisites to Filing a Lawsuit

The Ukrainian law does not establish a compulsory pre-court dispute resolution attempt. This is, however, a recommended step for a party planning to commence a court proceeding for

the sake of proving to the court the unscrupulous behaviour of a defendant.

## 2.6 Legal Representation

The Ukrainian procedural codes allow self-representation of parties to a case. In legal entities, a director or other specifically empowered person may serve as a representative in court proceedings. Otherwise, a party may only be represented by an attorney at law.

## 2.7 Interim Injunctions

The effective law provides for interim injunctions, and this procedural instrument is actively used by parties in patent cases.

The interim injunction may be granted if failure to take such a measure may significantly complicate or impede enforcement of a court decision or effective protection or restoration of an infringed right/interest of a plaintiff, and for other reasons, defined by law.

The motion for an interim injunction may be filed before filing a claim or at any stage of court proceedings. Measures, which may be applied, include:

- a prohibition from taking some actions (for example, prohibiting relevant authorities from proceeding with granting a potentially infringing marketing authorisation or introducing changes into the registration dossier);
- suspension of customs clearance of goods containing objects of intellectual property rights; and
- other measures prescribed by law.

The motion may be considered by the court *ex parte* within two days as from the date of its filing. In some instances, a court may summon an applicant for providing additional arguments

and/or evidence. In exceptional instances, a court may schedule a court hearing and summon all the parties to consider such a motion.

A patent owner should provide the court with sufficient evidence confirming that there are reasonable grounds to believe that infringement takes place and that measures to be applied are adequate and commensurate with the claims.

A ruling on interim injunction enters into force immediately, and an appeal against such a ruling does not suspend its enforcement.

## 2.8 Protection for Potential Opponents

If a potential defendant spots a motion for an interim injunction immediately after its filing, they may file a motion for consideration of that interim injunction in a court hearing before all the parties. Such a motion may increase the chances of the defendant being engaged in the interim injunction consideration process. A potential defendant may file objections against an interim injunction, which shall be considered by the court.

In addition, the effective Ukrainian law envisages a mechanism for securing the rights of a person against whom an injunction is applied as a counter-collateral. Namely, a court may require an interim injunction's applicant to deposit an amount to compensate potential damages that may be incurred by a defendant as a result of an interim injunction. Counter-collateral is usually provided by depositing funds in the court's deposit account in the amount determined by the court.

## 2.9 Special Limitation Provisions

According to the Civil Code of Ukraine, the general statute of limitations for applying to the court

is three years. This term applies to all claims arising out of patent infringements.

The statute of limitations period commences on the day when a person learned or could have learned about the infringement of its right or about an infringer.

According to the Supreme Court, commencement of the statute of limitations in intellectual property disputes may be related to the beginning of the relevant conflict or competition in the market rather than to the date of publication of information on registration of the intellectual property right(s) in question.

## 2.10 Mechanisms to Obtain Evidence and Information

Ukrainian legislation provides several tools for obtaining evidence from an opponent or third parties in intellectual property disputes.

### Inquiries to Government Agencies, Individuals and Legal Entities

Any person may request public information from public authorities. If the requested information is not confidential, an addressee shall provide a comprehensive response to a request within five working days.

Also, any person may apply to the UA PTO with a request to provide copies of the application case file regarding any intellectual property object. There is a fee for providing the said copies.

An attorney at law, being a representative of a person concerned, may also make attorney's requests to any person in order to gather evidence for the trial. Responding to an attorney's requests is mandatory (or otherwise requires providing a detailed justification for the inability

to disclose information or documents) and must be made within five working days.

## **Demands for Evidence from a Court**

Effective Ukrainian procedural law envisages the mechanism for securing evidence, in particular, by demanding it from any person within the pending court proceedings.

Measures to secure evidence shall be taken if there is reason to believe that evidence may be lost in the future or that its collection or filing may subsequently become impossible or difficult.

An application for securing evidence may be filed with the court either before or after filing a statement of claim. If such an application is filed before filing a statement of claim, an applicant should file a statement of claim within ten days as from the date of the court ruling on securing evidence. Failure to file a statement of claim within the specified period, as well as the return of a statement of claim or refusal to commence proceedings, will lead the court to revoke its ruling on securing evidence no later than the next day after the expiration of the said period.

A ruling on securing evidence is binding on any person to whom it is addressed.

## **2.11 Initial Pleading Standards**

According to the effective procedural law, a statement of claim shall include the content of the claims; ie, the remedy that a plaintiff requests a court to apply, a statement of the circumstances in which the plaintiff substantiates their claims, and evidence to support them, and other information. A claim for protection of intellectual property rights is no exception.

In a statement of claim, a plaintiff shall describe in detail the cause of action and provide all avail-

able evidence. Submission of evidence at a later stage of the trial is allowed only if a plaintiff proves good reasons for failure to submit evidence along with the statement of claim.

## **2.12 Representative or Collective Action**

The Ukrainian legal system does not envisage representative or collective actions.

It is possible, however, for several plaintiffs to jointly file a claim, if:

- the subject matter of a dispute concerns the joint rights or obligations of several plaintiffs or defendants;
- the rights or obligations of several plaintiffs or defendants arose on the same grounds; and/or
- the subject of the dispute is homogeneous rights and responsibilities.

## **2.13 Restrictions on Assertion of an Intellectual Property Right**

During a patent dispute consideration, a defendant may allege abuse of the right to sue by a plaintiff; however, in practice, courts rarely apply the respective procedural consequences of abuse of rights, and the relevant jurisprudence is not yet well-developed.

Unfair actions in the market may be considered a violation of the Law on Protection against Unfair Competition. The Antimonopoly Committee of Ukraine or its territorial branches shall consider such cases and impose fines on the infringers.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

In cases for termination of intellectual property rights infringement, a plaintiff may be a patent holder or its licensee directly granted with a right to initiate court proceedings against intellectual property rights infringements. Ukrainian law does not require such a licence agreement to be officially registered.

To substantiate one's standing for applying to the court, one shall submit a copy of a document confirming one's intellectual property right, or the respective extract from the register, or a licence.

In this category of cases, a defendant is a person whom a patent holder/licensee considers an infringer. Depending on the claims in a dispute, public authorities may be involved as co-defendants, such as the Ministry of Health of Ukraine, a state enterprise (eg, the State Expert Centre of the Ministry of Health of Ukraine).

### 3.2 Direct and Indirect Infringement

Ukrainian legislation does not explicitly distinguish between direct and indirect infringement.

The Patent Law provides that any encroachment on a patent holder's rights is considered an infringement, which entails liability. Therefore, at the request of a patent holder or a licensee, such infringement must be ceased, and an infringer is obliged to recover any damages caused to a patent holder by such infringement.

Courts will assess a fact of infringement in each given case based on evidence provided by parties and the courts' own convictions.

### 3.3 Process Patents

According to the Ukrainian law, a plaintiff bears the burden of proof with regard to its right's infringement. The same rule applies to cases regarding process patent infringement.

The Patent Law envisages that a process under a patent is considered used if each feature included in an independent claim or an equivalent thereof is used. Usually, such use is proven by expert reports either filed by a claimant along with its statement of claim or by a forensic expert report.

The Patent Law, however, stipulates that any product, manufacturing of which is protected by a patent, in the absence of evidence to the contrary, shall be considered manufactured with the use of such process, provided that at least one of the following two requirements is met:

- such product is new; and
- there are grounds to believe that such product is manufactured using a protected process, and a patent holder is unable by reasonable effort to determine a process used in the manufacturing of such a product.

In this case, the burden of proof that manufacturing a product, in fact, differs from a patented process rests with the person who is alleged to have infringed the patent holder's rights.

The Ukrainian legal system does not provide for separate regulation when an allegedly infringing process is practised outside Ukrainian jurisdiction.

### 3.4 Scope of Protection for an Intellectual Property Right

Under the Patent Law, the scope of legal protection is determined by patent claims. The

interpretation of claims is carried out within the specification of the relevant invention/utility model and corresponding drawings.

Ukrainian courts are keen to make use of expert reports while determining facts around the use of a certain invention/utility model and establishing the circumstances of a patent infringement. Experts usually assess both direct and equivalent use of the features of an invention.

For assessing equivalent use, the following conjunctive criteria are to be taken into account by an expert:

- the essence of the invention/utility model is not changed when replaced by an equivalent feature;
- the result achieved by application of the invention/utility model is not changed when replaced by an equivalent feature; and
- the means to replace a feature with an equivalent one are known.

If any of the above criteria is not present, replacing a feature of the invention/utility model cannot be considered equivalent, and, accordingly, there is no reason to claim patent infringement.

The prosecution history may be taken into account by an expert conducting expert examination, however, it is not obligatory, and the final interpretation of the scope of patent protection is made based on the granted claims.

### 3.5 Defences Against Infringement

If a patent holder files an infringement claim, a defendant may develop one or several of the following defence strategies.

### Proving Non-infringement with Appropriate Evidence

Under the Ukrainian law, a patent holder shall prove that a defendant used every feature included in an independent claim of an invention/utility model or a feature equivalent thereto.

At the same time, a judge should normally engage experts to opine on any technical matters requiring specific knowledge. Any party to a case, including a defendant, may also file a party-engaged expert report to confirm non-infringement. Such a party-engaged expert report will have the same evidential value in the court as the one drawn up upon request by the court.

### Counterclaim or Separate Claim for Patent Invalidation

A defendant in patent infringement case may either file a counter-claim or file a separate lawsuit against a patent holder for patent invalidation. In such a case, a defendant should prove inconsistency of invention/utility model with the patentability conditions.

If a separate lawsuit for patent invalidation is filed, the respective patent infringement proceedings may be stayed until the patent invalidation case is resolved. However, such suspension of proceedings depends on the matter and the judge's opinion.

### Bolar Exemption

In 2020 the Patent Law was amended with the Bolar provision, which in Ukraine has a rather limited scope of application.

Namely, importation of goods, manufactured using an invention/utility model, into the customs territory of Ukraine for research conducted to prepare and submit information for market-



ing authorisation of a medicinal product is not considered an infringement of a patent holder's rights.

If relevant, such provision may be used by a defendant in an infringement proceeding; however, at the moment, respective jurisprudence is not yet well-established.

### Compulsory Licensing

Under the Patent Law, the grounds for compulsory licensing are as follows.

- If a patent holder does not use/does not use sufficiently a patented invention for three consecutive years – in this case, the matter shall be decided by the court, and the burden of proof with regard to providing adequate reasons for such non-use lies with the patent holder; prior to filing a claim, a plaintiff shall approach a patent holder, and only after having the grant of a licence refused may they commence a court action.
- In case of dependent inventions – when a person seeking a licence holds a patented invention which is both (i) dependent on the other invention and (ii) may not be used without infringing the other patent.
- The Ukrainian government may allow a compulsory licence to ensure public health, national security, environmental safety, and other public interests.

The court shall assess the sufficiency of use depending on the circumstances of a given case. As some doctrinal sources assume, the “insufficient use” may be described as some minor use of an invention, which is characterised by both the volume of industrial use (almost not used in the production process of a patent holder or third parties) and the period of such use (a short period).

Each of these strategies may be used by a defendant in an infringement proceeding if circumstances allow.

### Prior Use

The Patent Law provides for prior use rights, according to which any person – who, before the date of filing an application with the UA PTO or, if priority was claimed, before the date of its priority, in good faith used in Ukraine a technical solution identical to the claimed invention/utility model, or made significant and serious preparation for such use – retains the right to continue such use free of charge or to use an invention/utility model, as implied by the preparation. Prior use rights are limited to the amount of such use as of the date of filing a relevant application with the UA PTO.

### Other Provisions

The Patent Law also envisages some other circumstances under which use of a patented product or process will not constitute an infringement of a patent, among which are:

- use of a patented product or process for non-commercial purposes, for scientific purposes, or experimentally; and
- manufacture of a product or medicinal product containing a product with the use of a patented invention, which obtained supplementary protection, for export to third countries and for conducting other actions if necessary for the manufacture of a product or medicinal product for export to third countries.

### 3.6 Role of Experts

Ukrainian procedural law provides that an expert report is a separate piece of evidence, assessed by a court along with other evidence in the case file, and has no prevailing value over any other



evidence. An expert is a person who has special knowledge in a certain field. In patent cases, experts are normally engaged to opine on matters requiring specific knowledge because a judge is not entitled to establish circumstances where it has no such specific knowledge (as a rule, Ukrainian judges do not have specific knowledge regarding inventions/utility models).

Expert reports may be either party-engaged or requested by the court. An expert should be informed of the criminal liability for providing a knowingly false report. An important aspect in assessment of an expert report is, in addition to its validity on the merits, its compliance with all the requirements of the effective procedural law. Both circumstances may affect admissibility of the expert opinion.

### 3.7 Procedure for Construing the Terms of the Patent's Claim

There is no separate procedure for construing the terms of patent claims in Ukraine. This is normally performed by an expert who opines in an infringement or invalidation case.

### 3.8 Procedure for Third-Party Opinions

Ukrainian procedural law does not envisage a system by which a court can seek or receive third-party opinions (amicus briefs). All statements are usually made by parties to a case. When necessary, a court may request certain information or documents from any third parties.

## 4. Revocation/Cancellation

### 4.1 Reasons and Remedies for Revocation/Cancellation

A claim for invalidation of a patent may be filed if an invention/utility model does not meet the patentability conditions.

Also, a patent may be invalidated if:

- there are features in the claims of a granted invention/utility model that were not present in the respective application;
- state registration of an invention/utility model was conducted in violation of third parties' rights; and/or
- the procedure for patenting an invention/utility model was carried out in violation of the Patent Co-operation Agreement.

To file a claim for the invalidation of a patent, it is usually necessary to prove that a plaintiff has a legitimate interest to file a lawsuit. In order to prove such circumstances, a plaintiff may use, for example, any evidence confirming infringement of the plaintiff's rights by a patent being challenged or the inability to receive market authorisation of a medicinal product that is in conflict with a disputed patent.

### 4.2 Partial Revocation/Cancellation

A patent may be recognised as invalid in whole or in part. The latter is done by excluding independent claims, excluding one or more independent claims along with dependent claims, or by amending independent claims, provided that such exclusions and/or amendments reduce the scope of legal protection granted by the patent.

At the same time, Ukrainian legislation does not provide for the invalidation of a patent in respect of solely dependent claims.

### 4.3 Amendments in Revocation/Cancellation Proceedings

A patent holder may at any time (including, during revocation/cancellation proceedings) waive its patent rights fully or in part by filing a respective request with the UA PTO. However, in such a case, the UA PTO shall conduct an examination

of a new edition of the claims as to their compliance with the patentability conditions.

If such amendments were introduced during pending court proceedings, parties and/or the court may decide on partial waiver of a suit, partial satisfaction of a suit, or waiver of a suit in full, depending on specific circumstances and the scope of amendments.

#### 4.4 Revocation/Cancellation and Infringement

Revocation and infringement may be heard together during the court case, the second being filed as a counterclaim. However, there is no rule explicitly stating the need to consider both claims in the same proceeding.

Such claims may also be heard separately in different proceedings if a defendant does not initiate a counterclaim within the patent infringement proceeding. If such claims are heard separately, a court may suspend one of the proceedings until the decision in the other enters into force, and vice versa.

## 5. Trial and Settlement

### 5.1 Special Procedural Provisions for Intellectual Property Rights

Ukrainian procedural law sets general rules for proceedings in all matters, including intellectual property cases. There are some differences between civil and commercial courts since those are regulated by separate procedural codes. For example, the Code of Ukraine on Commercial Proceedings explicitly prohibits considering intellectual property cases under a simplified procedure. At the same time, the Code of Ukraine on Civil Proceedings does not set forth such a restriction.

The Code on Commercial Proceedings envisages that intellectual property cases are to be considered by the High Court of Intellectual Property, which has not yet started its operation due to ongoing judicial reform.

While both procedural codes establish a one to three month term for case consideration per instance; practically, a typical timeline of the proceedings in intellectual property cases will depend on the jurisdiction in question. In commercial courts, consideration of a case may take several months per individual instance, while in civil courts cases can be considered for years. That is due to the overload of civil courts and the lack of judges.

Intellectual property cases usually require involvement of an expert having specific knowledge on the matter. Such an expert may be summoned to the court hearing to provide additional explanations regarding its expert report.

### 5.2 Decision-Makers

The Code on Commercial Proceedings envisages that intellectual property cases are to be considered by the High Court of Intellectual Property, which shall consist solely of judges specialised in intellectual property cases. As mentioned at 2.3 Courts with Jurisdiction, the Court, though established in 2017, has not started its operation yet due to ongoing judicial reform.

Currently, intellectual property cases are considered by all judges. The judges typically do not have a technical education, being qualified only in law. For establishing circumstances requiring specific knowledge, attested experts are usually engaged.

The parties do not have an influence on who the decision-maker will be since the claims are dis-

tributed among judges by an automated system at the moment of filing with the court. However, a party may challenge a judge if there are doubts over their impartiality during a case consideration.

### 5.3 Settling the Case

Ukrainian procedural law envisages a procedure for the settlement of a dispute with the participation of a judge. Such a procedure may be initiated by the parties to a case and may be commenced only once per case consideration.

During the settlement procedure, court consideration is suspended. A judge conducts a series of both open and closed consultations with parties, and any information disclosed in such consultations is strictly confidential.

The settlement procedure may conclude in a settlement agreement or with continuing case consideration.

The parties may also conclude a settlement agreement at any stage of the court proceedings without commencing a settlement procedure, that is, without engaging a judge in settlement negotiations.

### 5.4 Other Court Proceedings

Filing an invalidation action may be a good strategy for a defendant in an infringement action. It may be done by filing a counter-claim in an infringement proceeding or a separate claim.

Practically, it is rather a questionable issue as to whether an infringement case should be suspended pending the resolution of a validity attack. Some judges deem this appropriate, while others do not, and there is no unequivocal practice with regard to this question in Ukraine. However, the chances of suspension may be

high, depending on the specific circumstances of the matter.

## 6. Remedies

### 6.1 Remedies for the Patentee

#### Available Remedies

Injunctive relief (the court ordering the defendant to cease certain actions and/or perform certain actions) is the most sought after remedy in infringement actions. The patentee usually complements demands for general injunctive relief prohibiting certain actions with related and more precise demands, such as the obligation to withdraw the goods in question from turnover or the invalidation of marketing authorisations of medicinal products.

The Patent Law allows claims for monetary damages (actual damages suffered by the patentee and lost profits of the patentee) for infringement; however, practically, those are rarely sought given the difficulties in proving their amount. No enhanced or provisional damages are allowed.

#### Discretion of the Court

The court has minor discretion in ordering remedies – the plaintiff determines every demand and the court may grant it fully, in part or not at all, but is not allowed to go beyond the scope of the demands determined by the plaintiff.

#### Enforcement

Monetary remedies granted by the court are collected by the State Enforcement Service and/or by licensed private bailiffs. They may also enforce non-monetary remedies; the enforcement consists of official notification of the defendant to cease, refrain from or perform certain action ordered by the court. Failure to comply can result either in a fine imposed by

the bailiff or in referral to law enforcement for prosecution of wilful failure to enforce the court decision.

The prevailing plaintiff may also be entitled to reimbursement of their litigation costs (see **8.3 Responsibility for Paying the Costs of Litigation**).

## 6.2 Rights of Prevailing Defendants

The prevailing defendant may be entitled to reimbursement of litigation costs (see **8.3 Responsibility for Paying the Costs of Litigation**).

## 6.3 Types of Remedies

There are no different types of remedies for different technical intellectual property rights. All patents for inventions/utility models as well as commercial secrets provide for the same remedies.

## 6.4 Injunctions Pending Appeal

A judgment of a first instance court on merits is not enforceable until the 20-day term for filing an appeal expires or until the Court of Appeals considers an appeal. Therefore, there is no need for a stay of enforcement at the appellate stage.

The judgment becomes enforceable immediately upon its review by the appellate court or upon expiration of the term for filing an appeal. If a cassation appeal is filed, the Supreme Court may grant the stay of enforcement on a participant's motion or its own initiative.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

There are no special provisions concerning the appellate procedure for intellectual property

rights – appeals in IP cases are heard under general rules of appellate review as per the respective procedural code (Commercial or Civil).

## 7.2 Type of Review

An appellate court may review both the facts of the case and the application of law. It considers evidence related to arguments presented in the appeal and the response to the appeal. Evidence not filed with the court of first instance may be accepted only in exceptional situations. If the appellate court finds that the first instance court erred in matters of fact or law, it may cancel the first instance judgment on merits and issue a new judgment.

Supreme Court review is limited to matters of law. If the Supreme Court finds that the lower courts erred in applying the law, it may cancel their judgment(s) on merits and issue a new judgment based on facts determined by the lower courts. If it finds that the lower courts erred in the determination of facts, it may cancel their judgment(s) and remand the case to the first instance court or appellate court for reconsideration on merits.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

As per the procedural codes (Commercial and Civil), costs of litigation consist of the court fees, payable to the state budget for filing a lawsuit and certain motions, and litigation-related expenses. These comprise:

- attorney's fees, including fees for representation before the court and other case-related legal services, in particular preparation of the case for consideration, collection of evidence;

- expenses related to the engagement of witnesses, experts, specialists and interpreters, as well as to forensic expert examination;
- expenses related to requesting evidence from other persons, inspecting the evidence at its location and securing the evidence by the court; and
- expenses related to other procedural actions necessary for consideration of the case or preparation thereto.

Any litigation-related expenses from the above first three categories, except for forensic expert examination, can arise before filing a lawsuit. Aside from them, other costs arising before the lawsuit is filed can also be considered litigation-related expenses if they meet “the necessary for consideration of the case or preparation thereto” criterion.

In view of the above, most of the recoverable costs arising before filing a lawsuit will be evidence-related. Costs for cease and desist letters may also be recovered, but this is open to challenge as they are not “necessary” for the case. Any pre-litigation legal analysis needs to be directly related to a specific lawsuit for its costs to be recoverable.

## 8.2 Calculation of Court Fees

The court fee for commencing proceedings is calculated depending on the nature of the demands in the claim.

If the demands are monetary, the court fee is dependent on the amount of money (or the value of the property) claimed: 1.5% of that amount (value), but no less than approximately USD75 and no more than approximately USD26,000.

If the demands are non-monetary (invalidation of a patent, termination of an infringement, order-

ing to perform a certain action, etc), there is a fixed court fee per each non-monetary demand: approximately USD75.

## 8.3 Responsibility for Paying the Costs of Litigation

The structure of litigation costs is detailed in **8.1 Costs before Filing a Lawsuit**. In general, the litigation costs are paid by the losing party or they are split proportionally if the claim is granted in part.

Each party files a preliminary estimate of its costs with its first statement on the merits, else the court may deny recovery of all costs save for the court fees. The final amount of costs to be recovered is determined based on evidence (agreements, invoices, etc) provided before the parties’ closing arguments or no less than five days after the decision on the merits.

In the determination of the final amount of costs to be recovered, the court considers relevance, proportionality, and reasonableness of costs, as well as the party’s positive or negative behaviour (abuse of its rights, attempts to settle the case before or during the trial, etc).

It must be noted that Ukrainian judges are very reluctant to order costs recovery and will likely use any procedural defect in a legal position or evidence provided by the recovering party to deny recovery. It is also common for them to essentially decrease the attorney’s fees, even if the latter are supported by proper evidence.

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

Alternative dispute resolution is not a common way of settling an intellectual property case and is not common in Ukraine. Effective law provides for two kinds of ADR procedure:

- settlement of dispute with the participation of the judge; and
- mediation.

#### Settlement of Dispute with the Participation of the Judge

This procedure may be initiated during pending court proceedings. It is governed by the Code of Ukraine on Commercial Proceedings and the Code of Ukraine on Civil Proceedings.

If the parties agree, the judge may resort to this procedure before consideration of the case on merits begins. The judge stays the proceedings and commences a series of confidential meetings with the parties, which may be joint (with all parties present) and closed (only one party is present). The judge will inquire about the parties' positions, possible settlement options and may offer settlement options of their own. In closed meetings, the judge may also draw the party's attention to relevant jurisprudence. In no case is the judge allowed to opine on the evidence in the case file or provide legal advice to the parties.

The term for settlement of dispute with the participation of the judge is no more than 30 days and may not be extended. This procedure ends if:

- either party files a respective statement;
- the 30-day term expires; or

- the judge finds any party attempting to delay negotiations.

The procedure may not be prolonged or started over, and the ruling to finish the settlement may not be appealed. The end of the procedure also causes the transfer of the case to another judge.

If the procedure bears fruit, it may end with the one or both parties undertaking respective actions as agreed between them (settlement agreement, motion to leave the claim without consideration and not issue judgment on the merits, withdrawal of the claim, or admitting the claim).

#### Mediation

This procedure is governed by the Law of Ukraine "On Mediation". It is possible before filing the lawsuit and/or at any stage of the proceedings, including the stage of enforcing court decision.

Mediation is voluntary and confidential. It is conducted by an independent, neutral, non-biased mediator, whose job is to help the parties to communicate, negotiate and reach an agreement. They are not allowed to:

- combine the mediator's function with that of any other participant in the conflict;
- provide the parties with consultations and recommendations on the decision on the merits of the dispute;
- make such a decision; and
- be a party's attorney in the same case in which they have acted as mediator.

A mediator may perform their function for a fee or for free. The parties may choose the mediator and determine the relevant matters, options for settling the conflict, contents of a settlement agreement, etc. A person must pass training and



obtain a certificate to be eligible for the mediator's role, and must follow the rules of professional ethics.

Mediation is based on the oral or written mediation agreement concluded between the mediator and the parties. If successful, it ends with an agreement detailing mutually agreed obligations, terms and conditions of their fulfilment, and the results of a failure to fulfil those terms and conditions or improper fulfilment of them. Mediation ends:

- if no agreement is reached;
- with the expiration of its term;
- if any party or mediator declines to further participate in mediation or is unable to do so due to death, dissolution, incapacitation, etc; or
- for any other reason stipulated in the mediation agreement.

If the parties agree to initiate mediation during court proceedings, the hearing may be adjourned within procedural terms of case consideration. The parties may file a joint motion to stay the court proceedings for the period of mediation, in which case the court is obliged to stay the proceedings for a maximum of 90 days.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

Unless the law stipulates otherwise, agreement on assignment of IP rights shall be made in writing, otherwise it shall be considered null and void.

Registration of the assignment agreement with the UA PTO is obligatory with regard to patents. However, registration of commercial secret assignment agreements is not obligatory.

The parties shall determine a specific object of IP rights to be assigned (secret technical information, patent, etc) and specific rights to be assigned. Provisions of the assignment agreement which lead to a deterioration of the situation for the creator of respective objects compared to provisions of law, or limiting it in creating other objects, shall be deemed null and void.

Assignment of IP rights shall not affect validity of any licences issued with regard thereto.

### 10.2 Procedure for Assigning an Intellectual Property Right

The procedure for assigning an IP right depends on whether the assignment needs to be registered. If it must not, the procedure consists of executing the agreement. If it must, an original copy of the executed assignment agreement has to be provided to the UA PTO and a respective official fee (about USD66 per one IP object) should be paid to secure registration of the IP rights transfer.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

Licensing an IP right may be done either through a licensing agreement or via a licence as a separate unilateral written document. There is no mandatory registration of licensing agreements or licences with the UA PTO, though it may be done upon the request of the licensor or the licensee.

#### Licensing Agreement

A licensing agreement shall be executed in writing and contain:



- the type of licence (exclusive/sole/non-exclusive);
- the specific rights being licensed;
- the methods of use of the IP object in question;
- the territory for which the rights are licensed;
- the term for which the rights are licensed;
- the amount;
- the order;
- the terms for payment for the licence; and
- other provisions as the parties see fit.

If the type of licence is not indicated, it is deemed non-exclusive. If certain rights or methods of use are not mentioned in the licence, they are deemed not licensed. A right that was not valid at the time of licensing may not be licensed. If the territory is not defined, the licence is deemed to cover the whole territory of Ukraine.

An agreement may be executed for any term not exceeding the period for protection of licensed IP rights. If a certain term is not set forth in the agreement, it shall be deemed effective until the expiry of the licensed IP rights but for no more than for five years. If no party notifies the other to the contrary, after five years, it is extended for an indefinite time; however, any party may then dissolve the agreement with advance notice in six months (longer, if so agreed by the parties). Additionally, both licensor and licensee can dissolve the agreement if another party breaches its terms.

## Licence

Licences as separate written documents are issued by the licensor unilaterally. It is less formal than the licensing agreement. However, it still must contain the type of licence (exclusive/sole/non-exclusive), the specific rights being licensed, the methods of use of the IP object in question, and the territory and term for which the rights are licensed.

A licensee may sub-license if a licence or licence agreement explicitly contains a respective provision.

## 10.4 Procedure for Licensing an Intellectual Property Right

Given that registration of licence agreements or licences is not mandatory, the licensing is done by executing an original copy of the licence or licence agreement.

Contributed by: Oleksandr Mamunya, Ganna Prokhorova, Ilona Boliubash and Nataliia Badora, **Mamunya IP**

**Mamunya IP** is a Ukrainian specialty law firm with a leading depth of expertise and capability across the entire scope of IP work, covering patent, trade mark prosecution, strategy and litigation, as well as attendant issues such as regulatory advice and matters involving anti-counterfeiting, data protection and the intersection of advertising law and IP. The firm's team boasts 15 highly regarded intellectual property

professionals. Mamunya IP represents leading domestic and international clients on some of their most complex mandates. The firm's team offers extensive industry expertise in areas including life sciences and pharmaceuticals, consumer electronics, internet and e-commerce, as well as wine, spirits and food, fashion and luxury goods, FMCG, automotive, technology, media and telecoms, and art.

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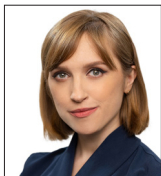
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## 1. Intellectual Property Rights and Granting Procedure

### 1.1 Types of Intellectual Property Rights

The USA offers protection of inventions through the intellectual property rights associated with patents or trade secrets. Patents provide broad, time-limited rights to the patentee in exchange for public disclosure of the invention. In contrast, trade secrets are not publicly known; have narrower rights; and, in principle, an indefinite duration.

Patents arise from federal law. Congress created the US patent system based on its authority in the US Constitution, which grants Congress power “to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” Title 35 of the US Code contains the federal laws related to patents.

Trade secret law is primarily based on state law. Specific definitions vary but, generally, a trade secret must not be known to the public, must confer economic benefit on its holder because it is not publicly known, and the trade secret-holder must take reasonable measures to keep such information secret. Most states have adopted the Uniform Trade Secrets Act, 1979, as amended, or a variation of it, so there is a measure of uniformity among the state laws. In addition to state law causes of action, the Defend Trade Secrets Act of 2016 provides a federal cause of action for trade secret misappropriation.

The statutory language creates a foundation for patents and trade secrets, but the law continues to evolve through case law as courts interpret legal terms and concepts.

### 1.2 Grant Procedure

#### Provisional and Non-provisional Applications

The US Patent and Trademark Office (USPTO) conducts the patent approval process and grants any resulting patents. Applicants file either a provisional or non-provisional patent application with the USPTO.

Provisional applications provide a quick and inexpensive way for inventors to establish a US filing date for their invention, which can be claimed in a non-provisional application that is filed later. A provisional application must contain a description of the invention and may include drawings necessary to understand the invention. A provisional application has fewer requirements than a non-provisional application but cannot develop into a patent without a corresponding non-provisional application filed within 12 months.

A non-provisional patent application must include both a description of the invention and claims describing the scope of the protections sought in the patent. A non-provisional application may be filed without a prior provisional application. However, a non-provisional application may gain the benefit of the earlier filing date of a corresponding provisional application if filed within 12 months of the provisional application.

Non-provisional applications undergo substantive examination by the USPTO to ensure compliance with the legal requirements for a patent. As a preliminary matter, a patent must claim patent-eligible subject matter. At a minimum, the US Supreme Court has stated that laws of nature, natural phenomena and abstract ideas are not patentable. Patents must also describe an invention that is novel and non-obvious with sufficient detail that a person of ordinary skill in

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the art of the invention can make and use the invention without undue experimentation.

## Patent Prosecution

The interaction between patent applicants (or their representatives) and the USPTO is called patent prosecution. During patent prosecution, an examiner at the USPTO will review the patent application and information already available to the public to determine whether the patent application meets the requirements for patenting based on the laws found in Title 35 of the US Code, the regulations listed in Title 37 of the Code of Federal Regulations and the guidance provided in the USPTO Manual of Patent Examining Procedure. If the examiner finds evidence that the invention has already been publicly disclosed or discovers another reason that the application does not comply with the patent requirements, the examiner may issue a rejection describing the deficiencies of the patent application. The applicant has an opportunity to respond to the rejection, which may include amending the claims in the application, having a phone conference with the examiner and presenting arguments that the rejection was improper. This process may be repeated until a final rejection or allowance of the application. If the patent application is allowed, the USPTO issues a patent creating enforceable rights for the patentee.

## Trade Secrets

By their nature, trade secrets are not disclosed publicly or registered with any agency. Information becomes a trade secret when the holder takes affirmative action to keep the information secret. This can include physical protection of the information, use of non-disclosure agreements or lawsuits to recover for misappropriation of the trade secrets.

## 1.3 Timeline for Grant Procedure

The time required to obtain a patent can vary greatly depending on many factors, including the subject matter of a patent, the number of rejections and appeals during patent prosecution and the type of USPTO examination programme. The USPTO has several patent application initiatives that can expedite patent applications meeting the respective programme requirements. For example, applications qualifying for Accelerated Examination may have a final disposition within 12 months. According to statistics provided by the USPTO, the average time for a final decision on a patent application is about two years, but some take several years.

Patent applicants are not obliged to be represented by a lawyer. However, the USPTO cautions that the patent application process is an undertaking requiring knowledge of patent law and rules, USPTO practices and procedures, as well as knowledge of the scientific or technical matters involved in the particular invention. Because of the complexities involved, most inventors employ the services of registered patent lawyers or patent agents.

The cost associated with obtaining a patent varies based on many factors. Administrative fees imposed by the USPTO depend on the type of entity (large, small or micro), the number of claims in the application, the amount of time taken to respond to the USPTO rejections, the use of patent application initiative programmes and other procedural details. Lawyers' fees in connection to the application may also vary depending on the complexity of the application and patent prosecution.



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## 1.4 Term of Each Intellectual Property Right

Generally, a patent expires 20 years after its filing date, but this term can vary depending on the timing of the patent application and patent prosecution. Patents issued and applications filed before 8 June 1995 expire either 20 years from filing or 17 years from issue, whichever is later.

Patent applications filed after 8 June 1995 expire 20 years after the earliest effective US filing date. This may be earlier than the filing date of the patent application if it claims priority to an earlier provisional or international application.

Under limited circumstances, a patent term may be extended to account for administrative delays when acquiring the patent. For example, if the USPTO does not issue a patent within three years after its filing date, the patent holder may obtain an extension of patent term equal to the period in excess of three years. For certain drug products and medical devices, a patent may be extended for up to five years to account for the regulatory review conducted by the US Food and Drug Administration (FDA).

## 1.5 Rights and Obligations of Owners of Intellectual Property Rights

The USPTO website provides general information about all US patents. Furthermore, the FDA maintains publications identifying patents applicable to certain approved pharmaceutical products. For drug products, the FDA publication is Approved Drug Products with Therapeutic Equivalence Evaluations (more commonly known as the “Orange Book”). Similarly, the FDA has the List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (known as the “Purple Book”) with information about approved biological products. The FDA maintains elec-

tronic databases on its website with the information contained in both the Orange Book and Purple Book.

A patent gives its owner the right to exclude others from making, using, selling and importing the patented invention. To maintain the enforceability of the patent, the USPTO must receive maintenance fees for the patent, due 3.5, 7.5 and 11.5 years after the date of issue.

The remedies available to the patent holder vary depending on the chosen forum of enforcement. In a district court, a patent holder may seek equitable remedies in the form of a preliminary or permanent injunction and may seek monetary damages for both past and future infringement.

At the US International Trade Commission (ITC), a patent holder may seek cease-and-desist orders and exclusion orders to prevent the importation of patent-infringing goods. The exclusion orders direct US Customs and Border Protection to exclude articles from entry into the USA. A limited exclusion order prevents specified entities from importing the articles and a general exclusion order prevents any entity from importing the articles. The ITC cease-and-desist orders can direct infringers to stop importing infringing articles and to stop sales of infringing articles in US inventory. The ITC cannot award monetary damages.

## 1.6 Further Protection After Lapse of the Maximum Term

The USA allows certain extensions of patent terms for administrative delays. Delays by the USPTO in the issue of patents can lead to patent-term extensions for the time of the delay. This extension does not apply to delays resulting from the patent applicant’s actions, including requests for continued examination or appeals.

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The possible extension for USPTO delays is unlimited.

Certain drug products and medical devices can receive annual patent term extensions if the product is undergoing administrative review by the FDA. These extensions are renewable for up to five years.

## **1.7 Third-Party Rights to Participate in Grant Proceedings**

Any third party may submit patents, published patent applications or other printed publications as part of a third-party pre-issuance submission. The submission must include a concise description of the asserted relevance of each submitted document. These submissions may be made online at the USPTO website. Submissions must be made before the later of six months after publication of the patent application or the date of a USPTO communication rejecting any claims in the application. However, a notice of allowance for the patent application immediately terminates the timeframe for third-party submissions.

## **1.8 Remedies Against Refusal to Grant an Intellectual Property Right**

During patent prosecution, the USPTO may issue a final rejection of the patent claims. If the applicant wishes to challenge the final rejection, the applicant may request continued examination or may file an appeal to the Patent Trial and Appeal Board (PTAB). The applicant may appeal PTAB decisions to the US Court of Appeals for the Federal Circuit. Further review may be sought from the US Supreme Court through a petition for a writ of certiorari.

## **1.9 Consequences of Failure to Pay Annual Fees**

Patent holders must pay maintenance fees to keep patents in force. The payments are due 3.5,

7.5 and 11.5 years after the date of issue. The USPTO allows payment of each fee six months before the due date, but does not allow any other pre-payment of the maintenance fees. Payments that are less than six months past the due date have a surcharge of USD125–500 in addition to the normal fee.

Under some circumstances, a patent can be reinstated after not paying the maintenance fee in a timely manner. The USPTO requires a statement that the delay in payment was unintentional and submission of a petition fee of USD525–2,100 in addition to the required maintenance fees.

## **1.10 Post-grant Proceedings Available to Owners of Intellectual Property Rights**

During some post-grant proceedings before the USPTO, the patent holder can amend claims of an issued patent. During *ex parte* re-examination, the patent holder may amend claims to respond to the USPTO's findings of substantially new questions of patentability. In an *inter partes* review (IPR) proceeding, if the challenged claims are determined to be invalid, the patent owner may seek to add substitute claims.

At any time before the expiration of the patent, a patent holder may seek reissue of the patent to correct certain errors, such as errors in the drawings or specification, or errors in the claimed scope of the invention. No new matter can be added during a reissue. If the reissue is sought within two years of the grant of the original patent, the scope of the claims can be narrowed or enlarged. Otherwise, only amendments that narrow the scope of the claims are permitted.

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## 2. Initiating a Lawsuit

### 2.1 Actions Available Against Infringement

A patent holder has several options when seeking enforcement of patent rights. District court litigation can provide injunctions, monetary remedies for infringement and declaratory judgments. As discussed at **1.5 Rights and Obligations of Owners of Intellectual Property Rights**, the ITC can issue exclusion orders and cease-and-desist orders. If an applicable contract provides for alternative dispute resolution proceedings, such as mediation or arbitration, or the parties agree to alternative dispute resolution proceedings, they may be used in lieu of litigation. Alternative dispute resolution proceedings can allow more flexible solutions and a final resolution can often be reached faster and less expensively. Additionally, the ITC and many courts offer mediation programmes.

### 2.2 Third-Party Remedies to Remove the Effects of Intellectual Property

A third party may challenge the validity of an issued patent through district court litigation or through post-grant proceedings at the USPTO. A party with standing may seek a declaratory judgment of patent invalidity in a district court. As a defendant in a patent infringement lawsuit, a party may argue patent invalidity as a counterclaim or affirmative defence. Patent invalidity may also be raised as a defence in an ITC investigation.

Challenges to patent validity at the USPTO take the form of post-grant review (PGR), IPR, ex parte re-examination and covered business method review (CBM). The timing and type of patent affect which of these proceedings is available to a third party.

#### PGR

PGR is available during the first nine months after the issue of a patent. Any party that is not the patent holder and has not challenged the patent validity in a civil action may request PGR. PGR allows the broadest grounds for challenging patent validity.

#### IPR

After the nine-month window of PGR, a third party may challenge validity through an IPR proceeding. As is the case with PGR, the IPR petitioner must not be the patent holder and must not have challenged the patent in civil litigation, but there is an additional requirement that the petitioner must not have been served a complaint alleging infringement more than one year prior to the IPR petition. The IPR also has more limited grounds to challenge patent invalidity, only allowing arguments of obviousness and lack of novelty based on patents and printed publications.

#### CBM

A CBM review has the most restrictive requirements: at least nine months must have elapsed since the patent was issued; the patent must be a financial product or service patent, excluding technological inventions; the CBM petitioner must have been sued or charged with patent infringement; and the CBM review petition must have been filed before 16 September 2020. The grounds for challenging patent validity in a CBM review are similar to those of PGR.

There are no actions available in the USA for a compulsory licence.

### 2.3 Courts With Jurisdiction

Federal district courts have original jurisdiction over patent matters. Parties may appeal district court decisions to the US Court of Appeals for

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the Federal Circuit. Decisions of the Federal Circuit are subject to discretionary appeal to the US Supreme Court through a petition for certiorari.

In certain circumstances involving importation of patent-infringing articles, the ITC may have jurisdiction. In an ITC investigation, an administrative law judge makes an initial determination on liability. A party may petition the ITC to review the administrative law judge's initial determination. After the ITC's final decision, a party may appeal the decision to the Federal Circuit, with further discretionary appeal to the US Supreme Court.

## 2.4 Specialised Bodies/Organisations for the Resolution of Disputes

Two administrative agencies provide a review of patents before administrative law judges. The USPTO has the PTAB, which provides a review of patent application rejections and several post-grant proceedings discussed above. The ITC conducts investigations related to importation of patent-infringing articles. Both PTAB and ITC decisions may be appealed to the US Court of Appeals for the Federal Circuit, with further review available from the US Supreme Court.

## 2.5 Prerequisites to Filing a Lawsuit

There are no prerequisites to filing a lawsuit in a district court, unless the parties' contract provides otherwise. Lack of pre-filing notice may, however, limit recovery of monetary damages in certain instances.

## 2.6 Legal Representation

While individuals are not required to be represented by a lawyer, all federal courts require corporations to have legal representation. It is generally viewed as exceedingly unwise for an individual to pursue patent litigation without experienced counsel. In proceedings before the

PTAB, at least one representative of each party must be a registered practitioner of the USPTO.

## 2.7 Interim Injunctions

A patent holder may seek a preliminary injunction to protect the rights of the parties while litigation is pending. Preliminary injunctions require a demonstration:

- of a reasonable probability of success on the merits;
- of irreparable harm to the party if the preliminary injunction is denied;
- that the balance of the hardships favour issuing a preliminary injunction; and
- that the impact on the public interest favours the party bringing the motion.

If a court determines that a preliminary injunction is appropriate, such an order will only be issued if the party seeking it posts a bond in an amount that the court considers proper to compensate the other party should the injunction be determined to have been improperly granted.

Although rarely granted, a patent holder could seek earlier relief through a temporary restraining order. In addition to meeting the requirements for a preliminary injunction, the patent holder must demonstrate that immediate and irreparable injury will result to the movant before the adverse party can be heard in opposition, and certify in writing any efforts made to give notice and the reasons why it should not be required. An ex-parte temporary restraining order may be granted only in the very limited circumstances where providing notice will itself prevent, or interfere with, the ability to obtain relief.

## 2.8 Protection for Potential Opponents

The potential opponent may oppose the preliminary injunction by arguing against the fac-

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tors described above for granting a preliminary injunction – most particularly that monetary relief at the end of the case will adequately compensate the plaintiff for any injury it incurs. Alternatively, a potential infringer could seek a declaratory judgment of patent invalidity or non-infringement in a federal district court. A party could also seek to challenge patent validity through one of the post-grant proceedings available through the USPTO.

## 2.9 Special Limitation Provisions

US law limits patent infringement damages to six years prior to the filing of the complaint or counterclaim for infringement. Additionally, the patent holder cannot recover damages for infringement prior to the point the infringer had notice of the infringement. Filing the lawsuit is notice of infringement, but the infringer could have earlier notice based on communications from the patent holder detailing the infringement, or from constructive notice by marking the patented articles with their patent numbers. Injunctive relief is available for any period the court finds appropriate up to the expiration of the patent rights.

## 2.10 Mechanisms to Obtain Evidence and Information

In general, a party cannot obtain relevant information and evidence from another party or any third parties before commencing a proceeding in a district court. However, once a lawsuit has commenced, the Federal Rules of Civil Procedure require the parties to exchange initial disclosures of information, including:

- the identity of each individual likely to have discoverable information;
- copies of all documents a party may use to support its case;
- a computation of claimed damages; and

- any insurance agreement that may satisfy all or part of a judgment.

Parties may then obtain non-privileged information that is relevant to any party's claim or defence and is proportional to the needs of the case, considering:

- the importance of the issues at stake in the action;
- the amount in controversy;
- the parties' relative access to relevant information;
- the parties' resources;
- the importance of the discovery in resolving the issues; and
- whether the burden or expense of the proposed discovery outweighs its likely benefit.

Parties may obtain discoverable information through depositions, requests for production of documents, written interrogatories or requests for admission.

Parties may subpoena third parties to provide discoverable information in the form of depositions or production of documents. Procedures are also available to obtain discovery from third parties located outside the USA through applicable treaties or letters rogatory (formal requests for assistance sent to foreign courts).

A party or any person from whom discoverable information is sought may seek a protective order from the court to limit the scope or use of the information.

## 2.11 Initial Pleading Standards

Patent litigation follows the same pleading standards as other civil cases. A complaint filed in district court must allege facts that state a claim to relief that is plausible on its face. At a mini-

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mum, a patent infringement complaint should identify the patent holder, the relevant patent(s), the accused infringer and the requested relief sought. For claims of indirect infringement, more details are typically required. Preferably, the complaint will provide additional information about the accused infringement, including the claims and elements infringed.

The Federal Rules of Civil Procedure govern amended and supplemental pleadings. A party may amend its pleadings once as a matter of course within 21 days of serving. Other amendments require the opposing party's written consent or the court's permission. To account for occurrences after a pleading, a party may supplement its pleadings with the court's permission.

## 2.12 Representative or Collective Action

There are no class actions available in intellectual property cases. However, a patent holder may join multiple accused infringers in a single federal lawsuit if the actions arise out of the same transaction, occurrence or series of transactions. It is not sufficient to have unrelated defendants infringe the same patent.

In situations where joining all defendants in a single case is not possible, there are other options to gain the advantages of consolidated actions. Cases across several districts that share a common question of fact may be co-ordinated for pre-trial proceedings before a Judicial Panel on Multidistrict Litigation. Similarly, multiple cases in the same district may be consolidated to promote judicial efficiency when there is a common question of law or fact.

ITC investigations of patent-infringing articles often involve multiple respondents. Because the ITC only needs jurisdiction over the imported

articles and not the infringers, it can be easier for a patent holder to proceed against multiple infringers simultaneously.

## 2.13 Restrictions on Assertion of an Intellectual Property Right

Some patent holder actions can limit the ability to enforce a patent against others. Under patent exhaustion – also referred to as the first-sale doctrine – the patent holder's right to control an individual article ends after an authorised sale. If the patent was procured through improper conduct before the USPTO, it could be unenforceable under the doctrine of inequitable conduct. A patent holder that expands its rights beyond the statutory patent grant may commit patent misuse. Finally, when the patent holder uses its patent impermissibly to gain market share or engages in other anti-competitive behaviour, antitrust laws may limit the enforceability of the patent.

## 3. Infringement

### 3.1 Necessary Parties to an Action for Infringement

Generally, the party bringing an infringement action must be the patent holder, although an exclusive licensee that owns "all substantial rights" in the patent may bring an infringement action in its own name without joining the patent holder. An ITC investigation requires the party filing the petition to have an interest in the patent and an injury to a domestic industry.

### 3.2 Direct and Indirect Infringement

Direct infringement occurs when a person makes, uses, offers to sell, sells or imports in the USA a patented invention without authority. Usually, the patent holder demonstrates this by showing every claim element, or its equivalent, is



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present in the accused article. When more than one party infringes the patent, there can still be direct infringement if one party directs or controls the actions of another.

A party induces infringement when it actively and knowingly aids and abets another's direct infringement. The inducer must have knowledge of the patent and actively encourage the acts that result in direct infringement. Induced infringement can result in both parties being jointly and severally liable for the infringement.

Contributory infringement involves supplying a component of a patented invention to another party that performs the direct infringement. The component must not be a staple article or commodity of commerce suitable for non-infringing use, nor can it have substantial non-infringing uses.

There are also rules primarily directed to the pharmaceutical industry. A party may engage in activities (such as testing) to support an Abbreviated New Drug Application (ANDA) for a generic version of an FDA-approved drug – even if that drug is patented – without incurring patent infringement liability. However, filing an ANDA is considered an act of “artificial” infringement if the ANDA applicant seeks approval to engage in the commercial manufacture, use or sale before the patent expiration.

The available remedies for patent infringement are discussed in **6. Remedies**.

### 3.3 Process Patents

An additional potential form of infringement applies to process patents. If a person makes, uses, offers to sell, sells or imports in the USA a product made by a process patented in the USA during the term of the patent, the person com-

mits infringement under 35 U.S.C. § 271(g). This includes instances where the patented process occurs outside of the USA.

### 3.4 Scope of Protection for an Intellectual Property Right

The scope of protection of a patent is determined by its claims, which describe the extent of the protection sought in a patent application. Often, significant dispute arises when determining the precise meaning of terms or phrases in the patent claims.

In 2018, the standard for claim interpretation became more uniform, whether in a district court, the ITC or in a post-grant proceeding at the USPTO. The “Phillips” standard seeks to interpret the claims from the perspective of a person having skill in the relevant art of the invention based on intrinsic and extrinsic evidence. Intrinsic evidence includes the patent's description of the invention, including the claims themselves, and the patent prosecution history. This means arguments and statements made to the USPTO during patent prosecution may limit how claims are interpreted later. Extrinsic evidence includes dictionaries, treatises and expert testimony. Extrinsic evidence can aid the decision-maker's understanding of how a skilled person would have understood the claims at the time of the invention.

During patent prosecution, the USPTO uses a slightly different standard for analysing patent application claims. Generally, the USPTO uses the same types of information described above, but seeks to determine the “broadest reasonable interpretation” of the claims for purposes of issuing patents.



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## 3.5 Defences Against Infringement

An accused patent infringer may seek to avoid liability by proving that no infringement occurred, the patent is invalid or the patent is unenforceable.

Several defences to patent infringement do not require challenging the patent itself, either by showing the accused article does not infringe or showing the use of the patent was lawful. For example, direct infringement requires all the elements of the patent claim be present, so demonstrating missing elements in the article can avoid liability by direct infringement. Showing an implied or express licence can negate the infringement requirement of unauthorised use of a patented invention. In the medical field, gathering data to support an ANDA for a generic version of a patented and FDA-approved drug does not create patent infringement liability – although the filing of the ANDA may. The courts also recognise a more general experimental use exception to liability, but it is a very narrow exception, requiring no commercial motive in the experimental use. Under certain circumstances, prior commercial use of an invention occurring more than a year before the patent application can avoid infringement liability. Finally, infringement damages are limited by law to the six years prior to the filing of the complaint, so infringement before this period would not incur liability.

The accused infringer may also challenge the validity of the patent because there will be no liability for an invalid patent. The grounds for challenging the patent may include lack of patent-eligible subject matter, lack of novelty, lack of enablement or written disclosure, obviousness of the invention, public knowledge or prior offers to sell.

The patent holder's actions can also be the basis of a defence against infringement. Inequitable conduct can result from improper conduct before the USPTO. Relying on a patent holder's conduct and representations may create equitable estoppel if the patent holder later acts inconsistently with the reliance. A patent holder that impermissibly expands its rights beyond the statutory patent grant may commit patent misuse. Under patent exhaustion – also referred to as the first sale doctrine – the patent holder's right to control an individual article ends after an authorised sale. In some circumstances, a patent holder's failure to keep patents together that are subject to a terminal disclaimer may be used as a defence to patent infringement.

That an accused infringer has its own patent does not, by itself, provide a defence to an infringement claim.

### Standard-Essential Patents

Some patent holders may have standard-essential patents (SEPs). An SEP is a patent that covers technology that is considered essential to an industry standard. These SEP holders generally have an obligation to license these patents on fair, reasonable, and non-discriminatory (FRAND) terms. If the SEP holder fails to offer a potential infringer FRAND terms, the accused infringer can assert the breach of FRAND obligations as an affirmative defence in a subsequent infringement action.

## 3.6 Role of Experts

Parties may submit expert reports in connection with the claim construction process to assist the court in construing disputed terms. Parties almost always rely on expert reports and expert testimony in connection with infringement, invalidity and damages issues. Experts are especially effective when a case involves a jury because a

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good expert can explain complicated information in a clear and understandable fashion.

Under the Federal Rules of Evidence, the court has authority to appoint an expert witness. However, this rule is rarely invoked. Generally, a party relying on expert testimony chooses and retains its own expert. In rare cases a district court judge faced with a technology with which they are unfamiliar, may appoint their own expert (the cost of which is typically split between the parties) to assist the court in understanding the technology. When this happens, it is often in the context of claim construction proceedings.

### **3.7 Procedure for Construing the Terms of the Patent's Claim**

Courts use specialised claim construction hearings called “Markman” hearings to examine evidence from the parties on the appropriate meaning of the relevant terms in a patent claim. In a district court, patent claim interpretation is performed by the judge, even if there is a jury trial.

### **3.8 Procedure for Third-Party Opinions**

Amicus briefs are very rarely (almost never) submitted at the trial court (district court) level. It is extraordinarily rare for a district court judge to solicit amicus participation in a patent case. Amicus participation at the Federal Circuit level is more common. A third party (typically an industry organisation, public interest group or group of academics) may seek permission from the court to submit an amicus brief, and such permission is typically granted. Once a patent case reaches the United States Supreme Court, amicus participation is the rule rather than the exception. In addition, the Supreme Court will often ask the Office of the Solicitor General (which represents the interests of the US government before the Supreme Court) to file a brief with its views either as to whether the Supreme Court should

hear the appeal at all or, if the Supreme Court has already accepted the case for appeal, on the merits.

## **4. Revocation/Cancellation**

### **4.1 Reasons and Remedies for Revocation/Cancellation**

In the federal court system, a final judgment of invalidity effectively revokes the invalidated claims of the patent. A decision that the patent holder committed some other actions that prevents liability for patent infringement, such as equitable estoppel or antitrust violations, may make a patent unenforceable.

The ITC makes similar decisions about patents, but its decisions are not binding on district courts. For example, an ITC decision of patent invalidity does not require a district court to treat the patent as invalid, but the district court may reach the same decision based on the persuasive influence of the ITC decision.

In post-grant proceedings, the USPTO may cancel some or all of the claims of a patent. A party challenging a patent in a post-grant proceeding does not need to have the standing necessary in a federal court. However, the ability to appeal the USPTO's decision to the Federal Circuit may be limited by a lack of standing.

### **4.2 Partial Revocation/Cancellation**

Patent invalidity is examined on a claim-by-claim basis. The remaining claims of a patent remain valid, even if some claims are found invalid.

### **4.3 Amendments in Revocation/Cancellation Proceedings**

During some post-grant proceedings before the USPTO, the patent holder can amend claims, but

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may not enlarge the scope of the claims. During ex parte re-examination, the patent holder may amend claims to respond to the USPTO's findings of substantially new questions of patentability. In the adversarial proceedings – IPR, PGR and CBM – the patent-owner may file a motion to amend claims.

#### **4.4 Revocation/Cancellation and Infringement**

In district court actions, patent infringement claims and defences may be heard together. Courts have broad discretion to control proceedings to promote judicial efficiency and avoid prejudice to the parties, so some issues may be “stayed”. Typically, a judge rather than a jury will determine equitable defences such as inequitable conduct or laches.

ITC investigations hear all infringement and defences together. The ITC has a shorter timeline than district courts and no juries to consider.

Proceedings challenging patent validity must be heard separately from infringement claims at the USPTO because the USPTO does not determine infringement. Often, there is a related district court case claiming infringement during post-grant proceedings at the USPTO. The district court may stay its proceeding to await the patent invalidity decision of the USPTO.

### **5. Trial and Settlement**

#### **5.1 Special Procedural Provisions for Intellectual Property Rights District Courts**

In district court proceedings, patent litigation is subject to the same rules as other civil litigation: the Federal Rules of Civil Procedure and the Federal Rules of Evidence. Most courts (and

some individual judges) that hear a large number of patent cases, such as the District of Delaware or the Northern District of California, have their own supplemental procedures that apply in patent cases.

The time to resolve patent litigation in district court varies widely and may take several years. Courts that are unusually efficient in getting cases to trial are often referred to as having “rocket dockets.” Examples of such courts are the Eastern and Western Districts of Texas, the Eastern District of Virginia, and the Western District of Wisconsin. Courts have broad discretion to control proceedings to promote judicial efficiency and avoid prejudice to the parties, and a case may be presented as a single trial or be bifurcated or staged to have successive trials on issues such as infringement, wilfulness or damages. However, it is extremely rare for a patent case in front of a jury (almost all patent cases involving claims for money damages) to be bifurcated. Witnesses (fact and expert) presenting testimony in a hearing (eg, on claim construction or preliminary injunction motions) are subject to questioning by the judge and cross-examination by the opposing party.

Unless the issue of damages has been bifurcated by the court (which is rare), infringement, validity and damages are typically decided at the end of a single trial by the jury or by the judge (in a bench trial). Injunctive relief is typically determined later, and that issue is always decided by the judge.

#### **ITC**

ITC investigations have their own procedures, but many of the rules are similar to those in district courts. One notable exception is the right to a jury. Unlike district court proceedings, there is no jury at the ITC or the USPTO. ITC investiga-

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tions are almost always faster than district court proceedings, with trial-like evidentiary hearings taking place within nine to twelve months from the filing of a complaint. Witnesses at an ITC trial are subject to cross-examination by the opposing party, and by the judge.

## IPR

IPR proceedings are quicker than district court litigation and follow a more regimented schedule. The process begins with the filing of an IPR petition that includes the patent claims challenged and the supporting evidence. Following this, the patent owner may optionally provide a preliminary response within three months. No more than three months following the patent owner preliminary response, the PTAB will make an institution decision on the IPR petition. If instituted, the IPR proceeds and the patent owner has three months to file its response and any motion to amend the patent claims. The petitioner has three months to reply to the patent owner response and oppose the claim amendments. The patent owner has an additional month to file a sur-reply. After the completion of briefing, an oral hearing is scheduled and the PTAB issues a final written decision no more than 12 months after the institution decision (except the PTAB may extend the time up to an additional six months for good cause).

In an IPR proceeding, direct witness testimony, including expert testimony, is presented in the form of an affidavit or declaration. The party presenting the witness will need to make the witness available for cross-examination by the opposing side, usually in the form of a deposition. Live testimony during the oral hearing is exceedingly rare, but the PTAB may permit it when the demeanour of the witness is critical to assessing credibility.

## 5.2 Decision-Makers

With respect to federal district court litigation, beyond choosing the particular forum in which to file suit, parties have little ability to influence who will be the decision-maker – unless they agree to waive their rights to a jury trial (which patentees almost never do). In a district court, unless a judge decides an issue in a pre-trial (eg, a summary judgment) or post-trial motion, issues of infringement, invalidity and damages are decided by a jury. Juries do not have technical expertise. There is no requirement that a judge have a technical background to preside over a patent case in district court, and most district court judges do not have technical backgrounds.

In 2011, 14 district courts began a ten-year Patent Pilot Program to enhance expertise in patent cases. New patent cases in those districts are assigned to a random judge. If the randomly assigned judge is not a designated judge in the Program, the judge may transfer the case to a participating judge in the district.

ITC investigations proceed before an administrative law judge. Because a large proportion of ITC investigations involve patents, many administrative law judges have developed substantial experience with patent cases, and many also have technical expertise. The ITC randomly assigns an administrative law judge to new investigations, and assignment is not based on any particular technical background of the administrative law judge.

The USPTO has administrative patent judges. These judges are typically experienced patent lawyers with technical backgrounds. If possible, the USPTO assigns cases to judges based on their technical background.

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Appeals from all patent cases at the district courts, ITC or USPTO go to the US Court of Appeals for the Federal Circuit. The judges in the Federal Circuit have significant patent law experience from the many patent-related appeals, but do not necessarily have a technical background.

### 5.3 Settling the Case

Settlement of patent disputes is quite common (except in certain types of pharmaceutical patent cases, where antitrust consideration can make settlement difficult or impossible). Parties may reach a settlement through a variety of possibilities, such as negotiation, alternative dispute resolution or mediation. Some courts require parties to attempt a resolution before proceeding with a trial. Settlement agreements can terminate the proceedings in a district court, usually without disclosure of the settlement details to the court.

The ITC has a non-mandatory mediation programme to aid resolution of disputes before pursuing a full investigation. After the investigation begins, parties may request termination of the investigation upon reaching a settlement, but a copy of any agreement will be submitted to the ITC in the process. Procedures are available to protect information within the settlement from public disclosure.

Post-grant proceedings before the USPTO follow similar settlement disclosure procedures as the ITC when seeking termination of a trial. The USPTO may continue a proceeding despite the parties' settlement agreement. This is more likely if the proceeding is nearly completed when the settlement occurs.

### 5.4 Other Court Proceedings

Federal courts have inherent authority to control their dockets, including the power to stay proceedings when there are co-pending mat-

ters in another forum. The courts may consider several factors when deciding to stay, including the progress of the court proceeding, whether the stay will simplify issues before the court or whether a stay would unduly prejudice a party. When there is a co-pending post-grant proceeding (such as an IPR), courts are more likely to stay proceedings if the USPTO proceeding has been instituted.

Generally, decisions reached in different fora are not binding on each other, except when a patent has been cancelled by the PTO in a post-grant proceeding or where a final, non-appealable judgment of invalidity has been entered in the district court litigation. This means a district court is not obliged to agree with a USPTO decision on patent validity, but the court may find the USPTO decision very persuasive because of its perceived expertise on patents. Similarly, the USPTO may consider the progress and findings of district court litigation or ITC investigations in its own proceedings. The law regarding the effect of a foreign anti-suit injunction is still unsettled and the decision in a particular case is likely to turn on the particular facts (and timing) involved.

## 6. Remedies

### 6.1 Remedies for the Patentee

In federal district courts, the patent holder may seek damages for patent infringement and injunctions to prevent ongoing infringement. By statute, damages for infringement should be adequate to compensate for the infringement, but not less than a reasonable royalty. A jury verdict will typically include a damages award, which is then reviewed by the district court judge (if a party files a motion requesting such a review) for compliance with certain legal

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standards regarding damages. Patent damages are limited to no more than six years before commencement of the lawsuit. In cases of wilful infringement, the courts may award three times the damages. Generally, each party pays its own lawyers' fees, but in "exceptional" cases, courts may impose fee-shifting to the losing party. In addition to monetary damages, a party may seek an injunction to prevent continued infringement.

Primary responsibility for enforcing a district court judgment lies with the patent owner, who has at its disposal a wide array of enforcement mechanisms, including seeking to execute the judgment against the debtor's assets. If a party fails to comply with an injunction, the other party may seek sanctions from the district court originally ordering the injunction.

The ITC cannot impose monetary damages for infringement, but can issue exclusion and cease-and-desist orders. The exclusion orders direct US Customs and Border Protection to exclude infringing articles from entry into the US. The ITC cease-and-desist orders can direct infringers to stop importing infringing articles and to stop sales of infringing articles in US inventory. The ITC retains broad authority to enforce any of its orders and a complainant in the original investigation can request a formal enforcement proceeding.

## 6.2 Rights of Prevailing Defendants

In the US legal system, each party typically pays its own lawyers' fees and costs. Similar to the description in **6.1 Remedies for the Patentee** for successful patent holders, a prevailing defendant may request lawyers' fees and costs if the case is determined to be "exceptional". Under US Supreme Court precedent, "an 'exceptional' case is simply one that stands out from others with respect to the substantive strength of a

party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated."

## 6.3 Types of Remedies

The available remedies do not vary based on the technical area of a patent.

## 6.4 Injunctions Pending Appeal

A successful patent holder in an infringement proceeding does not automatically get an injunction against the infringing party. Similarly, if the district court issues an injunction, its effect is not automatically stayed during appeal. Ordinarily, a permanent injunction is effective upon issue, but a court has broad equitable authority to modify relief. The defendant may seek a stay of the injunction by filing a motion with the issuing court or the appellate court – the US Court of Appeals for the Federal Circuit. In the absence of a stay, the injunction is enforceable pending appeal. When deciding to stay an injunction, the courts balance the likelihood of success on the merits against the equities of the parties and the public.

## 7. Appeal

### 7.1 Special Provisions for Intellectual Property Proceedings

The appellate procedure for patent litigation is the same as for other civil litigation, except that all appeals in patent cases go to the US Court of Appeals for the Federal Circuit. This includes patent cases from district courts, ITC investigations and USPTO proceedings.

### 7.2 Type of Review

The Federal Circuit can review factual and legal determinations of the proceedings in a lower



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court, if the errors were properly preserved in its record. The level of deference given to the decision-maker in a lower court varies depending on the type of error. For purely legal issues, such as statutory interpretations and judgments as a matter of law, the Federal Circuit applies a “de novo” standard where the court examines the record to form its own opinion, with no deference to the previous decision-maker. Factual determinations receive more deference, either “clearly erroneous” if the judge made factual determinations, or “substantial evidence” if the jury was the fact-finder. Equitable determinations, such as inequitable conduct, injunctions, or lawyers’ fees, are left to the discretion of the trial court judge, so a review of these decisions gets the highest deference, only being reversed for “abuse of discretion”.

## 8. Costs

### 8.1 Costs Before Filing a Lawsuit

Pre-litigation costs vary depending on the complexity of the issues and the amount in controversy between the parties. A patent holder may require legal and technical research for claim charts, warning letters to potential infringers and analysis of potential enforcement options. An accused infringer may accrue legal fees to weigh its options for challenging the alleged infringement through an affirmative defence in a lawsuit, a declaratory judgment of invalidity or non-infringement, or a USPTO proceeding challenging patent validity.

### 8.2 Calculation of Court Fees

In district courts, the fee for filing a federal civil complaint is fixed by statute, but the Judicial Conference of the United States may prescribe additional fees. Currently, the filing fee is USD350, plus a USD52 administrative fee.

The fee to file an IPR at the USPTO is USD41,500, and a PGR or CBM request is USD47,500.

### 8.3 Responsibility for Paying the Costs of Litigation

The traditional rule in the USA is that each party bears its own costs, but there are limited exceptions to this default rule. The Federal Rules of Civil Procedure allow a party to seek reasonable expenses, including lawyers’ fees, incurred when an opposing party makes improper representations to the court or commits discovery misconduct. These sanctions do not award all costs and lawyers’ fees, only the expenses associated with the violation. In patent litigation, a court may award all costs and reasonable lawyers’ fees to the prevailing party if the case is determined to be “exceptional”, that is “one that stands out from others with respect to the substantive strength of a party’s litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated.”

## 9. Alternative Dispute Resolution

### 9.1 Type of Actions for Intellectual Property

Alternative dispute resolution is common in civil cases, and its use in intellectual property disputes is becoming increasingly common. Parties may use alternative dispute resolution as an alternative to litigation either by mutual agreement, contractual agreement or court order (although a court cannot force the parties to agree to a mediator’s ruling). Some courts offer mediation or special masters for settlement purposes. Parties may prefer alternative dispute resolution to take advantage of its greater flexibility, confidentiality and cost effectiveness.



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Additionally, a patent owner can avoid the risk of a court's judgment of patent invalidity.

## 10. Assignment and Licensing

### 10.1 Requirements or Restrictions for Assignment of Intellectual Property Rights

Assignment of all or part of the rights in a patent must be in writing. The assignee or assignor may record the assignment with the USPTO, but recordation is not required to enforce the assignment.

### 10.2 Procedure for Assigning an Intellectual Property Right

Generally, the procedure to assign patent rights involves the same type of negotiations as other contract rights. The parties negotiate the terms of the agreement and execute a written assignment contract. An employer's employment contract may require its employees to assign rights to the employer for inventions developed during employment. Although not required, any assignments should be recorded with the USPTO.

### 10.3 Requirements or Restrictions to License an Intellectual Property Right

An intellectual property licence must describe the terms of the licence agreement in writing and clearly identify all parties and the intellectual property involved. The licence may be exclusive or non-exclusive. In an exclusive licence, the licensee receives all rights in the patent except ownership of title. This allows an exclusive licensee broader rights, such as the ability to sue for patent infringement. A non-exclusive licence can be granted to more than one party, but a licensee cannot enforce the patent against others. For public policy reasons, a patent licence cannot require payment of royalties beyond the term of the patent. The USPTO allows recording of licences, but recording is not required for a licence to be valid. No approval from the USPTO is necessary for a licence.

### 10.4 Procedure for Licensing an Intellectual Property Right

Licence agreements are contractual rights; the parties agree to the terms and execute the agreement in writing. Unlike an assignment of a patent, the rights assigned by licence revert to the licensor after the agreed time period.

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**Rothwell, Figg, Ernst & Manbeck PC** devotes more than half its work to intricate, multi-party patent litigation involving complex scientific and legal issues in district courts and the US Court of Appeals for the Federal Circuit, as well as before the International Trade Commission and the Patent Trial and Appeal Board (PTAB). As a firm dedicated solely to IP, its clients have the advantage of working with a patent litigation team in a highly collaborative environment. The majority of attorneys in the firm's patent litigation

practice earned undergraduate degrees in specialised fields – such as biology, chemistry, computer science, electrical engineering, biomedical engineering, mechanical engineering and biochemistry – and it has attorneys with PhDs and advanced degrees in areas such as electrical engineering, mathematics, chemistry, biotechnology and aeronautics. The team's higher education and prosecution experience means its attorneys understand the technical aspects of a client's IP at a deeper level.

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