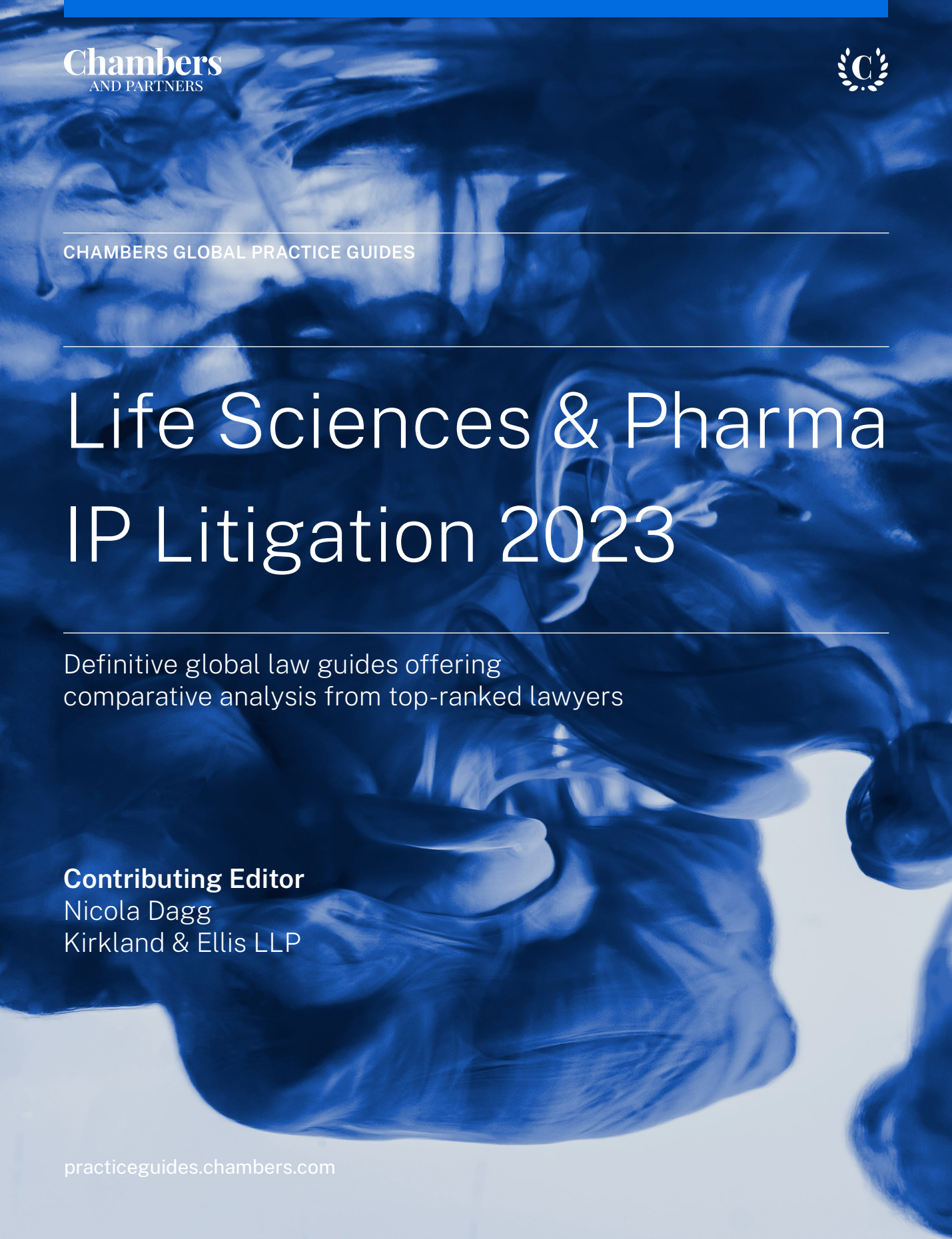

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Life Sciences & Pharma IP Litigation 2023

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Life Sciences & Pharma IP Litigation

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2023

Chambers Global Practice Guides

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Chambers' First Life Science & Pharma IP Litigation Guide

We are delighted to edit the first Life Science & Pharma IP Litigation edition of the Chambers Global Practice Guides, which provides an overview of litigation in the life sciences and pharmaceutical sectors in a number of countries, and an update to the trends and developments expected in the coming year by leading lawyers in each jurisdiction.

Litigation in the life sciences and pharmaceutical industries continues to be prolific. With increasing complexity of the technologies involved, innovators have ever more avenues to consider when protecting their inventions. However, the sociopolitical environment companies are operating in is ever more challenging – governments in key manufacturing jurisdictions, including China and India, have been taking steps to make their countries more attractive for innovators. If manufacturing countries become more patentee friendly, we could see changes in global lifecycle management and enforcement strategies and litigation dynamics in this sector, with an increased focus on enforcement against manufacturers of API and finished products in jurisdictions where enforcement of patent rights had previously been regarded as challenging.

Biologics (and biosimilar versions of originator biologics) are now firmly established at the forefront of pharmaceutical litigation, and comprise the vast majority of the current generation of blockbuster medicines. Whilst small molecule generic litigation continues to occur, the rise of biologics/biosimilars has had and continues to have an impact in terms of the dynamics of and key regular players in large-scale pharmaceutical patent litigation. Overall, the number of patent disputes in the sector has remained steady but the disputes are increasingly complex and high-stakes and are often fought in parallel across multiple jurisdictions. Other industry trends include the continued rise in the frequency of "innovator-on-innovator" disputes.

New Technologies on the Rise

In the wake of the pandemic, the rapid and remarkable success of the development of mRNA-based COVID vaccines has prompted a renewed focus on the use of mRNA-based vaccines and treatments for cancer and other diseases, as well as the application of other next generation technologies such as CRISPR gene editing and base editing. From an IP perspective, what each of those promising technologies has in common is that they may be regarded as "platform" technologies that are generally reliant on certain key features or fundamental technologies which are protected by patents and which in many cases have already given rise to IP disputes. The highly complex nature of these technologies, which generally involve many key processing steps and critical inputs, also lends itself to diversity of ownership of the IP covering different parts of the technology involved in a product and its manufacture. Together, these characteristics lead to conditions ripe for litigation as companies either try to clear the way for the launch of their products, or conversely enforce their patent portfolios against companies considered to be infringing without a licence or consent.

We have seen this come to pass in relation to the technology involved in COVID-19 vaccines – now that vaccines have become more generally available, litigation between and against the key players in the field has taken off in earnest,

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with both Moderna and BioNTech/Pfizer on the end of respective claims by Arbutus/Genevant and CureVac, and claims and counterclaims between Moderna and BioNTech/Pfizer for patent infringement of each other's mRNA technology. The stakes are high for the owners of these technologies, which have not only had significant revenues from vaccines, but also potentially form the basis for an entire new and promising class of vaccines and treatments for other diseases. The fight between the two mRNA vaccine giants in Moderna and BioNTech/Pfizer is bound to continue to attract attention in the coming year.

Approaches to Enforcement

The ability to obtain a preliminary injunction to prevent the launch of a generic or biosimilar medicine is an all-important consideration in any business/legal strategy to protect the exclusivity of an originator product. However, there has been a recent trend in traditionally more preliminary injunction-friendly jurisdictions like the UK and Australia towards fewer injunctions being granted and greater scrutiny of claimants' assertions of irreparable harm if the injunction they seek is denied. Perhaps relatedly, and with an increased awareness of the impact of public interest factors in the proportionality calculus, recent times have generally also seen greater forbearance on the part of claimants in seeking preliminary or final injunctive relief where critical medicines are concerned – notably in much of the litigation involving COVID-19 vaccines many claimants have not only refrained from claiming injunctive relief, but have in fact been at pains to highlight this. Each country guide includes an update on the steps required to obtain a preliminary injunction and the considerations for applicants.

EPO Developments

The Enlarged Board of Appeal (EBA) recently held an important hearing on plausibility (case G2/21), which seeks to clarify whether a technical effect can be relied on in support of inventive step when proof for the effect rests only on post-published evidence. The EBA's anticipated clarification on the requirement of plausibility, and whether the threshold for plausibility will be set high or low, will have significant ramifications for many patents across many industries, but particularly for the pharmaceutical industry and medical use patents. As the EBA has indicated it is prioritising the decision, a result may emerge as early as the first few months of 2023. From the preliminary opinion and questions raised at the hearing, it would appear that the EBA is leaning towards applying a standard where post-published data can only be disregarded if the skilled person would have significant reason to doubt the purported technical effect based on the application as filed. Meanwhile, conflicting decisions regarding the apparent requirement in the European Patent Office's Guidelines for Examination to adapt the description of a patent in line with its amended claims continues to vex practitioners, particularly in the biotechnology industry, where patent specifications (and claim sets) tend to be very long, detailed, and involved. Practitioners will be hoping for additional clarity and consistency of approach from the EPO on this issue in the coming year.

Changing Landscape in Europe

In Europe, the long-awaited Unified Patent Court (UPC) is now on track for commencement in Q3 2023, although its start has been postponed numerous times and time will tell if the planned launch in 2023 proceeds according to schedule. The new court will inevitably bring changes to the litigation landscape and strategy in Europe, albeit the general consensus appears to be that

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most life sciences companies will choose to opt out their key European patents during the transitional period. For patents remaining in the UPC regime, some of the significant developments will include pan-European injunctions, and the possibility of European-wide revocation actions and forum shopping within the UPC divisions. In the early days much attention will be focused on which industries with which types of patents are making use of the UPC (ie, not choosing to opt out) and accordingly playing a role in shaping its practices and precedents, as well as the way in which UPC case law and practice develops, particularly in relation to the myriad untested procedural issues which will inevitably arise.

The UK

The UK Patents Court continues to be busy with life sciences disputes. Two notable decisions in the UK last year were the Novartis v Teva (fingolimod) and Neurim v Teva (melatonin) preliminary injunction decisions, which in each case the English court denied injunctive relief sought by a patentee to prevent the launch of a generic version of a blockbuster small molecule drug. In each of those cases the court found that damages would be an adequate remedy for any harm suffered by the patentee absent an injunction, despite the patentees making the usual arguments regarding the downwards price-spiral upon generic launch (an argument that the court has previously often been receptive to on that issue).

These decisions mark a trend in the development of the English court's approach, which now appears less amenable to the grant of preliminary injunctions sought by pharmaceutical and life sciences patentees. The court now applies increasingly close scrutiny to patentees' claims of irreparable harm and the inadequacy of damages as a remedy. Additionally, in Novartis v Teva, the court 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.

The coming year may also see further developments in relation to the law in respect of recovery by the NHS and generic companies under the usual cross-undertakings as to damages in pharmaceutical cases, where the patentee successfully obtained a preliminary injunction preventing a generic or biosimilar product launch that was later found to have been unjustified (ie because the patent upon which the injunction was based is later found to be invalid or not infringed). This is the issue in question in the damages phase of the litigation concerning Warner-Lambert's blockbuster medicine Lyrica (pregabalin), which in 2023 is due to go to the first of a series of trials. The same issue in similar circumstances has been considered in Australia in a number of decisions that have significantly reshaped the landscape for the consideration of damages in pharmaceutical cases in Australia. The outcome of the pregabalin damages litigation is poised to do the same in the UK.

The USA

Numbers of patent cases, and federal appeal cases originating from patent cases, remain stable in the US courts, with the exception of ANDA litigation which is on the decline. Patent eligibility is likely to remain a contentious patent litigation issue over the next year. The US Congress has considered reforms to the patent laws, including to patent eligibility; however, any new legislation is likely to create additional litigation, even if it ultimately improves and clarifies certain rules.

INTRODUCTION

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The Supreme Court is set to address enablement under Section 112 enablement and written description requirements of antibody claims in the case of Amgen v Sanofi regarding anti-PCSK9 treatments for hypercholesterolaemia. The case will clarify the operation of the Section 112 requirements and will be particularly important in pharmaceutical cases where it is frequently arguable in some sense that it would be difficult to identify and make all of the embodiments of an invention without undue experimentation. Additionally, there are continuing challenges related to the written description requirement where the claims are to a wide dose range and not only the therapeutically effective dose.

Conclusion

Litigation in the pharmaceutical and life sciences industries is often highly complex and involves concurrent cross-border litigation in numerous jurisdictions. As the snapshot of issues provided by this brief overview illustrates, the law and practice in the area is constantly developing and continues to evolve, such that in navigating life sciences and pharmaceutical patent disputes it is essential to have up-to-date advice and information from experienced practitioners in the field. It is hoped that this guide is helpful to readers in providing a high-level overview of some of the essential features of life sciences and pharmaceutical IP litigation across the range of contributing jurisdictions.

INTRODUCTION

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Kirkland & Ellis International LLP (Kirkland) has a patent litigation practice comprising 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. The firm's attorneys have extensive experience of pharmaceutical and biologics patent litigation, co-ordinating global IP disputes, post-grant proceedings before the US Patent and Trademark Office's Patent Trial and Appeal Board. In addition, Kirkland's lawyers have taken part in appeals of high-stakes cases before the US Court of Appeals for the Federal Circuit and the US Supreme Court, the Court of Appeal of England and Wales, and the UK Supreme Court.

Contributing Editor

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1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Infringement Actions

In Australia, patent infringement actions may be commenced by the patentee, an "exclusive licensee", or both. If an exclusive licensee commences proceedings and the patentee does not consent to being an applicant, the patentee must be joined as a respondent.

To have standing as an "exclusive licensee", the court must be satisfied that the licensee has been authorised to undertake all relevant acts of exploitation in Australia, to the exclusion of all others. This is a question of fact, usually proved by simply tendering the exclusive licence agreement. An exclusive licensee may apply to record its interest in a patent on the Register of Patents. However, a failure to do so does not undermine an exclusive licensee's standing to sue.

Where a patent is co-owned by two or more persons, and one patentee intends to commence infringement proceedings, the Patents Act 1990 (Cth) (the "Patents Act") does not expressly provide for whether the other patentees must also be parties to the proceeding. However, if an exclusive licensee is a party to the proceedings, then all patentees must be joined either as co-applicants or respondents.

Revocation Actions (Sections 138 and 139 of the Patents Act)

Any person may commence proceedings seeking revocation of a patent. There is no requirement that infringement proceedings are also pending. In practice, however, the applicant in revocation proceedings is often an alleged actual/threatened infringer. The patentee, as well as any person claiming an interest in the patent (eg, an exclusive licensee whose interest is recorded on the Register of Patents), are parties to revocation proceedings. Notice of the application for revocation must also be served on the Commissioner of Patents, who has the option of appearing and being heard.

1.2 Defendants/Other Parties to an Action

Infringement proceedings may be brought against any person engaging in any relevant infringing acts in Australia (see **2.1 Infringing Acts**).

In practice, however, infringement proceedings are typically brought against the Australian sponsor of the therapeutic goods, the sale and supply of which is alleged to infringe the patent. Other entities involved in the supply chain, such as manufacturers or local distributors, are also sometimes sued.

Patents claiming methods of treatment are valid in Australia, which means that, occasionally, doctors and hospitals may technically infringe certain patents. However, for commercial and other reasons, infringement proceedings are almost never brought against those persons.

In any patent infringement or revocation proceedings, the Commissioner of Patents must be served with the initiating court documents, and may appear and be heard in the proceedings.

1.3 Preliminary Injunction Proceedings

General

Preliminary injunctions (or "interlocutory" injunctions, in Australian parlance) (PIs) are available in Australia, to restrain any actual or threatened infringement of the patent (see **2.1 Infringing Acts**). The application for a PI may be made with or without notice to the respondent, although

in pharmaceutical patent cases, the application is usually made on notice and the respondent given an opportunity to file affidavit evidence and make submissions.

Timing

A PI application may only be made as part of a substantive infringement proceeding, and is usually filed together with the initiating court documents of an infringement proceeding. Depending on the urgency of the matter, the hearing of the PI application usually occurs within three to six weeks of filing, with a decision on the PI application delivered within one to two weeks of the hearing. If there is an imminent deadline (such as an intended product launch date), the court will usually accommodate a sufficiently truncated timetable and hearing date.

Grounds

To seek a PI, the patent relied upon must have been granted (or, in the case of an innovation patent, granted and certified). To date, Australian courts have not decided whether an applicant may obtain a PI on the basis of a patent application alone, such as if an opposition has been unsuccessful but the resulting patent has not yet been sealed.

In deciding the PI application, the court will assess two main considerations, namely:

- whether the applicant has a prima facie case with a probability of success sufficient to justify the court making an order to preserve the status quo; and
- whether the balance of convenience favours granting the injunction. That is, a comparison between the inconvenience to an alleged infringer if he is restrained and later found to have been acting lawfully, and the inconvenience to the applicant if the alleged infringer is not restrained but later found to have infringed (which includes an assessment of whether damages would be an adequate remedy).

The court will also assess the overall justice of the case, and take into account discretionary considerations such as any relevant delay on the part of the applicant.

In cases where the alleged infringer would, but for the injunction, become the first generic or biosimilar product to enter the Australian market, the balance of convenience often weighs heavily in favour of the patentee/innovator, due to the significant and irreversible price consequences that occur upon the listing of a first new brand of an existing pharmaceutical item under Australia's Pharmaceutical Benefit Scheme. The pricing consequences under the PBS are complex, and are often the subject of evidence adduced in relation to applications for PIs.

Protective Letters

Australia does not have a protective letters system. However, as mentioned above, most PI applications in Australian pharmaceutical patent cases are heard and determined on notice, affording both parties an opportunity to adduce evidence and make submissions.

1.4 Structure of Main Proceedings on Infringement/Validity

Patent infringement and revocation proceedings are generally heard and determined together, by the same court and judge, with all issues of construction and validity determined within a single judgment. In cases where the applicant seeks pecuniary relief, it is common for all issues of liability to be heard and determined separately and prior to the quantification of any damages or account of profits.

Proceedings before the Australian Patents Office do not prevent a person from commencing revocation proceedings in a relevant court. The existence of pending court proceedings generally requires the Patent Office to stay any pending opposition proceedings until such time as the court proceeding has been finally determined.

1.5 Timing for Main Proceedings on Infringement/Validity

Time to Commence Proceedings

An action for patent infringement must be commenced by the later of:

- three years after the date on which patent was granted; or
- six years after the date of the act of infringement.

A patentee enjoys exclusive rights in the period commencing on the day on which the complete specification becomes open to public inspection, and ending with the ceasing or expiry of the patent. Section 57 of the Patents Act allows a patentee to, after grant, sue for infringements committed prior to grant but after the patent became open to public inspection, if those acts fall within the scope of the patent claims as granted.

There is no direct time limit on when a person may commence revocation proceedings. However, any counterclaim seeking revocation should generally be filed at the same time as the defence to any infringement claim – an attempt later to seek revocation only after the conclusion of infringement proceedings is likely to be struck out as an abuse of process.

Service

An applicant must serve the initiating court documents on the respondent. In the Federal Court of Australia, which is where the majority of patent matters are heard, service must be effected as soon as practicable and at least five days before the first return date fixed in the Originating Application. In urgent proceedings, the court may make orders abridging the time for service.

Pleadings

The Federal Court Rules establish a default timetable for the filing of pleadings, referable to the dates of service: defence to be filed within 28 days after service of the statement of claim, and any reply to be filed within 14 days of service of the defence. In practice, however, the court tends to make orders establishing a bespoke timetable, taking into account factors such as the availability of the court and the parties' representatives, any urgent interlocutory matters, and public holidays, etc.

Progress Through to Trial

The Federal Court operates a docket system, whereby each proceeding is generally case managed, heard and determined by the same judge from start to finish. The docket judge will set the pace for how rapidly or otherwise a matter will progress through to trial and judgment at first instance. The court will usually schedule regular case management hearings throughout the proceeding, to ensure the matter is progressing in accordance with the timetable, and to rule on any interlocutory disputes between the parties.

In a typical patent infringement/revocation proceeding, the matter may be listed for trial to take place anywhere between 12 and 24 months from the commencement of the proceeding. The timing depends significantly on the complexity of the issues in dispute, the judge's availability for hearing time, the extent of any contested interlocutory applications (such as discovery), and

the length of trial required to accommodate the cross-examination of each party's witnesses.

Judgment

There is no deadline by which judgment must be delivered following trial. In a typical patent infringement/revocation proceeding, judgment would be delivered around six to twelve months after the trial concludes, although there are exceptions (both shorter and longer).

1.6 Requirements to Bring Infringement Action

A main infringement action may be filed as soon as both:

- the patent relied upon has been granted (or, in the case of an innovation patent, granted and certified); and
- the applicant has a proper basis for alleging that the respondent has engaged in relevant acts of exploitation (see **2.1 Infringing Acts**), or has threatened to do so.

In some cases, publicly available material will not be sufficient to support an allegation that the respondent's conduct infringes a claim of the patent. This is particularly common for formulation patents, or patents claiming methods/processes used in the manufacture of biologic or biosimilar medicines, where the formulation and manufacturing information is invariably highly confidential. In these circumstances, a patentee may first need to commence proceedings seeking an order for preliminary (ie, pre-action) discovery from the prospective respondent (see **1.7 Pre-action Discovery/Disclosure**).

A patentee may sue for infringements that occurred during the term of the patent following the granting of the patent, and may also sue for infringements that occurred prior to grant but after the date on which the patent became open for public inspection: Section 57 of the Patents Act.

1.7 Pre-action Discovery/Disclosure

Pre-action discovery is available in Australia, by application to the Federal Court under Rule 7.23 of the Federal Court Rules 2011 (Cth). Under that provision, a prospective applicant may apply to the court for an order for preliminary discovery from a prospective respondent if it can establish that:

- the prospective applicant has a reasonable belief that it may have a right to relief in the court;
- after making reasonable inquiries, the prospective applicant requires further information before it can decide whether to commence a substantive infringement proceeding; and
- the prospective respondent is likely to hold documents directly relevant to the question of whether the prospective applicant has a right to obtain the relief, which would assist in making the decision to commence a substantive proceeding.

Except with leave of the court, documents obtained by a party pursuant to an order for preliminary discovery may only be used for the purpose of that proceeding and any substantive proceeding that follows, and no collateral or ulterior purpose: Hearne v Street (2008) 235 CLR 125, citing Harman v Secretary of State for the Home Department [1983] 1 AC 280.

1.8 Search and Seizure Orders

In light of the availability of pre-action discovery (see **1.7 Pre-action Discovery/Disclosure**), search and seizure orders are uncommon in life sciences and pharma/patent matters. However, Australian courts do have powers to make

orders for the inspection and preservation of property; orders allowing an applicant to enter a respondent's premises to inspect, remove or make copies of documents; and orders to force disclosure of persons with whom the respondent has had dealings. The legal source of these powers, and the relevant procedural rules, differ between different Australian courts (eg, state versus federal courts).

To obtain an order of this nature without notice (ie, an "Anton Piller" order), the applicant must generally demonstrate a strong prima facie case, that serious damage has been (or would likely be) suffered by the applicant, that there is clear evidence the respondent possesses documents or other materials that are relevant to matters in issue, and that there is a real possibility the respondent may destroy the documents or materials if given prior notice. A party seeking such an order is required to give an undertaking as to damages in favour of any person adversely affected by the order. An Anton Piller order may only be sought once substantive proceedings have been commenced; in that way, it differs from pre-action discovery where the prospective applicant is not yet in a position to commence a substantive proceeding.

Material obtained from the execution of an Anton Piller order cannot be used for ulterior purposes, including purposes in connection with proceedings in other jurisdictions (see, eg, Brooks Sports, Inc v Paul's International Pty Ltd (No 2) [2011] FCA 1000).

1.9 Declaratory Relief

Declaratory relief is a very common form of relief in Australian intellectual property disputes. Section 21 of the Federal Court of Australia Act 1976 (Cth) confirms the Court's power to make declarations in any proceedings in respect of which the Court has original jurisdiction, which relevantly includes all patent infringement and revocation proceedings. The Court will usually issue a declaration together with any other final relief such as a permanent injunction, damages or an account of profits, interest, and costs.

The Patents Act also permits a person to apply for a declaration of non-infringement (Sections 125 to 127 of the Patents Act). Such non-infringement declarations may be sought at any time after the patent has been granted, regardless of whether a patentee has made any allegation of infringement. To obtain such a declaration, the applicant must first seek a written admission from the patentee that the doing of the act in question does not infringe the patent (and the patentee must have failed to give that admission), and must give full written particulars of the allegedly non-infringing act which is done or proposed to be done.

To date, Australian courts have not adopted the so-called "Arrow" declarations.

1.10 Doctrine of Equivalents

Australian law does not recognise any doctrine of equivalents.

1.11 Clearing the Way

There is no obligation in Australia to "clear the way" ahead of a new product launch.

1.12 Experts

Expert evidence is required in almost all Australian patent disputes, and, in some cases, experts from multiple fields are required. Expert evidence assists the court with construing the patent claims, assessing infringement, and determining validity issues.

Expert evidence generally takes the form of written report(s) or affidavits, followed by oral evidence at trial under cross-examination. Typically, each party will have its own expert witness from within each of the fields of technology relevant to the patent(s) in suit. Experts are typically retained by the solicitors acting for a party. Experts must agree to be bound by the Court's Code of Conduct for Expert Witnesses, which includes a requirement that the experts remain impartial and are not an advocate for any party. The experts must also be briefed with all documents that they consider to be relevant, or identify any documents which they consider to be relevant that they have not been provided.

In patent cases, it is common for all expert witnesses who have expertise from within the same field to be required to engage in a series of conferences, in the absence of any of the parties' representatives, known as a "conclave". Following the conclave, they may be required to produce a "Joint Expert Report" identifying the areas of agreement and disagreement on the key issues in dispute relevant to their expertise. It is also increasingly common for expert witnesses from the same field to give their oral evidence concurrently at trial, in a process colloquially known as a "hot tubbing".

In Australian proceedings where opposing parties are present, it is rare for the court to appoint its own expert witness.

1.13 Use of Experiments

Experimental evidence is very uncommon in Australian patent cases. The court generally discourages its use, given the broad scope for potential challenges to both the methodology and the interpretation of the results. In an appropriate case, however, there is a mechanism to tender, as evidence, experimental proof of a fact in issue.

The procedure for experimental evidence is dealt with under Rule 34.50 of the Federal Court Rules 2010 (Cth). If a party wishes to tender such evidence, they must apply for orders in relation to the experimental evidence, and may seek orders in relation to:

- the service on other parties of particulars of the experiment and of each fact that the proponent asserts is, will or may be, proved by the experiment;
- any persons who must be permitted to attend the conduct of the experiment;
- the time when, and the place where, the experiment must be conducted;
- the means by which the conduct and results of the experiment must be recorded;
- the time by which any other party (the opponent) must notify the proponent of any grounds on which the opponent will contend that the experiment does not prove a fact that the proponent asserts is, will or may be, proved by the experiment.

1.14 Discovery/Disclosure

Discovery orders are common in Australian patent litigation. Discovery orders may be made at any time during the proceeding, but are most commonly made after the parties have filed their written evidence. The court also has a strong preference for making only narrow, targeted discovery orders, where a party is required to discover documents responsive to one or more specified categories. The party seeking a discovery order must persuade the court that the discovery order is reasonably necessary, and that the burden of complying with the order is proportionate to the importance of any docu-

ments likely to be produced and the facts in issue to which those documents relate.

Discovery orders require the discovery and production for inspection of existing documents responsive to the discovery categories that are within a party's control, subject to any valid claim for privilege. In this context, "control" is defined as meaning "possession, custody or power".

Australia does not use depositions. However, documents in the control of a party that record details of depositions conducted in connection with litigation in other jurisdictions (such as transcripts or video recordings) may be discoverable, subject to any objections on the basis of relevance and/or privilege.

1.15 Defences and Exceptions to Patent Infringement

The Patents Act contains a number of specific exemptions to infringement, namely:

- use in or on foreign vessels, aircraft or vehicles (Section 118);
- prior use (Section 119);
- acts for obtaining regulatory approval for pharmaceuticals (Section 119A) – the Australian equivalent of a Bolar-type exemption;
- acts for obtaining regulatory approval (non-pharmaceuticals) (Section 119B); and
- acts for experimental purposes (Section 119C).

In addition to the above exemptions, the court may refuse to award damages or an account of profits where there has been innocent infringement: Section 123 of the Patents Act.

Australian courts have accepted the so-called "Gillette" defence (that is, the argument that if a respondent is doing no more than something he has been doing since before the priority date, then either the patent is invalid, or the claims are not infringed).

In 2020, the High Court of Australia also recently embraced the "doctrine of exhaustion", overturning more than 100 years of Australian jurisprudence under the "implied licence doctrine": Calidad Pty Ltd v Seiko Epson Corporation (2020) 272 CLR 351. In an appropriate case, a respondent may avoid liability on the basis that the patentee has exhausted its rights in the articles embodying the invention as claimed in the patent.

1.16 Stays and Relevance of Parallel Proceedings

Australian court proceedings, including patent infringement and revocation proceedings, may be stayed at the court's discretion, in accordance with the general principles for granting a stay. An application for a stay on the basis of pending parallel proceedings in another forum is generally made shortly after the proceedings have commenced, or shortly after there is a change in circumstances giving rise to a potential entitlement for a stay.

The granting of a stay is discretionary. The considerations the court will likely take into account include that:

- an applicant is prima facie entitled to have its action tried in the ordinary course of the procedure and business of the court;
- it is a "grave matter" to interfere with that entitlement by staying proceedings, which requires justification on proper grounds;
- the burden is on the party seeking the stay to show that it is just and convenient that the other party's ordinary rights should be interfered with;

- the court must balance the justice between the two parties, taking into account all relevant factors; and
- each case must be judged on its merits.

Foreign court proceedings generally do not constitute an appropriate basis for the grant of a stay of Australian patent infringement and revocation proceedings, including due to the domestic nature of patents and the differences in substantive patent law across jurisdictions.

1.17 Patent Amendment

Australian patents may be amended during litigation by an application under Section 105 of the Patents Act. The patentee must give notice to the Commissioner of Patents, who may appear and be heard on the question of whether the amendment should be ordered. Any amendment must also comply with the requirements for allowable amendments (see Section 102 of the Patents Act). Even if the requirements are met, the court has a discretion whether to allow the amendment, in all the circumstances, including any relevant delay by the patentee in bringing the amendment application.

Where no relevant court proceedings are pending, a patentee may apply to the Commissioner of Patents to amend the complete specification of a patent, under Section 104 of the Patents Act. Unlike an amendment application when proceedings are pending, if the Commissioner is satisfied that the amendments comply with the requirements for allowable amendments under Section 102, they must grant the amendment application accordingly – there is no power to refuse the application on discretionary grounds.

1.18 Court Arbiter

First instance patent infringement and/or revocation proceedings are generally heard by the Federal Court of Australia, constituted by a single judge sitting alone. There are no juries involved in Australian patent litigation. Formally, there is no specialist patent or intellectual property Bench; however, the judges assigned to such cases tend to be very experienced in this field.

Although the Federal Court has registries all across Australia, most of the judges with significant patent law experience are based in Sydney and Melbourne, which is where most patent litigation is commenced.

2. Generic Market Entry

2.1 Infringing Acts

Acts of Infringement

The right to bring an infringement proceeding crystallises when a person engages in relevant infringing acts, or threatens to do so.

The relevant infringing acts for an invention that is a product are:

- making it;
- hiring it;
- selling it;
- otherwise disposing of it;
- offering to do any of the above;
- using it;
- importing it;
- keeping it for the purpose of doing any of the above; and
- authorising another person to do any of the above.

An offer to sell an infringing product, made within the term of a patent, will infringe the patent even if the intended supply pursuant to that sale is intended to occur after the patent expires.

The relevant infringing acts for an invention that is a method or process are:

- using the method or process; and
- doing any of the relevant infringing acts (in Australia) in relation to a product that results from the use of the method or process (whether in or outside Australia).

In addition, a person may infringe a patent by supplying a product, where the use of that product would infringe a patent (including any method/process patent), and either:

- that use is the product's only reasonable use, having regard to the product's nature or design; or
- the supplier had reason to believe that the product would be put to that use (where the product is not a staple commercial product); or
- that use is in accordance with the supplier's instructions or inducements that were supplied or contained in an advertisement published by or on behalf of the supplier.

Infringement Exemptions for Pharmaceutical Products

Under the Patents Act, a patent is not infringed by any person exploiting the invention if the acts of exploitation are done solely for purposes connected with obtaining marketing approval. A patent is also not infringed by acts done for experimental purposes relating to the subject matter of the invention, such as improving or modifying the invention.

Recent case law has confirmed that it is not an infringement for a person to lodge an application that seeks listing of pharmaceutical products on the Schedule of Pharmaceutical Benefits (PBS), being the Government's principal scheme for the funding of pharmaceutical products in Australia. The PBS application does not constitute an offer to supply. However, the act of lodging a PBS application is commonly relied upon as part of the factual matrix that demonstrates the PBS applicant intends imminently to exploit its pharmaceutical products in Australia and is thereby threatening to infringe the patent.

Parallel Imports

Parallel imports are not expressly dealt with under Australia's Patents Act. In most cases, however, the parallel importation of goods that embody a patented invention will not infringe a patentee's rights. The traditional support for that view was the implied licence doctrine – case authorities that upheld the implied right of a purchaser of goods to deal with the purchased goods as they think fit. In 2020, however, the High Court of Australia overturned decades of jurisprudence, and instead ruled in favour of the doctrine of exhaustion of patent rights: Calidad Pty Ltd v Seiko Epson Corporation. It is expected that the doctrine of exhaustion will likely achieve the same result in most cases of parallel importation, but there remains uncertainty as to how the doctrine will be applied in certain circumstances, such as where the patentee in Australia is a different legal entity to the patentee in the jurisdiction where the goods were purchased.

2.2 Regulatory Data and Market Exclusivity

Under Australian law, sponsors of products containing new pharmaceutical substances enjoy a data exclusivity period of five years from the date on which marketing approval of the innovator's product is granted. During this period, data provided to the Therapeutic Goods Administration (TGA) for the purposes of obtaining regulatory approval cannot be relied upon or referred to by others seeking approval for a generic or biosimi-

lar product containing the same pharmaceutical substance.

In Australia, the five-year data protection period cannot be extended. The period commences from the first inclusion in the Australian Register of Therapeutic Goods (ARTG) of products containing the pharmaceutical substance, and there is no additional/extended protection even if new indications (including paediatric or other extensions of indications), new formulations, or new dosage forms/routes of administration are later approved.

Disputes in relation to data exclusivity are not common in Australia, in part because the period of data exclusivity has usually ended before the expiry of any relevant patents. The exclusivity is established as a restraint imposed on the TGA under the Therapeutic Goods Act, meaning that if the TGA intended to use relevant data during the period of alleged data exclusivity protection, an interested person may apply for administrative or judicial review of the TGA's decision, and seek declaratory or injunctive relief to prevent the TGA from using that data until after the data exclusivity period has ended.

Australia has no formal period of market exclusivity. In practice, market exclusivity is usually enjoyed by an innovator for a limited period of time, due to the combined effect of Australian patent law and the data exclusivity arrangements discussed above.

2.3 Acceptable Pre-launch Preparations

The Australian Patents Act contains two infringement exemptions relevant to pre-launch preparations for generic and biosimilar pharmaceuticals:

- *regulatory approval*: a patent is not infringed by any person exploiting the invention if the acts of exploitation are done solely for purposes connected with obtaining marketing approval (Section 119A); and
- *experimental purposes*: a patent is also not infringed by acts done for experimental purposes relating to the subject matter of the invention, such as improving or modifying the invention (Section 119C).

Recent case law has also confirmed that it is not an infringement of a patent for a person to lodge an application that seeks listing of products on the Schedule of Pharmaceutical Benefits (PBS), being the Government's principal scheme for the funding of pharmaceutical products in Australia. The PBS application does not constitute an offer to supply.

2.4 Publicly Available Drug and Patent Information

Australia does not have a process of associating patents with marketing approvals equivalent to the United States' "Orange Book".

Australia's pharmaceutical regulatory system does contain a mechanism intended to cause patentees to be notified of relevant third-party applications for marketing approval, but it does not achieve that goal in practice. More specifically, when an applicant seeks regulatory approval for a pharmaceutical product the safety or efficacy of which the applicant seeks to establish (in whole or in part) based on information contained within another person's Dossier – as typically occurs in the case of applications for generic/biosimilar products – then the applicant is required to certify to the TGA either:

- that the applicant, acting in good faith, believes on reasonable grounds that the mar-

keting of its generic/biosimilar product would not infringe a valid claim of a patent (Section 26B(1)(a) of the Therapeutic Goods Act 1989 (Cth)); or
- that a patent has been granted in relation to the therapeutic goods, the applicant proposes to market the goods while the patent is in force, and the applicant has notified the patentee of the application for marketing approval (Section 26B(1)(b) of the Therapeutic Goods Act 1989 (Cth))).

In practice, sponsors of generics/biosimilars invariably elect to provide the first of these two certification options. The existence of pending regulatory applications is not made public until the application has been granted, which means that the first notice a patentee usually has about a relevant generic/biosimilar product is when the product is recorded on the publicly accessible Australian Register of Therapeutic Goods (ARTG). For this reason, patentees usually monitor the ARTG closely.

The product information available on the ARTG is generally limited, at least initially, to a two-page "Public Summary Document", which includes the name of the active pharmaceutical ingredient, the brand name, the approved indications, the dosage form and strength, a list of excipients (but not their relative weights/proportions), and the Australian sponsor's details. Sometime later, but before the product may be sold and supplied in Australia, the approved "Product Information" document (typically about 30 to 50 pages), and a "Consumer Medicines Information" document (typically about three to five pages) become publicly accessible.

2.5 Reimbursement and Pricing/Linkage Markets

In Australia, neither the grant of marketing authorisation, nor the listing of a product on the PBS, is formally linked to the existence/status of any patent. An innovator must generally monitor for marketing approvals having been granted for any product that may infringe the patent, and promptly engage in correspondence with the sponsor of that product to determine whether it intends imminently to exploit the product.

Where an innovator's product is the only brand of a pharmaceutical item listed on the PBS, the innovator will also usually become aware of any third-party application that seeks the listing of a first new brand of that existing pharmaceutical item on the PBS shortly after it has been made. The innovator usually becomes aware because the Commonwealth Department of Health must usually give notice to the innovator of the Commonwealth's intention to disclose the innovator's confidential pricing arrangements to the third party, so that the third party may confirm whether it agrees to list its product subject to those same pricing arrangements.

Pricing and reimbursement through the PBS is indication-specific. Where a pharmaceutical item already listed on the PBS is approved for a second medical use, the sponsor must apply for PBS listing for the new indication if it wishes for the product to be subsidised in that new setting. The per-unit price for a product listed on the PBS is usually the same for all of the indications for which the product is PBS-listed.

3. Biosimilar Market Entry

3.1 Infringing Acts

The relevant infringing acts for biologics or biosimilars are the same as for small molecule pharmaceuticals.

3.2 Data and Regulatory Exclusivity

The data exclusivity period for biologics or biosimilars is the same as for small molecule pharmaceuticals.

3.3 Acceptable Pre-launch Preparations

The acceptable pre-launch preparations for biologics or biosimilars are the same as for small molecule pharmaceuticals.

3.4 Publicly Available Drug and Patent Information

The publicly available drug and patent information for biologics or biosimilars is substantially the same as for small molecule pharmaceuticals, although the TGA tends to publish more information about its decisions (approvals and rejections) on marketing approval applications for biologics/biosimilars, in the form of Australian Public Assessment Reports, or "AusPARs".

3.5 Reimbursement and Pricing/Linkage Markets

There are no material differences between the reimbursement and pricing/linkage processes for biologics or biosimilars and small molecule pharmaceuticals.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Extensions of Term for Pharmaceutical Patents

The patentee of a standard patent that relates to one or more "pharmaceutical substances per se" may apply to the Commissioner of Patents under Section 70 of the Patents Act for an extension of the term of the patent of up to five years. No other extensions of term are available; only pharmaceutical patents that meet the requirements can be extended.

Application Requirements and Procedure

The applicant for an extension of term must satisfy the Commissioner that each of the following requirements is met, namely that:

- either (or both):
  - (a) one or more "pharmaceutical substances per se"; or
  - (a) one or more pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology,
- is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the patent claims;
- in relation to at least one of those pharmaceutical substances, goods containing or consisting of the pharmaceutical substance must be included in the ARTG;
- the period between the date of the patent and the date of the first regulatory approval of goods containing the substance on the ARTG must be at least five years; and
- the term of the patent must not have previously been extended.

The application must be lodged within six months after the later of (relevantly):

- the date of the grant of the patent; or
- the date of commencement of the first relevant inclusion in the ARTG.

Applications for an extension of term are open to public inspection, and, following acceptance by the Commissioner, may be opposed by any interested person. If no opposition is filed, or the Commissioner determines that the extension should be granted despite the opposition, then the Commissioner must grant the extension if satisfied that it meets the requirements outlined above: Section 76 of the Patents Act.

Duration of the Extension

The duration of the extended term, if granted, is calculated by taking the period between the date of the patent and the earliest first regulatory approval date, and reducing that period by five years (but not below zero): Section 77 of the Patents Act. This means that if the period between the date of the patent and the earliest first regulatory approval is less than five years, a non-zero extension of term will not be available.

Importantly, during the extended term of the patent, the patentee's exclusive rights are more limited than during the standard 20-year term of the patent. Specifically, during the extended term, the patent may only be infringed by the exploitation of products for therapeutic purposes that fall within the claim(s) relating to the "pharmaceutical substance per se". Other uses of the substance, or the exploitation of other claims of the patent (such as methods of treatment or manufacturing process claims) will not be considered an infringement during the extended term of the patent: Section 78 of the Patents Act. Finally, in the rare scenario where an extension of term is granted only after the standard term of the patent has expired, only the patentee (and not an exclusive licensee) will have rights to bring proceedings for infringements committed during the extended term: H Lundbeck A/S v Sandoz Pty Ltd [2022] HCA 4.

4.2 Paediatric Extensions

Paediatric extensions are not available in Australia.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

See **1.3 Preliminary Injunction Proceedings** for an overview of preliminary injunctions in Australia (formally "interlocutory injunctions", in Australian parlance) (PIs).

Undertaking as to Damages

A party seeking a PI is generally required to give an undertaking to the court in favour of any person adversely affected by the PI, known as the "usual undertaking as to damages".

The form of the undertaking required is an undertaking to the court:

- "to submit to such order (if any) as the Court may consider to be just for the payment of compensation, (to be assessed by the Court or as it may direct), to any person, (whether or not that person is a party), affected by the operation of the order or undertaking or any continuation (with or without variation) of the order or undertaking; and
- to pay the compensation referred to in [the preceding bullet point] to the person affected by the operation of the order or undertaking."

The party is usually bound by the undertaking for so long as the PI remains in force. The scope of the undertaking extends to persons who are not parties to the litigation, including relevantly the Commonwealth Department of Health that administers the PBS. Although they are infrequent, third-party claims on the usual undertaking as to damages are brought from time to time, including on the part of the Commonwealth for lost savings it could have made under the PBS had the generic product been listed and supplied in Australia sooner.

Enforcing PIs

No bond is required on the part of a party seeking to enforce a PI. PIs are binding and enforceable from the time that they are made. Where a party reasonably requires a short period of time to achieve compliance with the PI, the terms of the PI will likely afford the person such time as is reasonable in the circumstances. A breach of an injunction is considered a contempt of court, and a party seeking to enforce the PI may approach the court for further or alternative relief in response to any actual or imminent contempt.

As PI applications may only be brought within the context of a pending substantive proceeding, there is no need to commence additional proceedings after the PI application is heard and determined. Generally, PIs are granted either on an interim basis (ie, until a specific date or event occurs, such as the next case management hearing) or, more commonly, expressed to continue "until further order", which means that the PI will likely continue until the proceeding has been determined and final orders made.

Stay of PI

Where a party adversely affected by a PI wishes to appeal from the decision granting the PI, that party may apply to the court for a stay of the PI pending the proposed appeal. The usual principles for a stay of court orders apply (see **1.16 Stays and Relevance of Parallel Proceedings**). In most cases, a stay of the PI is unlikely to be granted, because the primary judge will have already weighed up the likely adverse impact the PI would have on the restrained party.

5.2 Final Injunctive Relief

As with PIs, final injunctions are enforceable from the time they are ordered, unless the court makes an order specifying otherwise. There is no requirement for a bond to be paid. The principles regarding the enforcement of final injunctions are consistent with those in relation to PIs (see **5.1 Preliminary Injunctive Relief**).

A party may seek a stay of execution of any final injunctive relief ordered by the court in its first instance judgment, pending any appeal from that judgment. The stay application may be heard by either the primary judge or a judge of the appeal court. The stay applicant bears the burden of satisfying the court that it should exercise the discretion to grant a stay, despite the ordinary principle that a successful party is entitled to the fruits of the judgment it has obtained.

One of the key considerations in stay applications of this nature is that the appeal proceeding should not be rendered nugatory. If the stay applicant can show that the execution of the injunction would render the appeal nugatory, the prospects of obtaining the stay are higher. Another key factor is the prima facie prospects of the appeal succeeding, which will be assessed with the benefit of the primary judge's reasons for judgment. Where an appeal has merit (as in the case of a clear error by the primary judge), the stay is more likely to be granted.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

In Australia, all injunctive relief is discretionary, and may be granted in addition, or as an alternative, to any pecuniary relief that may also be awarded (such as damages or an account of profits). In most cases where a finding of infringement has been upheld, the court will grant injunctive relief to restrain the impugned conduct during the term of the patent in suit. However, occasionally the court may decline to grant final injunctive relief, on the basis that the injury to the successful party may be adequately compensated by an award of damages and it would otherwise be inappropriate to grant a permanent injunction (for example, where the judgment is delivered only a month or two before the patent in suit is due to expire).

5.4 Damages

Damages or Account of Profits

A patentee may elect to pursue a claim for damages or an account of profits (but not both): Section 122 of the Patents Act. In pharmaceutical patent cases where an innovator is suing the supplier of a generic/biosimilar product, the quantum of damages usually far outweighs the quantum of an account of profits, and the election is therefore usually in favour of damages.

Where damages are sought, the court applies orthodox principles to assessing damages in tort – seeking to put the successful patentee/exclusive licensee, so far as money can do so, in the same position as it would have been in had the infringing conduct not occurred. In circumstances where the patentee or exclusive licensee sells its own product in Australia, damages payable to that entity are often assessed by quantifying the number of additional units that would have been sold, and the higher prices at which those units would have been sold, but for the infringements.

Where a patentee itself does not sell products within the jurisdiction, but would have made more money from its local subsidiaries had the infringements not occurred (eg, by reason of a transfer pricing arrangement or distribution agreement), then the patentee will be entitled to recover its losses in the form of the reduced transfer price/distribution fee adjustments. In circumstances where a patentee has licensed multiple third parties to exploit the invention the subject of the patent, an appropriate measure of damages may instead be a notional royalty rate that the court considers to be reasonable having regard to comparable royalty agreements.

Australian courts do not typically grant interim awards of damages.

Interest

A successful applicant may enjoy both pre-judgment and post-judgment interest on a damages award. Pre-judgment interest is at the discretion of the judge. It runs from the date on which the cause of action accrues, and, subject to some rare exceptions, the cause of action for patent infringement accrues on the date on which the infringing sales occur. Pre-judgment interest is usually calculated at a rate of 4% above the most recent cash rate published by the Reserve Bank of Australia immediately prior to each relevant six-month period: Section 51A of the Federal Court of Australia Act 1976 (Cth). Post-judgment interest accrues from the date on which final judgment is entered, and is calculated at a rate of 6% above the most recent cash rate published by the Reserve Bank of Australia immediately prior to each relevant six-month period: Rule 39.06 of the Federal Court Rules 2011 (Cth).

Additional Damages

The court has a discretion to award additional damages in appropriate cases, having regard

to the flagrancy of the infringement, the need for deterrence and any other relevant matters including the infringer's conduct: Section 122(1A) of the Patents Act.

Damages for Wrongful Injunction

As noted in **5.1 Preliminary Injunctive Relief**, if an alleged infringer is ultimately held not to have infringed a valid claim of the patent in suit, they may claim for compensation in the form of damages pursuant to the "usual undertaking as to damages" given by the PI applicant. Such a claim will only be heard and determined after all aspects of the substantive proceedings have been determined, including any appeals. Third parties adversely affected by the wrongful imposition of the injunction may also apply for an award of damages under the undertaking as to damages.

5.5 Legal Costs

The general rule in Australia is that legal costs "follow the event", meaning that a successful party is entitled to recover its costs of and relating to the proceedings. The standard costs order is for "party and party" costs, which usually equates to approximately 60–70% of the successful party's actual legal costs reasonably incurred. However, costs are always at the discretion of the court, and bespoke costs orders are common in cases with multiple unrelated parties and/or where the parties have each had a measure of success.

The beneficiary of a costs order can usually claim for disbursements incurred in connection with the proceedings, including court filing fees and other administrative fees. Costs orders are generally made, quantified, and satisfied, after all other aspects of the substantive dispute have been finally determined. Interim costs orders on discrete issues (such as the costs of a contested interlocutory application) are very common, but, except with the leave of the court, must only be enforced after the conclusion of the proceeding.

In an appropriate case, the court may award costs on an indemnity basis (rather than on a "party and party" basis). The typical recovery rate for indemnity costs orders is approximately 75–90% of the total costs actually incurred. Indemnity costs are typically ordered only where the manner in which a party has conducted the litigation has delayed or unreasonably added to the complexity of the proceeding, or where relevant offers to settle were not accepted (such as "Calderbank" offers).

The principles relevant to costs orders have largely developed through case law, with guidance on certain procedural matters addressed in the various court rules and practice notes.

5.6 Relevance of Claimant/Plaintiff Conduct on Relief

A successful claimant's own conduct is not generally relevant to the award of damages or an account of profits. However, it is a factor that may be taken into account by the court in deciding whether to award any injunctive relief, being a discretionary remedy.

Where a claimant is successful, but has engaged in objectionable conduct (such as causing significant delays, or unreasonably increasing the complexity of the matters in issue), the court may address this conduct in the form of costs orders. For example, the court may apply a discount to the order for costs in the successful claimant's favour, or may order that costs shall lie where they fall. In extreme cases, the court may even make an adverse costs order in favour of the unsuccessful party.

6. Other IP Rights

6.1 Trade Marks

In Australia, trade mark disputes in the life sciences and pharma sector are uncommon, but not unheard of.

A trade mark owner may protect their marks by:

- registration under the Trade Marks Act 1995 (Cth);
- actions for the tort of passing off; and/or
- actions for statutory misleading or deceptive conduct, in contravention of the Australian Consumer Law, being Schedule 2 to the Competition and Consumer Act 2010 (Cth).

Applications for registration under the Trade Marks Act 1995 may be rejected if the trade mark contains or consists of an International Non-Proprietary Name of a pharmaceutical substance (INN), or if the mark has a connotation of an INN. In some cases, such an objection may be overcome by the applicant agreeing to a condition of registration that limits the use of the mark to goods containing that substance. An application may also be rejected if the trade mark contains or consists of the words "patent" or "patented", among other proscribed terms.

6.2 Copyright

In general, there are no copyright law issues specific to the life sciences and pharma sector in Australia.

However, one specific issue that is unique to this sector concerns the copying of approved product information of another drug. Section 44BA of the Copyright Act 1968 (Cth) provides that it is not an infringement of copyright for a person to do certain acts in relation to product information that has been approved under Section 25AA of the Therapeutic Goods Act 1989 (Cth). The permitted acts are, in summary, those connected with seeking marketing approval and those that involve use/communication publicly for a purpose related to the safe and effective use of the medicine. These provisions enable sponsors of generic and biosimilar products to adapt the approved product information of reference products, in certain circumstances, without requiring permission from the innovator.

6.3 Trade Secrets

Trade secret disputes arise occasionally in the life sciences and pharma sector in Australia, but court proceedings are not common. Other forms of intellectual property protection are often considered more appropriate for innovations in this field (such as patents).

The main exception is the protection of confidential information relating to pharmaceutical product formulation and manufacturing processes, where the information will not necessarily become public (or liable to reverse-engineering) upon the launch of the product in the marketplace. Such information is often treated as highly confidential, and claims for breach of confidence pursued wherever there is a threat of information being misappropriated. Where such confidential information must be disclosed in the course of patent infringement proceedings, parties invariably seek and obtain confidentiality undertakings from the recipients, and a court-ordered confidentiality regime that preserves confidentiality by prohibiting further disclosure.

7. Appeal

7.1 Timing to Appeal Decision

Appeal From PI Decision

A decision to grant or deny an application for a PI is interlocutory, rather than final, and leave of the court is therefore required in order for any party to commence an appeal from the decision: Section 24(1A) of the Federal Court of Australia Act 1976 (Cth). An application for leave to appeal may be made orally at the time of the pronouncement of the judgment, or in writing within 14 days of the judgment in question: Rules 35.01 to 35.13 of the Federal Court Rules 2011 (Cth). In pharmaceutical patent cases, applications for leave to appeal from a decision on an PI application are typically heard and determined at the same time as the argument on the proposed appeal itself, such that the appeal court may determine the application for leave and the appeal in one judgment (assuming leave is granted).

Appeal From Judgment at First Instance

Parties have 28 days following the delivery of judgment in Federal Court proceedings to commence any appeal by filing a notice of appeal: Rule 36.02 of the Federal Court Rules. The timing for an appeal hearing is dependent on the court's availability. The Full Court of the Federal Court (ie, the appeals division of the court) generally only sits during four separate months of the year. Where proceedings have been bifurcated such that liability is heard and determined separately and prior to the question of pecuniary relief, the appeal process on the liability issues may be completed before the matter is remitted back to the primary judge for resolution of all outstanding issues (if any).

Standard of Appeal

Appeal proceedings are generally conducted as a rehearing on the merits; they are not proceedings conducted de novo. An appellant must generally demonstrate an error of fact or law on the part of the primary judge that affected the ultimate result.

Special Leave to Appeal to the High Court

From a judgment of the Full Court of the Federal Court, a party may apply to the High Court of Australia – Australia's highest appellate court – for special leave to appeal within 28 days of the judgment below. If special leave is granted, then the matter will be prepared for a substantive appeal before the High Court, which usually takes place in Canberra.

Implications of an Appeal for PIs

The commencement of an appeal does not automatically operate as a stay of the decision the subject of the appeal. Therefore, if a PI is granted, but the first instance judgment finds the patent invalid, the first instance judgment will discharge the PI and it would be up to the applicant whether it wishes to apply for a new PI pending the appeal proceeding.

7.2 Appeal Court(s) Arbiter

Patent litigation appeals are typically heard by a Full Court of the Federal Court of Australia, constituted by a panel of three judges. The appeal judges are drawn from the same pool as the first instance judges. Formally, there is no specialist patent law bench, although the judges assigned to patent cases tend to have significant experience in the area.

7.3 Special Provisions

The Federal Court has issued an Intellectual Property Practice Note, which provides guidance to litigants and practitioners involved in intellectual property proceedings. The practice note covers matters such as:

- urgent applications;
- commencing proceedings;
- case management hearings;
- use of primers;
- product, method or process description documents;
- use of experimental evidence; and
- other evidence considerations specific to intellectual property cases.

8. Other Relevant Forums/ Procedures

8.1 Other Relevant Forums/Procedures

The main forums for life sciences & pharma IP disputes are the Australian Patent Office, the Federal Court of Australia, and the High Court of Australia. Australia has no equivalent to US ITC proceedings.

9. Alternative Dispute Resolution

9.1 ADR Options

All standard ADR options are available for life sciences disputes in Australia. In practice, the most common ADR options are negotiations and mediations – usually conducted in parallel with court action. Binding ADR options (such as arbitration or expert determination) are uncommon in patent infringement/revocation disputes, but common in general commercial disputes within the industry sector (including patent licensing disputes).

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The application of Australian competition law to pharmaceutical patent settlement agreements has not yet been the subject of judicial consideration.

However, this is an area of interest for Australia's competition regulator, the ACCC. In March 2022, the ACCC issued a draft determination proposing to deny a request for authorisation of a settlement and licence agreement reached between Celgene, Juno and Natco regarding Celgene's Revlimid (lenalidomide) and Pomalyst (pomalidomide) patents.

Clayton Utz is a leading, full-service Australian law firm, with a storied 180-year history operating in the global economy for international and home-grown clients. With its Chambers Band 1 Life Sciences practice, comprising over 17 partners located across Sydney, Melbourne and Brisbane, Clayton Utz is internationally recognised for its genuine multidisciplinary, cross-practice approach, and for its work with major industry players across the full spectrum of life sciences issues. Specific areas of expertise include: pharmaceutical and medical device regulatory advice and litigation; intellectual property infringement (both defence and prosecution); competition law; and digital healthcare. The firm's prolific client roster includes: Bayer, Philips Healthcare, Roche, Merck Sharp & Dohme, Novartis and Sandoz. Clayton Utz is also the firm of choice for international law firms.

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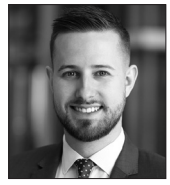

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Trends and Developments

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Overview

Significant decisions in 2022 will shape the Australian IP landscape for pharmaceuticals and life sciences in the coming year. The Full Federal Court provided welcome guidance on patent term extensions in a few different scenarios, and weighed in on important aspects of case management (specifically regarding expert evidence). An unsuccessful application to the Australian Competition and Consumer Commission (ACCC) for authorisation of a patent settlement agreement has, however, left some uncertainty regarding the regulator's views on potentially anti-competitive aspects of such agreements. Further, the relevance of a trade mark's reputation to the question of infringement is currently on appeal to the High Court of Australia.

In 2022, in-person hearings returned to the norm in the Federal Court of Australia and, by November, the court had revoked its COVID-19 "Special Measures" practice notes. While this brought an end to various conveniences and necessities arising from the pandemic, such as the acceptance of unsworn/unaffirmed affidavits, it did not signal the end of remote access to hearings. This has enabled clients and interested observers to view proceedings from the office and around the globe.

Market Developments

The pharmaceuticals and life sciences sector saw significant growth in Australia in 2022, a trend likely to continue in coming years in light of the substantial increase in the number of companies undertaking biotech research in Australia over the last few years, and a record number of new biotech listings on the Australian Stock Exchange. Areas of particular development included medical device technologies (including diagnostics), biotherapeutics, digital health and telehealth, accelerated by an influx of investment on the heels of the COVID-19 pandemic and the Australian government's continued support of a number of industry measures, including electronic prescriptions and the new tax concession for medical and biotechnology innovations (referred to as the "Patent Box"), which came into effect on 1 July. The recently elected Australian Labor Party included a number of important policy commitments in the lead up to its election, including to significant co-investment in advanced manufacturing capability and to drive the University Research Commercialisation Action Plan.

The growth and sustainability of the biosimilars market remained a key policy objective of the Australian government this year. Five biosimilar products were approved by the Therapeutic Goods Administration (TGA) in 2022, although the only "first" biosimilar was of ranibizumab, with Samsung Bioepis's BYOOVIZ joining Novartis's LUCENTIS. Three biosimilar products were listed on the Pharmaceutical Benefits Scheme (PBS), although none of these was the "first" biosimilar brand for any PBS-listed biologics. Eight of the top ten medicines by reimbursement cost to the Australian government in 2022 were biologicals, seven of which remain without biosimilar competition as at January 2023.

Sufficiency of Functional Antibody Claims – A Peek Into the Future Under the "Raising the Bar" Regime

The "Raising the Bar" (RTB) regime introduced higher standards for the validity of patents in Australia, with the intention of more closely aligning Australian law with that in the UK, Europe and the US. The multi-jurisdictional dispute regarding Amgen's patents for anti-PCSK9 antibodies defined by certain functional characteristics provides an opportunity to contrast the position under Australia's "old" laws with decisions overseas, which could represent the position under Australia's "new" laws.

In September 2022, the Australian Patent Office (APO) found the claims of Amgen's patents to be sufficient. In contrast, in Amgen v Sanofi, 987 F 3d 1080 (Fed Cir, 2021) the US Federal Court of Appeal found similar claims to lack sufficiency (although this will be revisited by the Supreme Court).

Under the "old" law of sufficiency in Australia, a claim will be sufficient where the disclosure of the specification enables the skilled addressee, armed with the common general knowledge, to produce "something" within the claim "without inventions or additions or prolonged study of matters presenting initial difficulty". That is, for a product claim, the skilled addressee need only be able to produce a single embodiment. The specifications of Amgen's Australian patent applications disclosed X-ray crystallography data indicating that two antibodies bound to certain epitopes and residues of PCSK9 identified in the claims, as well as the amino acid sequences of and methods of making those antibodies. Thus, the Delegate found that the skilled addressee could make "something" within the claims.

Under the "new" law of sufficiency in Australia, a claim must provide a "clear enough and complete enough disclosure". This requires the skilled addressee to be able to perform the invention across the full scope of the claim without undue burden. The US Federal Court of Appeal found that the art of generating antibodies was generally unpredictable, and that Amgen's US patent claims were far broader in functional diversity than the examples disclosed in the specification. Thus, the Court held that "undue experimentation" would have been required "to synthesize and screen each [antibody] candidate to determine which compounds in the claimed class exhibited the claimed functionality".

While it is difficult to assess the findings which would have been reached in Australia under the RTB regime, it is clear enough that the position under the RTB would likely be far less favourable to Amgen. We are likely to see further development of the Australian approach to sufficiency in 2023 in light of developments in the UK and Europe in this area.

Full Court Cracks the Whip in Case Management

In recent years, the Federal Court has been increasingly conscious of the overarching purpose of its civil practice and procedure provisions, namely to facilitate the just resolution of disputes according to law and "as quickly, inexpensively and efficiently as possible".

In Novartis AG v Pharmacor Pty Ltd [2022] FCAFC 58, Novartis filed affidavits by four neurology experts in response to Pharmacor's one neurologist. Pharmacor (represented by Maddocks) took issue with both the number of experts and the extent to which the evidence was overlapping, and applied to have the majority of the evidence excluded before trial. At first

instance, Justice Burley considered the evidence to be "substantially duplicative" and only permitted Novartis to rely upon one affidavit in full and another in so far as it was confined to factual evidence, with the other two excluded in their entirety. Novartis applied for leave to appeal to rely upon three of the affidavits.

The Full Court dismissed Novartis's application. The Full Court rejected Novartis's submission that the evidence was not substantially duplicative or that the experts' different knowledge was necessary to support its different case theories on validity. The Full Court considered these differences to be of minimal practical significance and the primary's judge's approach to be consistent with modern case management in patent litigation.

In a separate but concurring judgment, Justice Beach provided some helpful guidance for litigants, including that the default position is that a party should not adduce expert evidence from more than one expert in a single discipline, unless this has been flagged with the other side and the Court in advance. A party will need to justify any departure from the default position, for example by establishing that different questions had been asked of different experts (and why this was necessary) or that different experts had substantially different knowledge and experience.

As the scope and complexity of large-scale patent litigation only increases, this decision is a timely reminder for litigants to ensure expert evidence is confined to that which is necessary, so that proceedings are run efficiently and cost-effectively.

Trade Mark Infringement When Presenting a Product as an "Alternative" to a Competitor's

In October this year, the High Court heard an appeal which will shape the use of comparative advertising.

A dispute arose between Allergan, the owner of BOTOX trade mark registrations, and Self Care, who marketed a range of anti-wrinkle skincare products under the umbrella brand name "Freezeframe". The Freezeframe line of products includes:

- "PROTOX", a skincare product advertised as an injection-free solution to "prolong the look of Botox"; and
- "Inhibox", a skincare product advertised to be an "instant Botox® alternative".

The primary judge found that consumers were unlikely to mistake PROTOX for BOTOX in light of the ubiquitous reputation of the BOTOX marks. Further, "Botox" was not being used as a badge of origin, but as a descriptive word. The Court said that any possible conclusion that there was an association or approval by Allergan of the "Botox" brand was dispelled by the use of the word "alternative".

This decision was overturned by the Full Court. The Full Court held that PROTOX so nearly resembles BOTOX that there was a real risk that PROTOX would deceive or cause confusion as to whether the two might come from the same source. Further, the Full Court disagreed with the primary judge that Self Care's use of the mark in referencing a "Botox alternative" was descriptive. Even though the word "alternative" implied the two products were different, the phrase did not necessarily imply that the trade source was different. Thus, it was held that the phrase was

being used by Self Care to denote a trade source connection with Allergan's products.

In addition, despite accepting that the Inhibox product packaging identified Allergan as the owner of the BOTOX trade mark, the Full Court held this was not sufficient to dispel doubt as to the trade source of Inhibox products – a consumer might reasonably believe that Self Care had a licence or authorisation from Allergan to use the BOTOX trade mark on its packaging.

Self Care sought to rely upon the comparative advertising exemption to trade mark infringement under Section 122(1)(d) of the Trade Marks Act 1995 (Cth). The Full Court rejected these submissions, as follows:

- Section 122(d)(1) only applies to the use of "the" trade mark, which in this case was the registered trade mark BOTOX, not the phrase "instant Botox® alternative"; and
- Self Care's use of the phrase "instant Botox® alternative" did not involve any direct comparison between the Inhibox product and the BOTOX product, and hence was not used for comparative advertising. Rather, the phrase was used "to leverage off the reputation of BOTOX".

In a final blow, the Full Court found that Self Care had breached the misleading or deceptive conduct provisions, and the false or misleading representations provisions, of the Competition and Consumer Act 2010 (Cth) (CCA).

Self Care sought and obtained special leave to appeal to the High Court of Australia.

One of the key issues on appeal was the extent to which reputation of the BOTOX mark is relevant to the question of infringement. Both Allergan and Self Care submitted that it is not. During the hearing in October 2022, the High Court expressed concern that it was being asked to overrule a line of authorities regarding the issue of reputation without a contradictor. As a result, the High Court adjourned the matter to receive written submissions from amicus curiae before hearing further oral argument from the parties and amicus curiae in December 2022.

It is hoped that the High Court's much-anticipated judgment in this dispute will provide clarity to businesses with comparative advertising in their marketing strategies. Of particular interest is whether those defending an infringement claim can continue to rely on arguments that a well-known brand simply has too much reputation to allow any sort of confusion with a similar mark.

Pharmaceutical Patent Settlements – Seeking Authorisation From the Regulator

This year 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 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 com-

ment 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, we think parties should not lightly be deterred from reaching appropriate settlement arrangements.

Patent Term Extensions

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.

First in best dressed

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.

Patent licensing and PTE errors

PTEs were again in issue in the long-running litigation between H Lundbeck A/S and its Australian subsidiaries, on the one hand, and a number of generic companies including Sandoz Pty Ltd, on the other hand, this time in the context of patent licences: H Lundbeck A/S v Sandoz Pty Ltd [2022] HCA 4.

Lundbeck had a patent over the compound escitalopram, which was filed on 13 June 1989 and originally due to expire on 13 June 2009 (after the standard 20-year term). In February 2007, Lundbeck and Sandoz entered into a settlement agreement to resolve Sandoz's challenge to the validity of the patent. Clause 3 of the settlement agreement granted Sandoz a non-exclusive licence to launch two weeks before various possible expiry dates for the patent, namely the original expiry date, 9 December 2012 and 13 June 2014 (each being a potential extended expiry date), and any other date on which the patent expires.

On 12 June 2009, one day before the expiration of the patent, Lundbeck applied for an extension of time to apply for a PTE. Following various appeals, in June 2014 both the extension of time and the PTE were granted, which extended the term of the patent to 9 December 2012. In the meantime, Sandoz had launched its escitalopram products on 15 June 2009.

Lundbeck brought infringement proceedings against Sandoz in the Federal Court for infringement of the patent between 15 June 2009 and 9 December 2012. At first instance, Justice Jagot found against Sandoz. On appeal, the Full Court overturned Justice Jagot's decision, finding that Sandoz had held a non-exclusive licence from 31 May 2009 to 9 December 2012 through the operation of the settlement agreement. Lundbeck sought and was granted special leave to appeal to the High Court of Australia.

The principal ground of Lundbeck's appeal concerned the competing interpretations of clause 3 of the settlement agreement, including the expression an "irrevocable non-exclusive licence to the Patent".

The High Court considered that clause 3 had the effect that, regardless of what the expiry date of the escitalopram patent ended up being, the irrevocable non-exclusive licence was to commence two weeks before that date and end on the expiry date. Thus, clause 3 conferred on Sandoz no more than permission to sell pharmaceutical products containing escitalopram from 31 May 2009 to 13 June 2009 (being the original expiry date of the patent).

The High Court also clarified the position regarding standing to bring infringement proceedings under Section 79 of the Patents Act, whereby a patent has expired before a term extension is granted. While a patentee can bring proceedings under Section 79 (but only after the PTE is granted), an exclusive licensee has no standing to do so.

While the facts of this decision are unique and unlikely to be repeated, the guidance of the High Court is of general significance to the construction of contracts in Australia, and to IP licensing in particular. Notably, it confirms that Australian courts will construe commercial agreements by ascertaining what a reasonable person in the position of the parties would have intended, with inferences about that meaning to be drawn from information reasonably available to both parties. The High Court has also reminded lawyers drafting contracts in respect of statutory rights such as patent rights in Australia that the words used will ordinarily be interpreted by the court to have their statutory meanings.

Maddocks has extensive experience across the life sciences, pharmaceutical, biotech and digital health sectors, in both litigious and commercial matters. Maddocks' specialist teams provide strategic advice, freedom to operate advice, litigation, IP licensing and commercialisation services across the full spectrum of IP matters, in particular for patents and trade marks. The firm combines its IP expertise with market-leading healthcare and TMT practices in Australia to realise opportunities for its clients in 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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Trends and Developments

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Changes in Indian IP Jurisprudence Since the Abolition of the Intellectual Property Appellate Board

Patent litigation in India, especially in the pharmaceutical and life sciences sector, has by and large been associated with the jurisprudence that has emerged from the decisions of the High Court of Delhi, and to some extent the Intellectual Property Appellate Board (IPAB).

The year 2022 saw a change in this status quo. Legislative changes such as the abolition of the IPAB, as well as the inclusion of other civil courts in India (such as High Court of Himachal Pradesh and the High Court of Telangana) as venues in which pharmaceutical companies could "battle it out", were some of the contributing factors.

With the IPAB (a quasi-judicial body) abolished, High Courts in India have once again been tasked with sitting in appeal over decisions of the Indian Patent Office (IPO). As a result, 2022 saw several decisions which have clarified the law, not just on core issues of patent litigation, but also those concerning patent prosecution, and its governing legal principles.

Furthermore, the previous year also saw the Competition Commission of India decide (and dismiss) perhaps India's first antitrust complaint against a pharmaceutical entity which was accused of being anti-competitive for having denied a licence to an Indian entity.

This article enlists some of the key developments that have taken place in India in 2022.

Pharmaceutical Patent Licensing and Competition Law

The past 12 months have seen India's first ever decision by the Competition Commission of India concerning a claim of anti-competitive behaviour and abuse of dominance against a pharmaceutical entity. The case concerned allegations against Vifor, which holds a patent for Ferric Carboxymaltose (used for treatment of iron deficiency anaemia). (Re: Swarapn Dey and Vifor International (AG), Case No 05 of 2022)

The antitrust claims against Vifor were that it was preventing fair competition in the market, by granting licences only to two entities in India. Further, Vifor's supply to government institutions at a lower price than its market cost, was also claimed to be anti-competitive. However, the denial of a patent licence by Vifor to an entity named West Bengal Chemical Industries Limited was really at the heart of the dispute.

Although the Competition Commission of India held that it did have the jurisdiction to hear anti-competitive claims against a patent-protected drug, it dismissed the complaint against Vifor at the initial stage. The reasons of the commission are as follows:

- Vifor's patent licence agreements are short term (three years), with the possibility of extension. They are not restrictive or one-

sided, and do not impose any unreasonable limits that can be deemed anti-competitive.
- The patent is expiring in October 2023, and thus, all interested players can enter the market with their respective versions after that.
- Vifor has the freedom to choose its own trading partners. Not every company has the right to seek access to Vifor's patent, unless such companies can establish a legitimate need to access the patent.
- Not all price differentiation is discriminatory, especially if it is based on reasonable classification of consumers. Prices under government procurement programmes are not comparable with those applying to the open market (bulk v individual buying).
- Vifor did not receive a satisfactory request for a patent licence from third-party entities (barring its licensees). Any party interested in securing a licence must be able to demonstrate its ability to satisfy the requirements of the patent holder.

The decision by the Competition Commission of India is encouraging, and with pharmaceutical patents making their entry into the IP-competition law saga, India's first decision on this aspect makes for a healthy and welcome start.

Strengthening Jurisprudence on Patent Infringement

Indian patent law has come a long way in the last decade. Not too long ago, Indian IP was dominated by trade mark and copyright-related disputes. Patent decisions, which interpreted the law were few and far between.

In 2013, the Supreme Court of India passed a landmark judgment in Novartis v Union of India (CA 2706-16 of 2013) which interpreted the provision of Section 3 (d) of the Patents Act, 1970 in a manner unique to India. The Court held that a new form of a known substance would be entitled to patent protection, only if the new form possessed enhanced therapeutic efficacy over the known substance.

Two years later, in 2015, the Delhi High Court delivered two landmark, final decisions in the pharmaceutical patent field. F. Hoffman La Roche v Cipla Ltd (RFA (OS) 92/2012) and Merck Sharp & Dohme Corporation v Glenmark Pharmaceuticals, cs (OS) 586/2013 not only recognised infringement of patents but dealt with complex legal principles. These decisions discussed the importance of claim construction, a breakthrough invention, the understanding a Markush claim in a genus patent and deciding infringement of such a patent; the duty of candour, etc.

The year 2023 saw the courts recognise such and other principles of law on genus and species patents as being well-established and requiring no further reconsideration. As a result, with courts being well-versed in a multitude of issues, and having access to a vast body of work as reliable precedent, a large number of decisions on patent infringement were passed by Indian courts, in a rather short period of time.

Disclosure coverage, prior claims, etc, are no longer grey areas

A recent decision in Novartis v Natco Pharma, CS(COMM) 299/2019 (9 January 2023), concerning infringement of Natco's patent over its non-small cell lung cancer drug Ceritinib, saw the court reject the defendant's arguments with relative ease and clarity. This is an encouraging trend, because the defences raised by the defendant, until a year ago, were untested and would consume a lot of judicial time. Some of the concepts clarified by the Court in this case are as follows.

Prior claiming
Unless the cited prior art contains the same compound, which is the subject matter of the patent, prior claiming cannot be established.

Disclosure v coverage
Mere coverage of a compound, within a Markush structure given in prior art, is not equivalent to disclosure of the compound. Disclosure must be "enabling in nature", and the prior art must contain teachings to enable a "person of ordinary skill in the art (POSA) to make the correct substitutions to reach the compound of the subsequent patent". Therefore, obviousness is the determining criterion to assess disclosure and anticipation.

Obviousness and inventive step
The absence of a third party being able to reach the compound from the teachings in the genus patent is a relevant element in the determination of whether the invented compound is obvious. Further, hindsight bias must be factored and duly considered by the court. When the prior art being considered is a genus patent with a Markush moiety, the difficulty of establishing obviousness increases significantly.

FDA Orange Books, patent term extensions in the USA
It is common practice for patent owners to make declarations to authorities in the USA that a particular drug, if manufactured by a third party, would infringe multiple patents. Such declarations are found in the USFDA Orange Book, as well as applications filed for patent term extensions in the USA. However, this does not mean that the compound is disclosed in the genus patent. This is because a generic drug will infringe not only the specie patent claiming that compound (drug), but also an earlier, genus patent, which does not claim the drug. Therefore, Orange Book declarations and patent term extensions only show that the drug is covered by the genus patent, and do not in any manner, indicate disclosure and anticipation.

Doctrine of equivalents – with a new spin
A Division Bench of the Delhi High Court revisited the doctrine of equivalents, in the context of process patents (FMC Corporation v Natco, FAO (OS) (COMM) 301/2022).

It rejected the argument that the doctrine of equivalents is applicable only in the case of product patents. Instead, it held that, the three ingredients of the doctrine:

- performance of substantially the same function;
- such performance being substantially in the same manner; and
- the result achieved being the same,

may require a slight adjustment in the context of process patents. The Court held that to assess similarity of the two competing processes, a three-part test should be used:

- identify the essential elements of the two processes;
- identify the necessary steps of the two processes; and
- examine the interaction of the key elements at each step.

Only when there is substantial similarity in the three aspects of both the processes involved will infringement be established under the doctrine of equivalents. Further, any changes between the two processes must be minor and non-essential to establish infringement.

Balance of convenience favours a registered patent

Because the Patents Act, 1970 enables challenges to the validity of a patent at several stages, even after its grant, one of the most repeated arguments by generics players in patent litigation was that the grant of a patent is not a relevant factor in deciding whether an interim injunction should be granted against a generic drug.

However, this argument has gradually been rejected. One of the latest decisions to do so is MSN Laboratories v Novartis [COM CA 21/2021 (14th February 2022)], by the Telangana High Court. Here, the court held that the very fact that a patent has been granted after significant scrutiny and examination by the IPO significantly bolsters the patent holder's case.

Therefore, once the IPO has already taken a view that the patent is novel, has an inventive step and is capable of industrial application, the court will usually be persuaded to agree that the patentee has established a prima facie case on validity and that the balance of convenience favours the grant of an injunction. An interim injunction will be refused only once the defendant is able to establish a very strong case against the validity of the patent. The onus to prove this aspect is a very heavy one.

Clearing the way – the calculated decision to launch a drug during a patent's term ought to be awarded with an interim injunction

The High Court of Shimla has passed a number of orders granting interim injunction to Boehringer Ingelheim, restraining several generics players from manufacturing or selling generic Linagliptin (used in the treatment of type 2 diabetes).

In one such case, Boehringer Ingelheim Pharma v Excel Drugs & Ors., COMS Nos 7, 8 and 9 of 2022 (2nd June 2022), the High Court, after dismissing claims of prior claiming and evergreening, held that the defendant's action of launching an infringing drug during the term of the patent was a calculated decision. Before doing so, the defendant did not challenge the patent (through a revocation petition or other means), and this calculated decision works against it, and favours the plaintiff's claim for an interim injunction instead.

Injunction refused due to evergreening

The Delhi High Court rejected an interim injunction and allowed the manufacture and sale of the insecticide product, Chlorantraniliprole (CTPR). (FMC Corporation v GSP Crop Science Pvt. Ltd., CS (COMM) 662/2022) The claim in the patent concerned an intermediate used in the manufacture of CTPR.

The Court found that CTPR itself was the subject matter of at least 30 patents and applications in India, excluding the Markush patent, the compound patent for CTPR and the process patent involved in the suit. Calling it a "maze of patents", the Court observed that such patents and applications related to the preparation of intermediates, processes for various steps in the preparation of those intermediates, processes for preparing crystals comprising certain intermediates, methods for synthesising intermediates, and methods for preparing anthranilamide compounds.

The Court said that the law recognising multiple patents for different aspects of a product is one thing, while serial patenting to evergreen a particular monopoly, is quite another.

Another aspect leading to the denial of the requested injunction was the Court's observation that the process of the suit patent was

already disclosed and claimed in a prior patent concerning the process to manufacture CTPR. The differences in the claims of the two patents were found to be superficial.

The Court also found infirmities in the submission made before the Indian Patent Office (IPO) by the patentee during the patent's prosecution, as the IPO was not informed that the corresponding patent in EU had lapsed, and that the patent was abandoned in Japan.

Lastly, the Court also held that the fact that a patent had not been put to use in India for 19 years (out of a 20-year term) is also a relevant factor, in denying an interim injunction.

Simplicity No Bar to Grant of Patent

In Avery Denisson Corporation v Controller of Patents & Designs (2022/DHC/004697), concerning an appeal against the refusal of a patent for a "Notched Fastener", the Delhi High Court gave welcome and needed clarity to the IPO, that the mere simplicity of an invention is not a criterion for refusing patent protection.

As regards the assessment of inventive step, the Court held that one must also bear in mind the time gap between the prior art document and the invention under consideration. Lapse of a long period of time since the publication of the prior art, would work in favour of patenting an invention, no matter how simple it may be, especially if it resulted in unpredictable advantages over the prior art.

In its decision, reversing the IPO's refusal of a patent for the invention, the Court also considered that the corresponding patent had been protected in the USA, Japan, South Korea and China.

Amendment of Patent Applications Not to Be Rejected on Hyper-technical Grounds

An application to amend before the patent is granted should be treated with leniency

Nippon A&L Inc. v The Controller of Patents saw the Delhi High Court present an interesting difference between the treatment to be given to an application to amend a patent prior to its grant versus an application to amend a granted patent.

The Court held that the legislative scheme of the Patents Act, 1970 calls for lenient treatment for an application to amend claims and specification prior to the grant of a patent, while calling for a restrictive approach after the grant and advertisement of a patent.

The Court reiterated the well-established test that that so long as the invention is disclosed in the specification and the amended claims are restricted to disclosures already made in the specification, the amendment application should not be dismissed by the IPO at the threshold. With this test, the Court observed that the desire to amend the patent from a product-by-process patent to a process patent was admissible, as the scope of the patent application was being narrowed, and not expanded.

On this basis, the IPO was directed to rehear the application to amend the patent afresh.

No foreclosure of right to amend a patent at the time of national phase filing of a Patent Cooperation Treaty (PCT) application

A recent decision in Allergan Inc v Controller of Patents (2023/DHC/000515) saw the court hold that the right of a patent applicant to amend the claims (vis-à-vis the originally filed foreign PCT application) is not foreclosed, as there is no occasion provided to the applicant to amend the

claims at the time of the PCT application entering the India national phase.

In this case, the original application filed in the USA contained method claims. Such claims are recognised in the USA, and the patent was duly registered. In India, method claims are not patentable under Section 3 (i) of the Patents Act, 1970. Therefore, the invention as filed originally in the USA would not be patentable in India.

Thus, the patent applicant sought to amend the method claims into product claims. The IPO, however, had raised an objection, stating that the amendment may be impermissible, as the amended claims (product claims) were not contained in the claims as they were originally filed in the US application.

However, the court recognised the glitch, and remedied it by holding that since there was no occasion for patent applicants to amend the claims as originally filed in the USA, they could not be faulted for the national phase application not having the amended product claims.

Further, the court also held that while the US application claimed methods for treatment using intracameral implants; the amendment in India to claim the implants (product) should be allowed. This is because, the implants were disclosed in the complete specification of the US patent.

Next, the court had to interpret the test of Section 59 of the Patents Act, 1970 concerning the amendments sought in a patent, and whether they were disclosed in the original patent, or would fall within the scope of the claim of the original patent (as opposed to a divisional application, which is discussed later).

The court held that disclosure and "scope of a claim" cannot be assessed only by reading the original claims, while ignoring the complete specification. Dichotomising claims and complete specification is incorrect. Therefore, the court held in favour of the amendment, as the implants were disclosed in the specification of the original, US application.

Divisional Patent Applications

Boehringer Ingelheim v The Controller of Patents (2022/DHC/0026682), saw the Delhi High Court shed light on the concept of "plurality of inventions" and the circumstances under which the filing of a divisional application for an additional invention claimed in the parent application can or cannot be accepted.

The Court held that for the purpose of deciding whether there is a plurality of inventions in the parent patent application, the following aspects are relevant:

- Though the specification describes the invention, the scope of the invention itself is defined in the claims.
- Although the claims have to be based on the disclosure in the specification, if one wishes to ignore the specification and still identify the invention, the place to look is the claims.
- The unity of invention, plurality of inventions, and whether they form a single inventive concept, have to be gleaned from a perusal of the claims.
- If the subject matter of a divisional application is not contained in the claims, but is contained in the specification instead, such a divisional application cannot be granted. Allowing such applications would be ignoring the fundamental rule of patent law – ie, what is not claimed is disclaimed.

Based on this legal test, the Court denied the divisional application as the original DPP IV inhibitor was not claimed as a product claim in the parent application (albeit it was disclosed in the specification and was mentioned in the examples of the specification). The parent application contained only method claims, while the divisional application claimed products (medicaments or their combinations). Thus, the Court held that the claims of the parent application did not contain a plurality of inventions.

Conclusion

The past year has seen several decisions in India that show that the pharmaceutical patent regime has changed gears from being merely "mature" to having command and expertise of deep and complex aspects. The year 2023 promises to deliver compound interest on the investments made over the years by litigants, lawyers and judiciary alike.

Anand and Anand is a pre-eminent, full-service intellectual property law firm based in New Delhi, India. Founded in 1923, the firm's 100+ professionals (31 partners) work with leading businesses, brands, institutions, and personalities across the globe for their intellectual property needs. The firm offers a full range of legal services for the acquisition, commercialisation and building of IP portfolios and the enforcement of intellectual property rights in the areas of patents, designs, trade marks, copyrights, trade secrets, domain names, geographical indications, data privacy, and more. Highly regarded in the market, the firm has been instrumental in paving the way for a stronger IP regime in India and is committed to pushing the envelope when it comes to change in substantive and procedural law, and helping clients monetise their intellectual property.

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Contents

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Infringement

An infringement action must involve, on the plaintiff's side, the patent owner or its exclusive licensee; and, on the defendant's side, the alleged infringer and any party involved in the infringement whose participation is necessary to efficiently decide all issues of the claim.

Where a patent is co-owned, each co-owner may file an infringement claim. If the other co-owners (or the exclusive licensee) do not join as plaintiffs, the suing co-owner must name them as defendants. This is also true where a patent owner does not join an exclusive licensee's claim and vice versa.

A patent owner is defined under the Patents Law as "the person registered in the Register as the person to whom a patent was granted or to whom ownership of a patent has passed"; an exclusive licence affords its holder the right to "[exploit the claimed invention] as if it was the owner of the patent" and "prohibits the owner of the patent from exploiting in Israel the invention that is the subject of the patent".

Revocation

Any person may submit a motion for revocation, without being required to show any particular interest.

1.2 Defendants/Other Parties to an Action

Under Israeli law, a plaintiff must join to its claim all those parties whose participation is necessary to efficiently decide all issues involved in the claim. Where Life Sciences/Pharma cases are concerned, that usually means the manufacturers and/or importers of the infringing products (and/or those parties contributing to the alleged infringement). Other parties, such as health maintenance organisations (HMOs, called "sick funds" in Israel), although dealing in distribution of drugs, are not sued in practice. Doctors who prescribe drugs are not sued and they might be exempted under the rule de minimis non curiat lex or under the so-called private use exemption.

1.3 Preliminary Injunction Proceedings

Availability of Preliminary Injunctions and Timing of a Decision

A party bringing an infringement claim may move for the issuance of an interlocutory injunction against the alleged infringer, including ex parte. The plaintiff-applicant would normally file such motion alongside the filing of the case-in-chief, or beforehand, in situations of urgency, on the condition that the case-in-chief would be filed up to seven days following the issuance of a decision in the motion for preliminary injunction.

In urgent matters, motion for a temporary injunction may be filed ex parte, and a decision may be issued without hearing the respondent, within a day or two at most, according to which a hearing would be set as soon as possible, and, in any case, within 14 days. If the court is disinclined to issue a temporary injunction ex parte, it will schedule a hearing as soon as possible, usually immediately after the defendant-respondent filed its response to the motion for interlocutory remedies. Under the Civil Procedure Regulations (CPRs), the hearing will take one day and will include oral summations. The court will then issue its decision immediately after the hearing and, in any case, no later than 14 days following the hearing.

Considerations in Granting Preliminary Injunctions

A court with which a motion for a preliminary injunction has been filed must be convinced that the matter is urgent and will first consider whether the plaintiff-applicant has shown a prima facie case for infringement. While the defendant-respondent may argue non-infringement, they will not be able to challenge validity at that stage unless invalidity of the alleged patent – at a prima facie level – is abundantly clear and could be established without an in-depth review of the evidence.

In addition, the plaintiff-applicant must show that the balance of convenience tilts in its favour, namely that the injury that would be caused to the plaintiff-applicant by non-issuance is more severe than the injury the defendant-respondent would suffer as a result of the issuance of the injunction.

Finally, the court will weigh considerations such as laches (namely whether the plaintiff-applicant acted expeditiously enough to protect its rights upon learning of the need to do so) as well as good faith (namely whether the plaintiff-applicant had acted in an equitable manner and disclosed all pertinent facts).

Prerequisites to Filing a Motion for a Preliminary Injunction

A claim for patent infringement and a motion for a preliminary injunction can only be filed with respect to a granted patent, and the plaintiff-applicant must be able to show that the defendant-respondent has exploited – or is immediately about to exploit – the claimed invention, with such exploitation being defined as either "production, use, offer for sale, sale, or import for purposes of one of the said acts". Quia timet reliefs are available, provided that a substantial danger of infringement is shown.

Effecting Service of Motions for a Preliminary Injunction

If a motion for a preliminary injunction was filed ex parte, and an interim injunction was issued, the plaintiff-applicant must serve it on the defendant-respondent immediately and, in any case, no later than three days from the day in which it was issued. Usually, the defendant-respondent will be instructed to file a response prior to the hearing taking place.

If no order was issued, or if the motion for a preliminary injunction was filed inter partes, the plaintiff-applicant must immediately serve it on the defendant-respondent. In most cases, the court will set short deadlines to file a response to the motion, and, if no such deadline is provided, the defendant-respondent will have 20 days to file a response.

Both motion and response must be supported by an affidavit or affidavits detailing all those facts alleged by the parties.

1.4 Structure of Main Proceedings on Infringement/Validity

A defendant in an infringement claim may – in addition to arguing non-infringement – raise validity arguments in defence. This will not automatically lead to the proceedings' bifurcation: usually, both infringement and validity are heard concurrently, though the court has the discretion to instruct otherwise.

A defendant may also file a motion for the revocation of the patent with the Patent Office. In such case, the court hearing the infringement claim will decide which instances will hear the issue of validity – the Patent Office or the court

itself – and the Patent Office will not hear the revocation motion unless authorised to do so by the court. Where the defendant instituted the revocation proceedings before the plaintiff's filing of the action with the court, the patent office will proceed with the hearing of the revocation, unless the court instructs otherwise. There is no rule that prohibits a person from filing revocation proceedings while there are pending revocation proceedings (oppositions in Israel are conducted before the patent grant, following patent examination).

1.5 Timing for Main Proceedings on Infringement/Validity

According to Section 179 of the Patents Law, an infringement action shall be brought only after the patent has been granted; however, once an action for infringement is brought, then the court may – (1) award compensation for exploitation of an invention committed after the date of publication under Section 16A (basically, 18 months from priority date) and before the date of publication under Section 26 (publication for third-party oppositions after allowance); said compensation shall be set at a reasonable rate for royalties which the infringer would have paid had he been granted licence to exploit the invention at the scope in which its aforesaid exploitation was committed; however, said compensation shall not be awarded unless the court finds that it constitutes an infringement of the patent as granted, and on the condition the invention claimed in the application is identical in a substantive manner to the invention claimed in the application published under Section 16A; (2) grant relief for an infringement committed after the date of publication under Section 26.

Prescription

The period of limitations under Israeli law to launch an infringement action is seven years in accordance with the general principles set out in Section 5 of the Limitations Act 1958. If the patentee was not aware of the infringement for reasons beyond their reasonable control, the seven-year limitation period would only begin on the day on which the infringement has become known to the patentee (Section 8 of the Limitations Act). Further, in case of a continuing infringement, the continuing wrong doctrine would apply, and it will save all claims for recovery of damages but only to the extent of infringements committed within the seven-year limitations period. Thus, the patentee will be entitled to an injunction preventing prospective infringement as well as to damages with regard to the part of the infringement that is not subject to limitations.

Conversely, there are no limitation periods with regard to validity challenges, either as a defence against an infringement action or as part of a motion for revocation filed with the Patent Office; as long as a patent is alive, its validity may be challenged.

Acquiescence

Even if a given cause of action for infringement has not yet prescribed, it is possible that the defendant will raise an argument of acquiescence against it if the defendant is able to show that the plaintiff had actively provided a representation of waiving its cause of action; it is possible that the action would be rejected due to estoppel.

Effecting Service in Actions Before the Court

Under Israeli law, a court acquires jurisdiction by way of effecting service. There are several ways to effect service on a defendant: a copy of the statement of claim, which includes summons, may be served on the defendant themselves, at their home or at their place of business, either via

courier or via registered mail, on an adult family member living with them, on a person authorised to manage their business, or on their counsel. Where the defendant is a company, service is usually effected by delivering a copy of the statement of claim to their registered place of business. In those cases where the defendant is not Israeli, leave for service outside the jurisdiction would need to be secured, though it would also be possible to effect service by serving the claim on the foreign entity's business manager in Israel (if such exists).

Service should be carried out immediately upon filing and no later than three days from the date of the filing. While a plaintiff may choose to wait the entire three-day period, doing so would mean that the 60-day period to file a statement of defence would be counted from the date of actual service.

Effecting Service in Nullity Proceedings Before the Patent Office

Where proceedings before the Patent Office are concerned, the Patent Office would advise the patent owner of the filing of the motion for revocation using the "address for service" recorded on the Register, and the applicant may do the same, thus effecting service.

Duration of Proceedings on the Merits

Both infringement and nullity proceedings can take anywhere between 24 and 36 months and sometimes even longer.

If the case is heard before a court, the parties would first exchange pleadings (a statement of claim, a statement of defence, and a statement in reply), conduct discovery proceedings, file their evidence, appear for trial (cross-examinations), and then file their summations, following which a decision would be handed down by the court. In addition, motion practice is likely to take place, covering subjects such as discovery disputes, the responsiveness of evidence, filing of additional evidence, production of witnesses, and extensions of time.

The exchange of pleadings will take, in most cases, between three and nine months. Discovery may take an additional six months, while the production of evidence would take a year to eighteen months. The trial will usually not take more than a week or two, with summations taking up to a year.

Where nullity proceedings before the Patent Office are concerned, those would generally take less time than a court action would, as they do not include a discovery stage and unify the exchange of pleadings with the filing of evidence.

1.6 Requirements to Bring Infringement Action

Under Israeli law, a patent becomes assertable only once it is granted by the Patent Office, with no additional requirement, such as validation or the deposit of translations. The plaintiff bears the onus to show infringement (both the evidential burden as well as the burden of persuasion), while the defendant bears the onus to show invalidity.

Section 50(b) of the Patents Law provides for a reversal of burden of proof with respect to process patents, stating that "[F]or purpose of an invention that is a production process – in an action for infringement the defendant must prove that the process used by him for the production of an identical product differs from the patent-protected process". The Patent Law further provides that "an identical product which was produced without the consent of the paten-

tee shall, unless otherwise proven, be deemed a product produced by a patent protected process", subject to the patentee being unable to find out by reasonable efforts which production process was actually used, and it being highly reasonable that the identical product was produced by the patent-protected process.

1.7 Pre-action Discovery/Disclosure

The CPRs do not provide for pre-action discovery.

1.8 Search and Seizure Orders

Search and seizure orders are both available under Israeli law.

If filed in the framework of a motion for interlocutory remedies, that motion would be heard ex parte unless the court believes that hearing that motion inter partes would not thwart the purpose of those remedies.

A search and seizure order may not be executed by the applicant's attorneys, but rather the plaintiff-applicant should request the appointment of a temporary receiver, empowered to enter the defendant's premises in order to search, seize and assume possession over assets that are attesting to the infringing activity or are otherwise required for adjudicating the action (Anton Piller-type order).

The plaintiff-applicant will need to show – in addition to showing they have a prima facie cause of action – that there is strong prima facie evidence that, without the appointment of a receiver, the assets might be destroyed or otherwise become unavailable, thus thwarting the legal proceeding or the carrying out of the yet-unissued judgment.

1.9 Declaratory Relief

Israeli courts are generally empowered to issue declaratory relief if they deem it necessary, and the case law has established two main principles in that respect.

The first principle is that a declaratory order would not be issued if such issuance would result in a bifurcation of a given claim. In other words, the court would not grant a patent owner a declaration of infringement if it would only serve as a precursor to a separate claim for damages.

The second principle is that negative declaratory orders would be issued only in rare cases and subject to the existence of a legitimate interest.

Section 187 of the Patent Law includes specific stipulations regarding the issuance of a declaratory order with respect to non-infringement. Under this specific arrangement, a person intending to exploit any product or process may apply to the court for a declaration that the said exploitation does not constitute an infringement of a given patent.

Section 187 further provides that the court shall not grant the declaration, unless the applicant is able to show that they gave the patent owner full particulars of the product or process they wish to use, have asked them for the declaration for which they apply to the court, and the patent holder has refused to make it or has not made it within a reasonable period. In such proceedings – to which the patent owner and the exclusive licensee must be joined as respondents – the parties' costs shall be borne by the applicant for the declaration, unless the court orders otherwise, and no argument of invalidity will be heard, nor will its result have any bearing on the issue of validity.

1.10 Doctrine of Equivalents

The Patents Law provides that infringement may be established by exploiting the invention as defined in the claims (literal infringement) or by exploiting the "essence of the invention in light of the claims" (non-literal infringements). In order to address non-literal infringements, the Supreme Court of Israel, influenced by the US Supreme court ruling in Graver Tank & Manufacturing Co v Linde Air Products Co [339 US 605, 70 S Ct 854 (1950)] adopted the so-called Function-Way-Result test, which provides that if the accused device or process performs substantially the same function as the invention, in substantially the same way to reach the same result, it is infringing.

Later decisions employed this doctrine of equivalents with respect to pharmaceutical inventions. In one matter, the plaintiff claimed patent infringement over a formulation of a drug for the treatment of ulcers. The court found that the changes the defendant introduced into the formulation of its manufacture (the adding of an internal layer comprised of a sugar core) could not assist it in evading infringement, as it did not change the functioning of the accused formulation, which is done in the same way as the invention and also achieves the same result by applying the inventive solution of the patent.

1.11 Clearing the Way

Under Israeli law, a person may launch a product "at risk" – namely when there is a patent claiming it – and such a person does not have to first initiate legal proceedings to revoke those patents ostensibly blocking its path, or to obtain a legal opinion of freedom to operate; failing to implement precautions against a finding of infringement could, in certain circumstances, support a contention of infringement.

1.12 Experts

The use of expert evidence in infringement and nullity proceedings in Israel is commonplace. Expert evidence in patent infringement proceedings is normally filed by each of the parties in the form of expert opinions, with those experts being later cross-examined during the evidentiary hearings (trial). The drafts of such opinions, as well as all communications between an expert and the party by which it was retained, are privileged.

Where the questions in dispute relate to different fields, it is possible that a party will provide evidence from several expert witnesses to address each field separately.

While experts are retained by the parties, they are expected to assist the court in its fact-finding mission rather than serve as advocates for the cause of the party which had retained them.

The court may appoint its own expert in addition to the parties' experts. The parties may agree that the opinion of the court expert will replace the opinions of the parties' experts. The parties are entitled to cross-examine the court expert. The court is also empowered to appoint an assessor to advise the court on technical matters.

1.13 Use of Experiments

During both infringement and validity proceedings, it is possible to submit experimental results to show infringement or validity, eg, in support of claims of inventive step, lack of enablement, or lack of utility. Such results are filed with a supporting affidavit attesting to the conditions of the experiments and the results.

1.14 Discovery/Disclosure

Under Israeli law, parties to a claim (including an infringement claim) must disclose all relevant documents to the opposing party. Copies of non-privileged documents need to be provided to the other party for inspection, in full or redacted form (eg, in case they contain trade secrets).

1.15 Defences and Exceptions to Patent Infringement

A defendant may claim in defence that its activities do not fall within the scope of the claims, and/or that the patent is invalid under any grounds on which the grant of a patent may be opposed, and/or that its activities are permitted for other reasons as explained below.

Invalidity

Any grounds, on which the grant of a patent may be opposed, shall be a good defence in an action for infringement.

Under Israeli law, a patent-eligible invention is defined as "an invention, whether a product or a process in any field of technology, which is new and useful, can be used industrially and involves an inventive step". In addition, the Patent Law provides that the patent's disclosure must enable the person skilled in the art to make and use the invention to the full scope of the claim and that the claims must be unambiguous and reasonably arise from the included disclosure.

Defendants in patent infringement proceedings are entitled to challenge the patent's compliance with any of the above requirements as part of their defence in court proceedings, and they may also file a motion for revocation of the patent at the Patent Office.

In this connection defences such as the so-called Gillette defence or Formstein defence are applicable.

Exclusions From Patentability

The Patents Law excludes from patentability a "method of therapeutic treatment of the human body". The "method of treatment" exclusion is narrowly interpreted, with only a method, as such, excluded, and products or compositions used for the treatment of the human body allowed. In addition, Section 7(2) of the Patents Law excludes from patentability "new varieties of plants or animals, except microbiological organisms not derived from nature". As a result, defendants in patent infringement proceedings are entitled to argue that a claimed invention is excluded from patentability.

Fraud on the Patent Office

Under Israeli law, a patent applicant must – until the application is allowed – inform the Patent Office of all references relied upon by foreign Patent Offices examining patent applications for the same invention or those otherwise directly related to the application at hand. If the patent applicant knowingly fails to comply with this duty, the court may revoke the patent, give a licence to exploit the patent or shorten its period.

Statutory Exemptions

Section 1 of the Patents Law excludes from the definition of "exploitation of an invention": (i) non-commercial acts; (ii) experimental acts aimed at improving the invention or developing another invention; and (iii) experimental acts towards obtaining regulatory licences after the lapse of the patent (a Bolar-type exception).

The exploitation of an invention would not be considered an infringement where the use of the

invention was both on a non-commercial scale and of a non-commercial nature.

The second exemption – experimental use – relates to "an experimental act in connection with the invention, the objective of which is to improve the invention or to develop another invention". An act being experimental is insufficient in itself, and the defendant would have to show that the act falls within – or is necessary for – either of the two purposes provided: improving the invention or developing another.

Also exempted are experimental acts with the aim of obtaining regulatory approval. This is a Bolar-type exception.

Prior User

According to Section 53 of the Patents Law, a defendant, who would have exploited on the determining date, in good faith, in Israel, the invention for which the patent is sought, or if they in good faith made actual preparations towards exploitation, then they shall be entitled to exploit the invention themself and in the course of their business without consideration. The "determining date" is the filing date in Israel or – if priority right was claimed– the filing date of the priority application. The right under Section 53 cannot be transferred, except together with the business in which the invention was used.

Lapse of Patent

Under Israeli law, a patent should be renewed every several years by way of paying a fee, and if a renewal fee is not paid, the patent shall lapse. Section 58 of the Patents Law provides that if a renewal fee was not timely paid, and if the owner had not cured this within a six-month grace period, then any use of the patent following that grace period will not constitute an infringement. While the patent owner may yet reinstate the patent even after the grace period has lapsed, the Patents Law provides that any person who began to exploit the invention in Israel or made actual preparations for exploitation after the lapse of the patent was published in the Official Gazette, shall be entitled to continue to exploit the patent only for their business (Section 63). The Patents Law limits this right only to the business owner. In other words, this right "cannot be transferred, devolved or transmitted by inheritance, except together with the business in which that invention was used" (Section 64).

Exhaustion

Exhaustion could be raised as a defence to an infringement action, however the metes and bounds of such a defence has not been resolved, especially in cases where an exclusive licensee is recorded on the register. In the latter situation, there is a likelihood that the defence will not be recognised. The matter is not adequately resolved by case law.

Licence

A defendant in a patent infringement claim may argue that they were allowed to carry out the allegedly infringing act as licensees. The success of such a defence would likely depend on whether or not the licence agreement in question was breached: if the licensee had exploited the patent in breach of the terms of the licence (eg, field of use limitations), their acts might constitute both patent infringement and breach of contract. However, breaches that are not related to the actual use of the patented invention (eg, failure to pay royalties under the agreement) will probably give rise just to contractual causes of action, as long as the licence agreement is not duly cancelled.

Compulsory Licence

While the Patents Law empowers the Patents Registrar to issue a compulsory licence subject to the satisfaction of statutory criteria, such a licence would only allow the exploitation of a given invention after it is issued and not retrospectively. It so follows that while an infringer may seek a compulsory licence immediately after the claim against them was submitted, doing so ought not serve as a defence against past infringements.

Additional Exceptions

The Patents Law also provides for a number of additional exceptions to infringement.

Under Section 180, "the exploitation of a patented product which was validly forfeited to the State shall not constitute infringement". Under Section 181(1), the use of a patented invention in the body or accessories of a vessel registered in a WTO state other than Israel "exclusively for the needs of the vessel" while the vessel is "temporarily or incidentally in Israel's territorial waters" shall not constitute infringement. Similarly, the use of a patented invention in the construction or operation of an aircraft or land vehicle registered in a WTO state other than Israel, or their accessories, while they are "temporarily or incidentally in Israel" shall not constitute infringement (Section 181(2)).

1.16 Stays and Relevance of Parallel Proceedings

In general, Israeli courts follow the doctrine of lis alibi pendens, according to which the same issue would not be simultaneously heard in two different instances in Israel.

When it comes to patent infringement cases, a court hearing an infringement claim may stay the proceedings pending the Patent Office's decision in a motion for revocation if such was already pending when the action was first filed. It is also possible for the defendant to file a motion for revocation after the infringement claim was filed. In such a case, the court will decide whether validity issues will be heard by the Patent Office or by the court, and the court may also stay the infringement proceedings pending a decision by the Patent Office.

Foreign proceedings with respect to corresponding patents would raise a claim of lis alibi pendens since patents are territorial. Nonetheless, factual findings in foreign proceedings may establish issue estoppel.

1.17 Patent Amendment

During litigation, the court, upon an application by the patentee, may amend the specification and the claims of the patent (Section 190 of the Patents Law). There is no empirical data available on how common amendments during litigation are, though it is safe to assume they are not a rarity. The court would be receptive to such an amendment application and is empowered to order the amendment of the claims even without the submission of such application.

1.18 Court Arbiter

Patent infringement cases are heard before the district courts, which are intermediary-level courts (between the magistrate courts and the Supreme Court). The Israeli courts do not use a jury system, nor do they employ specialist judges. With that being said, each court usually has one or more judges to which patent litigation cases are usually referred, and the Patent Law further allows the court to nominate an independent scientific adviser (assessor) to assist in hearing the evidence and to advise the court. Judges may reflect different tendencies, but this is not dependent on the location of the court.

2. Generic Market Entry

2.1 Infringing Acts

Under Israeli law, exploiting an invention claimed in a patent without permission is considered an infringement. "Exploitation" means either of the following. Where the invention is a product – production, use, offer for sale, sale, or import for purposes of one of the said acts. In respect of an invention that is a process – use of a product directly derived from the process – infringement would encompass any act that is one of the following: production, use, offer for sale, sale, or import for purposes of one of the enumerated acts; and provided that such exploitation is not statutorily exempted (eg, non-commercial use, experimental use and experiments conducted with the aim of obtaining regulatory approval (a marketing authorisation) in accordance with Section 54A of the Patents Law.

It so follows that producing a patent-protected product – including a small molecule pharmaceutical product – would be infringing, as well as offering it for sale or actually selling it. While asking for – and even obtaining – a marketing authorisation would not be considered infringement, any attempt to enter the market on the basis of such authorisation during the patent term (even if the actual entry will take place once the patent lapses) would seem to amount to infringement.

2.2 Regulatory Data and Market Exclusivity

Israeli law allows for a fairly short marketing exclusivity (six to six and a half years) and only for new chemical entities (NCEs).

Section 47D of the Pharmacists Ordinance defines an NCE as a "drug which does not contain an active moiety, whether by itself or together with another active moiety, in a registered preparation or a preparation which was registered in the Register".

According to the Pharmacists Ordinance, the Israeli Ministry of Health will not issue a marketing approval in Israel to a new drug containing the active moiety of an NCE (the registration of which is based on confidential data (safety and efficacy data) filed for a previous drug containing the NCE) unless:

"(a) 6 years have lapsed from the registration date of the previous drug containing the NCE in the Israeli Pharmaceutical Register; or (b) 6.5 years from the registration date thereof in a Recognized Country (the U.S., Canada, a member of the European Union, Switzerland, Norway, Iceland, Australia, New Zealand, Israel, and Japan), whichever is earlier."

The marketing exclusivity is further dependent on the previously registered pharmaceutical preparation being the first registration of the chemical entity it contains. In addition, the marketing exclusivity period may be disregarded if the owner of the previous pharmaceutical preparation gave their consent to use the confidential information; if, in the framework of the registration of the new pharmaceutical preparation, full data to prove the safety, effectiveness, and quality of the new registration was provided; or in case of a national emergency.

It is important to note that the exclusivity provided under Israeli law relates only to the marketing of a follow-on drug, and a third party may seek registration of a follow-on drug on the basis of the data at any time. In general, a third party seeking registration of a follow-on drug product will be required to provide bioequivalence data.

No additional exclusivities exist (eg, orphan drug or paediatric exclusivity).

2.3 Acceptable Pre-launch Preparations

The 1998 Amendment of the Patents Law introduced a Bolar-type defence as Section 54A of the Patents Act, colloquially known as a "regulatory exemption".

This "regulatory exemption" applies if a given experimental act – which might otherwise be deemed to infringe the patent – is made in order to obtain regulatory marketing approval prior to the expiration of the patent in Israel or in another country whose laws also contain a Bolar-type defence. The application of this defence is subject to the products manufactured under Section 54A not being used for any purpose other than the obtaining of a regulatory permit.

In respect of this exemption, a (non-binding) district court decision provided that any action that can be reasonably related to the experimental act will also be covered by Section 54A.

2.4 Publicly Available Drug and Patent Information

Israeli authorities do not rely on the Orange Book, nor do they have an equivalent thereof. The Israeli Ministry of Health operates the online-available Israeli Drug Registry. This website includes data about all the drugs that are registered or were previously registered in the drug register of the State of Israel. The information includes, among other things, the composition of the active ingredients and their quantity, the indication approved in Israel, the form of administration of the medicine, the dose, the name of the manufacturer and the owner of the registration in Israel, the types of packaging, the registration number and the price. However, that information only becomes available to the public upon entry into effect, meaning that information regarding pending applications is not publicly available. Generally, the information in the database is updated once a week.

2.5 Reimbursement and Pricing/Linkage Markets

In Israel, granting of marketing authorisation is not linked to patent status but rather to whether a given product has already received authorisation in the US and in the EU. As for pricing and reimbursement, those are also not linked to patent status, but are subject to certain governmental arrangements, which include pricing control and a national reimbursement programme (which is indication-specific). Israeli HMOs are generally not required to purchase non-reimbursed drugs; while legal action over such refusal could theoretically be filed, the chances of success would seem generally slim.

3. Biosimilar Market Entry

3.1 Infringing Acts

See **2.1 Infringing Acts**.

3.2 Data and Regulatory Exclusivity

As noted above, the limited marketing exclusivity provided under Israeli law only mentions new chemical entities. This led the Israeli Ministry of Health to adopt the view that biologics would not enjoy marketing exclusivity. The issue is yet to be resolved by way of judicial review. However, the requirements for obtaining marketing authorisation for biosimilars in Israel require former authorisation in one of several other countries – in which there is data exclusivity – leading to a de facto exclusivity.

3.3 Acceptable Pre-launch Preparations

See **2.3 Acceptable Pre-launch Preparations**.

3.4 Publicly Available Drug and Patent Information

See **2.4 Publicly Available Drug and Patent Information**.

3.5 Reimbursement and Pricing/Linkage Markets

See **2.5 Reimbursement and Pricing/Linkage Markets**.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Under Israeli law, the term of a pharmaceutical patent may be extended by up to five years via an order called a Patent Term Extension Order ("PTE order").

The Patents Law provides that a patent claiming *any* of the following may be considered a "Basic Patent" eligible for a term extension, subject to the satisfaction of the below-described statutory conditions:

- active pharmaceutical ingredients (APIs);
- use(s) of APIs;
- finished drugs,
- manufacturing process(es) of APIs;
- finished drugs' manufacturing processes; or
- medical devices.

This means that it would not be possible to obtain a PTE order for a combination of previously registered APIs.

Assuming the patent in question claims the eligible subject matter described above and that the application for a PTE order was filed by the applicant of a pending application, the owner of a granted patent, or the exclusive licensee in such, the Patent Office would examine whether the following conditions – listed in Section 64D of the Patents Law – have been met:

- The PTE application was filed in good faith.
- The Basic Patent is in force.
- The pharmaceutical preparation of the drug containing the API is registered in the Israeli Pharmaceuticals Register.
- There are no other PTE applications for the same API or for the same Basic Patent.
- The registration in the Pharmaceuticals Register of a drug containing the API is the first one made.
- Marketing authorisation was issued in the US and/or in any of five EU Countries (England, France, Germany, Italy and Spain), and a US PTE and/or EU SPC (respectively) was granted before the expiry of the Basic Patent (the "Reference Countries" and the "Reference Patents").

Assuming that all of these conditions have been satisfied and that the applicant had acted in accordance with the timeframes and procedures set out in the Patents Law and applying regulations, the term of the patent would be extended.

The duration of an Israeli PTE order shall equal the shortest term of extension in any of the Reference Countries in which PTE or SPC orders were issued and, in any case, would not exceed five years or 14 years from the issuance of the first marketing approval in any of the Reference Countries. In addition, a PTE order would expire upon the revocation of the PTE/SPC orders (or underlying Reference Patents) on the basis on which it was granted in any of the Reference Countries.

Any person may oppose the issuance of a PTE order before such is granted, as well as move for a post-grant revocation of a PTE order, on the basis that the above-listed conditions were not met or that the procedural requirements were not adhered to.

4.2 Paediatric Extensions

At present, paediatric extensions are not available in Israel.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

Securities

Under Israeli law, issuance of an interlocutory injunction is conditioned on the deposit of an in personam undertaking by the applicant to compensate the respondent (against which the order is directed) for whatever damages are incurred as a result of the issuance of the injunction if the injunction is revoked or if it is reduced in scope. Such an undertaking must be attached to the motion for interlocutory injunction.

In addition to the in personam guarantee, and in the absence of extraordinary circumstances requiring otherwise, the court shall order the deposit of an in rem guarantee at a sufficient amount at the discretion of the court.

As the interlocutory injunction remains in place until a final judgment is entered (if not revoked beforehand), all securities deposited will remain in effect until such a time.

The injunction would not go into effect until all securities have been deposited, though the court is authorised to instruct otherwise. In addition, where the preliminary injunction was filed for prior to the case-in-chief being submitted, the applicant will have seven days from the decision date to file the main claim, with failure to do so resulting in the preliminary injunction's revocation.

Service

Under Israeli law, an interlocutory injunction is enforceable immediately upon lawful service on the enjoined party, assuming all relevant securities were deposited (if necessary).

The court will usually provide instruction on how the order is to be served on the respondent, but, in the absence of such, there are several ways to effect service: a copy of the decision may be served on the respondent themselves, at their home or at their place of business, either via courier or via registered mail, on an adult family member living with them, on a person authorised to manage their business, or on their counsel. Where the respondent is a company, service is usually effected by delivering a copy of the order to their registered place of business. In those cases where the respondent is not Israeli, leave for service outside the jurisdiction must be secured, though it would also be possible to effect service by serving the order on a business manager in Israel (if such exists).

As for timeframes, the court will usually instruct the applicant to effect service immediately. The applicant is incentivised to do so regardless, as the order would not be enforceable before lawful service is effected.

Enforcing Execution

If a party against which an interlocutory injunction was issued does not abide by that injunction, the prevailing party may seek to compel the losing party to do so by filing a motion under the Contempt of Court Ordinance. Under this

ordinance, a non-compliant party is subject to a monetary fine and, in extreme cases, to imprisonment for as long as the breach of the order is taking place.

Staying Execution

A party against which interlocutory injunctive relief was issued may seek (alongside filing for leave to appeal) a stay of execution from either the court of first instance or from the court of appeal. If the motion for leave to appeal is yet to be filed, the court of first instance will hear the motion for a stay; if the motion for leave to appeal has been filed, then the court of appeal will hear it. In order to prevail in such a motion, the applicant must demonstrate to the court that it has a good chance of winning the appeal and that, if the injunction enters into effect, it would be either impossible (or very difficult) to go back to the previous state of affairs, or that the applicant would suffer irreparable injury.

A court allowing a stay of execution may make such stay subject to the satisfaction of whichever conditions it deems fit, such as the deposit of a security or the placing of a limitation on the price charged for the now-enjoined product/process.

5.2 Final Injunctive Relief

Enforceability of a Final Injunctive Relief

Under Israeli law, a final injunction is enforceable immediately upon its lawful service on the party which it enjoins – service which can be effected either by the court issuing the order or by the prevailing party, the earlier of which will start the clock on the 60-day term for lodging an appeal.

A final injunctive relief will not require the prevailing party to deposit a bond, as there is no longer a chance that the claim will ultimately be rejected, and there can be no cause of action in tort over the wrongful issuance of the injunction.

Enforcing Execution

If a party against which an injunction was issued does not abide by that injunction, the prevailing party may seek to compel the losing party to do so by filing a motion under the Contempt of Court Ordinance. Under this ordinance, a party failing to comply with a duly issued court order is subject to a monetary fine and, in extreme cases, to imprisonment for as long as the breach of the order is taking place.

Staying Execution

A party against which a final injunctive relief was issued may seek – alongside the filing of an appeal – a stay of execution. If the appeal is yet to be filed, the court of first instance will hear the motion for a stay; if the appeal has been filed, then the court of appeal will hear it. In order to prevail in such a motion, the applicant must demonstrate to the court that it has a good chance of winning the appeal and that, if the injunction enters into effect, either it would be impossible (or very difficult) to go back to the previous state of affairs, or the applicant would suffer irreparable injury.

A court allowing a stay of execution may make such stay subject to the satisfaction of whichever conditions it deems fit, such as the deposit of a security or the placing of a limitation on the price charged for the now-enjoined product/process.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

The Patent Law provides that a prevailing plaintiff is entitled – as a matter of right – to both an injunction as well as to damages. The language of the law does not allow the court discretion to

award damages in lieu of an injunction. Nonetheless, an injunction relief is a remedy in equity, and the court would have the discretion to refrain from issuing an injunction in rare cases.

5.4 Damages

Calculation of Damages

A prevailing plaintiff is entitled to damages, with Section 183(b) of the Patents Law providing that in awarding compensation, the court shall take into consideration (i) the direct damages caused to the plaintiff, (ii) the extent of the infringement, (iii) the profits derived by the infringer from the act of infringement, and (iv) the reasonable royalties which the infringer would have had to pay in consideration for a licence. The plaintiff may opt between damages due to loss of profit and the profit made by the defendant amounting to unjust enrichment. Adjudication of reasonable royalties may be warranted where the plaintiff's business model is to issue licences at arm's length.

The Patents Law further empowers the court to order the infringer to provide accounts on the basis of which calculation of damage may be effected. If such an order is made, it is possible that a supplementary judgment would be issued, in which only the issue of the damages is addressed. Otherwise, the claim for damages would be heard as part of the main claim.

In addition, Section 183(c) of the Patents Law provides that if an infringement was committed after the patentee or its exclusive licensee warned the infringer, the court may order the infringer to pay punitive damages in an amount that will not exceed the damages adjudicated by the court, thus enabling the adjudication of double damages.

In general, damages accrue from the time when the infringement commenced. However, Section 179 of the Patents Law provides that damages may only be adjudicated from the time the patent application was published under Section 16A of the Patents Law (namely, 18 months from the priority date), with such damages being capped at reasonable royalties until the application was published for oppositions, from which the regular rate of damages provided for in Section 183 of the Patents Law shall apply. However, those reasonable royalties shall not be awarded unless the court finds that the exploitation in question constitutes an infringement of the patent as granted and that the invention claimed in the patent stage is substantively identical to the invention claimed in the application published under Section 16A.

The court may add interest and linkage to any sum it adjudicates as damages, from any date it deems fit (but not earlier than when the cause of action came to be) until the date on which the damages are to be paid (usually within 30 days of the judgment). If the damages are not timely paid, a much higher and compounding arrears interest will apply.

Damages for Revoked Injunctions

If an interlocutory injunction is either revoked or limited in scope, the enjoined party can turn to the guarantees provided by the applicant – in rem and in personam both – to obtain compensation for damages sustained. The defendant may base its claim on the doctrine of the unjust enrichment made by the plaintiff due to its exclusive position in the market, during the preliminary injunction term.

Procedurally, this can be done either by counterclaiming (if the period to do so has not yet lapsed) or by filing a new independent claim.

The defendant will need to prove their damages – usually, the profits they have lost during the period they were enjoined – on the basis of factors such as anticipated market share, anticipated sale price for the defendant's product, average profit margin, etc. The defendant may seek to disgorge the plaintiff of those profits they obtained by virtue of any exclusivity afforded to them by the interlocutory injunction since revoked.

Third parties are unable to seek damages over a revoked injunction, though they could theoretically attempt to seek disgorgement if they were charged a premium as a result of the plaintiff's de facto exclusivity mentioned above.

5.5 Legal Costs

Under Chapter 18 of the CPR (Regulations 151–157), the prevailing party is entitled to recover its actual legal costs, with consideration being given to the results of the proceedings, the resources required, and the conduct of the parties.

As a result, Israeli courts are instructed to adjudicate fair and reasonable legal costs at the conclusion of the proceedings unless they have found that there are extraordinary reasons not to do so.

Where attorney's fees are concerned, the courts are instructed not to go below the minimum rates set by the Israeli Bar Association (unless there are extraordinary reasons to do so), and to take into account the proportion between the remedy actually adjudicated and the remedy originally requested, the manner in which the parties conducted themselves, the complexity of the case, the resources spent to conduct it, and the sum of the fees requested by the prevailing party.

Where other costs are concerned, the courts are instructed to adjudicate all costs actually made and required for the proceedings, subject to the prevailing party detailing those costs in their summations and providing documentation in support.

In addition, if the court finds that a party has caused the unnecessary elongation of a proceeding (including an interlocutory proceeding), it may order that party – regardless of the result of the action – to pay the costs of that proceeding to either the opposing party or the State of Israel.

5.6 Relevance of Claimant/Plaintiff Conduct on Relief

In Israel, all legal actions – including the launch of litigation proceedings and the conduct of such – are subject to good faith. Failure to act in good faith may result in the non-granting of equitable relief (such as an interlocutory injunction) or in a limitation on the enforceability of a substantive right (in forms such as reduced damages or an injunction with a delayed entry into force).

6. Other IP Rights

6.1 Trade Marks

Trade mark law in Israel is governed by the Trade Mark Ordinance of 1972, and, to a lesser extent, by the Commercial Torts Law of 1999 (which deals with the law of passing off).

There have been several cases of trade mark disputes relating to the life sciences and pharma sector, centred mostly around naming and get-up – either names or get-ups which were too close for comfort to the name or get-up of an existing, established drug, or names that were too similar to the relevant International Non-pro-

prietary Names (INN), which should remain open to the trade and therefore excluded from trade mark protection.

In respect of the first kind of disputes, the case law provides that where a consumer's mistake, however unlikely, could bring about severe health hazards – as is the case with pharmaceuticals and medical devices – even a lesser degree of similarity is sufficient to establish the misleading similarity needed for a finding of trade mark infringement. The same is true for passing off, where – subject to a showing of goodwill inured to the benefit of the plaintiff or its product – using misleadingly similar get-up is prohibited.

In respect of the second kind of disputes, the case law provides that INNs or the dominant parts thereof cannot be registered as trade marks, either because those should remain open to the trade (if the preparation is based on the same API) or because they could lead to confusion between different preparations using the same API (albeit differently).

6.2 Copyright

The issue of copyright in Israeli law is governed by the Copyright Law of 2007. The copyright law provides, among other things, protection for textual works. Copying of any text which is original and fixed – such as use instructions of a given preparation – could amount to copyright infringement.

A plaintiff in a copyright infringement may pass the burden of proof on to the defendant if it is able to show that the defendant had access to and produced a work similar to the original.

6.3 Trade Secrets

The issue of trade secrets in Israeli law is governed by the Commercial Torts Law of 1999, which forbids the misappropriation of trade secrets, defined therein as "Commercial information of any kind, which is not public knowledge, or which cannot readily and legally be discovered by the public, the secrecy of which grants its owner an advantage over his competitors, provided that its owner takes reasonable steps to protect its secrecy."

While trade secrets disputes in the life sciences and pharma sector are not common in Israel, there are many types of trade secrets associated therewith – such as lists of clients, lists of providers, and marketing strategy documents – and so such disputes can theoretically arise.

7. Appeal

7.1 Timing to Appeal Decision

District court decisions may be appealed to the Supreme Court by right. Leave to appeal interlocutory decisions, including decisions in motions for a preliminary injunction, must be obtained. The term for filing an appeal is 60 days from the date the judgment was issued to the appealing party. The same applies to motions for leave to appeal.

7.2 Appeal Court(s) Arbiter

There is no specific arrangement in place regarding patent litigation appeals. Assuming the first instance was the district court, an appeal thereon will be heard before three Supreme Court judges, whereas an appeal over an interlocutory decision (for which leave must first be secured) will be heard by one Supreme Court judge.

7.3 Special Provisions

Once an intellectual property case is filed with a regular civil court – be it a court of first instance or that of appeal – it is governed by the CPRs.

Where nullity proceedings are concerned, they are governed by a separate set of regulations, namely the Patent Regulations, which closely resemble the CPRs and rely thereon.

8. Other Relevant Forums/ Procedures

8.1 Other Relevant Forums/Procedures

While the Israeli Customs Authorities are not authorised to seize patent-infringing goods, they are able – and will – seize counterfeit pharmaceuticals, as well as products that infringe the trade marks and/or copyrights of another.

The seizure procedure under Israeli law closely resembles the arrangement provided in Part III, Section 4 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In addition, the Israeli Customs Authorities may seize and destroy shipments containing trade mark/copyright infringing goods and have set up a simplified procedure whereby they confiscate shipments of infringing goods without requiring the trade mark or copyright owner to take legal action or file a bank guarantee.

9. Alternative Dispute Resolution

9.1 ADR Options

Israeli law allows for both mediation and arbitration, though both require the consent of the parties.

Mediation is not binding and could be stopped at any moment, with all information exchanged remaining confidential. Mediation usually takes place before litigation – especially if there is an agreement between the parties so necessitating – or during litigation, at the suggestion of the court. Turning to mediation enables parties to reach a confidential settlement, whereas a court judgment would usually be made public.

Arbitration is different from mediation, as it is binding (if previously agreed on), with arbitration agreements being vigorously enforced. In addition, unless a right to appeal is specifically provided for, it is very difficult to set aside an arbitral award, as the criteria to interfere as such are very narrow. Arbitration in Israel – be it local or international, with Israel as either the seat or the governing law – is usually faster than court proceedings and – subject to the agreement of the parties – can be confidential. The parties are free to appoint their arbitrators, as well as to determine every other attribute of the proceedings, such as the procedural law and the degree to which the tribunal would be bound by evidence law or have to reason its decision.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The Economic Competition Law of 1988 prohibits the making of arrangements involving restrictions that are likely to prevent or reduce competition, unless such are cleared in advance by the Israel Competition Authority.

Under Section 3(2) of the Economic Competition Law, arrangements whose restrictions all relate to patent use rights (and other listed intellectual property rights), entered into directly by the patent owner and the party receiving the rights, will not be deemed “restrictive arrangements”.

However, a patent owner or its exclusive licensee may still be accused of abusing their monopolistic power, for example, by charging too high a price. To that end, the relevant market would

have to be determined, and, if indeed a finding of a monopoly is reached, it is possible for a patent owner to be found liable for such abuse, as was recently the case with a pharmaceutical company ordered to pay ILS8 million for charging exorbitant prices.

Gilat, Bareket & Co, Reinhold Cohn Group is one of the leading intellectual property firms in Israel, specialising in litigation and legal counselling relating to intellectual property rights, including patents, patent term extensions, trade marks, designs, copyrights, trade secrets and plant breeders' rights, as well as litigation and legal counselling in IP-related fields. With years of professional experience, Gilat, Bareket & Co has been recognised for successfully litigating landmark cases and representing local and international clients. As part of the Reinhold Cohn Group, the firm works in close co-operation with the patent and trade mark attorneys of Reinhold Cohn & Partners, creating a unique and effective platform for maximising the value of IP assets and securing optimal protection.

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JAPAN

Law and Practice

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Contents

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Patentee

A patentee may file an infringement action. Even when a patentee has granted an exclusive licence to a third party, they may file an action without consent or involvement of the licensee. A co-owner of a patent may file an infringement action without consent or involvement of the other co-owners.

Exclusive Licensee

An exclusive licensee may file an infringement action and seek both injunction and damages without consent or involvement of a patentee. Registration is required for a valid exclusive licence.

Non-exclusive Licensee

Japan distinguishes a sole non-exclusive licensee (a licensor may not grant a licence to other third parties) from a usual non-exclusive licensee (a licensor may grant a license to other third parties). A sole non-exclusive licensee may file an infringement action without consent or involvement of a patentee but can seek only damages, not an injunction. A usual non-exclusive licensee may not file an infringement action.

Standing for Invalidity Trial

A defendant may raise an invalidity defence in infringement litigation. Another option is an invalidity trial before the Japan Patent Office (JPO). A petitioner at an invalidity trial before the JPO must have some legal interests. This standing requirement is liberally construed by the court and is met if a petitioner's future business conflicts with the patent.

1.2 Defendants/Other Parties to an Action

Usually, suppliers, manufacturers, and local distributors/wholesalers are sued as defendants in infringement actions. It is highly unlikely that a patentee sues pharmacists, doctors, hospitals, or HRAs in Japan. Infringement and nullity proceedings do not require notification to or involvement of HRAs/IPOs.

1.3 Preliminary Injunction Proceedings

Preliminary Injunctions Are Available in Japan

Preliminary injunctions are generally available in Japan, but they are almost always inter partes and not quick. In pharmaceutical cases, the court may refrain from granting a preliminary injunction and wait for the litigation outcome because of the significant impact of the injunction.

Procedures

The procedures are very similar to those of permanent injunctions. Inter-partes hearings will be held every one to two months, both parties are given opportunities to file allegations and evidence several times, and it takes about six to ten months in total to determine the case as Japanese judges carefully review both infringement and validity. Typically, a patent owner can initiate a preliminary injunction procedure soon after patent registration as far as the patent owner themself is implementing the patent. Only one who has legal interest in the case can access the documents, and even such access may be prohibited upon request by a party showing that the part contains a trade secret.

Notification of Preliminary Injunction

A written demand for preliminary injunction is served on an opponent. It can be served by Express Mail Service on a foreign opponent together with an English translation, which takes only several weeks. The following proceedings

may be delayed if the service is delayed. The opponent will be given opportunities to file counterarguments and evidence. The court carefully reviews allegations and evidence submitted by both parties.

Requirements

The requirements for preliminary injunction are not so strict for patent infringement cases, and it will be granted if an accused infringer causes substantial harm to a patent owner by infringing a valid patent. The court usually finds substantial harm as long as a patent owner is implementing the patent by themself.

Life Sciences Cases

Drug sales/manufacturing application itself does not constitute infringement in Japan. Thus, a patent owner typically must wait for a drug sales/manufacturing approval grant and a launch of infringing products for a preliminary injunctions grant.

1.4 Structure of Main Proceedings on Infringement/Validity

Infringement and Validity Are Bifurcated

Usually, both infringement and validity issues are disputed and reviewed in an infringement action before the courts.

Invalidity Trial Before Japan Patent Office

An accused infringer may separately file an invalidity trial proceeding before the Japan Patent Office (JPO).

Relationship Between Litigation and Invalidity Trial

In Japan, invalidity trial proceedings before the JPO are not restricted by parallel infringement litigation. Therefore, often the same invalidity issues are disputed in these two tracks. Some court judges tend to wait for the JPO decision if it will be granted in a few months, but others do not. Both first instance infringement litigation and the JPO invalidity trial outcomes may be appealed before the Intellectual Property High Court (the "IP High Court"). Inconsistencies between these two tracks are expected to be solved by the IP High Court.

1.5 Timing for Main Proceedings on Infringement/Validity

Statute of Limitations

Litigation

An injunction claim may be filed as long as the infringement of an unexpired patent continues. On the other hand, a damages claim should be filed within the earlier of (a) three years from when a patentee recognises infringement and an infringer or (b) twenty years from infringement. Even after this period, an unjust enrichment claim can be filed if it is within the earlier of (c) five years from when a patentee recognises that the claim can be filed and (d) ten years from infringement.

Patent Office proceedings

Invalidity trial proceedings before the JPO can be filed even after patent expiration to inhibit a damages claim, which can be filed even after patent expiration within the statute of limitations explained above.

Service of Complaint/Written Demand

Litigation

A complaint should be served on the defendant in an infringement action. Usually, it is served via specifically certified mail. The service usually takes a few weeks if the defendant is a domestic entity. If the defendant is a foreign entity, the plaintiff must prepare a translation of the complaint, and the service itself takes around three to six months. The whole timeline of litigation will be delayed if service is delayed.

Patent Office proceedings
A written demand for invalidity proceedings before the JPO also should be served on the patent owner under similar requirements. However, a foreign patent owner is supposed to designate a Japanese patent administrator under the Japanese Patent Act, and a written demand against the foreign patent owner will be served on the patent administrator.

Timeline
Litigation
Oral hearings will be held every one to two months. Each party files briefs and evidence every few months. Judgment will be granted in about 12 months (injunction only) and about 18 months (injunction and damages). When a plaintiff seeks both an injunction and damages, a court discloses its preliminary conclusion at the end of the infringement and invalidity stage, and decides whether to proceed to the damages stage.

Patent Office proceedings
Typically, both parties have one or two opportunities to file assertions and evidence before an oral hearing. After the oral hearing, typically, a preliminary conclusion will be disclosed to give the opportunity to amend claims when the JPO considers that the patent claims should be invalidated. A decision will be granted about three to four months after the oral hearing. The total procedure takes about ten months.

1.6 Requirements to Bring Infringement Action
A patent must be granted and registered before filing an infringement lawsuit. There are no additional requirements such as validation or translation. The types of patents do not matter to the requirements for bringing an action.

1.7 Pre-action Discovery/Disclosure
Japan does not have discovery at all. There are pre-action evidence preservation procedures, but availability is significantly limited due to the strict standard. Japanese courts generally accept materials legally obtained in other jurisdictions without limitation. In fact, US discovery under 28 USC Section 1782 is sometimes used to collect evidence for Japanese infringement actions.

1.8 Search and Seizure Orders
Search and seizure orders are not available for patent cases. A court grants a document production order under certain circumstances, but the availability and scope are substantially limited.

Recently, Japan newly established an inspection procedure which allows a court-appointed expert to inspect the manufacturing plant of an accused infringer. However, a patent owner first must show a certain level of probability of infringement to use this procedure, and the availability is limited.

Japanese courts generally accept materials legally obtained in other jurisdictions such as US discovery without limitation.

1.9 Declaratory Relief
Declaratory Judgment of Patent Dispute
Currently, Japanese courts are very reluctant to grant declaratory judgments for patent disputes. Typically, a patent owner's intent to assert a patent with knowledge of details of accused products is required to support the necessity of a declaratory judgment. Once standing is found, the plaintiff of the declaratory judgment proceeding may typically seek judgment declaring non-infringement and/or invalidity.

Declaratory Judgment in the Life Sciences Field

In the life sciences field, Tokyo District Court recently denied the standing of a declaratory judgment filed by a generic drug company that filed a generic drug marketing application, holding that the application alone does not support the standing of a declaratory judgment, even though a new drug applicant expressed the possibility of patent assertion once the generic drug is approved. Under this decision, it is difficult to judicially resolve the patent issues between a new drug company and a generic drug company before a marketing approval grant.

Once a generic drug is approved and launched, a generic drug company likely may file a declaratory judgment action to seek declarations of non-infringement and invalidity. However, often a generic drug application cannot get approval due to the substance/dosage/usage patent of a new drug applicant, and the only option for a generic drug company will be invalidity trials before the JPO under such circumstances.

1.10 Doctrine of Equivalents

The Doctrine of Equivalents (DoE) in Japan has five requirements:

(1) the difference between a claim and an accused product is not an essential part of a patented invention;

(2) the invention can achieve the same purpose and function even with the replacement of the difference;

(3) a person ordinarily skilled in the art could easily conceive the replacement at the time of manufacture of the accused product;

(4) configuration of the product was neither publicly known nor easily conceived at the time of the patent application; and

(5) there are no special circumstances such as prosecution estoppel.

Requirement (3) is a significant difference from other jurisdictions such as the US. If a patent is granted to the replacement, it might be difficult to assert infringement under the DoE.

Requirement (4) corresponds to the Doctrine of Ensnarement or the Formstein Defence.

As to requirement (5), Japanese courts traditionally have adopted a “complete bar”, meaning that, if a patentee excluded part of a claim during a prosecution history, the DoE does not apply to the excluded part whatever the reason for the exclusion was. However, a recent lower court decision adopts a more flexible approach, so future case law will need to be watched closely.

1.11 Clearing the Way

Japan basically does not have patent linkage as to a new drug, and there is no obligation to “clear the way” ahead of a new product launch. As a result, an approved new drug might be sued for patent infringement after launch and can be excluded from the market later on.

1.12 Experts

Expert declarations often help parties persuade judges on technical issues both on infringement and validity. There are no specific requirements or procedures for evidence from experts, but the parties file written declarations instead of oral testimonies as Japanese procedures are highly focused on written evidence.

Sometimes, a party retains multiple experts, but too much focus on technical issues is usually not effective nor persuasive to the judges as most of them do not have technical backgrounds. However, it is highly important to choose a good expert trustworthy to Japanese judges.

The Japanese court separately appoints an expert who supports the judge's understanding of technical aspects of the case from a very early stage in the proceedings.

1.13 Use of Experiments

Japan does not have specific mechanisms or procedures to submit experimental results. Any forms of experimental result report are admissible as long as the person who prepared the report signs and/or seals it. As most Japanese judges do not have technical backgrounds, too complicated or lengthy a report is not preferable, and it is helpful to attach an expert declaration explaining the meaning of the results.

1.14 Discovery/Disclosure

Japan does not have discovery even in the post-action stages. There are document production order and inspection procedures, but their availability is limited, as explained in **1.7 Pre-action Discovery/Disclosure**.

1.15 Defences and Exceptions to Patent Infringement

In Japan, invalidity is the most frequently asserted defence in infringement actions. Also, the consent/licence, prior use, exhaustion, and experimental use defences are available.

In the life science field, it is often asserted that an injunction is vastly against the public good, but it is highly unlikely that the court will refrain from granting an injunction based on this ground. Japan has a compulsory licence system, but it has never been granted.

1.16 Stays and Relevance of Parallel Proceedings

Japan does not have any official framework to stay litigation due to parallel proceedings. Some court judges tend to wait for the outcome of an invalidity proceeding before the JPO if it will be granted in a few months, but others do not. It is important to know your judge. Japanese courts generally do not wait for foreign proceedings.

1.17 Patent Amendment

Even during infringement litigation, a patent owner may file an amendment demand before the JPO, and the JPO may grant a decision allowing the amendment. A patent owner is required to file an amendment demand to raise an amendment re-defence against an invalidity defence in the infringement litigation, so it is highly important to timely file an amendment demand before the JPO. (In some circumstances, such as when a patent owner cannot file an amendment demand due to the timing limitation imposed by the Patent Act, an amendment demand is not required to raise the re-defence.) The amendment re-defence is often used and effective in infringement actions.

1.18 Court Arbiter

All patent litigation cases in Japan are decided by a panel of three judges from IP-specialised divisions. Japanese courts have divisions highly specialised in IP, but they are not specific to pharma/life sciences patent litigation.

There is little room for forum selection in Japan. Tokyo and Osaka District Courts have exclusive jurisdiction over first-instance patent-related cases. In some circumstances, patent owners may have options between these two courts, but

there is no significant difference between these two courts. Tokyo District Court has more cases.

2. Generic Market Entry

2.1 Infringing Acts

Infringement Acts

Japan does not have infringing activities specific to pharmaceutical products. Thus, just like general patent infringement, selling, making, using, exporting, importing, and offering to sell generic drugs constitutes infringement. Other acts such as a marketing approval application or grant; an application for reimbursement, pricing or listing; a submission or award of tender; or offer to supply after patent term expiry usually does not constitute infringement.

Skinny Labelling

In Japan, an invention for a new use of a known substance is allowed as a product patent. This means that a product patent can be granted for a second medical use. But the scope of such a patent is not clear. The government agency (Ministry of Health, Labour and Welfare of Japan (MHLW)) grants approval for skinny labelling generics. However, it is not clear whether and to what extent skinny labelling avoids infringement.

Parallel Importation

Generally speaking, parallel importation usually does not constitute patent infringement unless (a) there is an agreement between a patent owner (or an entity substantially identical to the patent owner) and an original buyer which excludes Japan from the sales area, and (b) the agreement is displayed on products. Depending on the facts, this exception may apply to drugs and the parallel importation may constitute patent infringement, although there is no case law and it is not clear.

2.2 Regulatory Data and Market Exclusivity

The typical data exclusivity periods in Japan are as follows:

- new substance drug – eight years;
- orphan drug – ten years;
- paediatric drug – ten years;
- new administration route – six years; and
- new indications, combinations, reclassifications – four years.

Challenges to data exclusivity is not common in Japan.

(To be more accurate, Japan does not have official data exclusivity periods. There are periods for post-grant re-evaluation of effect/efficacy and safety. The government agency, MHLW, substantially utilises these re-evaluation periods as data exclusivity periods.)

2.3 Acceptable Pre-launch Preparations

Experimental use exception applies to generics, and activities necessary for clinical trial do not constitute infringement.

2.4 Publicly Available Drug and Patent Information

Japan does not have a publicly available list of new drug patents such as the Orange Book. New drug applicants voluntarily report substance and use patents covering their new drugs to the government agency, MHLW, so MHLW has a non-public list of patents. MHLW does not grant marketing approval if a generic drug is covered by substance or use patents of new drug applicants.

2.5 Reimbursement and Pricing/Linkage Markets

Japan does not have an official patent linkage scheme but has an informal process based on rules set by notifications by the government agency, the MHLW. The process has two stages.

In the first stage, the MHLW decides if a generic drug infringes (a) substance patent, (b) effect/efficacy patent, or (c) use/dosage patent of new drug applicants. In determining this, the MHLW relies on the non-public list of patents voluntarily submitted by new drug applicants. If there is no patent infringement found, it proceeds to the second stage.

In the second stage, the MHLW requests the generic drug applicant to negotiate and solve problems with other patents (such as dosage form or manufacturing method patents), if any, before the drug pricing. Even if the generic drug company fails to solve the problem, it does not matter to the price listing.

Typically, even if there is a second medical use patent, a generic drug application can be approved but the patented use should be excluded from the indication.

Unlike ANDA in the US, Japan does not have specific litigation procedure for generic drugs. Thus, typically, a new drug applicant files litigation against generics after launch.

3. Biosimilar Market Entry

3.1 Infringing Acts

There are no differences between small molecules and biologics in terms of infringement acts, skinny label, and parallel importation.

3.2 Data and Regulatory Exclusivity

The data exclusivity periods of biologics are basically the same as small molecules.

3.3 Acceptable Pre-launch Preparations

There are no differences between small molecules and biologics in terms of acceptable pre-launch preparations. Experimental use defence applies to biologics, and activities necessary for clinical trial do not constitute infringement.

3.4 Publicly Available Drug and Patent Information

There are no differences between small molecules and biologics in terms of publicly available drug and patent information. New drug applicants of biologics voluntarily report substance and use patents covering their new drugs to the government agency, MHLW, so MHLW has a non-public list of patents. MHLW does not grant marketing approval if a biosimilar drug is covered by substance or use patents of new drug applicants.

3.5 Reimbursement and Pricing/Linkage Markets

Japan does not have an official patent linkage scheme. The approval process for biosimilars is unclear, just internally being handled by the government agency, MHLW. But MHLW reveals that the process is similar to the two-stage process of generic drugs.

Unlike the Biologics Price Competition and Innovation Act (BPCIA) in the US, Japan does not have specific litigation procedures (ie, patent dance) for biosimilars. Thus, typically, a new drug applicant of biologics files litigation against biosimilars after launch.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Japan has a patent term extension for a shorter period (i) from the start of clinical trials to the marketing approval grant, and (ii) from the patent registration to the marketing approval grant. The maximum extension period for a patent is five years even if it takes longer than that.

Japan adopts a flexible policy in terms of patent term extension. Not only substance patents but also other patents such as use/dosage patents can be extended. Unlike the US and many European countries, each plurality of patents that covers the same product can be extended. If a plurality of marketing approvals were granted to product(s) covered by one patent, the extension of the patent can be possible for each approval as long as the subsequent approval is not encompassed by the preceding approval.

To obtain an extension, a patentee or its licensee must be the one who was granted marketing approval.

4.2 Paediatric Extensions

Patent term extensions specific to paediatric drugs are not available in Japan. But Japan gives a ten-year data exclusivity period for paediatric drugs.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

In order to enforce a preliminary injunction, usually, a bond to secure potential damages to be incurred by an accused infringer is required. The bond should be deposited within the term determined by the court, which is usually three to seven days from notification of the amount. In determining the amount, the court considers various factors including the monetary size of the case and the degree of proof of infringement. The amount can be huge, especially in pharmaceutical disputes. Thus, preparing for bond well before the order is necessary. A patent owner may require a return of the deposit after it wins the patent infringement litigation.

Usually, the order is enforceable upon proving the deposit of the bond. It is necessary to initiate an ex-parte enforcement procedure before the court to enforce the preliminary injunction order against patent infringement. Typically, it will be enforced by imposing a duty to pay a certain amount of money during continuing infringement.

There is no term limitation for the effect of the preliminary injunction, but the accused infringer may require a patent owner to file litigation seeking a permanent injunction; and, if the patent owner fails to do so, the preliminary injunction will be revoked.

To stay the enforcement, the accused infringer must clearly show a change of situation denying the fulfilment of preliminary injunction requirements, irreparable harm, etc, in opposition or revocation procedure. A bond is required for the stay.

Also, if the preliminary injunction order allows payment of a certain amount of deposit to lift the order, such a deposit will be a basis for revocation of the order.

5.2 Final Injunctive Relief

Final injunctions are enforceable when they become final. Usually, it is when the final appeal before the Supreme Court is dismissed.

Final injunctions are enforced through separate enforcement procedures before the courts, but it is not so common to enforce permanent injunctions because many infringers obey the court decisions and voluntarily stop infringement. It will be enforced by imposing a duty to pay a certain amount of money during continuing infringement. Also, the disposition of product stock can be sought and enforced.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

The court does not have the discretion to award damages in lieu of an injunction. An accused infringer often makes public interest arguments to avoid an injunction, but the Japanese court does not accept such an argument and grants an injunction.

5.4 Damages

Damages Presumptions

Damages are presumed based on:

- marginal profit of plaintiff's product multiplied by quantity of infringing products sold by defendant;
- marginal profit of defendant's product multiplied by quantity sold by defendant; or
- reasonable royalty.

The first two listed are available when a plaintiff could have obtained profits but for infringement. Typically, it means that the plaintiff has competing products, but it is not strictly limited to such a situation. A plaintiff may assert more than one of these three options, and the court adopts the highest amount among these.

A defendant may rebut the presumption by proving factors such as market difference, existence of other competing products, its marketing effort, or product features other than invention.

Special Damages for Pharma

Basically, there are no special damages for pharma cases. Japan does not allow treble damages for intentional infringement. However, if the drug price dropped because of infringing generic/biosimilar products, the dropped price can be included in damages.

Interest on Damages

Interest of 3% per year from each infringing activity is payable.

Damages Examination

The court first examines infringement and validity. Then, if the court thinks the accused infringer infringes a valid patent, the court discloses a preliminary conclusion, and then proceeds to the damages examination stage.

Timing of Damages Payment

Often, the damages are preliminarily enforceable soon after the first instance court judgment. Theoretically, it must be paid soon after the rendition of the judgment, but usually the accused infringer appeals before the Intellectual Property High Court and seek pending enforcement by depositing around 80% of the damages awarded by the first instance court.

Wrongful Injunction Damages

Usually, damages for a wrongful injunction are not available because an injunction is not enforceable until the judgment becomes final.

Third Party

Theoretically, a third party may seek damages (as long as they suffer damage caused by pat-

ent infringement) through the usual civil litigation, but it is not common in Japan.

5.5 Legal Costs

Court costs including court fees paid by a winning party are recoverable from a losing party, but they are often neglected because the amount is small.

5.6 Relevance of Claimant/Plaintiff Conduct on Relief

In patent infringement lawsuits, the court may not withhold or reduce relief as a penalisation for negative conduct from the plaintiff.

6. Other IP Rights

6.1 Trade Marks

Trade mark disputes in the life sciences and pharma sector are somewhat common in Japan. Just like the usual trade mark disputes, the cases are governed by the Trade Mark Act. Often, the main issue of the case is whether the trade mark causes consumer confusion about the product's source, just like usual trade mark cases.

The government agency notified rules for generic drug naming, so trade mark disputes between brand-name and generic products are not common.

6.2 Copyright

Copyright disputes are not common in the life sciences and pharma sectors in Japan. Potentially, the copyright of software (such as health tech software or drug research software) can be disputed.

6.3 Trade Secrets

Unlike the tech sector, trade secrets disputes are not so common in the life sciences and pharma sectors in Japan. However, such disputes could happen in the future because many pharma companies now develop and use AI or high-tech software for drug discovery. The Unfair Competition Prevention Act governs trade secrets disputes.

7. Appeal

7.1 Timing to Appeal Decision

Appeal Against Preliminary Injunction

An accused infringer may file an appeal within two weeks from the service of a preliminary injunction order. The appellate court reviews the case without deference. Also, opposition and revocation procedures are available, and the preliminary injunction will be vacated if the injunctive right no longer exists due to significant situation change after the preliminary injunction order grant.

Appeal Against Permanent Injunction

A defendant may appeal within two weeks from the service of a judgment ordering a permanent injunction. The first hearing will be held within a few months from the appeal, and the judgment will be granted about six months after the appeal. The appellate court reviews the case without deference. A party who lost in the appellate court may file a final appeal before the Supreme Court although the success rate of the final appeal is as low as 1%.

7.2 Appeal Court(s) Arbiter

A panel of three judges from the Intellectual Property High Court, which has exclusive jurisdiction over patent appeal cases, hears and decides a patent litigation appeal. The court often retains a court expert who supports judges' understanding of technical aspects of the case.

7.3 Special Provisions

Patent litigation is governed by the Civil Procedure Code, just like normal civil litigation. However, the court usually expects more professional litigation activities from both parties, and delayed submission of arguments and evidence might be more strictly evaluated than usual civil cases and can be dismissed.

8. Other Relevant Forums/ Procedures

8.1 Other Relevant Forums/Procedures

A custom suspension to prevent the import of infringing products is available. A panel appointed by Japan Customs reviews the case, but they often wait for a court decision, especially in a complex case. Thus, the effectiveness of the custom suspension is often limited for a pharma patent owner. However, it is often effective for suspension based on a trade mark.

9. Alternative Dispute Resolution

9.1 ADR Options

ADR in the life sciences and pharma sectors is not common at all in Japan so far. Many patent owners choose litigation over mediation or arbitration, trusting formal court procedures. Recently, Tokyo and Osaka District Courts started providing arbitration services for IP-related disputes, but they are directed to simple cases and are not suitable for complex patent infringement disputes.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

Japan has not experienced antitrust cases regarding “pay for delay” or “reverse payment”. However, depending on the facts of each case, “pay-for-delay” or “reverse payment” might violate Japan’s Anti-Monopoly Act.

Ohno & Partners is one of the leading intellectual property law firms located in Tokyo, Japan. Currently, the firm has 28 attorneys highly specialised in IP litigation and prosecution. Despite its relatively small size, the firm has represented many difficult litigations and has established numerous case laws before the Supreme Court and the Intellectual Property High Court. Attorneys-at-law, Mr Seiji Ohno and Mr Hirofumi Tada have handled many pharmaceutical litigations of both small molecules and biologics. For example, the current Japanese antibody patent practice is largely based on the case law established by the team. The firm promises to offer its clients the highest quality total solution service in all areas of intellectual property rights.

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MEXICO

Trends and Developments

Contributed by:
Adolfo Athié
Basham, Ringe y Correa see p.94

Mexico's Supreme Court Rules on Patent Compensatory Time Due to Administrative Delays and Holds That the Effective Term of a Patent May Not Be Less than 17 Years – Part II

In 2018, the introductory comments on the topic at hand were published for the first time in the El Foro (full version) and La Barra (short version) magazines under the heading *Dilación en el Otorgamiento de Patentes y su Regulación en el TLCAN* ("Delay in the Granting of Patents and the Regulation under the North American Free Trade Agreement."). Our article reflected an initial point of view that, at the time, was an incomplete idea of the unfair system that had prevailed and still exists in Mexico on the validity of patents under the then Industrial Property Law (IPL) and the new Federal Law for the Protection of Industrial Property (FLPIP), in effect as of November 5, 2020. Such an academic idea, but with a more precise and evolving approach, was taken up in a constitutional action we filed and later on by the Second Chamber of Mexico's Supreme Court and is the reason for the second part of my comments on this exciting area of the law.

For a long time, it was a common practice to assume that a patent would be valid for 20 years from the filing date of the patent application. Analysing the different Mexican statutes that have governed this issue, we find that some included a 20-year term from the filing date rule. However, no one seems to have ever questioned whether this rule was fair or in line with the federal Constitution; it was generally accepted that since this was what the regulations said, the law had to be unequivocally complied with. Was it right to just accept this unfair rule as normal? Could it be legally challenged? Nevertheless, we hold that not everything a statute provides is constitutional. When a rule appears to conflict with common sense, there might be an unconstitutionality issue to contend with.

In the past, it was commonplace to find that the effective term of a patent would differ from one patent to another, depending on how long each examiner took to study the application; in other words, under the 20-year filing date rule, a patent could be granted at any time between two to seventeen or more years after filing; in fact, there were cases where either the patentee would enjoy only a single year of protection or the patent would be born dead, a result absolutely preposterous, unfair, uncertain, discriminatory, and unpredictable, and thus unconstitutional. Contrary to what the supporters of such a system may claim, a pending patent application is not the same as a patent already granted. Either a legal action against an infringer or the benefits arising from the supply of pharmaceutical drugs to the government under no-bid contracts will necessarily require a patent legally granted and not only a pending patent application.

The Second Chamber of Mexico's Supreme Court understood the problem and sought a legal solution based on a systematic interpretation of the law, moving away from the uncon-

stitutionality issue of Article 23 of IPL, finding a way out from the unfair but prevailing patent validity system thereunder, and establishing a historical and transcendental principle, thereby substantially doing away with the possibility of extending the effective term of a patent, and setting a different theory with equally different consequences. Thus, compensatory time is not to extend the patent's validity but rather to give the patentee a period of effective protection.

Furthermore, Article 126 of FLPIP introduced a so-called "supplementary certificate" ("*certificado complementario*"), pursuant to the November 30, 2018, United States, Mexico and Canada Agreement (USMCA), which–under certain circumstances–allows for compensatory time to offset the excessive time taken by the patent process, when resulting in delays of more than five years between the filing date in Mexico and the granting of the patent; the patent date being the date on which the granting of the patent is communicated to the patentee. However, the following question arises: does the communication imply either a notice attaching the patent certificate or a notice to pay the required fee for the issuance of the certificate? In addition, this new statute contains an unfair formula of one-day compensatory time for every two days of delay.

The Bayer case

On January 12, 2000, Bayer Corporation (later Bayer Healthcare LLC) applied for the protection of an oncological substance invention under an international Patent Cooperation Treaty application ("PCT application"), namely "Ω-Carboxyaryl Substitutes Diphenyl Ureas as Raf Kinase Inhibitors," (granted on July 26, 2006).

The Mexican Institute of Industrial Property (IMPI for its Spanish acronym) took six years and six months to grant the patent and eight months to notify the invention certificate under patent number 238942. It should be noted that in Mexico and internationally, the average time to grant a patent is three years; however, in this case, IMPI took twice as long; thus, the patent's validity was cut short to three years and six months. Hence, Article 1709 (12) of the North American Free Trade Agreement (NAFTA), to which Mexico was a party, recognised this type of delay and opened the possibility for the patentee to obtain compensatory time for the time taken in granting the patent, thus giving effective protection to the patentee. Notably, both our trading partners–the United States and Canada–have a much more suitable patent protection system than Mexico. In Canada, the protection is for 17 years from the granting of the patent (thus providing legal certainty to patent holders)–and in the United States, it is 20 years from the filing of the patent application (like the Mexican system); adding compensatory time for the time taken by red tape delays, thereby covering the time lost in the administrative process. Unfortunately, in Mexico, we are faced with a very unfavourable scenario and a system prone to legal uncertainty because the patentee has no idea how long it will take for the patent to be granted by IMPI and the time the protection sought will be effective. This situation places Mexico at a disadvantage in patent rights compared to those granted by its trading partners.

As mentioned above, Article 126 of FLPIP now regulates the issuance of a limited and unfair supplementary certificate, arbitrarily providing compensatory time to offset the time lost in the patent process by allowing one day of compensation for every two days of delay. We wonder what the logic behind the rule of one day of compensatory time for every two days of delay is. Is allowing one day of compensatory time for

a one-day delay not a better formula? In other words, if a statutory rule does not have a rational logic, such a rule is likely considered unfair.

In the Bayer case and starting from the Roman concept of justice expressed by Ulpiano: *Iustitia est constants et perpetua voluntas ius suum cuique tribuendi* (Justice is the constant and perpetual will to give each person their due), Bayer was entitled to three years and six months of additional exclusive exploitation of its patent, taking into account that this is a benefit contemplated under NAFTA–an international treaty to which Mexico was a party and above federal laws (as provided by Article 1 of Mexico's federal Constitution), including IPL. Therefore, a civil right should be given the broadest interpretation for the benefit of private parties. Then, the government improperly interpreted the rule to the detriment of the patentee and refused to grant compensatory time for the validity of the patent without analysing the benefits that NAFTA provided and that IPL omitted.

Under NAFTA, member countries are required to establish a protection period of at least seventeen years from granting the patent or, alternatively, twenty years from the filing application date. We should consider what the NAFTA parties intended when they negotiated and agreed on this wording. Seemingly, their aim was to establish a protection period of not less than seventeen years, considering that an application's study and the administrative process will normally take three years before the patent is finally granted. Furthermore, they recognised that there might be situations that force the government to spend more time when granting a patent, and, in those cases, the notion of compensatory time could be used to offset the excess time required for the patent to be granted. It is unfair and unreasonable that some patentees are granted an exclusive right to exploit the patent for seventeen years, whereas others are only protected for fourteen years or less based on administrative and red-type issues. Such dissimilar treatment emphasises that the effective term of a patent is paramount to the patentee due to the enormous investment and outrageously expensive research behind every invention. In addition, the exclusive protection bestowed by a patent is a right recognised both under international treaties and by Article 28 of the federal Constitution. The ideal protection should be seventeen years after subtracting the customary three-year processing time by the respective Patent Office.

Analysis of the opinion

On October 14, 2020, the Second Chamber of Mexico's Supreme Court (on the amparo action under review 257/2020 and based on the draft opinion authored by Justice Yasmín Esquivel-Mossa) adopted (in what is relevant to our topic) a systematic interpretation of Article 23 of IPL and Article 1709 (12) of NAFTA. It reaffirmed that in all cases, the effective term of a patent may not be less than seventeen years from the granting date of the patent. On page 76 of the opinion, the following wording appears:

"We find that, regardless of the [maximum] terms set under the Administrative Rulings [issued by IMPI], and as mentioned above, the interpretation of Article 23 of the Industrial Property Law read in conjunction with the applicable provisions of Article 1709 (12) of the North American Free Trade Agreement, allows us to conclude that the effective term of patents cannot be less than either twenty years from the filing date or seventeen [years] if the granting date is considered (emphasis added); consequently, if it is proven that there was a delay in the administrative approval process, the protection period

must be extended in order to offset such delay, thereby preserving the effective term of the patent which, we insist, cannot be less than seventeen years.[…]"

As already pointed out, the Second Chamber of Mexico's Supreme Court opted for a systematic interpretation of the legal provisions under review instead of: (i) either directly holding that Article 23 of IPL was unconstitutional (since there were no accurate parameters to determine what should be a uniform effective term for all patents); or (ii) potentially applying the notion of compensatory time contemplated by Article 1709 (12) of NAFTA, as a result of the failure by the legislature to enact a statutory rule on a minimum term for the validity of all patents or a maximum term for a delay in the granting of a patent–a situation that has now been corrected by the systematic interpretation held by the Supreme Court of seventeen years from the granting date for all patents.

Notwithstanding the above, in my opinion, such systematic interpretation fails to cure the unconstitutionality issue of Article 23 of IPL as it does not establish either a maximum term for the delay in granting a patent or a compensatory mechanism for the time lost in the patent approval process. This situation restricts the actual effective term of a patent, and furthermore, the maximum terms set by IMPI under its Administrative Rulings do not remedy the statutory oversight–on the contrary, it goes beyond what the law allows. Thus, Article 126 of FLPIP now provides that a supplementary certificate may be issued by IMPI, at the request of the patent holder, if the delay has exceeded five years and is both unreasonable and attributable to the government; however, it provides that only one day of compensatory time will be granted for two days of delay.

Despite the above, the systematic interpretation of the Supreme Court cures the legislative error of Article 23 of IPL and solves the historical problem of the patent system where the patentees had no idea of the exact duration of their patent rights, leading to complete legal uncertainty. How many patents could have benefited from the interpretative rule of the Supreme Court by offsetting the time lost in the process? They must have missed two, three, four or more years of the patent's effective term. It is a fact that patentees in Mexico have lived through very unfortunate times without the benefit of a proper interpretation.

The recent Supreme Court opinion is much more benign and favourable for patent holders than the provisions of the new FLPIP since it mandates a minimum effective term of seventeen years from the granting date and not the preposterous rule of one day of compensatory time for every two days of delay from the filing of the patent application in Mexico, which again involves a serious unconstitutionality issue. What is the legal and common-sense justification for limiting compensatory time to one day for every two days of delay? Why not provide one day of compensatory time for one day of delay?

Supreme Court opinion

As an aftermath of Bayer case already mentioned, on January 8, 2021, the Supreme Court published the following summary:

- Digital registration: 2022603.
- Court: Second Chamber.
- Tenth period.
- Subject(s): Administrative.
- Precedent: 2nd. LV/2020 (10a.).
- Source: Federal Weekly Judicial Gazette. Book 82, January 2021, Volume I, page 662.
- Type: Single opinion.

PATENTS. WHEN DELAYS IN THE APPROVAL PROCESS ARE ATTRIBUTABLE TO THE ADMINISTRATIVE AGENCY, THE EFFECTIVE TERM OF A PATENT MAY NOT BE LESS THAN SEVENTEEN YEARS FROM THE GRANTING DATE (SYSTEMATIC INTERPRETATION OF ARTICLE 23 OF THE NOW-REPEALED INDUSTRIAL PROPERTY LAW).

Facts: A legal entity challenged the refusal by the Mexican Institute of Industrial Property (IMPI) to offset, for purposes of determining the effective term of a patent, any delays in the granting process, alleging that Article 23 of the Industrial Property Law (now repealed), cited by said agency as grounds for the refusal, gives rise to a legal uncertainty because the effective term of a patent that would have been in effect for twenty years, was shortened due to delays in the approval process.

Held: The Second Chamber of the Supreme Court determined that a systematic interpretation must be given to Article 23 of the Industrial Property Law (now repealed) and held that any delays attributable to the administrative agency in the approval process must be taken into consideration, as the effective term of a patent may not be less than seventeen years from the granting date.

Grounds: From the systematic interpretation of Article 23 of the Industrial Property Law, read in conjunction with other provisions of the same statute, and with Article 1709 (12) of the North American Free Trade Agreement (NAFTA), we find that notwithstanding that Article 23 fails to set terms within which a patent application should be examined to decide whether the formal and substantive legal requirements are complied with, this does not create any legal uncertainty. This is so because, given the peculiarities and degrees of complexity involved in the administrative examination process of each patent application, it would not have been possible for Congress to specify different terms for different types of patents (taking into account that the time required for an in-depth examination of the substantive requirements may vary). As such, Congress opted for generic terms under rulings that should set maximum terms for IMPI to notify the findings from the examination of applications, hence providing legal certainty to the applicants. Subsequently, we concluded that although a patent will be valid for twenty non-renewable years counted from the filing application date, the application must still be subject to a formal examination process, and since delays involved in the administrative approval process may occur, such delays could have a negative impact on the effective term of the patent; however, if there is a delay, the effective term of a patent should not be less than seventeen years from the granting date, since based on the provisions of NAFTA a patent protection period of a patent should be either at least twenty years counted from the filing application date or seventeen years from the granting date of the patent; this in no way would imply an extension of the effective patent term.

Amparo under review 257/2020. Bayer Healthcare, LLC. October 14, 2020. Five affirmative votes from Justices Alberto Pérez-Dayán, Luis María Aguilar-Morales, José Fernando Franco-González-Salas, Yasmín Esquivel-Mossa and Javier Laynez- Potisek, this latter disclosed that he would submit a concurring opinion; the majority of three affirmative votes on the principle contained in this opinion. Dissidents: Justices Luis María Aguilar-Morales and José Fernando Franco-González-Salas, who proposed to dismiss the action regarding Article 23 of the Industrial Property Law. Justice authoring the

proposed opinion of the Court: Yasmín Esquivel-Mossa. Secretary: Claudia Mendoza-Polanco.

This opinion was published on Friday, January 08, 2021 at 10:09 a.m. on the Federal Weekly Judicial Gazette.

Conclusion and recent developments

In the foregoing opinion, the Supreme Court appears to have recognised that there may be a disparity in effective patent terms–although Article 23 of IPL does not give rise to legal uncertainty, the truth is that should there be any delay in the granting of a patent attributable to the government, its effective term may not be less than seventeen years in accordance with Article 1709 (12) of NAFTA. The ratio decidendi of this court opinion is that there are two systems: (i) one of twenty years from the filing application date and (ii) the other of seventeen years from the patent granting date (with the proviso that in the event of any administrative delays, patents must have a minimum effective term of seventeen years from the granting date, and not twenty years from the filing patent application date).

The above interpretation directly impacts those patents that took more than three years to be granted. This Supreme Court's opinion corrects the flawed patent system that for many years had prevailed in Mexico under Article 23 of IPL and prior statutes and that, unfortunately, has caused severe damage to those who sought effective protection for their inventions but were completely unaware of the unfair shortening of the effective term of patents due to unreasonable delays by the government. Patent holders and intellectual property advisors have overlooked this. In our opinion, the interpretation embraced by the Supreme Court fully upholds the constant and perpetual desire to put into practice the principle of justice by providing to every person what rightfully belongs to them and without declaring that Article 23 of IPL was unconstitutional.

It should be emphasised that the recent opinion of the Supreme Court applies only to patent applications filed prior to July 1, 2020, while NAFTA was in effect. However, any patent applications filed between July 1 and November 4, 2020, before the new FLPIP came into effect, may fall into an interpretation limbo since, on the one hand, they are subject to UMSCA, while on the other, the former IPL continued in full force and effect, which was the legal grounds taken by the Supreme Court to issue its opinion. It would be interesting to see how federal courts would react when deciding this time factor in a conflict of laws situation.

Recently, in a new case concerning compensation/adjustment for the validity of a patent (active pharmaceutical ingredient) litigated by the authors' firm, a Federal Court for Administrative Matters of the First Circuit confirmed the resolution of a Federal District Court, indicating that it is feasible to compensate the time lost in the processing of a patent, despite the fact that it has expired, as long as it is within seventeen years from the granting of the patent, and it has been processed in accordance with the previous Industrial Property Law and the NAFTA.

This new relevant case opens the possibility of requesting compensation for expired patents before IMPI within the range of seventeen years established by the criteria of the Supreme Court of Justice in the Bayer Healthcare LLC. case issued on 14 October 2020 in Amparo Revisión No 257/2020, which was also handled by the authors' firm.

Basham, Ringe y Correa is one of the leading full-service law firms in Latin America. Established in Mexico in 1912, Basham draws on a century of experience assisting its clients in conducting business throughout Mexico and abroad. The firm's clients include prominent international corporations (many of them on the Fortune 500 List), financial institutions and individuals. The firm's large group of lawyers and support staff are committed to maintaining the highest professional and ethical standards. Constantly exposed to the international legal system, many of Basham, Ringe y Correa's lawyers and other professionals have completed graduate studies at foreign universities and have worked in companies and/or law firms abroad. Basham's preventive and strategic advice on all types of law allows the firm to offer its clients effective, complete, and timely solutions to their concerns.

Author

Adolfo Athié has been a partner at Basham, Ringe y Correa since July 2008 working in the intellectual property and IT and privacy and data protection practices in the firm's Mexico City office. Actively involved in complex Amparo actions before the federal courts for the protection of intellectual property rights against falsification and unfair competition, constitutional (amparo) proceedings focus on administrations subjects particularly in intellectual property and antitrust cases and data protection. Adolfo has a strong practice in adjustment of patent terms and identified a significant mistake in the patent validity system which was recognised and confirmed by the Supreme Court of Justice in the famous Bayer case.

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NORWAY

Law and Practice

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Contents

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Revocation Actions

As long as a patent is in force, any party may initiate an action to have the patent revoked, including individual co-owners and third parties such as licensees.

Infringement Actions

The patentee and an exclusive licensee – ie, a licensee that has the exclusive right to make, sell and/or put the invention on the market – has standing to commence an action for patent infringement. Registration or recording of an exclusive licensee is not required in order for it to bring an action.

The patentee does not need to be joined as a party to the infringement action. However, if infringement proceedings are commenced by a licensee, the patentee must be notified. The same applies if the patentee brings an action – licensees registered in the official patent register must be notified.

1.2 Defendants/Other Parties to an Action

The parties in life sciences/pharma actions in Norway are, almost without exception, manufacturers of pharmaceuticals. The Norwegian Industrial Property Office (NIPO) is required to be notified if a revocation action is initiated, but they have no role in revocation or infringement actions between pharmaceutical manufacturers.

1.3 Preliminary Injunction Proceedings

Preliminary injunctions (PIs) are available in Norway, including ex parte PIs. A PI is available on the condition that the claimant establishes as probable that there is either:

- an infringement of a patent; or
- the defendant has made significant preparatory acts with the aim of carrying out an infringing act.

Moreover, the claimant must establish that an injunction is necessary, as pursuing the claim would otherwise be substantially more difficult or cause substantial harm or inconvenience. Additionally, the court must find that an injunction is justified when taking into account the interests of both parties. Upon granting a PI, the court may order the claimant to provide a guarantee for compensation to the defendant in the event that it is later established that the injunction was unjustified.

A patentee should not delay in commencing the PI action once they become aware of potential imminent infringement or actual infringement. A warning letter with a short deadline (normally two weeks, or shorter if there is urgency) should be issued first, followed by filing a request for a PI fairly soon thereafter – normally within two to four weeks. Note that protective letters are not available in Norway.

Inter Partes PIs

The timeline in inter partes PI proceedings is typically as follows.

- The patentee will file a PI request, together with evidence to support that the defendant's product constitutes infringement and that infringement is imminent.
- The defendant will be notified of the request by the court and then normally allowed a short limited period of time in which to file a defence.
- Where matters concerning validity and/or infringement involve complex scientific issues, the court will usually allow time for

experts to submit reports – for example, within a limited time period of one or two months.
- A hearing takes place in court, which could last between three and seven days. The hearing and the proceedings correspond in many respects to an ordinary case on the merits.
- A verdict is normally delivered two to four weeks after the hearing took place.

The verdict may be appealed within a month to the court of appeal, which normally will assess the matter based on the written pleading and evidence.

Ex Parte PIs

The criteria for obtaining an ex parte PI are based on extreme urgency and the threat of substantial harm to the patentee's interest if inter partes proceedings are allowed. The threshold for the grant of an ex parte injunction in Norway is high in pharma patent cases. In complex patent cases, they are rarely granted.

1.4 Structure of Main Proceedings on Infringement/Validity

In Norway, revocation claims and infringement claims are dealt with in the same proceedings.

1.5 Timing for Main Proceedings on Infringement/Validity

A typical timeline for a revocation and/or infringement action in Norway is as follows.

- A writ is filed with the Oslo District Court, which is the mandatory venue for patent cases.
- The defendant is normally granted a time limit of three weeks in which to file a defence to the writ. The time limit may be extended by another three to four weeks in complex cases.
- A case management conference with the judge and counsel is held a few weeks after the defendant has submitted the defence. Hearing dates, appointment of expert lay judges, etc, will be decided at this conference.
- A main hearing, typically lasting four to nine consecutive court days, would normally take place between six and ten months from commencement of proceedings.
- A judgment from the Oslo District Court can be expected within six to ten weeks, depending on complexity.

1.6 Requirements to Bring Infringement Action

Infringement actions are normally brought on the basis of a granted patent. In theory, an infringement action can be filed before the grant or validation of a patent, but there are very few examples of this in practice.

1.7 Pre-action Discovery/Disclosure

There is no pre-action discovery/disclosure as such in Norway.

One may, however, initiate measures for securing of evidence prior to proceedings. This is relevant if the evidence is at risk of being lost otherwise. Additionally, securing of evidence prior to proceedings is possible if done in order to provide an opportunity to assess a claim and possibly reach an amicable settlement.

The securing of evidence – specifically, information related to patent infringement – can under certain conditions be obtained prior to an action for infringement. The securing of evidence does not necessarily imply that the claimant may obtain access to the evidence, especially if the evidence is confidential. As mentioned earlier, the claimant must show that:

- there is a clear risk that the evidence will be lost or considerably impaired otherwise; or
- there are other reasons that make it particularly important to obtain access to the evidence before the lawsuit is instigated.

A request for such evidence may also be made ex parte if there is reason to fear that notice to the opposite party could lead to obstruction of the securing of evidence. If granted, the opposite party will be allowed an oral hearing. The petitioner shall, in that case, not be allowed access to the evidence until the ruling is final.

The issue of confidentiality may be resolved by the court appointing an expert to look into the material and give the court advice concerning the relevance of the material and its suitability as evidence in the case at hand. The petitioner pays all costs – including those of the defendant – in this kind of procedure, which is very rarely used in patent matters. The authors are not aware of examples where it has been used in pharma patent litigation.

Note that materials obtained by discovery or disclosure requests in other jurisdictions can be used in Norwegian proceedings.

1.8 Search and Seizure Orders

Norway has implemented quite a similar customs regime to Customs Regulation (EC) No 1383/2003, under which the court can issue a PI ordering the custom authorities to seize products if importation of the products will constitute infringement of IP rights. An injunction can be issued even where the recipient of the products is unknown. If necessary, a PI can be issued without an oral hearing of the evidence.

The customs authorities can also, ex officio, decide to withhold goods for up to ten days if they have reasonable grounds to suspect that the goods will constitute infringement of IP rights. If the goods are withheld, notice shall be given to the recipient of the goods and the patent owner. To prevent further release of the goods, the patent owner must obtain a preliminary injunction.

1.9 Declaratory Relief

Declaratory relief is - in principle available – in Norway, both in the form of declarations of non-infringement as well as in the form of “arrow declarations”.

1.10 Doctrine of Equivalents

Norwegian courts recognise a Doctrine of Equivalents (DoE). The legal test follows from the Norwegian Supreme Court decision in the “Donepezil” matter (Rt-2009-1055).

The three questions to be answered in the DoE are:

- Does the variant achieve the same solution/solve the same technical problem as the patented invention?
- Would a person skilled in the art find the modifications from the patented invention obvious?
- Does the variant belong to the available prior art?

If these three questions are answered affirmatively, infringement of the original patent can be established. The Norwegian DoE is, however, rather narrow in scope. According to the Supreme Court in the above-mentioned decision, protection by equivalence is a matter of claim construction and can only encompass modifications that are “fairly identical” to the features set out in the patent claim.

1.11 Clearing the Way

Filing a claim for revocation and/or a non-infringement declaration is often used as a strategy to "clear the way" before the launch of a new product. However, there is no legal obligation for a potential competitor to clear the way ahead of product launches.

1.12 Experts

In matters where complex scientific issues are involved in terms of validity and/or infringement, the party-appointed experts will normally submit reports and provide testimony during the proceedings..

In a PI action, the court will normally appoint independent expert witnesses with particular expertise in the relevant field. Typically, two court-appointed experts will attend the hearing including the evidence; at the end of evidence, they will deliver a report and also expand their view by oral testimony to the judge. Thereafter, it will be for the counsel to put further questions to the court-appointed experts – following which, the experts will leave the courtroom and not take any more part in the proceedings.

In an action on the merits, with infringement and/or validity issues at hand, there will be no court-appointed experts as per PI proceedings; instead, expert lay judges will be appointed by the court. They will typically have technical expertise in the relevant field. In some pharma patent litigation cases, the expert lay judges have comprised one technical expert (eg, a professor in biochemistry) and a patent attorney working within life sciences.

The expert lay judges participate during the hearing as members of a panel of three, including the patent judge. In the court of appeal, this will be a panel of five (including three legal judges).

1.13 Use of Experiments

Results from experiments may be filed as evidence in order to prove/disprove infringement/validity of patents and Norwegian courts allow experiments in patent cases. There are no specific procedures that must be followed in order for the experimental results to be admissible; however, the courts will assess the relevance of the experiments based on the protocols of the experiment(s).

1.14 Discovery/Disclosure

In response to an infringement claim, the defendant will normally provide evidence in form of product or process description. Confidential information in such descriptions may be redacted.

1.15 Defences and Exceptions to Patent Infringement

The most relied-upon defence against an infringement claim is a counterclaim for invalidity. A separate claim for revocation must be filed, leading to the validity and infringement being assessed in the same case before the Oslo District Court.

Another ground for defence is that the defendant is entitled to a compulsory licence. Other available defences include the defendant being entitled to a prior use right on the basis that they were already using the invention before the priority date, experimental use and exhaustion. For life sciences cases, the Norwegian "bolar" exemption is particularly relevant (see **2.4 Publicly Available Drug and Patent Information**).

1.16 Stays and Relevance of Parallel Proceedings

As the Oslo District Court is the mandatory venue both for infringement cases and revocation actions, infringement and revocation actions

will be joined and heard together in most cases. Thus, the infringement proceeding will normally not be stayed.

When Norway acceded to the European Patent Convention (EPC) on 1 January 2008, the Patents Act was amended with a provision stating that a court may decide to stay a trial until a final decision concerning the same patent is delivered by the European Patent Office (EPO). In practice, this also applies to Norwegian patents granted nationally, but the court will normally only stay the proceedings if a decision from the EPO can be expected within a few months. The fact that the validity of a corresponding patent is disputed in another country is normally not considered directly relevant for proceedings in Norway.

If invalidity or revocation proceedings are pending before both the NIPO and a court at the same time, one of the actions will be stayed. In most cases, this will be the proceedings before the NIPO.

1.17 Patent Amendment

A patent can be amended in administrative proceedings before the NIPO or in a trial before the court. After the opposition period, a patent may also be amended upon request by the patent owner. Amendments can be made to the claims or the description.

Furthermore, the patent holder may file auxiliary requests to the court in revocation/cancellation proceedings. The amendments made in the auxiliary requests must not extend the scope of the patent as granted.

1.18 Court Arbiter

The Oslo District Court has a panel of judges with particular experience in patent matters, who will hear all cases brought before the court. However, requests for PIs must be initiated in accordance with the general law on civil procedure – meaning that the venue will normally be either the district court where the alleged infringer has its headquarters or, alternatively, the court at the place of infringement. If an infringement action or revocation action is already pending, the venue for the request for a PI must be filed to the Oslo District Court.

As mentioned, in proceedings on the merits there will be two appointed expert lay judges in both the first and second instance. These expert lay judges will be accompanied by one legal judge in the first instance and three legal judges in the second instance. The expert lay judges are normally appointed upon (often joint) proposal from the parties and have their background within the technical field to which the case relates.

Expert lay judges cannot be appointed in PI proceedings, but it is common to use court-appointed experts in such proceedings. These experts are not associated with any of the parties and will be appointed to assist the legal judge in their assessment of the case. They are not part of the panel of judges, but will hear the trial and deliver an opinion on the matter in open court. Often, they also deliver a written opinion.

2. Generic Market Entry

2.1 Infringing Acts

An application for a marketing authorisation (MA) is not an infringing act, and will not in itself be considered sufficient for the grant of a PI. However, the court will consider if there are additional circumstances that – together with the grant of an MA – constitute sufficient evidence that infringement is either imminent or likely in the near future.

A communication to customers of the intended launch date after patent term expiry will normally be viewed as an offer to deliver after expiry; this is generally considered an infringing act in Norway. Responding to a request for tender, where supply would take place after expiry of the relevant rights, may equally be classed as an act of patent infringement. In theory, a PI application could be made on such basis, but the authors are not aware of any such PI being granted in Norway.

2.2 Regulatory Data and Market Exclusivity

EU legislation on data and market exclusivity is included in the EEA Agreement and implemented in Norwegian law under the Norwegian Medicine Regulation of 18 December 2009 No 1839 (NMR).

Chapter 3 of the NMR, as a main rule, distinguishes between an eight-year period of data protection (Section 3-10(c) and 3-10a(b)) and a ten-year period of market protection (Section 3-11(b) and 3-11a (b)) (the "8+2 system"). During the two-year period after expiration of the data protection, the market protection prohibits the placing on the market of a generic medicinal product but does not prohibit preparatory actions prior to putting the product on the market.

In addition, under Chapter 3, Sections 3-11b and 3-11d, the MA holder of the reference product may qualify for another year of market exclusivity if the MA holder is granted further marketing authorisation for a significant new indication for the relevant medicinal product (the "8+2+1 system").

However, Chapter 3 of the NMR does not distinguish between the data and market protection where the reference product application was filed prior to:

- 12 January 2010, if made way by of the national procedure (NP); or
- 1 November 2005 (or later), if made by way of the central procedure (CP).

NP applications filed in the period between 1 November 2005 and 12 January 2010, and CP applications filed prior to 1 November 2005, enjoy a ten-year period of data protection with no additional market protection period (Sections 3-10(b), 3-10a(a), 3-11(a) and 3-11a(a)). NP applications filed prior to 1 November 2005 enjoy a six-year data protection period with no additional market protection period (Sections 3-10(a) and 3-11(a)).

2.3 Acceptable Pre-launch Preparations

The Bolar exemption introduced in Directive 2001/83/EC Article 10(6) has been implemented in the Norwegian Patent Act Section 3(5). The Bolar exemption applies to patents and Supplementary Protection Certificates (SPCs) covering pharmaceuticals, and allows the undertaking of "tests, trials and similar" of pharmaceuticals that are necessary for obtaining market authorisation. Furthermore, the Bolar exemption is applicable for obtaining marketing approvals in all WTO-signatory countries – ie, the Bolar exemption is not limited to EU/EEA countries.

As mentioned previously, applying for an MA or a pricing and reimbursement (P&R) decision is not an infringing act and will not in itself be considered sufficient for the grant of a PI. See **2.1 Infringing Acts** for exceptions.

2.4 Publicly Available Drug and Patent Information

Publicly Available Information

The Norwegian Medicines Agency (NOMA), which is the authority responsible for granting MAs and P&R decisions, publishes updates to the following different lists on their website.

- A list, which is updated from time to time, of first-time generic and hybrid mutual recognition procedure (MRP), decentralised procedure (DCP) and NP applications. The list includes information about the active ingredient, marketing status, Anatomical Therapeutic Chemical (ATC) classification, procedure, grounds for the application (eg, hybrid or generic application), and date of the application. The product name, the applicant and other countries involved (including the reference country) are not published.
- A list containing all new granted MAs in CP, MRP, DCP and NP applications is updated on a monthly basis and thus becomes publicly available. The list includes information about product name, MA status, MA date, MA holder, MA number, application procedure, the active ingredient, medical indication, prescription status and product type and dosage.
- A list of P&R decisions that includes the above-mentioned information (as per the MA granted listed), as well as information about pricing and reimbursement.
- When approved, generic drugs for which generic substitution applies, will also appear on the so-called "substitution list". This list is updated on the first and the 15th day of each month.

In addition, information about granted MAs, P&R decisions, and substitution status is made available in NOMA's public database (*Legemiddelsøk*). The database is updated shortly after NOMA has granted the MA. Hence, information may be published in NOMA's database before the aforementioned lists and databases are updated.

Moreover, the product must be listed in the database of the Association of Pharmacies (*Farmalogg*). In practice, a product is available on the market when it is included in *Farmalogg*. This register is also updated on the first and 15th day of each month.

Freedom of Information Requests

Freedom of information requests to NOMA are available under the Freedom of Information Act. Usually, when requests under the Norwegian Freedom of Information Act are made to NOMA, a reference will be made to the published lists and databases without giving any additional information. Additional information about pending applications is generally classed as trade secrets, and therefore excluded from the right to information (see Section 13 of the Norwegian Freedom of Information Act and Section 30 of the Norwegian Medicine Act). NOMA will not notify the generic MA applicant/holder if someone (eg, the MA holder of the reference product) requests information under the Norwegian Freedom of Information Act.

2.5 Reimbursement and Pricing/Linkage Markets

Generally, NOMA will neither consider the patent situation on its own – nor act upon notifications from the patent holder covering an innovative product – when it comes to marketing authorisation, pricing and reimbursement, and generic substitution.

There is one exception, however. According to Section 2.3 of NOMA's guidelines regarding the

substitution list, generic drugs covered by a second indication patent are still added to the substitution list – albeit with the instruction that the drug is not to be substituted if the pharmacy is aware that the drug is prescribed for the patented use. Hence, the holder of a second indication patent will regularly notify NOMA following the grant of an MA to a generic product for which the originator holds a second indication patent.

The holder of the MA for the reference product is not notified of any MA, P&R or listing applications made by a generic or biosimilar, nor of the grant of such applications. Information may be obtained through freedom of information requests or, alternatively, by monitoring publicly available lists and databases (see **2.4 Publicly Available Drug and Patent Information**).

3. Biosimilar Market Entry

3.1 Infringing Acts
See **2.1 Infringing Acts**.

3.2 Data and Regulatory Exclusivity
See **2.2 Regulatory Data and Market Exclusivity**.

3.3 Acceptable Pre-launch Preparations
See **2.3 Acceptable Pre-launch Preparations**.

3.4 Publicly Available Drug and Patent Information
See **2.4 Publicly Available Drug and Patent Information**.

3.5 Reimbursement and Pricing/Linkage Markets
See **2.5 Reimbursement and Pricing/Linkage Markets**.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates
SPC protection is available in Norway. This is regulated by the relevant EU regulations and these have been implemented into Norwegian law by application of the EEA agreement. SPCs are therefore available for patents that cover an authorised medicinal or plant pharmaceutical product.

The relevant law is Regulation 469/2009 concerning the supplementary protection certificate for medicinal products; however, this has been amended at EU level through Regulation 2019/933 implementing the SPC manufacturing waiver. The waiver enables manufacturers of generics and biosimilars to manufacture such medicines for the purpose of exporting them outside the EU during the SPC protection term. The waiver will be implemented in Norwegian law with effect from 1 February 2023.

4.2 Paediatric Extensions
Paediatric extensions are available in Norway and regulated by EU law. The Paediatric Regulation was introduced into Norwegian law and entered into force 1 September 2017, bringing some statutory amendments that make it possible to apply for a six-month extension to the period of validity of SPCs.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief
The court may provide for when the PI should be enforced and how long it should last. Enforcement of a PI shall take place as soon as request-

ed by the claimant, and must follow the rules of the Enforcement Act of 1992.

If the court has required a bond in relation to a PI, the PI will not take effect before a bond is in place. The value of the bond is normally calculated on the basis of the potential damage the defendant could suffer in the period before delivery of judgment in the first instance (after which the PI will be lifted, if the defendant is successful).

For a PI to be enforced, the patentee is not required to have commenced a main action; however, the claim in question must normally be established as probable. If a PI is granted, the courts will normally set a deadline for the patentee to initiate main proceedings.

5.2 Final Injunctive Relief

Final injunctions are granted if the claimant is successful at proving at trial that infringement or significant preparatory acts with the aim of carrying out an infringing act took place. Such injunction will normally not be enforceable pending an appeal.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

Preliminary Injunctions

The court will assess the proportionality of a PI in PI proceedings. In such assessment, the court may also take public interest arguments into account.

Final Injunctions

If requested by the defendant, a court may – in lieu of an final injunction – award a licence against reasonable compensation to the patentee. However, the defendant must establish that there are some special circumstances in order for such a licence to be awarded. To date, this narrow exception has not been used by a Norwegian court.

5.4 Damages

Damages are calculated on the basis of lost profits. In order to estimate the potential damages exposure, one would need to provide proof of the suffered damages (eg, loss of sales of a generic or biosimilar). The time period for claiming damages based on a patent infringement is three years from when the cause of action accrued. This period will commence at the time of infringement; however, if the infringement has been concealed during this three-year period, the damage claim is not time-barred until the expiration of a one-year period from the time when the claimant should – with reasonable diligence – have discovered the infringement.

Damages are normally assessed as part of the infringement action – ie, there is no separate procedure for establishing the quantum of damages. The infringer is liable for damages in the form of remuneration for the exploitation of the invention and, if applicable, compensation for any further economic loss to the claimant caused by the infringement. The patentee can also choose to claim the infringer's profits. Thus, the patent owner can either claim their own lost profits, reasonable royalties on sales by the defendant, or the defendant's profits.

If the infringement has been committed intentionally or through gross negligence, the patentee can claim compensation corresponding to 200% of a reasonable royalty.

With the exception of the option of claiming 200% of a reasonable royalty when the patent infringement was wilful or grossly negligent, punitive damages are not an option under Norwegian law.

5.5 Legal Costs

Legal costs are normally recoverable from the losing party unless the court decides to reduce the amount, owing to it being unreasonably high. Hence the losing party will typically be required to pay all costs to the party that prevails in a litigation.

5.6 Relevance of Claimant/Plaintiff Conduct on Relief

The court may decide that the winning party should bear its own costs partially or in full – for example, if the winning party is to blame for the matter coming before a court or has declined a reasonable settlement offer. The Dispute Act further provides that a party may recover costs that arise from the counterparty's conduct, such as censurable actions or omissions that make the procedure more complex than it already is. The parties' conduct prior to the proceedings is also relevant – for example, if the claimant fails to notify or inform about the existence of relevant evidence.

6. Other IP Rights

6.1 Trade Marks

Trade mark disputes within the life sciences and pharma sector not very common in Norway. The few cases that have been tried before the courts concern medical devices and repacking issues related to parallel import of pharmaceuticals.

6.2 Copyright

Copyright issues may also arise in the life sciences and pharma sector, but are very seldom litigated before the courts.

6.3 Trade Secrets

Trade secrets disputes have been seen within the life sciences and pharma sector, particularly in relation to a company's former consultants or employees. The relevant sources of law are the Norwegian Trade Secrets Act of 2021 and the Norwegian Marketing Act of 2009.

7. Appeal

7.1 Timing to Appeal Decision

Preliminary Injunctions

A PI decision may be handled in the second instance if appealed. An appeal may be filed within a limited one-month time period. The appellate court will normally only review the case based on the written submissions and evidence.

Main Actions

A judgment in infringement (and/or revocation) proceedings from the Oslo District Court may be appealed to the "Borgarting" Court of Appeal. A court of appeal hearing in Norway implies hearing the case all over again with evidence, expert witnesses and legal arguments; also, new evidence and arguments are allowed. The appeal hearing in appellate court will normally take place about a year after an appeal was made. A judgment is normally expected within four to ten weeks of the hearing, depending on the complexity of the case.

A further appeal is possible to the Supreme Court; however, leave for appeal is only granted if the appeal raises principal points of law for which guidance from the Supreme Court would be deemed useful. The appeal hearing in the Supreme Court will normally take place within three to five months of an appeal being made to the Supreme Court. A judgment is normally expected two to four weeks after the Supreme Court hearing.

7.2 Appeal Court(s) Arbiter

The "Borgarting" Court of Appeal decides patent litigation appeals from Oslo District Court in the first instance. The appeal is heard by three legal judges and there is no specialisation in patent matters; however, the appellate court will be assisted by two appointed expert lay judges.

An appeal to the Supreme Court is heard by five legal judges and, as in the Court of Appeal, there is no specialisation in patent matters.

7.3 Special Provisions

Oslo District Court is the mandatory venue for design, trade mark and patent cases. IP proceedings are, however, dealt with in accordance with the general procedural rules set out in the Norwegian Dispute Act.

8. Other Relevant Forums/ Procedures

8.1 Other Relevant Forums/Procedures

The holder of the relevant right may request that the Customs Authority retains goods that are in the authority's control if there is reasonable suspicion that the importation of said goods will constitute:

- a violation of the individual's rights under the Norwegian Marketing Act; or
- an infringement of their IP rights such as a patent or copyright.

This may be done if the infringement consists of an imitation of someone else's product, characteristic, advertising material or other similar material.

The holder of the right must send an application to the Customs Authority containing, among other things:

- the applicant's name and address;
- potential agent's name and address;
- a list of the IP rights in question; and
- information making it possible to identify authentic goods.

9. Alternative Dispute Resolution

9.1 ADR Options

The parties are not required to undertake mediation before commencing court proceedings. Nevertheless, according to Section 5-4 of the Norwegian Civil Procedure Act, the parties shall consider whether it is possible to reach an amicable settlement of the dispute before action is brought and shall make an attempt at settlement.

According to Section 8-1 of the same Act, the court shall also – at each stage of the case – consider the possibility of a full or partial amicable settlement of the legal dispute through mediation or judicial mediation, unless the nature of the case or other circumstances suggest otherwise. Mediation or arbitration is, however, not commonly used in patent disputes.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The parties cannot agree upon terms prohibited by Norwegian competition law or EEA/EU competition law. Terms that restrict competition in the relevant market and extend the monopoly conferred by the patent – for example, by

restricting the licensee's use of its own technology – might be unlawful under competition law.

Wikborg Rein Advokatfirma AS is one of Norway's leading law firms, with headquarters in Oslo and offices in Bergen, London, Singapore and Shanghai. The firm's long-standing presence overseas distinguishes Wikborg Rein as the Norwegian law firm with the most international experience and expertise. Wikborg Rein's practice group for IP and Technology offers its clients a breadth of knowledge and significant expertise in the field. The team consists of highly qualified and dedicated lawyers with a varied skillset in the legal and technology areas relating to IP. The firm assists its clients in enforcing and defending all types of IP rights, as well as providing advice on patent issues from a range of technology areas, including pharmaceuticals, biotechnology, oil and gas, electronics and fish farming.

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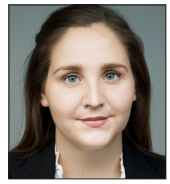

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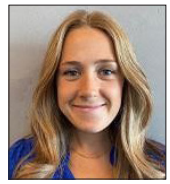

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SWITZERLAND

Law and Practice

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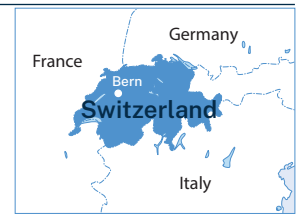

Contents

SWITZERLAND

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

The patent owner always has standing to sue for patent infringement.

Exclusive licensees have standing to sue for patent infringement, unless the licence agreement specifically excludes this right. However, the exclusive licensee's standing to sue exists only with regard to licence agreements entered into or renewed after 1 July 2008. The exclusive licensee's standing to sue does not depend on the licence being registered with the Patent Register.

Where an exclusive licensee brings the action for infringement, the patent holder does not need to be joined to the proceedings.

Non-exclusive licensees have no statutory standing to sue for patent infringement. However, they can join a damages claim to claim their own damages. Therefore, for non-exclusive licensees, it is essential that the relevant licence or distributorship agreement contain a clause requiring the patentee to take action for patent infringement.

Distributors are often granted a licence to distribute the patented products, whereas such licence can be implicit. Therefore, the same rights apply as for licensees – unless expressly excluded in the agreement. An exclusive distributor can take action against unlicensed distributors, whereas non-exclusive distributors are prevented from taking legal action.

Where a patent is owned by two or more persons, each of them can bring an action for infringement of the patent (Article 33, paragraph 2, Patent Act) and does not need to join the other co-owners.

As previously outlined, exclusive licensees are entitled to bring infringement claims in their own right. "Exclusive licence" within the understanding of Swiss law means a licence where the right granted is exclusive even vis-à-vis the patent owner.

Under Swiss civil procedure, it is generally not possible to add parties during litigation without the other parties' consent. However, a (co-) claimant can withdraw any particular claim made against any or all of the defendants.

Any person who can demonstrate an interest in the invalidation/nullity of the IP right concerned can file a nullity action. The threshold of the standing to sue for invalidity is, in practice, low – for example, a competitor whose business is disturbed by the registered IP right can sue for invalidity, regardless of whether they are already distributing a potentially infringing product.

1.2 Defendants/Other Parties to an Action

Any person who is allegedly infringing or threatening to infringe an IP right has standing to be sued and can thus be a defendant. In practice, suppliers, manufacturers and local distributors/ wholesalers are typically targeted when it comes to IP infringement litigation in the life sciences space.

Since 2019, "acts undertaken as part of a medical activity concerning an individual person or animal and involving a medicinal product" – such as the prescribing, dispensing or use of medicinal products by legally authorised persons – have been explicitly exempted from the scope of the patent (Article 9(1)(g) PA). The same is true of the

"direct individual preparation of medicinal products in pharmacies in accordance with a doctor's prescription or to acts concerning medicinal products prepared accordingly" (Article 9(1)(h) PA). Therefore, medical practitioners – in particular, doctors, nurses or pharmacists – cannot be sued for patent infringement in relation to acts involving medicinal products. Importantly, these provisions do not apply to acts of medical practitioners that do not involve medicinal products, such as the treatment of the human body or the use of medical devices.

Health regulatory authorities do not need to be notified of infringement lawsuits and do not need to be given an option to join such proceedings. In the event that they contribute to the infringement of IP rights, a government entity (the Swiss Confederation or the relevant canton or local government) can have standing to be sued for infringement. However, with regard to damages claims against the state, special regulations are applicable, including different rules on jurisdiction.

1.3 Preliminary Injunction Proceedings

Preliminary injunctions (PIs) are available if the following requirements are met:

- there is a prima facie case of infringement and validity;
- the applicant will suffer not easily reparable harm if the injunction is not granted;
- the requested relief is proportionate to the harm caused by the alleged infringement; and
- the requested relief is urgent.

With regard to the final requirement, the case law of the Federal Patent Court requires only "relative urgency". Relative urgency applies whenever the decision on the PI can be handed down earlier than a decision in ordinary proceedings on the merits if the patentee initiates such proceedings immediately upon becoming aware of the infringement. In practice, relative urgency generally applies if the applicant files a request for PI less than 14 months after learning of the infringement.

Ex Parte Injunctions

In cases of special urgency and where there is a strong prima facie case of infringement, ex parte injunctions are available. "Special urgency" means that immediate action is required and the claimant cannot be expected to wait until the conclusion of inter partes PIs or that hearing the other side would defeat the purpose of the injunction. The claimant is expected to act immediately – ie, generally not more than a few days after learning of the infringement. However, in practice, ex parte injunctions are rarely granted in patent matters.

Actions started through an ex parte application require confirmation in inter partes proceedings. In addition, all PI proceedings require confirmation in main proceedings. After issuing a preliminary judgment, the court will set a deadline for the commencement of the main proceedings. If no main proceedings are initiated, the injunction lapses and the applicant is liable for any damages caused to the defendant.

PI proceedings in patent matters are normally conducted within six months – although they may last four to ten months and can take up to one year in highly complex cases.

The defendant can (and often will) dispute the validity of the patent in PI proceedings. It is sufficient to make a credible showing of the invalidity of the patent under a "more likely than not" standard. Unlike in some other jurisdictions, the Federal Patent Court will examine the valid-

ity and infringement of the patent-in-suit rather thoroughly in PI proceedings.

In the area of patent law, the Federal Patent Court decides as the court of first instance and only one appeal (limited to matters of law) to the Federal Supreme Court is available. The appeal to the Federal Supreme Court is very limited in PI cases and is inadmissible on most occasions.

The Federal Patent Court will almost always appoint a hearing in PI cases. The main hearing generally takes place within a few months of the filing of the request.

Decisions upon ex parte requests are generally handed down very quickly. If there is a high sense of urgency, the Federal Patent Court can decide on the day of the filing of the request.

Filing of a Preliminary Injunction Request

Preliminary relief is available if the above-mentioned requirements are met (ie, prima facie case of infringement and validity, not easily reparable harm, proportionality, urgency).

The applicant must credibly show that they are the owner (or exclusive licensee, as per Article 75, Patent Act) of a patent formally in force in Switzerland and that the defendant is infringing or threatening to infringe the scope of protection of this patent through acts attributable to them. (Federal Patent Court of 28 February 2019, S2018_006, consid. 16).

There are no translation or validation requirements with regard to European patents in Switzerland.

The patent must have been granted at the latest when the decision is handed down. The Federal Patent Court allows the request for a PI to be filed before grant, although it will assess the probable timeline of the grant.

If it appears that the patent grant will be delayed (eg, because a parallel entitlement lawsuit is pending), the court will suspend the proceedings until the grant (Federal Patent Court of January 4, 2022, S2021_007). If the grant is imminent, the final wording of the patent-to-be-granted is known and there are no reasons to think the grant will be delayed, the Federal Patent Court will conduct the proceedings as though the patent were already granted; however, it will not issue a decision before the actual grant of the patent (Federal Patent Court of 2 June 2022, S2022_002).

The claimant must show that either:

- infringing acts have already occurred and there is a risk of reiteration; or
- the infringement is imminent.

Specific Considerations in Life Sciences Cases

Imminent infringement requires a certain minimum intensity. Filing for regulatory authorisation of a medicinal product is, in itself, generally not sufficient for a finding of imminent infringement.

However, further acts are considered sufficient for a finding of imminent infringement, including:

- the request for reimbursement from the health regulatory authorities;
- enquiries with pharmacists for future placement of orders; or
- the inclusion of the product into third-party product databases aimed at potential clients (notwithstanding the fact that no actual orders are possible).

Notification of a Preliminary Injunction Request

Court decisions – ie, the decision on the grant or dismissal of the PI (inter partes and ex parte) – and submissions of the opposing party are subject to a qualified service effected by the court via the Swiss Post, municipal authorities or the local police (if in Switzerland) or via diplomatic notification channels (if outside Switzerland). Receipt must be acknowledged.

Within Switzerland, service is generally effected within a day. If acknowledgment of receipt is not possible, the delivery is deemed to have occurred seven days after the unsuccessful delivery attempt. In the case of personal delivery, if the addressee refuses the receipt and this is recorded by the person delivering the item, service is deemed effected on the day of the refusal.

Notifications abroad are subject to the delays inherent in diplomatic notifications and can take anywhere between a few days and several months, depending on the country. In some cases, ex parte decisions have been issued precisely because it seemed impossible to effect notification of the relevant court documents within a reasonable deadline.

The court can notify by publication in the local official journal or in the Swiss Official Gazette of Commerce if:

- the defendant does not have any known address (inside or outside Switzerland) and reasonable attempts to locate one have failed; or
- a notification would be impossible or overly complicated and the defendant has not designated an address for service in Switzerland.

The Federal Patent Court generally sets fixed deadlines (dates) if the party is domiciled in Switzerland or has appointed an address for service in Switzerland.

Submission of the Opposing Party

If the PI request is not obviously inadmissible or unfounded, the opposing party is given the opportunity to submit a written statement in all cases.

Ex parte injunctions must always be confirmed inter partes. The defendant will be invited to a hearing or given a time limit in which to submit a written response. After hearing the parties, the court immediately decides whether the ex parte injunction is:

- to remain in force as a PI;
- to be amended; or
- to be revoked.

In complex cases, the court may order a second exchange of written submissions (reply and rejoinder).

Admissible means of evidence are limited in PI proceedings. All evidence must, in principle, be provided through documents. Other means of evidence are only admissible if they do not significantly delay the proceedings or if the purpose of the proceedings so requires.

Filing of Protective Letters

A party who fears that it may be subject to an ex parte request can file a protective letter. The court will not notify the protective letter to the potential claimant and keep it on record until an ex parte application is filed.

If an application is filed, the court will consider the arguments set out in the protective letter to

determine whether to grant an ex parte injunction. If no ex parte application is filed within six months, the protective letter will be returned to the potential defendant.

In the Federal Patent Court, the protective letter may be renewed for subsequent periods of six months.

Factors to Consider in the Grant of a Preliminary Injunction

If the risk of a PI request is known, it is often advisable to file a protective brief with the Federal Patent Court.

Companies in the pharma and medical device industry should be aware that the Federal Patent Court does not examine the public interest when issuing a PI. In other words, if there is a strong case of infringement and validity but the alleged infringer wants to argue that there is a compelling public interest to leave its product on the market, it is advisable to file a request for a compulsory licence under the applicable provisions of the Patent Act.

1.4 Structure of Main Proceedings on Infringement/Validity

The defendant in infringement proceedings can challenge the validity of the patent by way of a defence or a counterclaim. Infringement and invalidity are dealt with in the same proceedings before the same court (ie, there is no bifurcation). Therefore, if the defendant in infringement proceedings seeks to invalidate the patent, the invalidity action can be brought in the same proceedings.

Nullity proceedings related to the Swiss part of a European patent can be brought regardless of whether opposition (or appeal) proceedings are pending in the European Patent Office (EPO). The Federal Patent Court can – but will not necessarily – suspend the proceedings pending the outcome of the EPO proceedings.

1.5 Timing for Main Proceedings on Infringement/Validity

In principle, a revocation (nullity) action can be brought at any time after patent grant, even several years after the patent has been granted by anyone who has standing to sue for revocation.

Infringement actions can also be brought at any time after the patentee learns of the infringing acts. Although an infringement action can be filed before the patent grant, the decision of the court will not be issued before the grant (see **1.3 Preliminary Injunction Proceedings**).

However, IP-related claims are subject to forfeiture. Forfeiture is not to be assumed lightly, according to settled Supreme Court practice. IP claims are forfeited if the following (cumulative) requirements are met.

- The infringement has been going on for a long time. There is no fixed deadline, as the acceptable time before taking action depends on the specific circumstances and the intensity of the infringement. Generally, forfeiture is not assumed before two years and it is generally accepted that claims are forfeited after the right-holder has waited for more than eight to ten years after learning of the infringement.
- The right-holder has been aware of the infringing act (actual knowledge) or, at least, should have been aware of it the right-holder observed the market diligently (constructive knowledge).
- The infringer has acquired a position on the market that is worthy of protection.

- There is evidence of good faith on the part of the alleged infringer.

Claims for financial compensation (damages, hypothetical licence fee, disgorgement of profits) are subject to the statute of limitations. The limitation period is three years from the knowledge of the existence of the claim (relative period) and, in any event, ten years after the occurrence of the damaging event at the latest (absolute period).

The procedure for notifying the alleged infringer of an infringement action or notifying the patentee of a nullity action is the same as per service in the case of preliminary injunction requests (see **1.3 Preliminary Injunction Proceedings**).

The timeframe of patent infringement proceedings (main proceedings on the merits) depends on the complexity of the technology in question, the number of patents and/or patent claims allegedly infringed, and the defences raised. In principle, the Federal Patent Court aims to conclude patent infringement proceedings within 18 to 24 months, except in cases involving complex technology. In order to reach this goal, the Federal Patent Court generally sets binding deadlines of:

- six weeks for filing the statement of defence and answer to the counterclaim; and
- four weeks for filing the reply, rejoinder, and reply to the counterclaim, as well as the rejoinder to the counterclaim and the comments on new allegations and new evidence in the defendant's rejoinder.

Parties can generally obtain a single two-week extension of these deadlines. Further extensions can generally only be obtained with the other party's consent. However, in complex cases or under extraordinary circumstances, the court can grant longer extensions.

The Federal Patent Court and some cantonal courts will summon the parties to an instruction hearing after the first exchange of briefs, which is a few months after the filing of the statement of claim. The goal of this hearing is to clarify any procedural issues, provide a first informal opinion of the case and attempt a settlement. Between 20% and 50% of main proceedings are settled, usually at the instruction hearing.

If no settlement is reached, the court will order a second exchange of briefs. At the Federal Patent Court, the technical judge of the panel will then issue a written opinion on the question of validity and infringement. Eventually, the proceedings are concluded in a main hearing. If non-documentary evidence is to be taken (party declarations, witness testimony, court-mandated experts), further hearings can be appointed.

Fast-track procedures are available in cases where the facts are undisputed or can be immediately proven and the legal situation is clear. These cases are handled in summary proceedings and a judgment can generally be expected within six months.

1.6 Requirements to Bring Infringement Action

The timeline for filing a main infringement action is the same as that for PI proceedings (see **1.3 Preliminary Injunction Proceedings**) and, similarly, there are no requirements regarding the grant, translation or validation of European patents in Switzerland.

In patent infringement proceedings, the plaintiff must allege and prove all relevant facts – in particular, the infringing acts, the existence and

amount of the damage and, if the infringing defendant raises corresponding objections, the validity and scope of protection of the patent.

It is usually difficult to prove infringing acts in the case of process patents. The owner of a process patent also enjoys protection for the direct products of the process.

The Federal Patent Act contains a reversal of the burden of proof in favour of the patent owner in one case – namely, if the invention concerns a process for the production of a new product, any product of the same quality is deemed to have been produced according to the patented process until proven otherwise. If this reversal of the burden of proof is not applicable because the product was not new, the law still alleviates the burden of proof of the patentee by stating that it is sufficient to establish a prima facie (more likely than not) case of infringement.

1.7 Pre-action Discovery/Disclosure

US-style pretrial discovery is not available in Switzerland. Generally, parties do not have an obligation to disclose relevant documents and materials to their opponent. However, some limited – yet effective – options are available for obtaining documents and materials before initiating infringement proceedings.

Under the Patent Act, the court can order – as a preliminary measure – a description or seizure of the allegedly infringing product, process and means of production based on a prima facie showing of actual or imminent infringement. This option is available before initiating proceedings and the findings resulting from the description or seizure can be used in later infringement proceedings in Switzerland or abroad. The party seeking this measure does not need to show irreparable harm (ie, that the evidence is likely to be destroyed or abandoned). Showing another legitimate interest (aside from the interest necessary to establish whether an infringement has been committed) is not required either. A member of the Federal Patent Court carries out the order and, if necessary, is assisted by a court-appointed expert or local authorities (eg, the police).

In addition, a party can request at any time (that is, even before initiating proceedings) the court order the provisional seizure of evidence if it is prima facie established that the relevant evidence is likely to be destroyed or abandoned.

Fishing expeditions are not allowed. The applicant must give details on:

- the documents or items that are the object of the description or seizure;
- why it believes that these documents or items can be found at the relevant site; and
- their relevance to its case for infringement.

During the proceedings, a party can ask the court to order that the other party surrender documents (except for documents subject to legal privilege) that are relevant for the proceedings and that are controlled by the other party. However, there are no direct sanctions if the other party refuses to comply, except for taking the refusal into account when weighing the evidence and drawing negative inference from it.

There are no general restrictions on the use of material obtained through a seizure or description order in a Swiss court. However, upon request of the targeted party, the court can order specific confidentiality measures, which can include a prohibition from using the relevant information outside of the Swiss proceedings.

1.8 Search and Seizure Orders

The means of collecting evidence in a pretrial situation, as described in **1.7 Pre-action Discovery/Disclosure**, are also available during the proceedings.

In addition, a party can ask the court to order the other party to surrender documents (apart from those subject to legal privilege) that are relevant to the proceedings and that are controlled by the other party. However, there are no direct sanctions if the other party refuses to comply – although the refusal will be taken into account when weighing the evidence and negative inference may be drawn from it.

1.9 Declaratory Relief

Under Swiss law, an alleged infringer can bring a lawsuit to obtain a declaratory judgment that an act does not – or that a proposed act would not – constitute an infringement of a patent, provided it has a legitimate interest in obtaining such judgment. This is usually the case if either:

- the alleged infringer has received a cease-and-desist letter; or
- the patent owner has otherwise asserted that, in its opinion, the claimant is infringing the patentee's patent.

An alleged infringer is generally barred from bringing a lawsuit to obtain a declaratory judgment on non-infringement if the patent owner has not yet given any indication that it considers the alleged infringer's activities to be infringing. However, in disputes involving foreign IP rights-holders, it is recognised that an alleged infringer in Switzerland can also bring proceedings to obtain a declaratory judgment of non-infringement to secure a forum in its home jurisdiction in order to avoid practical disadvantages (eg, a foreign jurisdiction or the use of a foreign language).

The threshold for an alleged infringer to sue for invalidity is generally lower. An alleged infringer will have standing to sue for invalidity if the parties are in a competitive relationship and the scope of protection of the patent extends to the alleged infringer's field of activity.

1.10 Doctrine of Equivalents

The doctrine of equivalents (DoE) is an integral part of Swiss patent law. To extend the scope of protection beyond the strict literal meaning of the words of the claim, any element that is equivalent to an element specified in said claim is taken into account. Therefore, the scope of protection conferred by a patent claim is not limited to the identical use of the features of the construed claim by the defendant's product or process. It also extends to equivalent elements if the following three conditions are met:

- the equivalent element has the same effect;
- this same effect is obvious to the skilled person; and
- a skilled person would have considered the equivalent element as having the same value.

1.11 Clearing the Way

In general, there is no obligation to "clear the way" ahead of a new product launch. However, failing to clear the way can be taken into account when assessing the amount of court costs or a damages claim, for example, as failing to clear the way can be a sign of negligence or intentional breach.

1.12 Experts

In general, only testimony by court-appointed experts is formally considered a means of evi-

dence in Swiss civil procedure. Private expert reports are considered mere party allegations.

To date, the Federal Patent Court does not appear to have appointed experts or heard court-appointed expert witnesses because the Federal Patent Court has a vast group of technical judges who are relied upon for technical issues within the panel of judges. In patent infringement and validity cases, the opinion of the technical judge is formally notified to the parties before the main hearing and the parties can comment on it either in writing or orally at a hearing.

Private Experts

Opinions of private experts are sometimes used in support of specific allegations (for example, in relation to infringement and validity issues or calculation of damages). The evidential value of private expert opinions is relatively low, as the Federal Supreme Court and the Federal Patent Court consider them mere party allegations rather than proper evidence. Nonetheless, Swiss courts – and, in particular, the Federal Patent Court – will review and take into account private expert reports if they are scientifically and technically sound and well-founded. Private expert opinions can also be important, as they provide guidance to the (technical) judges and any court-appointed expert.

Court-Appointed Experts

Before the establishment of the Federal Patent Court, court-appointed experts played a significant role in patent proceedings in Switzerland. However, this has changed, as there is always at least one judge with a technical background, which allows the court to decide without retaining further experts. In highly complex cases or cases relating to a remote field of technology, external court experts may still be needed and appointed – although this does not appear to have occurred yet.

1.13 Use of Experiments

The Code of Civil Procedure lists the admissible means of evidence exhaustively: testimony, documents, inspection, expert opinion, written information, and party questioning. An experiment can be conducted (and was conducted in at least one past case) as an "inspection" before the court during an evidentiary hearing.

1.14 Discovery/Disclosure

In Swiss civil procedure, the parties must present to the court the facts and all means of evidence on which they base their legal claims. In principle, no evidence is taken ex officio and the other party is not obliged to help in collecting evidence. Therefore, Swiss civil proceedings are heavily front-loaded: both parties need to present all facts and means of evidence in their briefs.

As set out in **1.7 Pre-action Discovery/Disclosure** and **1.8 Search and Seizure Orders**, description and seizure orders are available in certain cases both before and after filing a lawsuit.

Additionally, the front-loaded character of civil proceedings is alleviated by the following two mechanisms.

- During the proceedings, the court can order a party to produce specific documents that are in the party's custody if the party seeking the production can prove their relevance to the outcome of the case. No fishing expeditions are permitted. Failure to comply with a court order can be taken into account by the court when weighing the evidence. The court can also compel third parties to produce specific

documents relevant to the outcome of the case.
- The court can order the production of a defendant's accounting documents and information on the extent of infringing activities, in order to allow the claimant to quantify its monetary claims (damages and disgorgement of profits).

1.15 Defences and Exceptions to Patent Infringement

An alleged infringer can use the following defences.

- The product/process does not fall within the patent claims if properly construed.
- The patent is invalid.
- Exemption from patent infringement. Under Swiss law, patent rights do not extend to:
  (a) acts done privately for non-commercial purposes;
  (b) acts done for experimental purposes;
  (c) acts done for the purpose of obtaining a marketing registration (Bolar-type exemption);
  (d) use on vehicles, ships, and aircraft temporarily or accidentally entering Switzerland;
  (e) acts undertaken as part of a medical activity concerning an individual person or animal and involving a medicinal product – in particular, the prescribing, dispensing or, use of medicinal products by legally authorised persons; and
  (f) the direct individual preparation of medicinal products in pharmacies in accordance with a doctor's prescription, or acts concerning medicinal products prepared in this way.
- Exhaustion of rights – this applies if the patented product or the product resulting from a patented process has been sold in Switzerland or in the European Economic Area (EEA) by the patentee or with the patentee's consent. Generally, Switzerland adheres to the principle of regional exhaustion – except for patented products with regulated prices (such as pharmaceuticals), to which the principle of national exhaustion applies. Biological materials can also be multiplied for their intended use.
- Antitrust violation in the case of parallel importation of patented products from a country outside Switzerland and the EEA – albeit only in exceptional circumstances
- Prior user right – this only applies if the alleged infringer had already used or made all necessary preparations to use the invention claimed by the patent at the patent's priority date.
- The patentee is estopped from enforcing an otherwise valid and infringed patent because they have delayed the lawsuit for a substantial period of time. However, this defence is limited to rare cases where the patentee – through its conduct – has given the alleged infringer reasonable grounds to believe that it would not bring any claim for patent infringement. Mere inactivity of the patentee, even for a long period of time, is generally not sufficient.

Compulsory Licensing

If none of the above-mentioned defences proves successful, the alleged infringer can argue that it is entitled to a compulsory licence – in particular, when:

- the alleged infringer has an invention that is dependent on the prior invention;
- the patented invention is not exploited in Switzerland; and
- there is a public interest in granting a compulsory licence.

The grant of a compulsory licence must be requested in separate proceedings and it can be filed as a counterclaim to an infringement lawsuit.

There are currently no published decisions related to standard essential patent (SEP) disputes in Switzerland.

1.16 Stays and Relevance of Parallel Proceedings

Switzerland is not a member state of the EU. Therefore, the Brussels Regulation (recast) is not applicable to Switzerland. However, Switzerland is a signatory state of the Lugano Convention and Swiss courts generally follow the CJEU case law issued under the (substantively identical) provisions of the Brussels Regulation.

As a general rule, where proceedings are already pending between the same parties on the same subject matter before a foreign court, a Swiss court will stay proceedings until the foreign court issues a decision on its jurisdiction. Some scholars have argued that if the foreign court in which the lawsuit was filed has clearly no jurisdiction to hear the case ("torpedo" action), the action before the foreign court constitutes an abuse of law and should not justify a stay of the Swiss proceedings.

Under the most recent case law, if the plaintiff files a preliminary injunction request and a statement of claim in main proceedings on the same subject matter, the Federal Patent Court will stay the main infringement proceedings until the decision on the co-pending PI.

If opposition or appeal proceedings are pending before the EPO, defendants can request the stay of Swiss proceedings. However, the Federal Patent Court does not normally stay the proceedings in these circumstances, unless a final decision of the EPO is expected shortly or the stay is requested by both parties.

If a defendant is sued in Switzerland for the infringement of a foreign IP right and the defendant challenges the validity of the foreign right, Swiss courts no longer have jurisdiction over the dispute - given that the question of validity of the foreign patent falls under the exclusive jurisdiction of the courts of the country in which the patent was issued. According to case law, this does not only apply in the case of a counterclaim, but also if the defendant challenges the validity of the IP right by way of a defence.

In practice, if the defendant challenges the validity of a foreign patent, the court will stay the infringement proceedings and order the defendant to initiate invalidity proceedings in the country in which the patent was issued. If the defendant fails to initiate invalidity proceedings, the court will deal with the question of invalidity as a preliminary question to infringement.

Although foreign decisions do not bind any Swiss court, the Federal Patent Court gives some deference to decisions issued in parallel proceedings by other European courts. The Federal Patent Court will, in general, look in great detail into the reasoning of the foreign court and decide on a case-by-case basis whether it will follow the same argument or decide differently.

1.17 Patent Amendment

It is possible for the patentee to amend the patent claims during proceedings (both in infringement and invalidity proceedings), but only until the closure of the exchange of briefs, which occurs after the second exchange of briefs in main proceedings and with the first exchange of briefs in PI proceedings.

The patent claims can only be limited and never extended. The patent can be restricted by eliminating patent claims altogether or by combining independent patent claims and dependent claims. In addition, patent claims can be restricted by adding further features based on the description. In such cases, the restricted claims must relate to the same invention and define an embodiment that is still supported by the description of the original application (as well as the published patent in the case of Swiss patents).

If invalidity is only raised by way of a defence (and not by way of a counterclaim), the patent can be limited with inter partes effect only – that is, the patent will remain in the register as it had been granted, irrespective of the outcome of the proceedings.

1.18 Court Arbiter

All patent cases are decided by judges; there are no juries in Switzerland.

Forum shopping is limited to non-patent IP cases, as all patent infringement and validity cases (both in main proceedings and in PI proceedings) are dealt with in first instance by the Federal Patent Court. Non-patent IP cases are dealt with by cantonal high courts and forum shopping/forum running is available in these cases, provided that several cantonal courts potentially have jurisdiction (eg, where the infringing acts have occurred in all of Switzerland).

2. Generic Market Entry

2.1 Infringing Acts

If infringement is imminent, but has not yet started, the Federal Patent Court requires evidence of imminent acts of a certain minimum intensity. In generic entry cases, an application for marketing authorisation in itself is generally not sufficient for a finding of imminent infringement. However, further acts are considered sufficient for a finding of imminent infringement (see **1.3 Preliminary Injunction Proceedings**).

The rules governing the infringement of second medical-use patents have been subject to some controversy since the amendment of the Patent Act in 2019. Under the relevant amendment, "acts undertaken as part of a medical activity concerning an individual person or animal and involving a medicinal product" (eg, the prescribing, dispensing or use of medicinal products by legally authorised persons) have been explicitly exempted from the scope of the patent (Article 9(1)(g) PA). The same is true of the "direct individual preparation of medicinal products in pharmacies in accordance with a doctor's prescription or to acts concerning medicinal products prepared accordingly" (Article 9(1)(h) PA).

Under the current case law of the Federal Supreme Court, contributory infringement of patent rights only qualifies as an infringement if the main infringing acts take place in Switzerland and are unlawful. In the case of second medical-use patents, the main infringing act – ie, the prescribing, dispensing or use of medicinal products by medical professionals – is not "unlawful" under the new law. Hence, it is unclear under what legal theory the manufacturer or the distributor of a product protected by a second medical-use claim qualifies as a contributory infringer. It is expected that the Federal Patent Court will clarify these issues in the coming years.

The Federal Supreme Court has held that a patentee who has a dominant position in the relevant market can be liable for an antitrust violation if it enforces its patent in order to pre-

vent the parallel import of a patented product already sold in another country. However, this only applies if the following conditions are met:

- the patentee has a dominant position in the relevant market;
- the legal and economic conditions of the country where the first sale occurred are comparable to those of Switzerland; and
- the enforcement of the patent only seeks to maintain substantially higher prices in Switzerland, thereby sealing off Switzerland in an abusive way.

Some scholars have argued that market-dominant patentees are generally obliged to grant compulsory licences if both:

- the use of the patented technology is indispensable for a third party that wishes to offer new products; and
- the patentee does not have legitimate grounds to refuse the grant of a licence.

Finally, the Federal Patent Act specifically provides for compulsory licences on diagnostics in the case of antitrust violations. There is no published case law on compulsory licenses so far in Switzerland.

2.2 Regulatory Data and Market Exclusivity

The Swiss Agency for Therapeutic Products (Swissmedic) grants the following data exclusivity periods for medicinal products:

- ten years for a medicinal product containing at least one new active substance;
- three years for a new dosage or route of administration;
- three years for a new indication, but a ten-year period can be granted for a new indication if a significant clinical benefit over existing treatments can be expected as a result;
- ten years for medicinal products specifically and exclusively destined for a paediatric indication, if the indication is supported by relevant clinical data;
- 15 years for an important medicinal product for orphan diseases; and
- ten years for a fixed combination of medicinal products if the combination contains at least one new active substance.

There is no data exclusivity granted for a new device for administration of the same product, unless it results in a new route of administration.

Challenges to data exclusivity are possible. Decisions of Swissmedic can be appealed to the Federal Administrative Court and, in the final instance, to the Federal Supreme Court. Appeals to the Federal Administrative Court typically last 12 to 30 months, depending on the complexity of the case. Appeals to the Federal Supreme Court are generally decided within seven to nine months.

2.3 Acceptable Pre-launch Preparations

The scope of a patent does not extend to acts undertaken for research or experimental purposes in order to obtain knowledge about the subject matter of the invention (ie, the experimental use exemption). Similarly, the scope of a patent does not extend to acts necessary for obtaining marketing authorisation for a medicinal product in Switzerland or in countries with equivalent medicinal product control (Bolar-type exemption).

2.4 Publicly Available Drug and Patent Information

There is no equivalent of the Orange Book in Switzerland. Swissmedic does not verify nor

takes into account the existence of patent rights when issuing marketing authorisations (MAs).

Granted MAs are published in the *Official Journal of Swissmedic* once a month. In order to obtain access to the content of the MA request, a Freedom of Information request must be filed with Swissmedic, whereby Swissmedic will not disclose any personal data, confidential information or data protected under the data exclusivity regulations.

Swissmedic does not proactively inform MA holders of generic MAs.

2.5 Reimbursement and Pricing/Linkage Markets

Neither the grant of an MA nor the pricing or reimbursement are linked with patent status. The regulatory authorities (Swissmedic and the Federal Office of Public Health) do not take into account the patent status and will decide to issue MAs or approve pricing irrespective of existing patents.

Nonetheless, the Federal Office of Public Health will take the patent status into account when determining the applicable amount of the reimbursement. In particular, the Federal Office of Public Health will examine, upon patent expiry, whether the conditions of reimbursement - in particular, the condition of economic efficiency – is still fulfilled.

3. Biosimilar Market Entry

3.1 Infringing Acts

The details outlined in **2.1 Infringing Acts** regarding generics are also broadly applicable to biologics and biosimilars. In particular, requesting marketing authorisation alone is not sufficient for a finding of imminent infringement, but an imminent infringement will be found if additional steps have been taken in view of future distribution in Switzerland.

3.2 Data and Regulatory Exclusivity

Biosimilars can be authorised only with referencing to a medicinal product with complete documentation. In other words, biosimilars themselves cannot be authorised as reference products.

In principle, all indications and corresponding dosage recommendations of the reference product can be submitted for authorisation for the biosimilar.

An application for the authorisation of biosimilars can be submitted as early as two years before the ten-year data exclusivity (see **2.2 Regulatory Data and Market Exclusivity**) of the reference product expires. The decision will then be issued potentially before the document protection expires but with a date in the future (ie, the first day after the document protection expires at the earliest).

Biosimilars approved for the first time are not considered a new active substance and therefore no data exclusivity is granted, bar special cases as outlined in **2.2 Regulatory Data and Market Exclusivity**.

3.3 Acceptable Pre-launch Preparations

The details outlined in **2.3 Acceptable Pre-launch Preparations** regarding generics are also broadly applicable to biologics and biosimilars. In particular, the exemptions from the scope of the patent are identical.

3.4 Publicly Available Drug and Patent Information

The details outlined in **2.4 Publicly Available Drug and Patent Information** regarding generics are also broadly applicable to biologics and biosimilars.

3.5 Reimbursement and Pricing/Linkage Markets

The details outlined in **2.5 Reimbursement and Pricing/Linkage Markets** regarding generics are also broadly applicable to biologics and biosimilars.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

The Patent Act provides for Supplementary Protection Certificates (Article 140a et seq, Patent Act). The rules in the Patent Act are directly inspired by the EU SPC Regulation (No 469/2009) and the Federal Supreme Court adheres to most of the case law of the CJEU on SPC matters, except where there is a compelling reason to depart from CJEU jurisprudence, in particular when it appears that the Swiss legislature sought to issue a different set of rules (see Federal Supreme Court, BGE 144 III 285).

The SPC is granted to the owner of the patent. The SPC is granted if, at the time of the application, the product (ie, the active ingredient or combination of active ingredients) is protected "as such" by a patent or if a process for manufacturing it or its use is protected by a patent. In addition, it is required that a medicinal product containing the relevant active ingredient (or combination) be authorised in Switzerland.

In principle, one SPC will be granted per product and per applicant.

However, several SPCs may be granted for a product if the applications are based on different patents from different patent owners (Article 140c (3), Patent Act). A patent owner who submits several SPC applications based on different patents for the same product must choose only one of these applications in the course of the examination procedure. An applicant who has already been granted an SPC may not be granted further SPCs for the same product on the basis of another basic patent (Etanercept decision, BVGE 2010/48).

Combination products:

When assessing whether an SPC has already been granted, the following applies: If an SPC has been granted for an active substance A, an SPC may be granted for a combination of active substances A + B because it is a different product. This also applies in the reverse order, and even if it is the same basic patent.

In 2018, the Federal Supreme Court initiated a change in case law to follow the practice of the CJEU (BGE 144 III 285): If the basic patent designates only one of two active substances, a product cannot be claimed as an SPC if it is composed of two active substances. Rather, Article 140b of the Patent Act is to be interpreted in accordance with the EU Regulation (Article 3 of Regulation [EC] No 469/2009) in such a way that the active substances of the product must be claimed in the basic patent by naming them in the patent claims or by the patent claims – interpreted in the light of the description (Article 51(3), Patent Act; Article 69, European Patent Convention 2000) – at least implicitly but necessarily referring to these active substances, and in a specific manner.

Because the product of the SPC must be protected by the basic patent, a patent with a combination of active substances as the subject matter of the invention may not be used as the basis for a "single substance" SPC. This is not affected by the fact that the individual active ingredients can be administered separately.

Contrary to the European Union, Switzerland has not implemented an SPC manufacturing waiver. Although a parliamentary motion on this topic is pending, it is unclear whether it will be pursued and the introduction of a manufacturing waiver is not imminent.

4.2 Paediatric Extensions

Both independent paediatric supplementary protection certificates and paediatric extensions of supplementary protection certificates are available in Switzerland.

The duration of a paediatric SPC is six months from the expiry of the longest term of the patent. The conditions of the grant of a paediatric SPC are that (i) the medicinal product reflects the results of all studies performed in accordance with the paediatric test concept and (ii) the application was made no later than six months after the application for initial MA in the EEA for the medicinal product containing the relevant active ingredient. The paediatric SPC and the "ordinary" SPC are mutually exclusive, that is, no "ordinary" SPC will be granted if a paediatric SPC has been granted and vice versa.

The paediatric extension of an SPC can be granted for six months if the MA contains confirmation that the information on the medicinal product reflects the results of all studies performed in accordance with the paediatric test concept and that the application was made no later than six months after the application for the initial MA in the EEA for the medicinal product containing the relevant active ingredient. The term of the SPC can only be extended once and paediatric SPCs cannot be extended.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

In the event of an unjustified preliminary injunction, the claimant must pay compensation for damages suffered by the defendant. However, if the claimant filed the request for a preliminary injunction in good faith, a court can either dismiss or reduce the amount of the compensation.

If the preliminary injunction was unjustified, the defendant must be placed in the position it would have been in if no preliminary injunction had been issued. To this end, the defendant must substantially prove the loss it suffered as a result of the unjustified preliminary injunction, notably lost profits.

The Federal Patent Court can order the claimant to post a bond to ensure payment of compensation in the event of an unjustified preliminary injunction. The amount of the bond is determined by the Court. The bond is released once it is clear that no damages are claimed. The Federal Patent Court can impose a time limit on the defendant for filing a damages action.

Actions started through an ex parte application require confirmation in inter partes proceedings. In addition, all preliminary injunction proceedings require confirmation in main proceedings. After issuing a preliminary judgment, the Federal Patent Court will set a deadline for the commencement of main proceedings. If no main proceedings are initiated, the injunction lapses and

the applicant is liable for any damages caused to the defendant.

In preliminary injunction proceedings, an appeal is only available if the defeated applicant can show that it would suffer an irreparable harm of a legal nature. The Federal Supreme Court has a strict interpretation of the requirement of legal irreparable harm, which means that the possibility to appeal a preliminary injunction decision is excluded in most cases.

5.2 Final Injunctive Relief

The patentee has the right to request a permanent injunction against the infringer.

An injunction is strictly confined to the infringing product or process. It only binds the defendant(s) to the proceedings and therefore has no direct effect on third parties (such as suppliers or customers) and cannot be enforced directly against them.

The Federal Patent Court can grant cross-border or extra-territorial permanent injunctions if it has jurisdiction over the dispute (that is, if the defendant is domiciled in Switzerland and does not challenge the validity of the foreign patent).

Court decisions, including the final permanent injunction, are served on the parties or their representatives as judicial documents by Swiss Post. Injunctions in patent matters are enforced exclusively by the Federal Patent Court, while monetary awards are enforced through the general rules applicable to debt enforcement and bankruptcy.

The injunction can be enforced through a variety of means, such as (i) seizure and destruction of the infringing goods, (ii) a penalty for non-compliance for each day of continuing infringement and (iii) criminal proceedings for contempt of court against the directors of the infringing entity (a monetary penalty of up to CHF10,000). It is essential that the claimant specifically request these or further means of enforcement by filing appropriate motions at the outset of the main proceedings.

Permanent injunctions issued by the Federal Patent Court are immediately enforceable. An appeal to the Federal Supreme Court does not have suspensive effect, but the appellant can request that the Federal Supreme Court grant suspensive effect if the appellant can show that the enforcement of the injunction may cause irreparable harm. The Federal Supreme Court has broad discretion in granting suspensive effect for the duration of the appeal proceedings.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

It is currently the majority view in Switzerland that the court does not have discretion to refuse injunctive relief if it finds the patent valid and infringed. In particular, proportionality is not considered a pre-requisite of the grant of permanent injunctions. In addition, public policy considerations are currently not taken into account when determining whether a permanent injunction can be granted. In other words, if the patent is valid and infringed and the claimant requests a permanent injunction, the court has no discretion to deny the grant of the injunction. There are no exemptions for particular subject matter or for particular claimants, such as non-practising entities.

If the defendant claims that there is a compelling public interest to refuse a permanent injunction, the defendant needs to apply for a compulsory licence.

The court cannot award damages in lieu of an injunction either.

5.4 Damages

Calculation of Damages

Similar to common tort actions, monetary remedies in patent actions are assessed on the basis that the claimant must be placed in the position it would have been in, if no infringement had occurred. The claimant can request:

- compensation for the pecuniary loss that it has suffered due to the infringement (damages);
- surrender of the profits the infringer made as a result of the sale of the infringing products (disgorgement of profits); or
- surrender of any unjust enrichment of the infringer deriving from the infringing act (notably a reasonable royalty).

The claimant must choose between damages, disgorgement of profits, or the surrender of unjust enrichment. Usually, the claimant will pursue multiple remedies in parallel as alternative claims, and, after the infringer has opened its books and provided information on the profit it made out of the infringement, choose the remedy that yields the best result.

In addition and cumulatively to damages, account of profits, or surrender of unjust enrichment, the claimant can seek damages for ancillary losses arising from the infringement. Ancillary losses can include:

- legal expenses incurred before initiating the action (for example, the cost of obtaining an opinion on infringement from patent counsel);
- expenses directed at mitigating the impact of the infringement (for example, advertising expenses directed at minimising confusion in the market place); and
- lost sales of ancillary products (for example, lost sales of unpatented equipment, spare parts, and so on, which the patentee ordinarily sells alongside its patented articles).

Generally, the Federal Patent Court will first issue a decision on the permanent injunction and order the defendant to disclose internal accounting information about the turnover made with the infringing products. The quantum of monetary remedies is then assessed at a separate stage of the proceedings. Because almost all infringement cases are settled after the decision on the permanent injunction, there are only very few published decisions on the quantum of financial compensation. Therefore, there is no settled practice as to many essential issues, in particular the royalty rates for a hypothetical licence in the pharmaceutical/biopharma/medical device industries.

Typical Damages Awards

Financial compensation is only awarded in the final decision; provisional enforcement of financial compensation is not available.

If the court orders the payment of damages, the infringer must also pay interest on the amount of the compensation at the statutory rate (currently 5% per annum), calculated from the date of the relevant infringing acts. Treble damages or punitive damages are not available in Switzerland and foreign decisions awarding treble or punitive damages are not enforced in Switzerland.

The Supreme Court has made it clear that the basis for the calculation of damages in cases of complex devices where only a part of the device constitutes infringement is the “indivisible trade unit” in which the infringing element is included.

The "indivisible trade unit" refers to the set of elements that are generally sold on the market as one product.

Financial compensation is payable immediately upon the notification of the decision of the Federal Patent Court, except if the losing party appeals the decision and successfully requests that the enforcement of the decision be suspended.

Damages for Wrongful Injunctions
In the event of an unjustified preliminary injunction, the claimant must pay compensation for damages suffered by the defendant. However, if the claimant filed the request for a preliminary injunction in good faith, a court can dismiss a compensation claim in full or reduce the amount of the compensation.

Furthermore, after issuing a preliminary judgment, the Federal Patent Court will set a deadline for the commencement of the main proceedings. If no main proceedings are initiated, the injunction lapses and the applicant is similarly liable for any damages caused to the defendant.

There are very few published decisions on damages for a wrongful injunction. Given that the threshold of proving actual loss is very high in Swiss law, many cases fail to yield a substantial amount of compensation.

Third-Party Damages
Non-exclusive licensees have no statutory right to sue for patent infringement. However, they can join a damages claim filed by the patentee or an exclusive licensee and claim damages covering their own loss. In practice, it is important for non-exclusive licensees and distributors that the relevant licence or distributorship agreement contains a clause requiring the patentee to take action for patent infringement.

5.5 Legal Costs

There are three types of costs involved in patent litigation:

- court costs;
- attorneys' fees; and
- disbursements, including patent agent costs.

On average, a party should expect to incur between EUR90,000 and EUR230,000 to take a case through to a first instance decision. In complex cases, costs may be higher.

Court costs must be paid in advance by the plaintiff.

Court costs and the award for attorneys' fees both depend on a tariff based on the value of the litigation and the complexity of the case.

Under the "loser pays" rule, the losing party is eventually ordered to pay the court costs and reimburse the winning party's attorneys' fees. Disbursements of the winning party (including patent agent costs) must be paid by the losing party based on the amounts actually spent.

After assessment by the court, the successful party will generally recover about 20% to 50% of legal costs and all disbursements actually incurred in the proceedings. Patent agent costs are considered as disbursements and, therefore, fully recoverable in principle. However, the Federal Patent Court generally reduces compensation for patent agent costs to the amount of attorneys' fees awarded under the applicable tariff, unless an exceptionally complex technology justifies a higher amount.

5.6 Relevance of Claimant/Plaintiff Conduct on Relief

The court can, exceptionally, refuse to make a costs award in favour of the winning party or can penalise this party if it has abused the process of the court, or has contributed to an undue delay of the proceedings in any other way.

If the plaintiff has filed a lawsuit without engaging in pre-action correspondence and the defendant does not resist the lawsuit, the court can also refrain from any cost award to the plaintiff or even order the (successful) plaintiff to bear all costs.

6. Other IP Rights

6.1 Trade Marks

Trade mark disputes in the life sciences and pharma sectors are common in Switzerland. The rules on pharmaceutical trade marks are the general rules laid out in the Federal Act on Trade Marks and Indications of Origin and the specific rules laid out in the administrative regulations of Swissmedic.

Among the relevant rules of pharmaceutical trade mark law, it is notable that the use of a trade mark for a specific indication does not, in principle, count as use for all indications of pharmaceutical products in Class 5 of the Nice Classification. As a result, the owner of a trade mark in Class 5 cannot always prevent the use of a similar mark for pharmaceutical products for a different indication.

Brands for pharmaceutical products must be approved by Swissmedic. When assessing a new brand for pharmaceutical products, Swissmedic does not take into account the trade mark situation. Swissmedic is only responsible for ensuring that the name of a product does not lead to confusion with another product, that the name is not incorrect or misleading with regard to the indication, quality, risks or safety of the product, and that the name does not promote abuse of the product.

6.2 Copyright

Copyright law is based on the Federal Act on Copyright. Copyright has a generally limited relevance in the life sciences and pharma sector. Copyright can, however, be very important in the medical device space, in particular in relation to software as a medical device. The Swiss rules on copyright ownership and works made for hire can vary from other European jurisdictions and need to be assessed in each individual case.

6.3 Trade Secrets

Switzerland is not a member of the EU. Consequently, it is not obliged to implement and has not implemented the EU Trade Secrets Directive (the "EU TS Directive") in its national law.

Switzerland is a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Right (TRIPS), which explicitly addresses trade secret protection in Article 39.

There is no separate statute in Switzerland that exclusively governs trade secrets. Rather, there are several sets of isolated provisions in various statutes. The following are the most relevant statutes under Swiss law:

- the Swiss Federal Act against Unfair Competition (UCA);
- the Swiss Criminal code (CC);
- the Swiss Code of Obligations (CO), in particular its sections on employment law, agency law and corporate law;

- the Swiss federal act on data protection (FADP); and
- the Codes of Procedure (civil, administrative, criminal) related to the protection of trade secrets in proceedings before courts and administrative bodies.

As a consequence of the scattered nature of the legal sources, Swiss law does not have one single unified theory to protect all trade secrets. Instead, depending on the circumstances, trade secrets will be protected under the doctrine of tort law, contracts or criminal law.

In short, Swiss law does not treat trade secrets as a formal intellectual property right, but as a factual position that still enjoys strong protection under the various applicable legal sources.

In a case of trade secret misappropriation, the plaintiff can request injunctive relief and/or financial compensation. As set out in **5.4 Damages**, financial compensation can take the form of:

- compensation for the loss suffered by the plaintiff as a result of the misappropriation (damages, Article 41, Code of Obligations);
- payment of the unjust enrichment accrued with the infringer as a result of the misappropriation (Article 62, Code of Obligations); or
- the surrender of the profits made by the infringer through the use/distribution/sale of the infringing products (disgorgement of profits, Article 423, Code of Obligations).

Defences in trade secrecy litigation may include the following arguments by the alleged infringer:

- the relevant information is no longer confidential or has never been confidential (lack of secrecy);
- the trade secret owner has not taken appropriate measures to ensure secrecy and thus does not have an interest in maintaining secrecy (lack of subjective interest in secrecy);
- the trade secret was obtained lawfully from a third party;
- the alleged infringer understood in good faith that the disclosure of the trade secret was made with the authorisation of the trade secret owner;
- the alleged infringer has discovered or developed the trade secret independently;
- the relevant information does not constitute a trade secret but rather general industry expertise or knowledge; and
- the disclosure of the trade secret was authorised or required by law.

7. Appeal

7.1 Timing to Appeal Decision

There are special rules of jurisdiction regarding intellectual property litigation. Intellectual property cases are tried at first instance by the Federal Patent Court (patent cases) or the high court of the relevant canton (non-patent cases). In both patent and non-patent cases, only one level of appeal exists to the Federal Supreme Court.

Appeal proceedings in the Federal Supreme Court generally last seven to nine months.

An appeal in civil matters against a decision (on preliminary injunctions or in main proceedings) must be lodged with the Federal Supreme Court within 30 days of its notification.

The appeal is limited to a review of legal issues (as opposed to facts). More specifically, the

appellant must show that the first instance court misapplied or misinterpreted federal law (that is, patent law or procedural law) or international law. Findings of fact and the assessment of evidence can only be reviewed if they are blatantly wrong or arbitrary.

In preliminary injunction proceedings, an appeal is only admissible if the appellant can show that it suffers irreparable harm of a legal nature as a result of the decision. The Federal Supreme Court has a strict interpretation of the requirement of irreparable harm of a legal nature, which means that appeals against preliminary injunction decisions are inadmissible in most cases.

7.2 Appeal Court(s) Arbiter

Appeals against decisions of the Federal Patent Court or of the cantonal High Court are decided by a panel of three or five judges of one of the civil law senates of the Federal Supreme Court. There are no specialist or technical judges at the Federal Supreme Court.

7.3 Special Provisions

There are no special provisions for intellectual property proceedings in the Federal Supreme Court.

8. Other Relevant Forums/ Procedures

8.1 Other Relevant Forums/Procedures

The owner of an intellectual property right can request that the customs authorities seize any infringing goods. Upon notification, the patentee needs to file a request for an (ex parte) preliminary injunction within ten days, otherwise the customs authorities will release the goods. The patentee can collect samples and verify whether the goods infringe upon the intellectual property right.

If the seizure or destruction of the goods proves to be unjustified, the right-holder is liable for the resulting loss.

9. Alternative Dispute Resolution

9.1 ADR Options

Arbitration is available to resolve patent disputes if the parties to the dispute have agreed on the competence of an arbitral tribunal. In Switzerland, both patent infringement and invalidity disputes can be submitted to arbitration. However, arbitration proceedings are rarely used to resolve pure patent infringement and invalidity disputes. It is more common for parties to conclude an arbitration agreement in patent licensing agreements, which also empowers the arbitral tribunal to decide on underlying patent infringement and validity issues.

An arbitral award declaring a patent invalid will be recognised and enforced by the Swiss Institute for Intellectual Property in the same manner as a court order to the same effect.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The Federal Supreme Court has held that a patentee that has a dominant position in the relevant market can be liable for an antitrust violation if it enforces its patent to prevent the parallel importation of a patented product already sold in another country. However, this only applies if the following conditions are met:

- the patentee has a dominant position in the relevant market;
- the legal and economic conditions of the country where the first sale occurred are comparable to those of Switzerland; and
- the enforcement of the patent seeks only to maintain substantially higher prices in Switzerland, thereby sealing off Switzerland in an abusive way.

Some scholars have argued that patentees with a dominant position in the relevant market are generally obliged to grant compulsory licences if both:

- the use of the patented technology is indispensable for a third party that wishes to offer new products; and
- the patentee does not have legitimate grounds to refuse the grant of a licence.

Finally, the Federal Patent Act specifically provides for compulsory licences on diagnostics in the case of antitrust violations. There is no published case law on compulsory licences so far in Switzerland.

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TAIWAN

Law and Practice

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Contents

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Patent infringement cases are brought by the patent holder; if held jointly, not all joint owners need to be present as the plaintiff. Exclusive licensees may, as the plaintiff, bring an infringement action within the scope of its licence even if they have not been registered as a licensee.

In Taiwan, there is no court proceeding to invalidate a patent. All invalidation petitions must be brought before the Intellectual Property Office of the Ministry of Economic Affairs (TIPO). Only interested parties may file an invalidation petition on the grounds that "the patent application was not filed by all joint owners of the patent" or "the applicant is not the patentee", while there is no standing requirement for invalidation petitions based on any other legal ground.

1.2 Defendants/Other Parties to an Action

Based on the authors' observations of life sciences/pharma cases in Taiwan, defendants have primarily been generics pharmaceutical companies, with a small minority of generics manufacturers or channel suppliers. A Taiwan court has the right to summon TIPO (as the competent authority) to participate as an intervener in a patent infringement case. However, there is no basis in law for a Taiwan court to require the Ministry of Health and Welfare (MoHW), the health regulatory competent authority in Taiwan, to participate in a life sciences/pharma patent infringement case, nor is there any record of the MoHW appearing in such proceedings.

1.3 Preliminary Injunction Proceedings

Preliminary injunctions are available, including on an ex parte basis if the court believes the circumstances warrant such a measure. In a patent infringement action, there is usually a one to two month gap between the petitioner's preliminary injunction application and argument, and a total time of about three months from the petition to the court's decision; the actual time required will vary on a case-by-case basis. There is no specific requirement with respect to the earliest point in time a preliminary injunction may be filed. The relevant elements for granting a preliminary injunction in patent infringement cases are no different from those in other civil matters, namely:

- whether the injunction is necessary to prevent imminent and serious harm (or other similar circumstances) to petitioner;
- whether the determination of the injunction will cause irreparable losses to the petitioner or respondent;
- likelihood the petitioner may prevail in the substantive action;
- balance of interests between the petitioner and respondent; and
- impact on the public interest.

Per the wording "imminent" in the first bullet point above, quia timet relief is available in Taiwan if supported by sufficient evidence. There is no consideration specific to preliminary injunctions in life sciences/pharmaceuticals matters.

There is no black-letter law on notice requirements to the respondent. In Taiwan practice, the court handles service to the other party, and in an inter partes preliminary injunction proceeding, the court will generally serve the respondent at the same time it asks both parties to submit their arguments. Service is generally effectuated through mail, and delays in mail delivery would not in principle cause any deadlines to

be extended, but the respondent may request to court for an extension at a hearing.

1.4 Structure of Main Proceedings on Infringement/Validity

Per **1.1 Claimants/Plaintiffs to an Action**, infringement and validity proceedings are completely separate in Taiwan, and the courts do not directly invalidate a patent. If the defendant argues in an infringement action that the patent should be invalidated, the court will consider the argument's merits on its own but will not stay the infringement proceedings to do so. For the same reason, there are no court nullity proceedings, only patent office opposition proceedings.

1.5 Timing for Main Proceedings on Infringement/Validity

Infringement Actions

The relevant statute of limitation periods for initiating an infringement action is two years after the patentee becomes aware of damages incurred and the identity of the infringer liable for such damages, or ten years after the act of infringement. Service is effectuated in the same way as described in **1.3 Preliminary Injunction Proceedings**. Statistics from the Intellectual Property and Commercial Court indicate that for the first three quarters of 2022, the average time to resolve a first instance patent-related matter was 247 days.

In Taiwan, once the case is on the court's docket, the court will hold a series of preparatory hearings in which the judge hears arguments presented by the parties. The judge has discretion to conclude the preparatory hearings once he or she believes there is sufficient evidence to make a decision and convenes oral arguments hearing in which the parties make a summary argument before the proceedings are officially concluded and a decision is rendered soon thereafter. Since the duration of the preparatory period depends greatly on the complexity of the case and the judge's discretion, there is no data available on the average timeframe of those interim steps.

Invalidation Proceedings

The invalidation proceeding is an administrative proceeding in Taiwan. No statute of limitations apply with respect to bringing an invalidation petition to the TIPO; it is in principle still possible to bring an invalidation petition even if the patent right has already been extinguished if the petitioner has a recoverable legal right from the invalidation.

The TIPO handles the service to the patent holder. Service is also effectuated through mail delivery as in other civil litigation. The patent holder has one month to respond after being served the copy of the invalidation proceeding. There is no statutory time limit for the invalidation proceedings, but TIPO's published guidance documents on various patent-related petitions indicate that the average invalidation proceeding before the TIPO lasts about 15 months.

1.6 Requirements to Bring Infringement Action

The action may be initiated as soon as the patent holder or the exclusive licensee becomes aware of the infringement. As long as the plaintiff is the patent holder or the exclusive licensee, Taiwan law does not stipulate any other prerequisite conditions to meet before initiating the infringement action. There is also no material difference attributable to the type of patents asserted with respect to the procedure to initiate an infringement action.

One notable presumption in Taiwan patent law that affects the burden of proof between the parties is that a product made by the defendant that

is "identical to the product made pursuant to the plaintiff's manufacturing process patent" shall be deemed as made pursuant to such patent, if the plaintiff's product is not on the market prior to such patent. In such cases, the defendant would have the burden of proof to show that its product was manufactured pursuant to a different method before it can assert a non-infringement defence.

1.7 Pre-action Discovery/Disclosure

Discovery is not available in Taiwan as an evidence gathering mechanism.

1.8 Search and Seizure Orders

The closest equivalent to a search and seizure order in Taiwan is a "preservation of evidence" order, which is typically a form of preliminary injunctive relief petitioned by the plaintiff before the substantive litigation commences to take the relevant evidence into the protective custody of the court, where in the absence of court action it is likely to be destroyed or altered in the course of the litigation proceeding.

1.9 Declaratory Relief

Declaratory relief may be granted by a Taiwan court if requested by a party. In general, declarative relief must take one of the following three forms:

- the confirmation of the (non-)existence of a specific legal relationship under private law;
- the confirmation of the (non-)existence of the facts underlying such legal relationship; or
- the authenticity of a certificate document.

The party seeking declaratory relief must therefore have a definitive legal relationship in dispute, the confirmation of which would either confer a legal benefit on the party or remove a legal threat to the party.

In a life sciences patent proceedings context, declaratory relief sought is often in the form of a court decision that an upcoming pharmaceutical product in the middle of the market authorisation process does not infringe on a specific patent on grounds that the patentee failed to file an infringement action against the applicant of the said pharmaceutical product permit within the stipulated period under the Pharmaceutical Affairs Act.

1.10 Doctrine of Equivalents

In Taiwan, the doctrine of equivalents is not expressly recognised in statute. However, in the "Key Points of Patent Infringement Determination" published by TIPO as a guide for adjudicating patent infringement matters, a section is dedicated to the doctrine of equivalents that the courts consult and apply in practice. Thus, the doctrine of equivalents as a concept is often applied and argued in patent infringement actions in Taiwan.

The current tests for the doctrine of equivalents in Taiwan as detailed in the above document include the "triple identity" test, in which equivalency is found if (i) it performs substantially the same function in (ii) substantially the same way for (iii) the same result, as well as the "insubstantial difference" test and the "interchangeability test" ("a person with ordinary skill in the art would have been aware of the differences and the changes still result in the same function").

Defences to the doctrine include the "all elements rule" ("every element of the claims of the patent or its substantial equivalent must be present in the alleged infringing product"), patent prosecution estoppel, prior art ensnarement ("equivalents cannot cover prior art") and the contribution principle ("techniques disclosed in

but not specifically claimed in the patent application are not protected").

1.11 Clearing the Way

In applying to the Taiwan Food and Drug Administration (TFDA) for a drug permit for a generic drug, (one that is not a new chemical entity – "non-NCE") a new drug and a biosimilar in Taiwan, the applicant must make a declaration regarding the status of the patents of the corresponding branded drug and initiate the patent linkage mechanism. One possible declaration is that the "patent rights corresponding to the branded drug shall be revoked, or the generic drug does not infringe on such patent rights" (the "P4 Declaration"). If the P4 Declaration is made, the applicant must follow up with a notice ("P4 Notice") to the patent holder of the branded drug in which the applicant asserts such declaration in writing, with supporting evidence. The patent holder must then initiate a patent infringement action against the applicant within 45 days of its receipt of the P4 Notice in order to suspend the issuance of the permit for a period of 12 months. If no infringement action is timely commenced, the TFDA may proceed to issue the drug permit to the applicant if the permit application is compliant with the relevant laws and regulations.

Other than as described above, there is no other "clear the way" obligation in Taiwan.

1.12 Experts

During the court proceedings, a party may submit a written opinion provided by an outside individual, or an individual may be summoned by the court to provide testimony. However, Taiwan civil procedure does not distinguish between lay witnesses and expert witnesses, so no preferential value is attached to such written opinion or witness testimony, even if they are supposedly from an expert in the field. In fact, for fact determinations in highly technical cases, Taiwan courts generally rely on their internal "technical officers" who assist the court's judges in understanding those technical issues, or from assessments, as detailed in **1.13 Use of Experiments**.

There is, however, a draft amendment to the Intellectual Property Case Adjudication Act, which is still under review that would bring the use of experts in intellectual property disputes in line with the practices in other jurisdictions, such as allowing the parties to directly present expert testimony, and allowing one party's expert to interact with and question the other party's expert upon the approval of the court. As of the date of this writing (January 2023), the draft amendment has passed the legislature but has not yet become effective.

1.13 Use of Experiments

Civil litigation in Taiwan has an evidence "assessment" mechanism in which upon petition by a party (or the court on its own initiative), the court will select an individual, who is typically an expert in the field, to assess the relevant evidence and render an (expert) opinion. In a patent infringement action context, this assessment may be carried out by way of experiment(s) to assist the court in understanding the infringement/patent validity issues at dispute. Petitions for an assessment are often granted by a court when the infringement action involves highly technical knowledge or a large amount in controversy, but the court is not bound by the findings of the assessment.

1.14 Discovery/Disclosure

As mentioned in **1.7 Pre-action Discovery/Disclosure**, discovery is not available in Taiwan as an evidence gathering mechanism. The draft amendment to the Intellectual Property Case Adjudication Act mentioned in **1.12 Experts**

would allow a party to apply to the judge for appointing an "investigator" who will audit the documents or facilities held or managed by the other party or a third party.

1.15 Defences and Exceptions to Patent Infringement

Common defences asserted in a patent infringement action in Taiwan include invalid patent, prior use, patent exhaustion, experimental use and prior art. In actions involving life sciences cases, some of the more notable arguments in defence include whether a generic is able to evade a patent for a specific pharmaceutical purpose by excluding specific indications, and whether a different crystalline structure of a prior art compound is considered an inventive step.

1.16 Stays and Relevance of Parallel Proceedings

Per **1.4 Structure of Main Proceedings on Infringement/Validity**, it is possible for the infringement proceedings to exist in parallel with the invalidation proceedings, as the infringement court is not obliged to wait on or be bound by the results of the invalidation proceedings. In actual practice, however, the lagging proceedings may nevertheless give some deference to the reasoning of other proceedings that have reached a decision earlier in order to prevent inconsistent results.

1.17 Patent Amendment

It is a relatively common tactic in Taiwan for a patent holder in patent litigation to apply to amend the claims of the patent in question as a defensive measure against invalidation arguments. In such cases, the court will generally wait for the results of the amendment application unless the amendment application is improper as a matter of law or there is no longer any infringement under the amended patent.

1.18 Court Arbiter

Although Taiwan has established the Intellectual Property and Commercial Court for adjudicating civil intellectual property rights disputes, it does not have exclusive jurisdiction in those cases; a party may also file the dispute before any district court with jurisdiction to hear the case. However, trends in recent years have shown a clear preference for resolving life sciences/pharma patent infringement cases before the Intellectual Property and Commercial Court due to the expertise and experience of its judicial personnel.

2. Generic Market Entry

2.1 Infringing Acts

Small Molecule Pharmaceutical Products

With respect to the relevant conduct for filing a patent infringement action, no special treatment is provided for small molecular pharmaceutical products in Taiwan. In other words, any conduct that falls within the scope of exclusive rights granted to the patent holder – such as manufacture, sales, offer for sale, use and import for the aforementioned purpose – can in principle give rise to a patent infringement action.

The research, testing and other practices of the patent for obtaining a drug registration are considered outside the scope of exclusive patent rights, but those acts may be deemed infringing if they were conducted for any other purpose, such as hospital clinical trials.

Filing a permit application for non-NCE new drugs (including generics) is also in principle not considered an infringing act. However, the analysis may change depending on the circumstances. For example, if a generic drug maker has already obtained the permit and completed the pricing procedure, a court may grant an

injunction to prevent continued infringement of the patent.

The courts have generally deemed a submission or award of tender as insufficient to constitute an offer for sale, but the facts of an individual case may lead to a different result.

For an offer to supply after patent expiration, since the patent would have expired and the patent protection have been extinguished, it is very likely that a court will deem such offer as not infringing.

Skinny Labelling & Parallel Imports

A generic drug permit applicant may exclude indications of the corresponding branded drug that is still under (second medical use) patent protection to prevent infringing on such patents. However, the act of skinny labelling does not by itself create any presumption of non-infringement, and the court will examine whether the revised labelling of the generic drug is medically reasonable as well as the clinical test results to determine on a case-by-case basis whether the generic drug is infringing.

For parallel imports, Taiwan recognises "international patent exhaustion", so the patent holder may no longer assert its patent rights over any product that it has manufactured or otherwise agreed to circulate in the market, regardless of which country's market the product first appeared in. Regardless of patent status, a firm looking to import a pharmaceutical product into Taiwan must still apply to the MoHW for registration of the drug and obtain a permit before importing.

2.2 Regulatory Data and Market Exclusivity

Generics Sales Exclusivity

The first generics manufacturer who makes a P4 Declaration and successfully prevails in an infringement challenge or otherwise successfully avoids a patent is entitled to a 12-month sales exclusivity period. However, sales exclusivity is not granted to a generic drug that only differs from the branded drug in (skinny) labelling.

Orphan Drug Sales Exclusivity

The permit for a registered orphan drug has a term of ten years, during which the MoHW will refuse the registration of the same type of orphan drug. If manufacturing or import of the orphan drug is still needed after the expiration of the permit, the permit may be extended beforehand for up to five years per extension. However, during the extended term, the MoHW will start to accept applications to register the same type of orphan drug.

New Chemical Entity (NCE) Drug Data Exclusivity

NCE drugs are entitled to a three-year data exclusivity period starting from the date the NCE permit is issued, during which all other pharmaceutical firms (including generic firms) may not cite the data in the NCE drug's permit application for their own registration without the NCE permit holder's consent. After the three-year data exclusivity term expires, the MoHW will accept registrations from other firms and issue permits starting from the day after the fifth anniversary of the issuance of the NCE permit.

A NCE drug that has obtained market authorisation overseas may obtain data exclusivity in Taiwan if registered with the MoHW within three years of obtaining such market authorisation.

New Indication Data Exclusivity

For a period of two years after the MoHW's approval of an added or changed indication for a pharmaceutical product, no other pharmaceutical firm will be allowed to cite the data for their own permit application for the same indication. The MoHW will accept applications after the two-year period and issue permits starting from the day after the third anniversary of the approval of the added or changed indication. If the holder of the permit for the pharmaceutical product with the added or changed indication will be engaging in clinical trials in Taiwan with respect to the new indication, permits for other firms will only be issued from the day after the fifth anniversary of the approval.

A new or changed indication that has obtained market authorisation overseas may obtain data exclusivity in Taiwan if registered with the MoHW within two years of obtaining such market authorisation.

Taiwan law currently has no specific rules for data/sales exclusivity of paediatric drugs, combinations and reclassifications, nor have the authors found any precedents in Taiwan that challenged the data/sales exclusivity conferred on a product.

2.3 Acceptable Pre-launch Preparations

As mentioned in **2.1 Infringing Acts**, patent rights do not reach any act that was conducted solely for the purpose of registration of the product or market authorisation in a foreign market. This includes pre-clinical and clinical trials and any directly related manufacturing, offers for sale, sales, uses and imports of the product.

2.4 Publicly Available Drug and Patent Information

The TFDA has established the Patent Linkage Lookup System, a pharmaceutical products database that enable generics firms to time their market launch and challenge patents if needed. Branded drug firms may also stay updated on the use of their patents by others and timely act to protect their patent rights.

The following information is currently publicly available in the database: information about the drug (name, indication, active ingredient, dosage type, etc), market authorisation information, holder of the drug permit and patent information.

Per **1.11 Clearing the Way**, the branded/reference drug firm typically becomes aware of generics or biosimilar permit applications through the P4 Notice provided by the generics firm.

2.5 Reimbursement and Pricing/Linkage Markets

Relationship Between Patent Status and the Drug Permit

In Taiwan, the issuance of the permit for a generic drug is not directly linked with the patent status of the corresponding branded drug. Per **1.11 Clearing the Way**, when applying for the permit for a new generic drug, the applicant firm must make the declaration regarding the patent status of the corresponding branded drug, including:

(i) the branded drug has no patent on record;
(ii) the patent(s) for the branded drug have expired;
(iii) recognition that the patent(s) for the branded drug are currently in effect, and the application is requesting the issuance of the permit after the patent(s) have expired; or
(iv) the P4 Declaration.

The permit will be issued immediately if (i) or (ii) is declared and the application is in order. For a (iii) declaration, the MoHW will wait until the relevant patents have expired before issuing the permit.

Relationship Between Patent Status and Listing and Pricing

The primary considerations for listing and pricing as made by the National Health Insurance Administration (NHI) in Taiwan is primarily focused on health, medical ethics, medical cost benefits and the finances of the national health insurance programme rather than the patent status of the drug in question.

In principle, the permit for the generic drug must be obtained first before applying to the national health insurance programme for pricing considerations. If the P4 Declaration and P4 Notice results in a patent infringement action between the generic drug firm and the branded drug firm, even though the MoHW will suspend the permit issuance process, the MoHW will nevertheless notify the generic firm that it has fully reviewed the application and the generic firm may proceed to submit the listing and pricing application to the NHI.

In contrast to the permit application process, the generic drug firm has no obligation under Taiwan law to inform the corresponding branded drug firm that it is applying for listing and pricing of the generic drug.

Listing and Pricing for Second Medical Use Patents

In applying for a new listing and pricing for the second medical use of an already listed drug with the NHI, the permit holder will need to present either:

- a head-to-head comparison of the efficacy of the second medical use versus the most commonly prescribed and effective drug on the market; or
- an indirect comparison through clinical test results that show the second medical use has a marked improvement in clinical efficacy.

A rejection of the listing and pricing application for the second medical use may in principle be contested via initiating administrative litigation against the NHI. However, as mentioned above, the NHI is granted a level of discretion in its listing and pricing decisions, and an administrative court will only vacate the NHI's rejection if there is a clear violation of law or error of fact committed by the NHI. As a result, litigation against the NHI for the rejection of listing and pricing for the second medical use is quite rare in practice.

3. Biosimilar Market Entry

3.1 Infringing Acts

Biologics or biosimilar patents are not treated any differently in terms of patent litigation, thus all relevant rules are as indicated per **2.1 Infringing Acts**.

3.2 Data and Regulatory Exclusivity

Data exclusivity for biologics is identical to that for NCE drugs (a three-year period).

Biosimilars in Taiwan are generally subject to the same patent linkage mechanism as generics. As such, they may be entitled to the same 12-month sales exclusivity period per **2.2 Regulatory Data and Market Exclusivity**.

3.3 Acceptable Pre-launch Preparations

There are no relevant differences between biosimilars and generics in this regard – see **2.3 Acceptable Pre-launch Preparations**.

3.4 Publicly Available Drug and Patent Information

There are no relevant differences between biosimilars and generics in this regard – see **2.4 Publicly Available Drug and Patent Information**.

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3.5 Reimbursement and Pricing/Linkage Markets

There is no material difference in the listing and pricing for biologics. For biosimilars, the NHI applies an accelerated "new category model" system that, in practice, shortens the overall listing process by about three months. All the other NHI pricing considerations per **2.5 Reimbursement and Pricing/Linkage Markets** are also applied to biosimilars.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

A one-time patent extension may be granted with respect to the first permit granted to a medical drug or its manufacturing process in consideration of the time taken up by the permit approval process. The extension may only be as long as the time that the patent could not be enforced due to the permit approval process and in any case up to a maximum of five years. The application should be submitted by the holder of the patent three months after obtaining the first permit but no later than six months before the expiration of the patent.

In the case of a single patent covering multiple product permits (eg, a permit for product A based on claim 1 and a permit for product B based on claim 2), if an extension based on the permit for product A is approved, the patent may no longer be extended based on the permit for product B. In the case of a single product (permit) that covers multiple patents, only one of the patents may be chosen for extension. Finally, only the objects, purposes or methods claimed in relation to active ingredient and its indication as stated in the permit are extended; all other objects, other purposes or methods claimed in the patent that are not included in the permit are not extended.

4.2 Paediatric Extensions

Taiwan does not have a system specifically for extensions of paediatric drugs. Those drugs in principle must follow the same patent extension process per **4.1 Supplementary Protection Certificates**.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

The common elements to the grant of a preliminary injunction are as stated in **1.3 Preliminary Injunction Proceedings**. There is no basis in Taiwan to obtain a preliminary injunction solely based on a damages undertaking.

A preliminary injunction order in an intellectual property right case that was granted without inter partes arguments is immediately enforceable at the time of the court's decision. Details regarding service of the preliminary injunction order to the respondent are as stated in **1.3 Preliminary Injunction Proceedings**. The respondent may contest the preliminary injunction order

by filing an appeal within ten days of service. The petitioner must also initiate the main action within 30 days of service of the court's decision to grant the preliminary injunction, otherwise the court may, upon application or on its own, revoke the preliminary injunction order.

A patentee may be required to pay a bond before the court will grant the requested preliminary injunction order if the court believes the patentee's arguments were not sufficient.

In general, the appeal does not stay the compulsory enforcement proceeding of the preliminary injunction order. However, where stipulated exceptions exist, such as petition for a recovery of status quo ante, the court may suspend the compulsory enforcement if necessary or upon the provision of an adequate and full security bond. The respondent may also pay an amount to obtain a stay of the enforcement of the preliminary injunction order if the preliminary injunction order will cause irreparable losses to the respondent or the losses that the petitioner suffered may be covered by monetary reimbursement. As the purpose of the bond is to protect the other party from the harm caused by a (meritless) preliminary injunction order, the amount is typically set by the court based on an estimated valuation of such harm incurred by the other party.

5.2 Final Injunctive Relief

Final injunctions are often granted alongside a decision in favour of the patent holder, in which the defendant may be forever enjoined from directly or indirectly, either by itself or with another, manufacturing, offering for sale, selling, using or importing the relevant product, among other appropriate forms of injunctive relief.

In principle, a final injunction can only be enforced when the court decision in favour of the patent holder is also final – ie no further appeals are possible. Accordingly, there is no stay of a final injunction. The patent holder does not need to pay any bond or take any other legal action to enforce a final injunction or keep it in force.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

The court may not order relief that a party has not requested. Per **1.3 Preliminary Injunction Proceedings**, public interest and proportionality are both concerns considered by the court in granting preliminary injunctive relief regardless of subject matter. In the context of life sciences and pharma patent litigation, the court may deny the patent holder's request for the (preliminary) suspension of sales of an allegedly infringing drug on public interest grounds if such drug is shown to be essential to the health and treatment of certain patients.

However, as the grant for final injunctive relief is based on whether infringement was found, the court does not have to consider the balance of interests between the parties and the impact on the public interest.

5.4 Damages

Pursuant to the Taiwan Patent Act, only the patent holder or the exclusive licensee may claim damages as a result of intentional or negligent infringement of patent rights by the defendant. Third parties, including government bodies such as the MoHW, do not have a right to claim damages; the court will reject any claim of damages that is not from the patent holder or the exclusive licensee.

Calculation of Damages

The Patent Act stipulates a number of options for the calculation of infringement damages:

- Damages pursuant to the Taiwan Civil Code – this includes provable actual damages and lost profits. If the amounts cannot be proved, the patent holder may subtract the actual profits from the practice of the patent with the alleged infringement from the expected profits from the practice of the patent to estimate its damages.
- The defendant's unjust enrichment from the infringement.
- A reasonable royalty that the defendant would have paid for a licence to practise the patent.

The court may grant a plaintiff's request for the defendant to pay treble damages if the infringement is determined to be intentional.

Interest on damages

There is generally no time limit imposed on when the damages must be paid, but the plaintiff may claim interest accrued starting from the date the complaint is served on the defendant.

Amount of Damages

In the life sciences and pharma litigation context, for damages claimed based on the unjust enrichment of the defendant, the Intellectual Property and Commercial Court have taken a variety of approaches in determining the amount. For example, in one case, the court used the annual sales turnover of the drug as submitted by the patent holder; and in another case, the court agreed with the patent holder using the NHI-approved price of the drug as sold to hospitals as a basis to calculate the damages amount. For reasonable royalties, even if the patent holder has never licensed another party to practise the relevant patent, the court will determine the amount through considering a number of factors, such as royalties for similar patents, the nature and scope of a reasonable licensing agreement based on the facts of the infringement, the market position of the patent holder and the licensee, the degree of contribution of the patent to the infringing product, and the market share of the infringing product, among others.

Claiming Damages for a Vacated Injunction

As to damages based on a vacated preliminary injunction order, the Code of Civil Procedure only requires the petitioner to pay damages to the respondent in the following three circumstances:

- the preliminary injunction was vacated because it was improper to grant ab initio;
- the preliminary injunction order was vacated because the petitioner failed to timely initiate the main action; or
- the petitioner requested to withdraw the preliminary injunction order.

In practice, the courts have interpreted "improper to grant ab initio" as "improper for a court to grant the preliminary injunction order based on the objective circumstances at that time". No damages claim will be granted for a preliminary injunction order that is vacated due to the petitioner's loss in the main action.

5.5 Legal Costs

In Taiwan, the losing party of a civil action bears the "litigation costs", which, pursuant to the Code of Civil Procedure, include (i) the court fees, which are calculated based on a percentage of the amount in controversy; and (ii) all other necessary expenses for the litigation, such as photocopies, translations and witness/court-appointed expert fees. If both parties prevail in part and lose in part, the court may choose

to allocate the litigation costs proportionally between the parties, or order each party to bear their own respective litigation costs. Notably, attorney's fees are only awarded in the third and final instance, in which attorney representation is required.

In practice, the court does not detail in the decision how the litigation costs are determined. The calculation is generally only carried out when the decision is confirmed as final (ie, where there is no appeal from the losing party/no further appeals are possible) and the prevailing party requests the court to determine the litigation cost amount.

5.6 Relevance of Claimant/Plaintiff Conduct on Relief

(Negative) plaintiff conduct is taken into consideration in the court's deliberation on whether to reduce or even deny relief in an infringement action. Actual discussions by the courts on the impact of plaintiff conduct on relief granted have involved the following:

- Plaintiff's failure to indicate the patent number on the patented object – Taiwan's Patent Act requires the patent number to appear in a conspicuous place on the patented object. Pursuant to the Intellectual Property and Commercial Court's holdings, a failure to indicate the patent number would cause the plaintiff to have to further demonstrate that the defendant was aware or should have been aware that the object in question was patented.
- Constructive waiver and "laches" – in principle, a patent holder's excessive delay in exercising its rights and engaging in conduct that gave others a reasonable understanding that it did not intend to exercise its rights may result in the court disallowing the patent holder's claim against the alleged infringer on violation of good faith grounds. However, in the relatively few Intellectual Property and Commercial Court cases in which the defendant has raised such a defence, the court has not found the argument persuasive because the defendant could not substantiate that the plaintiff had acted in a way that caused the defendant to properly form a good faith belief the plaintiff did not intend to exercise its patent rights.

Finally, per **1.1 Claimants/Plaintiffs to an Action**, exclusive patent licensees need not be registered as a licensee in Taiwan in order to initiate an infringement action against a third party.

6. Other IP Rights

6.1 Trade Marks

Trade mark disputes in the life sciences and pharma sector are very common in Taiwan, in particular counterfeit trade mark civil and criminal cases, with over 30 cases over the past five years.

The trade mark-related laws that a life sciences/pharma dispute may involve include but are not limited to the Trademark Act and the Enforcement Rules of the Trademark Act, the Implementation Regulations for Customs to Detain Articles Infringing the Rights in the Trademark, the Regulations Governing Customs Measures in Protecting the Rights and Interests of Trademarks, as well as the TIPO's trade mark review standards. There is no standard or special consideration, however, that is specifically stipulated for the life sciences and the pharma sector.

6.2 Copyright

Copyright disputes in the life sciences and pharma sector are relatively rare in Taiwan. There have been a few disputes in recent years regarding the packaging design of pharmaceutical products, or alleged copyright infringement of the package insert.

The relevant laws are the Copyright Act and the Implementation Regulations for Suspension of Release of Goods Infringing on Copyright or Plate Rights by Customs Authorities.

6.3 Trade Secrets

While public searches do not reveal any life sciences and pharma sector trade secret dispute cases in the past five years in Taiwan, there have been an increasing number of trade secrets disputes in the Taiwan hi-tech sector in recent years arising from the movement of high-level personnel. It is therefore anticipated that such disputes will arise in the life sciences and pharma sector. The primary source of law for trade secrets in Taiwan is the Trade Secrets Act.

7. Appeal

7.1 Timing to Appeal Decision

Appeal Against a Preliminary Injunction Decision

As mentioned in **5.1 Preliminary Injunctive Relief**, the respondent has a fixed ten days after service of the preliminary injunction decision to contest it. In principle, the appeal would not suspend the enforcement of the preliminary injunction. In reviewing the grant of the preliminary injunction, the appeals court will consider the matter de novo without deference to the lower court's findings, including factors such as the enforceability of the preliminary injunction and the scope/extent of the injunction imposed. If the appeal is found to be persuasive, the preliminary injunction decision may be reversed or amended; a decision to reject the appeal may not be further appealed.

If the basis for the preliminary injunction is extinguished as a result of an appeal or the petitioner's loss in the main action, the respondent must still petition the original court that issued the preliminary injunction to lift the preliminary injunction order.

Appeal Against a First Instance Patent Infringement Decision

In general, an appeal of a first instance decision in a patent infringement dispute should be made to the Intellectual Property and Commercial Court within a fixed 20 days of the service of the decision. The second instance is considered a de novo review that covers questions of facts and questions of law without deference to the first instance court's fact findings. Per the Intellectual Property and Commercial Court's internal rules, second instance proceedings should be concluded within two years from the date the case is assigned to a judge, or such case will be recorded as a delayed case. The losing party in the second instance may further appeal the matter to the Supreme Court for a third instance proceeding.

Appeal Against a TIPO Invalidation Decision

Per **1.5 Timing for Main Proceedings on Infringement/Validity**, the invalidation proceeding is an administrative proceeding. To contest the TIPO's decision on an invalidation petition, a party will need to file for an administrative appeal with the Ministry of Economic Affairs (of which the TIPO is a part), and a decision is generally rendered within three months. A party can contest the administrative appeal decision by initiating administrative litigation, the first instance

of which will be before the Intellectual Property and Commercial Court. Statistics from the Intellectual Property and Commercial Court for 2022 Q1 to Q3 indicate that administrative litigation generally lasts an average of 207 days. If necessary, the second and final administrative litigation instance will be before the Supreme Administrative Court.

7.2 Appeal Court(s) Arbiter

The second instance of a civil patent litigation case is adjudicated by a panel of three judges. As mentioned in **1.12 Experts**, if the appeal is brought before the Intellectual Property and Commercial Court, the court has technical officers assisting the judges in understanding the technical issues of the dispute, collecting information and providing analysis.

The third and final instance of a civil patent litigation case is before the Supreme Court and adjudicated by a panel of five judges.

7.3 Special Provisions

The Intellectual Property Case Adjudication Act stipulates procedural rules for IP rights disputes that take precedence over the general civil/criminal/administrative procedure rules (although those rules still apply for procedural matters not specified in the Intellectual Property Case Adjudication Act). There is, however, no procedural rule dedicated to handling IP rights disputes in relation to life sciences and pharmaceutical products.

8. Other Relevant Forums/ Procedures

8.1 Other Relevant Forums/Procedures

A patent holder may request the customs authority in Taiwan to seize inbound goods that the patent holder believes to be infringing by substantiating its allegations in writing and providing a bond equivalent to the estimated value of the imported goods after customs tax. The other party may stay such seizure by providing an amount double that of the bond provided by the patent holder. However, no special rules for life sciences and pharma IP litigation are stipulated for the above customs seizure application.

9. Alternative Dispute Resolution

9.1 ADR Options

While arbitration and mediation are available in Taiwan for resolving life sciences disputes, based on the authors' public searches, in practice, a large majority of those disputes are still resolved through court actions.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

Settlement or other kinds of agreements entered into by an applicant/holder of a drug permit, a drug patent holder or exclusive licensee that involve the manufacturing, sales or exclusive sales of pharmaceutical products shall be reported to the Taiwan Fair Trade Commission (the authority for competition law) in addition to the MoHW if such agreement involves reverse payments. As such, it is recognised that certain agreements between the aforementioned parties carry antitrust concerns.

Although the authors have not found any precedent for antitrust investigations initiated over settlement agreements between the aforementioned parties in public searches, in May 2021, the Taiwan Fair Trade Commission ruled that there was concerted action by two pharma-

ceutical companies in their use of an "exclusive distributor agreement" to cause one company to pay royalties and become the exclusive distributor of the other company as the distributor has never sold the other company's products.

Lee, Tsai & Partners is a full-service boutique local firm servicing the Greater China region and including around 30 attorneys. The firm's headquarters are in Taipei, co-operating with a local partner law firm in Shanghai and a representative office of local IP consulting firm in Beijing. The firm's biotech and pharmaceutical law team and dispute resolution practice group includes former judges, a former prosecutor and experienced attorneys and is led by Dr Chung-Teh Lee. The firm has substantial experience representing companies in all instances of Taiwan courts and on landmark cases. Lee, Tsai & Partners also regularly advises clients on the strategic planning and management of IP rights in relation to the biotech industry, including obtaining patents and trade marks, IP licensing issues, and litigation. The firm's client profile includes the largest online search engine providers, semi-conductor manufacturers, telecommunication companies, pharmaceutical companies, medical devices companies, infrastructure providers, and venture capitalists.

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1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

In England and Wales, only the proprietor(s) of the patent or the exclusive licensee can bring an action for infringement.

Where multiple proprietors exist, a single co-owner may bring infringement proceedings but the other owner(s) must be joined to the proceedings – either as a co-claimant or, if they do not wish to take part in the action, as a non-participating defendant.

An exclusive licensee can bring infringement proceedings on their own, although the patentee must be joined as a co-claimant or – in a similar manner to co-owners – as a defendant if they do not wish to participate. An exclusive licence can be granted for part of a patent (eg, a particular embodiment of the invention) or some of the rights (eg, manufacturing); however, the exclusive licensee's right to bring proceedings is limited to the rights that have been licensed. Exclusive licensees should ensure their licence is registered on the patent register in order to avoid consequences that potentially limit their ability to recover costs. Nevertheless, the licensee may still bring infringement proceedings even where the licence has not yet been registered.

Any party can initiate action for revocation of a patent, and a party challenging the validity of a patent does not need to show standing to bring a claim. A revocation action may be brought either before the courts of England and Wales or before the UK Intellectual Property Office (IPO). Infringement and validity opinions are also both available from the UK IPO but these are non-binding. A patent may be revoked if it is found to be invalid in a UK IPO opinion, however.

1.2 Defendants/Other Parties to an Action

In life sciences and pharma cases, claims for infringement are most often brought against companies who manufacture or supply the alleged infringing product to the market. Other entities involved in the import of the product (or the supply or import of a part thereof) may also be sued. Albeit theoretically possible, it is not the practice in England and Wales to sue healthcare practitioners or hospitals for patent infringement; the threat or perceived threat of such actions is viewed harshly by the courts and may give rise to counter-actions for unjustified threats.

If an interim injunction would affect dealings with regard to a pharmaceutical product or medical device purchased by the National Health Service (NHS), the Department of Health must be notified and the court will consider whether the applicant for such an interim injunction should pay any damages the NHS may suffer as a result of the interim injunction sought if it is ultimately found that such injunction ought not to have been granted (ie, if the patent is later found to be invalid). Per the court's current usual practice, applicants for such interim injunctions will typically be required to provide cross-undertakings in damages in favour the NHS if the interim injunction is granted.

Additionally, the IPO must be served with proceedings for the revocation of a patent but does not have the option to join in such proceedings.

1.3 Preliminary Injunction Proceedings

Preliminary injunctions (PIs) are available in the UK as an interim equitable remedy, and the court grants them where there is a serious issue to be tried and the balance of convenience favours the grant of the PI (as detailed later in this section). PIs can be applied for on an ex parte basis if

appropriate and can be granted on the day of a hearing if there is sufficient urgency; however, this is rare. It is more common for an application for a PI to be issued inter partes within the context of main proceedings commenced in parallel, and for the application and evidence to be served on the defendant – and exchanges of evidence to take place – before a hearing.

In particular circumstances, where the form of the claims to ultimately be granted is sufficiently clear and certain, PIs can be applied for before the grant of a patent and can be based on an application. (This has only recently been confirmed and, in general, a party will still seek a PI on the basis of a granted patent.)

As English is one of the official languages of the European Patent Office (EPO), translation of a European patent or its claims is not required. (However, if the language of the description the European patent in suit is French or German, it would be highly advisable to provide an English translation.) Validation is not required before entry to the UK IPO register, either. Patent validity is not assumed in PI proceedings and the alleged infringer has the opportunity to introduce evidence to the contrary in the PI proceedings – although invalidity decisions from other jurisdictions are not normally a significant factor.

The timing and length of PI proceedings depend largely on facts and are based on commercial urgency. The court can also order an expedited trial of the main action to take place within months, in addition to (or instead of) issuing a PI. As a discretionary equitable remedy, courts expect that a party seeking a PI will do so expeditiously – the failure of an applicant to act with sufficient urgency in all of the circumstances is likely to count as a factor against the grant of the PI sought.

An application for an ex parte PI would normally be heard at a hearing lasting one or two days, with a decision from the court reached at the end of the hearing. A return hearing, at which both parties must be present, will then take place within a couple of weeks.

An application for a PI on notice would generally be heard within a couple of months. Judgment could be extemporaneous or handed down within days to weeks, depending on the complexity and urgency of the matter.

A first-instance PI decision may be maintained pending the result of the appeal of the PI decision or pending the final result of the main proceedings. A hearing and decision on a PI appeal will occur within days of the lower court's decision if heard on an urgent basis, which will often be the case if there is a risk of an infringing pharmaceutical product entering the market.

When obtaining a PI, the claimant must provide a cross-undertaking to compensate the alleged infringer for damages in the event the injunction was found to have been unjustified (eg, the patent is ultimately found to have been invalid). The undertaking remains in place until a final order is made following the first-instance action and any appeal. The amount of damages is decided in a separate damages inquiry following the main action (if not settled).

Considerations for Granting a PI

The considerations to be taken into account when granting a PI are well established by case law and include the following.

- There must be a serious issue to be tried.
- Damages are not an adequate remedy for the claimant (ie, the claimant will suffer intangi-

ble, unquantifiable or irreparable harm if the injunction is not granted).
- The cross-undertaking in damages is an adequate remedy for the defendant if it is later found that the PI was unjustified.
- If damages are not an adequate remedy for either side, the court will consider where the balance of convenience lies in granting the PI – including the merits of preserving the status quo pending determination of the main substantive proceedings.
- PIs are only granted where the matter is urgent. It will be for the applicant to show that there is an urgency in granting the injunction, as demonstrated by reference to both damage to the business without a PI and to the speed with which the claimant has sought the PI. The applicant will likely be required to show why it did not issue proceedings earlier if there was an opportunity to do so.

Specific Considerations for Life Sciences and Medical Devices

In pharmaceutical cases where a PI is sought to prevent the launch of a generic or biosimilar version of the patented medicine, the court will consider whether the generic or biosimilar entering the market would irreparably damage the market for the branded product and whether damages can be adequately quantified.

Until recently, it was generally considered that the entry of a generic or biosimilar causes an irreversible price spiral in respect of the medicine in question and, as such, that damages cannot be adequately quantified. This was often a decisive factor in the court finding that a PI should be granted to restrain generic or biosimilar entry.

Lately, however, courts have shown an increasing tendency to strongly pressure test applicants' assertions that failure to grant a PI will result in such an irreversible price spiral. Courts have become cautious in granting a PI restraining generic or biosimilar entry if it is considered only difficult – rather than impossible – to quantify damages. In order to support any claims of an irreversible price spiral, applicants will be expected to adduce detailed evidence that directly addresses and is highly tailored to the particular economics and market circumstances of the product in question.

When considering whether to grant a PI, the court will also consider whether the generic or biosimilar company sought to "clear the way" (or sought a declaration of non-infringement) before bringing their product to the market – or, conversely, whether the generic or biosimilar company sought to act surreptitiously in their launch activity. Parties that have not sought to clear the way and/or are considered to have acted surreptitiously are likely to be at greater risk of a PI against them. Similar considerations apply to branded products where there is a relevant third-party patent.

As a discretionary equitable remedy, the proportionality of the grant of a PI (or, indeed, final injunction relief) in all of the circumstances will also be a relevant factor considered by the court – especially in the context of pharmaceutical and medical device litigation, where the granting of injunctive relief may have significant consequences for patients. The courts of England and Wales have shown significant flexibility when exercising their discretion to grant injunctive relief, including a willingness and ability to provide for:

- carve-outs from injunctions for certain patient populations that might otherwise go untreated; and

- a delay to the commencement of injunctions in order to allow patients and their health-care professionals a period of training and transition between products (in the context of medical devices where re-training with the patentee's product was required).

Quia Timet Relief for Threatened Infringing Acts

A preliminary injunction can be obtained on a quia timet basis as part of infringement proceedings where an entity threatens to infringe a patent but before those infringing acts have actually been committed. However, the grant of a marketing authorisation in and of itself is not considered enough to obtain a PI – the claimant must show additional evidence of an intention to launch an infringing product.

Notification of PI Request

For inter partes PI applications, a defendant will be provided with the application for a PI, which includes the claimant's evidence in support. The defendant will therefore have the opportunity to make representations to the court as part of the hearing on the issue of granting a PI.

The defendant is not normally notified before an ex parte application. The defendant has the opportunity to make its representations at the above-mentioned return hearing and the claimant is required to give full and frank disclosure (including making points that support the defendant's case) as part of its ex parte application. The defendant can write to the court and request permission to serve or provide evidence; however, protective letters are not part of the law or practice in England and Wales.

Identifying New Court Actions That May Include PIs

Parties can monitor the court's electronic filing service for new claims that are issued. They will know about the parties to a claim and the type of claim (eg, issued in the Patents Court) but will not be able to view detailed information until a number of weeks later when the defendant has participated in the action. They will also not know if the action includes a PI application.

1.4 Structure of Main Proceedings on Infringement/Validity

Issues of infringement and validity are dealt with in the same proceedings in England and Wales. The liability trial addressing any issues of infringement and validity takes place before a separate quantum trial, in which the court can decide the amount of damages that applies where infringement has been found (if this amount cannot be agreed through settlement at that stage).

It is possible (and common) to file nullity proceedings in England and Wales based on the UK designation of a European patent while there are parallel EPO opposition proceedings pending in respect of the patent in suit. The proceedings will run concurrently but, upon application by a party/the parties, the court may stay the national proceedings while the EPO proceedings are ongoing.

In theory, the "default" position is that the national proceedings should be stayed pending the final determination of the opposition proceedings in the EPO. However, in practice – owing to the significant length of time it typically takes for opposition proceedings to run their course (in particular, the appeal stage) in the EPO compared with the relative speed of proceedings in England and Wales – that default position is overturned in most cases by the need for com-

mercial certainty on the part of the party that has commenced the national proceedings.

When adjudicating upon an application to stay national proceedings pending parallel opposition proceedings in the EPO, the court will also consider the (lack of) availability of remedies – for example, infringement decisions and non-infringement declarations and Arrow declarations cannot be granted by the EPO, yet can be given by the national court. The court will also consider if the parties have agreed to undertakings for damages if the patent in question would ultimately be revoked in the national proceedings after a stay was lifted.

1.5 Timing for Main Proceedings on Infringement/Validity

Starting an Action

Actions relating to patent infringement or revocation may be brought at any time after the grant of a patent, with recovery of damages for acts of infringement dating back six years or from the publication of the patent application (whichever period is less).

To start an action, a claimant must prepare a Claim Form, Particulars of Claim and – depending upon whether the claim relates to patent infringement or revocation – either a Particulars of Infringement or Grounds of Invalidity. For high-value claims before the Patents Court, the particulars are relatively high-level at this early stage and contain very little detail. This is also the case for the defendant's response in its defence and any counterclaim, with detailed information following when the timetable to trial is set - particularly at the disclosure/discovery and expert evidence stages.

Notification to the Defendant

The claimant normally has four months to serve the action on a UK defendant or six months for a defendant outside the jurisdiction. Permission from the court is required (with limited exceptions) to serve documents outside the jurisdiction.

Actions are often served as soon as possible after issue, in order to start the "litigation clock" for providing a defence and moving towards agreeing the timetable to trial. Typically, the claimant's solicitors serve the action by sending the above-mentioned documents by courier or post to the defendant's registered address. Where the patentee is the defendant, service can also be effected by sending these documents to the patent agent's address recorded with the UK IPO.

Timing of Patent Cases

Once a claim has been served, a UK defendant has 28 or 42 days to provide its defence for invalidity or infringement actions respectively – as long as a pro forma "acknowledgement of service" document is filed at court within 14 days (otherwise, the defence is due within 14 days). Any counterclaim is usually expected when the defendant provides its defence. Opportunities to file replies (including, in the claimant's case, a defence to any counterclaim) are then available for the next approximately 1.5 months – at which point, the "pleadings stage" is closed.

A case management court hearing takes place after pleadings are closed (if the parties cannot agree the trial timetable between themselves). The court will hear the parties and decide the trial date and timetable to trial, including deadlines for important steps (eg, disclosure, expert evidence and any necessary fact evidence). No preliminary opinions are issued by the court;

however, there may be interim hearings on specific issues of the case, such as:

- listing the trial at an early stage (recent trends favour standalone applications to list trial rather than waiting for the case management hearing, owing to congestion in the Patents Court trial diary);
- the extent and timing of disclosure; and
- applications for a stay of proceedings.

As previously mentioned, issues of validity and infringement are considered at the same trial in the UK.

The Patents Court aims to bring cases on for trial within 12 months of the claim being issued. However, this has not been possible in recent years, owing to the busy workload of the court. Cases are therefore taking closer to 18 months to come to trial. Expedition is possible – thereby allowing the timeline to be almost halved or even further shortened – if the court considers this to be appropriate based on:

- evidence in an expedition application;
- the nature of the case; and
- the availability of an earlier trial date.

A "shorter trial scheme" – allowing trials within 12 months – is also currently available in the Patents Court; however, this pilot scheme is only appropriate for less complex actions. In all cases, judgment is normally reserved at the end of trial and subsequently handed down within two to three months. However, the authors have observed delays – with some judgments taking significantly longer to hand down (particularly in the case of longer trials and/or where the issues in dispute are complex).

England and Wales also offer a court for simpler, low-value patent claims (and other IP rights) called the Intellectual Property and Enterprise Court (IPEC). Unlike in the Patents Court, damages are limited to GBP500,000 and legal costs recovery is limited to GBP60,000. A trial in the IPEC lasts for a maximum of two days, and expert and evidence is limited. The IPEC aims to bring cases on for trial between nine to 12 months after issue. A first-instance decision should be handed down within three months of the trial but may take longer.

1.6 Requirements to Bring Infringement Action

A main action for patent infringement can be filed at any time once a UK national patent has been granted and, in certain circumstances, before it is granted – for example, where the examination procedure in the EPO has concluded with a decision that a patent should be granted but the formal grant is yet to take place. As is the case with PIs (see **1.3 Preliminary Injunction Proceedings**), translation of a European patent or its claims is not required – nor is validation prior to entry to the UK IPO register.

For process patents producing a new product, the burden of proof may be reversed in certain circumstances that require the maker of an infringing product to show that the product was not produced in the process claimed in the patent.

1.7 Pre-action Discovery/Disclosure

Pre-action disclosure is not available as of right. Orders for pre-action disclosure can be sought if the would-be claimant can demonstrate that this may settle the dispute without the need for proceedings (as opposed to fishing for information to make out its claim). Pre-action disclosure has been ordered in some cases – including

disclosure of samples of pharmaceutical product, which would enable the potential claimant to determine if the product did in fact infringe. The court can also order a third party to disclose documents to an applicant before proceedings have started in order to enable the applicant to commence proceedings against the appropriate party.

Disclosure in the main proceedings in patent cases is most common in relation to the issue of infringement rather than validity. Disclosure by an alleged infringer on the issue of infringement is commonly provided by way of a Product and Process Description (PPD) – a self-contained document, provided in lieu of the relevant underlying documents, which sets out sufficient information for the court to determine whether or not the patent has been infringed.

Disclosure in the main proceedings follows the provision of an "Initial Disclosure List", which is provided by the parties when they provide their initial pleadings and sets out the documents upon which they rely. Significantly, there is no requirement to disclose documents that adversely affect a party's case as part of the Initial Disclosure List.

Unless ordered otherwise (upon application to the court and supported with good reasons), use of documents obtained in disclosure – pre-action or at another point – is restricted to the English proceedings and cannot be used in other jurisdictions.

1.8 Search and Seizure Orders

Search and seizure orders are available as a form of interim mandatory injunction and applications are made ex parte. As a result, the applicant for a search and seizure order is under an obligation to give full and frank disclosure upon the application and must give an undertaking for any appropriate damages if it is later found that the search and seizure order should not have been granted. Most applications for search orders are made before the issue of a claim but they can be made at any stage of proceedings, including when enforcing a judgment.

Unless the court orders otherwise, the defendant in an action is only able to apply for an interim remedy such as a search order after it has filed an acknowledgement of service or served a defence. Search orders should be applied for as soon as possible, and any delay in applying may result in the application being denied. Search orders may also be granted against non-parties to a claim (eg, third parties).

The material obtained during the search and seizure may only be used for the purpose of the claim unless the court orders otherwise. As a general rule, the court is unlikely to allow this material to be used in other jurisdictions unless it is in aid of applications for contempt of court or protective measures.

Unlike the *saisie-contrefaçon* procedure available in France and certain other jurisdictions, search and seizure applications are not a regular feature of patent litigation in England and Wales. These orders are generally regarded as highly invasive and, as such, very good reasons – supported by strong evidence – must be provided by the applicant in order to meet the high bar for securing a search and seizure order. Such an order may be justified where, for example, there is a real risk of the defendant destroying infringing products or evidence so as to frustrate attempts to bring proceedings against them.

1.9 Declaratory Relief

Declaratory relief is available in the courts of England and Wales and is commonly sought in patent actions. A subsisting cause of action need not be established, although some real dispute must exist between the parties. The English courts have shown an increasing willingness to consider the use of their discretion to award declaratory relief if this may be useful (in particular, in recent telecommunications litigation).

A declaration of non-infringement may be granted by the Patents Court and IPEC in main proceedings, or upon application to the Comptroller. (For an explanation of the differences between the Patents Court and IPEC, see **1.5 Timing for Main Proceedings on Infringement/Validity**.)

Arrow declarations (ie, declarations that a claimant's process or product was obvious or not novel) can be sought to guard against future infringement proceedings for patents granted at a later date. Arrow declarations are available in England and Wales and can be granted where "they will serve a useful purpose". Although the court has a broad discretion to grant them, it will assess the justice to the claimant and defendant and the proposed utility of the declaration. Arrow declarations have not been ordered in many cases in England; however, when they have been ordered, they have all been in relation to pharmaceutical products.

Arrow declarations are not available for the sole purpose of aiding the claimant in foreign proceedings – for example, they will not be ordered if no infringement is threatened in the UK.

1.10 Doctrine of Equivalents

The English Doctrine of Equivalents (DoE) is a relatively recent development. The normal interpretation applied by the English courts is "purposive construction" – ie, considering the words of the claim as understood by a skilled person in context of the patent. Claimants can now plead infringement by an immaterial variant and the court will consider the following legal test.

- Despite the fact that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, ie, the inventive concept revealed by the patent?
- Would it be obvious to a person skilled in the art, who reads the patent at the priority date but knows that the variant achieves substantially the same result as the invention, that the variant does so in substantially the same way as the invention?
- Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

In order to establish infringement as an immaterial variant, a patentee would have to establish that the answer to the first two questions was "yes" and that the answer to the third question was "no".

The DoE was established in a 2017 case where only infringement was at issue (Actavis v Eli Lilly). This led to ambiguities as to whether the DoE might extend the scope of patent protection to prior art processes or products. However, discussions in recent UK cases suggest that a defence to this possibility – referencing the Formstein defence arising from the German authority – may be available in the future. No binding decision has been made on this issue as yet.

1.11 Clearing the Way

Although there is no strict legal requirement to "clear the way" ahead of the launch of a new product, it is a relevant consideration in PI proceedings. Failure of a generic or biosimilar company to clear the way ahead of market entry may be a factor in favour of the grant of a PI.

1.12 Experts

Expert evidence is a key feature of patent litigation proceedings in the UK. Each party will retain an expert (or multiple experts where the court considers this necessary). The experts' overriding duty is to the court in facilitating its understanding of their area of expertise so that the court can decide the issues in dispute. Unlike in some jurisdictions, it is important that experts maintain their impartiality and do not argue the case of the party who engaged them.

Experts normally prepare a written report during proceedings followed by a reply report responding to the report from the opposing party's expert. Further reply reports may also be issued if considered necessary by the court. The expert will be expected to attend trial for oral cross-examination by the other side's counsel in main proceedings. Cross-examination is unusual in preliminary injunction proceedings or appeals.

Each party to proceedings will generally have its own expert, unless specific circumstances apply – for example, all of the claimants in multiparty proceedings will generally be expected to share experts as much as possible in order to preserve court time and costs. In patent cases, it is common to have two or three experts on each side, with each expert forming a part of the theoretical skilled team to whom the patent in suit is addressed.

Instructions to experts are highly regulated and may become disclosable upon application by the other party. Parties must be careful to instruct experts in a particular way: discussing the state of the art and concepts relevant to the common general knowledge of the skilled person first and subsequently providing prior art for discussion before moving on to providing and discussing the patent. This is necessary to avoid criticism that the expert's views were tainted by hindsight because they saw the patent at an early stage of their analysis.

There is an increasing expectation from the court that, in cases with more than one expert on each side, the experts should have the opportunity to discuss their views with the other experts on the same side as they would have in the hypothetical skilled team. The giving of concurrent evidence and a joint meeting of the experts can be ordered by the court, although this has not gained popularity in the Patents Court. It is rare for the court to appoint an expert, but it is possible. Scientific advisers may be appointed by the court; however, this is also rare.

1.13 Use of Experiments

Experimental evidence may be used, with the permission of the court, to prove or disprove facts that are relevant to the determination of issues of infringement or validity. The court will often allow experiments in pharmaceutical cases. For experimental results to be admissible, the following steps must be observed.

- A party wishing to rely upon experimental data must first serve on the other parties a Notice of Experiments, which is a formal document setting out the facts it intends to prove by way of experiments and disclosing how the experiments are to be conducted.

- The other party may request the opportunity to inspect a repetition of some or all of the experimental data in the notice, and must then respond to the notice stating whether or not each fact is admitted.
- The party wishing to rely on the experiment will then apply to the court for permission to rely on the experiments, which will normally be granted. If the experiments are repeated in the presence of the other party it is the results of those experiments that will be relied upon at the trial.

The experts will also give evidence concerning the design and results of the experiments and may be cross-examined. The other party can also apply to conduct its own experiments.

Parties considering experiments must be careful in producing any data or documents, as these may become disclosable to the other side.

1.14 Discovery/Disclosure

Under a series of procedural reforms, and further to developing practices in the Patents Court (and in the courts of England and Wales more generally), the approach to disclosure in England and Wales has moved steadily away from a US-style broad, inclusive approach to disclosure/discovery and towards a narrower model that encourages parties to make specific and limited disclosure requests (if any). The courts' approach is guided by the overriding considerations of relevance, reasonableness and proportionality. The current disclosure regime also places the onus on the parties to proactively disclose relevant documents; in particular, there is a continuing duty on the parties to disclose any "known adverse documents".

In patent proceedings, as noted in **1.7 Pre-action Discovery/Disclosure**, disclosure is most common in relation to the issue of infringement rather than validity and is typically done by way of service of a PPD. Disclosure in relation to issues of validity (including inventive step as well as lack of sufficiency) is now difficult to obtain in light of the courts' scepticism concerning the relevance of such disclosure to validity issues in most cases. However, if a patentee decides to rely on – and therefore proactively discloses – a selection of its own documents as evidence in support of some factual contention, disclosure of other documents (eg, assignment or licensing agreements, laboratory notebooks and employment contracts, where relevant) potentially related to that issue may be warranted in response.

Pre-action disclosure and provision of "initial disclosure" upon service of pleadings is also discussed in **1.7 Pre-action Discovery/Disclosure**.

1.15 Defences and Exceptions to Patent Infringement

The primary defences to infringement actions are invalidity and non-infringement of the patent – or a combination of the two in the form of the "Gillette defence" squeeze, where a defendant says that their product or process existed in the prior art.

Additionally, there are a variety of further defences to infringement available, including:

- consent;
- compulsory licence;
- private use;
- prior use (which has a jurisdictional restriction so that the use must be in the UK);
- mere repair;
- experimental use (a form of which is the Bolar exemption – see **2.3 Acceptable Pre-launch Preparations**);
- exhaustion; and

- extemporaneous preparation in a pharmacy of a prescribed medicine.

1.16 Stays and Relevance of Parallel Proceedings

Infringement and validity proceedings can be stayed pending the outcome of the EPO opposition proceedings (see **1.4 Structure of Main Proceedings on Infringement/Validity**). It is less common pending proceedings in other jurisdictions.

The court may note the outcome of parallel proceedings, particularly in the EPO, but is not bound to follow the results of such proceedings in other jurisdictions.

1.17 Patent Amendment

Patents can be amended post-grant upon application to the UK IPO, which may grant the amendment with any conditions it sees fit. Amendment is not permitted as of right while there are pending validity proceedings before the court or the IPO but may be granted following an application to the court and advertisement by the IPO. There is an opportunity for opposition to the proposed amendments. If part of court proceedings, the opposition would generally be heard during the trial. Conditional amendments (ie, in the event that the claims as granted would otherwise be found invalid) are permitted in England and Wales.

Claim amendments may also be made for European patents either:

- through the central limitation procedure at the EPO; or
- in the course of opposition proceedings (eg, by way of auxiliary requests ultimately upheld in the course of such proceedings).

It is common for patents to be amended by one or more of these mechanisms in the course of patent litigation, particularly given that there will frequently be parallel EPO opposition proceedings in respect of the patent in suit.

1.18 Court Arbiter

Specialist judges decide cases in the Patents Court and IPEC (which deals with less complex patent cases, among other work). Patent cases in the Patents Court are assigned a technical complexity rating in the early stages of the case. The more complex cases (ie, those that receive a technical complexity rating of 4 or 5 out of 5) are assigned to one of a list of judges, each of whom has particular expertise and experience in patent cases, that are approved to hear such cases. In the IPEC, cases are not assigned a technical rating; however, if they are complex and require extensive expert evidence, they may be transferred to the Patents Court.

Other than choosing whether to issue an action in the Patents Court or the IPEC, no forum shopping is available within England and Wales.

2. Generic Market Entry

2.1 Infringing Acts

The right to bring an action for infringement in respect of small molecule pharmaceutical products is the same as for other pharmaceutical products.

An application for – or the grant of – a marketing authorisation (MA) or an application for reimbursement are not considered infringing acts in themselves but can be seen as an indication that the applicant has serious plans to enter the market and therefore infringe the rights of the patent holder. The submission of a response to a

request for tender or an offer to supply a product covered by a patent that is made before the patent expires is not seen as an infringing act if the actual supply is to occur after expiry.

In the UK, applications for marketing authorisations (MAAs) and reimbursement are not readily available on the public record – nor are submissions of responses to a request for tenders. However, the grant of an MA is in the public record once granted. The holder of a MA for a reference product is not notified of new generics or biosimilar MAAs, and will only find out that a MA has been granted once it is public information.

The grant of a MA is often the trigger for engagement with the alleged infringer by the patentee/exclusive licensee. A new market entrant that does not wish to risk being enjoined should be willing to state that it will not enter the market until after the patent expires.

Second Medical-Use Patent Considerations

In the UK, medicines are generally prescribed based on their international non-proprietary name rather than the brand name. In addition, courts will primarily consider the external presentation of the medicine – ie, the indications for which the generic medicine is approved and which appear in the packaging and inserts for the product – when considering infringement of a second medical-use patent. Accordingly, apart from in exceptional cases where there is strong evidence to suggest an actual intention by the generic manufacturer to sell its product for the patented indication, it is now difficult to establish infringement of a second medical-use patent if a generic product has carved a patented indication out of its label (ie, it has a "skinny label").

Parallel Imports

The viability of parallel importation of patent protected medicines into England and Wales depends on the approach to the exhaustion of IP rights that the UK chooses to adopt following Brexit. This issue currently remains under consultation, and is subject to clarification and potential change in the near future.

As things stand, the position between the UK and the EEA is asymmetric. The UK continues to adopt a regional exhaustion approach that extends to the EEA, while the EEA no longer includes the UK in its regional exhaustion regime. This means that IP rights subsisting in goods placed on the UK market will not be exhausted in the EEA, whereas rights in goods placed on the market in the EEA will be considered exhausted in the UK market. It remains to be seen how the UK government decides to change the law, and what the ultimate outcome for IP rights-holders in the UK will be.

2.2 Regulatory Data and Market Exclusivity

Regulatory data exclusivity provides eight years of exclusive rights to the MA holder for the data submitted in their MA application for branded reference products. This means that, during this period, a generic or biosimilar cannot file an application for an MA that relies on the data submitted in relation to the branded reference product.

Market exclusivity provides an additional two years after the expiry of regulatory data exclusivity. The generic or biosimilar cannot be placed on the market during this period; however, an MA application can be filed relying on the data submitted in relation to the branded reference product. An additional year of market exclusivity protection can be obtained if, during the

first eight years after the grant of the MA for the branded reference product, the MA holder obtains authorisation for a new therapeutic indication that is deemed to provide a significant clinical benefit. Overall, there is a maximum of 11 years of exclusivity (the "8+2+1" year formula).

Challenges to data and market exclusivity are uncommon in the UK. The method for challenging decisions of the Medicines & Healthcare Regulatory Authority (MHRA) in relation to data and market exclusivity is by judicial review proceedings in the administrative division of the High Court.

Paediatric Extensions

Upon the completion of paediatric studies in compliance with the relevant paediatric investigation plan for a medicine, and their inclusion in the summary of product characteristics (SmPC), an MA holder may receive the benefit of a "paediatric extension" to one of the protections for that medicine. This can take the form of either:

- a six-month extension to a Supplementary Protection Certificate (SPC) in relation to that medicine; or
- an additional two years of orphan market exclusivity (in the case of orphan medicines).

Importantly, the MA holder cannot seek to obtain both paediatric extension rewards. If it wishes to opt for the SPC extension, it must take steps to remove the orphan designation from the product.

Orphan Medicines

In order to encourage the development of orphan medicines, the relevant indication will benefit from 10 years of market exclusivity from when it receives marketing authorisation. Orphan market exclusivity prevents products with the same therapeutic indication as a similar medicinal product from being granted an MA within the period of protection. Orphan exclusivity therefore grants protection that is broader than normal market exclusivity.

2.3 Acceptable Pre-launch Preparations

Generics companies are able to rely on the "Bolar exemption" to conduct the necessary activities to obtain the required regulatory approvals prior to patent expiry. Recent amendments to the UK Patents Act have clarified that activity conducted for the purpose of medicinal product assessment is expressly covered as a particular species of the general experimental use exemption from patent infringement. This exemption therefore covers not only activity by generic and biosimilar companies for the purposes of seeking regulatory approval but also applies to the preparation and running of clinical trials for innovative drugs that would otherwise infringe a patent.

2.4 Publicly Available Drug and Patent Information

The UK does not have the Orange Book or any other patent linkage regime. However, the British National Formulary (BNF) publication does provide information on medicines and branded and generic products available from the NHS.

See **2.1 Infringing Acts** for a discussion of MAs.

2.5 Reimbursement and Pricing/Linkage Markets

The grant of an MA and pricing and reimbursement are not linked with patent status in the UK. See **2.4 Publicly Available Drug and Patent Information** for discussion regarding public availability/notification in relation to MAs and pricing and reimbursement.

In England, the National Institute for Health and Care Excellence (NICE) assesses the cost of new medicines against their effectiveness and the price set by the manufacturer. It is likely to enter into discussions with the manufacturer and then make a recommendation that, in practice, will determine whether or not access to the medicine will be subsidised by the government and made available through the NHS. Judicial review proceedings can be brought against NICE if a manufacturer considers that an illegal decision has been reached with regard to pricing or, for example, the recommendation that a drug should be used off-label instead of the originator product.

NICE health technology guidelines are specific to a medicine for the treatment of a condition (or multiple conditions), as listed in the guidance.

Administrative suits by way of judicial review proceedings can be filed against NICE or other public bodies for the decisions made regarding:

- whether treatment is to be funded;
- the terms of its availability; or
- how NHS Clinical Commissioning Groups issue guidance to prescribers on which medicines to prescribe (including off-label use of generic drugs).

These challenges are rare.

3. Biosimilar Market Entry

3.1 Infringing Acts
This does not apply in the United Kingdom.

3.2 Data and Regulatory Exclusivity
The MHRA's guidance on the licensing of biosimilar products (issued in 2021) confirmed that the MHRA does not intend to require comparative clinical trials for new biosimilar products unless there is a scientific rationale for doing so. This will enable biosimilars to potentially enter the market much earlier than they would have otherwise.

3.3 Acceptable Pre-launch Preparations
This does not apply in the United Kingdom.

3.4 Publicly Available Drug and Patent Information
This does not apply in the United Kingdom.

3.5 Reimbursement and Pricing/Linkage Markets
This does not apply in the United Kingdom.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates
SPCs are available in the UK to provide protection for patented medicines beyond the term of the relevant basic patent. Regulation EC No 469/2009 sets out the regime for human and veterinary medicinal products. The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 imported the SPC regulation into UK law after Brexit.

The product that is the subject of the SPC must be protected by a basic patent that is in force. An MA must also be in place for the product and it must be the first MA to place the product on the market. The product must also not already have been the subject of a SPC.

An SPC extends the protection of the patent for up to five years for a particular indication, and an additional six months' protection can be

obtained if a paediatric extension is available (see **2.2 Regulatory Data and Market Exclusivity**). An SPC must be applied for within six months of the date of the MA for the relevant medicinal product or, where the SPC is granted based on the patent, within six months of the date of grant of the basic patent. An application for a paediatric extension to an SPC must be lodged no later than two years before the SPC expires.

An applicant for an SPC must hold the basic patent forming the basis of the application; however, the applicant need not be the holder of the MA. As such, so-called "third-party SPCs" are allowed. Given that the patentee and MA holder can be separate unlinked entities, situations may arise where an SPC is applied for by a patent holder without the consent of the MA holder and, therefore, the patentee is prevented from obtaining an SPC. This has led to situations where the MA holder has tried to have the SPC revoked or ultimately had to obtain a licence in order to be able to market its product.

SPCs are no longer available for a different application (ie, second medical use) of a product for which an earlier MA has already been granted. Only the first use of an ingredient or combination authorised by an MA can be granted an SPC.

At present, the case law in England and Wales concerning SPCs continues to be mostly derived from referrals to the CJEU prior to Brexit, and there are numerous issues that have not been fully settled or on which the law on SPCs in England and Wales may diverge from the EU following Brexit.

SPC manufacturing waivers – largely imported from EU regulations into UK law via The Intellectual Property (Amendment etc) (EU Exit) Regulations 2020) – are available in the UK, as in the EU, and allow for the medicinal product covered by an SPC to be manufactured by third parties while the SPC is in force for the purpose of:

- exporting from the UK and EU; or
- stockpiling for the final six months prior to SPC expiry in order to enable "day-1 market entry" post-SPC expiry.

4.2 Paediatric Extensions

Paediatric extensions of six months are available for SPCs where studies have been conducted in accordance with a paediatric investigation plan. See also **2.2 Regulatory Data and Market Exclusivity**.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

Cross-undertakings for damages are required from the applicant for a preliminary injunction and are covered at **1.3 Preliminary Injunction Proceedings**. The NHS is likely to be party to any cross-undertaking for damages in life sciences patent cases.

Preliminary injunctions are enforced by a court order that is served by the court or the party obtaining the injunction against the potential infringer. If a person subject to an injunction does not comply with the court order, proceedings for contempt of court and other enforcement actions can be applied for from the court. However, it is rare that such actions need be taken in patent litigation cases.

A preliminary injunction application will normally be filed in the context of a parallel main action or, if a preliminary injunction is sought and ordered

before a main action is issued, the injunction is normally granted with the condition that a main infringement claim will be brought against the entity being enjoined.

It is sometimes (albeit rarely) possible to obtain a stay of a preliminary injunction that has been obtained, pending appeal to the Supreme Court. There is no option to pay a bond in order to lift a preliminary injunction.

5.2 Final Injunctive Relief

Injunctions are enforced by way of the order of the court and are effective upon service on the defendant. A party (or a company's directors, as applicable) subject to an injunction that breaches the order may be subject to fines, imprisonment, or committal of assets. Further applications can be made to the court to enforce an injunction.

Stay of a final injunction can be obtained, pending appeal or pending a decision on an application for leave to appeal. Examples of this include cases concerning critical life sciences products where, in the public interest, the parties agree to stay the final injunction pending appeal in order to prevent a supply chain/patient access from being interrupted. Prospects for obtaining a stay of a final injunction are otherwise limited. There is no option to pay a bond to lift a final injunction pending appeal.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

An injunction is the default remedy for patent infringement. However, the court will consider whether it is proportionate in the circumstances to award an injunction and, in particular, whether damages would be an adequate remedy. As discussed in **1.3 Preliminary Injunction Proceedings**, the English courts have shown a willingness to tailor the terms of an injunction by way of carve-outs and delaying the commencement of a final inunction.

5.4 Damages

Damages for infringement are available from the publication of the application underlying the infringed patent or the first date of infringement (if later). The patent proprietor can elect to receive the alternative award of an account of profits; however, monetary relief in the form of damages is chosen in the overwhelming majority of cases. Interest is payable on the final award.

Quantum is decided in a separate hearing following the conclusion of the main action on liability. The date for payment of damages is provided in the final order following judgment and is generally within a few weeks. Interim awards are not available. Damages inquiries are evidence-heavy and time-consuming, and damages can be assessed by a range of different assessment methodologies, including lost profits and reasonable royalty approaches. Where the court exercises its discretion not to order final injunctive relief, it may instead decide to order damages in lieu of the injunction.

Where a cross-undertaking as to damages has been given – ie, in return for a preliminary injunction – by a patentee who is ultimately unsuccessful at trial, the beneficiaries of the cross-undertaking (which in pharmaceutical cases will often include the NHS) will be parties to the damages inquiry as well.

5.5 Legal Costs

Legal costs (or a proportion thereof) are recoverable and follow the general principle that the losing party pays the winner's costs. However, the court has wide discretion in relation to costs orders.

If the successful party in the Patents Court wins on all the issues raised in the litigation, it may recover its proportionate and reasonable costs (which equates to around 60%-70% of their costs). If the losing party has conducted itself unreasonably in the litigation such that the court decides to make an order for costs on an "indemnity basis" as opposed to the "standard basis", then the winner will be entitled to its reasonable costs without reference to the proportionality of those costs – thereby resulting in a higher costs award in the region of 80%-90% of the winner's costs. This amount is likely to be reduced if the winner is considered to have lost on any particular discrete issues in the case. Additionally, the court will take into account offers the parties have made to settle the proceedings.

The court may make a summary assessment of costs (where costs are assessed by the judge who heard the case) or order a detailed assessment to be performed by a costs officer. Given the complexity and expense of the detailed costs assessment process, parties in patent litigation will typically reach an agreement on costs rather than resorting to that procedure.

Costs are recoverable from when the action is filed and include court fees. The court may choose to make an award on costs of an interim application at the time of hearing that application. It is also common for courts to require an interim payment of costs following first-instance judgment, pending assessment of costs or agreement between the parties on costs.

Recovery of legal costs is capped at GBP60,000 in the IPEC.

5.6 Relevance of Claimant/Plaintiff Conduct on Relief

When making an assessment of the recoverability of costs, the court will keep in mind the overall conduct of the parties during the whole course of the litigation. A party that is seen to conduct itself improperly during litigation may be subject to an adverse costs award, including the higher indemnity costs recovery threshold where the party's conduct is considered to be outside the norm. Additionally, costs are not recoverable if they are unreasonably incurred or unreasonable in amount (unless indemnity costs have been awarded). Owing to the nature of patent litigation cases, there is generally no requirement to engage in pre-action correspondence and the parties are not penalised on costs for failing to do so.

In addition, for equitable forms of relief (eg, injunctive relief) and relief that is generally at the discretion of the court (eg, declaratory relief), improper conduct on the part of the party seeking relief is likely to be taken into account in the court's assessment of whether it is appropriate in the circumstances for the court to exercise its discretion to grant the relief sought. In general, it is said that a party seeking equitable relief must come to the court "with clean hands" and a party "who seeks equity must do equity".

6. Other IP Rights

6.1 Trade Marks

Trade mark disputes in the pharma sector are uncommon in England and Wales but are most commonly seen with regard to products where there may be confusion for the end customer or misuse of a company's goodwill. They are more commonly seen in relation to consumer health-

care products rather than pharmaceuticals or medical devices.

6.2 Copyright

Copyright issues are rare in the life sciences sector in England and Wales.

6.3 Trade Secrets

To date, trade secrets disputes have been uncommon in the life sciences and pharma sectors in England and Wales – despite the number of prominent life sciences trade secrets cases in other jurisdictions such as the US. However, the increasing prevalence of collaborations between partner companies in life sciences and the increased mobility of the professional workforce between companies may see an increase in trade secrets disputes in England and Wales in future.

7. Appeal

7.1 Timing to Appeal Decision

An appeal against a first-instance main decision must be applied for within 21 days of the date the decision is handed down in the IPEC or the Patents Court (or of any deadline set by the court).

Appeals against decisions in patent litigation are not available as of right – permission to appeal from a decision of the High Court must be sought. Permission may be granted by the judge who made the decision (typically at the "form of order" hearing that follows judgment) or directly from the appellate court if permission is initially denied by the first-instance judge.

Appeals can be made to the UK Supreme Court within 28 days of the appellate court's judgment. The grounds of appeal are that the lower court was either wrong in reaching its decision or that the decision was unjust because of a serious procedural or other irregularity in the proceedings.

When considering whether to grant permission to appeal, the court will consider whether the appeal has a real chance of success and if there is some other compelling reason for the appeal to be heard (eg, significant questions of law to be decided). For the UK Supreme Court to take an appeal against a decision of the court of appeal require the appeal to raise an arguable point of law that is of general public importance.

Generally, an appeal will be limited to a review of the lower court's decision on legal issues, rather than issues of fact – unless, in the circumstances, it would be in the interest of justice to hold a re-hearing of the case. Even on a review, the court still has discretion to receive fresh evidence.

Where a preliminary injunction has been granted, an appeal must be lodged within 21 days. If the appeal is granted, it is usually expected to be heard with some urgency.

Where a preliminary or final injunction decision is overturned on appeal, the injunction is automatically lifted. If the EPO or UK IPO were to revoke a patent where a preliminary injunction had been granted, an application must then be made to the court for the preliminary injunction to be lifted. An urgent application to lift the preliminary injunction would likely be heard within days or on the papers.

7.2 Appeal Court(s) Arbiter

Appeals from the IPEC (other than the IPEC Small Claims Track, which are heard in the IPEC) and Patents Court are to the court of appeal and

then the Supreme Court upon further appeal. Although there are judges in the court of appeal that were previously judges in the Patents Court, there is no guarantee that they will sit on the case.

7.3 Special Provisions

The Patents Court and the IPEC have special procedural requirements, which derive from parts of the English court rules (the Civil Procedural Rules) that make specific provisions for IP proceedings. Additional guidance is given in court guides, especially in the Patents Court Guide.

8. Other Relevant Forums/ Procedures

8.1 Other Relevant Forums/Procedures

Applications for customs actions are available in the UK, particularly in relation to counterfeit products. Once an application for customs action has been issued, the customs authorities will automatically seize suspected goods identified at the border.

9. Alternative Dispute Resolution

9.1 ADR Options

The court encourages the parties to explore ADR, especially mediation. Arbitration is also an option for life sciences disputes. However, in large-scale patent cases, litigation before the court through to a final judgment is the most common option.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

In the past few years, the UK's Competition and Markets Authority (CMA) has taken an increased interest in the pharmaceutical industry and the cost that the NHS pays for medicines. The CMA has pursued several "pay-for-delay" cases and imposed significant fines. The CMA has also pursued cases where it suspects abuse of dominant market position.

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Kirkland & Ellis International LLP (Kirkland) has a patent litigation practice comprising 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. The firm's attorneys have extensive experience of pharmaceutical and biologics patent litigation, co-ordinating global IP disputes, post-grant proceedings before the US Patent and Trademark Office's Patent Trial and Appeal Board. In addition, Kirkland's lawyers have taken part in appeals of high-stakes cases before the US Court of Appeals for the Federal Circuit and the US Supreme Court, the Court of Appeal of England and Wales, and the UK Supreme Court.

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1.1 Claimants/Plaintiffs to an Action

In the US, all parties with substantial rights must be named for plaintiffs to have standing in patent infringement actions. Generally, a party with substantial rights will not have standing if any co-owner is not named in the suit (AntennaSys, Inc v AQYR Techs, Inc, 976 F.3d 1374, 1378 (Fed Cir 2020)).

Those with less than all substantial rights in patents may need permission from the patentees to bring suit. Non-exclusive licensees need to bring suit with the licensor to have standing. However, exclusive licensees can establish standing alone (Aspex Eyewear, Inc v Miracle Optics, Inc, 434 F.3d 1336, 1340 (Fed Cir 2006)). The Federal Circuit also requires joinder of any exclusive licensee, given that exclusive licensees are usually necessary parties in actions in equity (Id. at 1344.)

Those seeking freedom to operate (FTO) around another's patents can file a declaratory judgment action. Federal courts have discretion as to whether to exercise jurisdiction over a declaratory judgment action under 28 USC § 2201, even when the suit satisfies subject matter jurisdictional requirements (Wilton v Seven Falls Co, 515 US 277, 282 (1995)). The scope of this discretion is unclear, but the Federal Circuit has emphasised that there must be well-founded reasons to decline exercising jurisdiction over a declaratory judgment action (Mitek Sys, Inc v United Services Auto Ass'n, 34 F.4th 1334, 1347 (Fed Cir 2022)).

To establish standing in declaratory judgment actions:

- the plaintiff must have suffered an injury in fact;
- there must be a causal connection between the injury and the defendant's conduct; and
- it must be likely that the plaintiff's injury would be redressed by a favourable decision.

(3M Co v Avery Dennison Corp, 673 F.3d 1372, 1377 (Fed Cir 2012))

There is no standing requirement for an inter partes review (IPR) before the Patent Trial and Appeal Board. However, there is a standing requirement to appeal a PTAB's decision in an IPR. Specifically, parties appealing to the Federal Circuit must show (and maintain throughout the appeal):

- injury in fact;
- that is "fairly traceable to the challenged action"; and
- it is likely that "a favourable judicial decision will redress the injury".

(Lujan v Defenders of Wildlife, 504 US 555, 560 (1992))

Such standing may be lost if there is an intervening abandonment of the controversy, such as settlement (ModernaTx, Inc v Arbutus Biopharma Corp, 18 F.4th 1352, 1362 (Fed Cir 2021)). Therefore, a petitioner may not be able to challenge the PTAB's decision – even if they could have at the outset of the petition.

1.2 Defendants/Other Parties to an Action

Typically, the entities named in life sciences lawsuits are those that are named as sponsors of

US Food and Drug Administration (FDA) filings such as New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), abbreviated Biologics Licence Applications (aBLAs), Biologics Licence Applications (BLAs). In a typical Hatch-Waxman suit, for example, patentees will sue the entity that filed the ANDA.

Beyond this, determining which entities will be sued is fact-dependent. Entities such as suppliers, distributors and doctors are rarely sued in typical Hatch-Waxman or Biologics Price Competition and Innovation Act (BPCIA) actions because these actions often occur before the accused products are approved and distributed. Suppliers are more likely, for example, to be the subject of subpoenas for discovery where the accused product is not approved.

1.3 Preliminary Injunction Proceedings

PIs are available in ANDA proceedings. Under the ANDA framework, a 30-month stay ensues if a brand product patent owner files an infringement suit against generics applicants within 45 days of receiving an ANDA notification (21 USC § 355(j)(5)(B)). In addition, infringement by submitting an ANDA under § 505(j) of the Federal Food, Drug and Cosmetic (FD&C) Act could result in a court-ordered delay of product approval until at least the expiration of the infringed patent under 35 USC § 271(e)(4)(A).

Otherwise, PIs are ordered if the four-factor test is met. A plaintiff must establish that:

- they are likely to succeed on the merits;
- they are likely to suffer irreparable harm in the absence of relief;
- the balance of equities tips in the plaintiff's favour; and
- an injunction is in the public interest.

Winter v Natural Res Def Council, 555 US 7, 20 (2008).

The Federal Circuit has held that "no one factor, taken individually, is necessarily dispositive" (Chrysler Motors Corp v Auto Body Panels of Ohio, Inc, 908 F.2d 951, 953 (Fed Cir 1990)). A strong showing of likelihood of success and irreparable harm can overcome a weaker showing, for example, on balance of hardship or adverse public interest.

Demonstrating a tendency that is somewhat peculiar to life sciences cases, a court may consider whether the accused product provides a patient population with a unique role that cannot be replaced (Hybritech Inc v Abbott Laboratories, 849 F.2d 1446, 1458 (Fed Cir 1988)). On the other hand, courts may also consider whether an ANDA filer's launch will irreparably harm the market otherwise dominated by a brand product (Abbott Lab'ys v Sandoz, 544 F.3d 1341, 1361-62 (Fed Cir 2008)). Factors such as the impact on patient populations and changes in patentees' market shares are considered even if the subject matter of the cases differs (eg, cases involving pharmaceutical products or medical devices). See, for example, Abbott, 544 F.3d at 1361-62 and Hologic, Inc v Senorx, Inc, 2008 WL 1860035 at *19 (ND Cal 25 April 2008).

Courts may issue preliminary injunctions (PIs) only after notice has been provided under FRCP 65. Alleged infringers can file evidence to oppose motions for PIs. The average timing from filing to a decision for a PI varies across districts – for instance, decisions take on average four-and-a-half months in the District of Delaware, 2.8 months in the Northern District of California, and 3.4 months in the Eastern District of Texas.

When an injunction is requested also depends on the type of action. Given that the "irreparable harm" factor considers the immediacy of the harm, PIs in ANDA actions are often filed after the expiration of the 30-month stay and approval of the accused product if there is evidence of potential imminent launch by the generic challenger.

aBLA applicants must provide notice to the sponsor 180 days before commercial marketing begins, but this notice may be provided after filing an aBLA — even before the applicant receives FDA approval to license its biosimilar (Sandoz Inc v Amgen Inc, 137 S Ct 1664, 1677 (2017)). However, this notice alone may not be sufficient to establish "immediacy" in harm (see Genentech, Inc v Amgen Inc, 2019 WL 3290167 at *2–3 (D Del 18 July 2019)).

Unlike Hatch-Waxman actions, BPCIA actions involve different phases. The first phase ensues if the biosimilar applicant initiates the "patent dance" – ie, a statutory system established to facilitate information exchange between the applicant and patent owner before an action starts (42 USC § 262(l)(2)). During the patent dance, parties identify which patents will be litigated as part of the first phase and which patents will be subject to dispute in the second phase in accordance with 42 USC § 262(l)(3). The second phase starts after the reference product sponsor (RPS) receives the 180-day notice; at this point, the RPS can seek a PI to prohibit the manufacture or sale of the biosimilar. 42 USC § 262(l)(8)(B). The RPS may assert any patents identified in the patent dance. However, if a PI is not granted at this time, the biosimilar can launch during litigation.

Protective letters are not filed in the US.

1.4 Structure of Main Proceedings on Infringement/Validity

In the US, infringement and validity proceedings are generally not bifurcated, and they tend to be handled together. Sometimes, the issue of damages may be handled separately – either upon application or by sua sponte order of a court.

It is possible to file patent actions while the Patent Office is conducting IPR. It is also possible to file for an IPR during the pendency of district court proceedings on patents. The cancellation of patents by IPR will render moot the parallel district court action (Dragon Intell Prop, LLC v Dish Network LLC, 956 F.3d 1358, 1361 (Fed Cir 2020)). As a result, district court cases are often – although not always – stayed if there is a parallel IPR proceeding.

1.5 Timing for Main Proceedings on Infringement/Validity

In 2017, the Supreme Court made it more difficult to maintain a laches defence in patent infringement cases (SCA Hygiene Prods Aktiebolag v First Quality Baby Prods, LLC, 137 S Ct 954 (2017)). However, pursuant to 35 USC § 286, a patentee may generally only reach back six years prior to the filing of the complaint for infringement damages.

Parties in patent proceedings are notified of the action by service. Service is governed by Federal Rules of Civil Procedure (FRCP) 4 and 5, as well as local rules of the district in which the case is filed.

Under FRCP 4(m), a defendant must be served within 90 days after the complaint is filed. Service can be delayed if service cannot be effected, and the remainder of the deadlines in the case do not run until service is effected. A party can waive formal service in return for an auto-

matic extension on the deadline to answer the complaint (FRCP 4(d)).

The usual time to a final decision varies greatly by district. In the District of Delaware, for instance, termination by judgment takes an average of 28.1 months; however, it takes 19.8 months in the Eastern District of Texas.

1.6 Requirements to Bring Infringement Action

A patent can only be asserted in an infringement action after it is granted.

The type of patent asserted varies by type of action. In Hatch-Waxman actions, process patents are not permitted to be listed in the Orange Book and are therefore typically not litigated. However, process patents (eg, process claims for manufacturing biosimilars) can be – and often are – litigated in BPCIA actions. Generally, in order to maintain an action for infringement of a process patent, the process must occur in the USA.

Regardless of patent type, the burden of proving infringement remains with the entity asserting the patent.

1.7 Pre-action Discovery/Disclosure

Pre-action discovery is generally not available. The closest alternative is asking for an order to depose someone to perpetuate their testimony under FRCP 27. This is a means to preserve evidence that may not be available later. Under FRCP 27(a)(4), a deposition to perpetuate testimony may be used under FRCP 32(a) in district court actions involving the same subject matter if the deposition is admissible. Such depositions are exceedingly rare.

However, there are pre-action exchanges in Hatch-Waxman and BPCIA cases.

In Hatch-Waxman actions, an ANDA holder challenging an Orange Book-listed patent is required to send a notice letter along with an offer of confidential access. This offer of confidential access defines the terms under which the ANDA holder is willing to provide access to their ANDA so the brand company can determine whether a lawsuit may be brought.

In BPCIA actions, aBLA holders can – but are not required to – participate in the aforementioned patent dance governed by 42 USC § 262 (Sandoz Inc v Amgen Inc, 137 S Ct 1664, 1675–76 (2017)). aBLA filers who do participate in the patent dance must provide their application and manufacturing information within 20 days of the FDA accepting their application for review (42 USC § 262(l)(2)). The RPS then provides a list of patents they believe are infringed within 60 days of receipt of the applicant's information under 42 USC § 262(l)(3). The parties go on to exchange contentions on those patents to then settle on a final set of patents to litigate in BPCIA actions (42 USC § 262(l)).

1.8 Search and Seizure Orders

Search and seizure orders are not available in US patent litigation. Even in discovery, parties are not permitted to search for or remove materials in the same way that search and seizure orders are conducted in other contexts. Instead, parties must use discovery requests – such as interrogatories or requests for production – to obtain information.

However, it is possible to use pre-action discovery materials obtained in other jurisdictions – provided there is no restriction from the originator court on such use.

1.9 Declaratory Relief

Declaratory relief is available both to life sciences patentees and patent challengers. Exemplary types of declaratory relief available in life sciences patent proceedings are:

- declarations of non-infringement;
- declarations of invalidity; and
- declarations regarding damages issues, such as a finding that a case is exceptional pursuant to 35 USC § 285.

In BPCIA actions, however, if an aBLA holder does not participate in the patent dance or fails to follow the patent dance disclosure requirements, they may not bring a declaratory judgment action against the RPS (42 USC § 262(l)(9)).

1.10 Doctrine of Equivalents

If an accused infringer does not literally infringe, they may still infringe under the Doctrine of Equivalents (DoE), which is typically analysed as follows:

- function-way-result ("whether the accused product performs substantially the same function in substantially the same way to obtain the same result"); and
- insubstantial differences ("whether the accused product or process is substantially different from what is patented").

(Mylan Institutional LLC v Aurobindo Pharma Ltd, 857 F.3d 858, 866-67 (Fed Cir 2017))

"The doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." (Warner-Jenkinson Co, Inc v Hilton Davis Chem Co, 520 US 17, 29 (1997)).

Other considerations for DoE include the following.

- Ensnarement - this bars a patentee from asserting an infringement claim that would ensnare the prior art. Jang v Boston Sci Corp, 872 F.3d 1275 (Fed Cir 2017).
- Claim vitiation - this prevents the application of DoE if it would eliminate a claim element. Edgewell Pers Care Brands, LLC v Munchkin, Inc, 998 F.3d 917, 923 (Fed Cir 2021).

1.11 Clearing the Way

There is no per se obligation to "clear the way" ahead of a new product launch. However, FTO analyses are often conducted before launches in the form of formal opinions from counsel, which are used by businesspersons to weigh whether to launch a product. Such formal opinions may be used later in litigation to defend against allegations of wilful infringement – although such use will also result in waiver of attorney–client privilege.

1.12 Experts

It is common for courts to use expert evidence to determine infringement and validity issues, as well as occasionally during claim construction. The use of expert evidence may even be required in some contexts – for example, expert evidence is usually required for means-plus-function claims (Elcommerce.com, Inc v SAP AG, 745 F.3d 490, 506 (Fed Cir 2014)).

In the US, parties retain their own experts. Courts do not typically appoint experts. It is typical for each party to retain multiple experts across several disciplines in life sciences cases to address infringement and validity issues.

FRCP 26(a)(2) governs the disclosure requirements for expert testimony in advance of trial, including requirements for written reports. Opposing counsel may take an expert's deposition and conduct oral cross-examination at trial.

Expert testimony can be significant in decision-making, especially in Hatch-Waxman cases where a judge – rather than a jury – decides the case. As such, experts are expected to be impartial and may be disqualified for having conflicts of interest.

1.13 Use of Experiments

In the US, experimental results from testing conducted by experts may be used to assess infringement and validity issues. Experts can conduct experiments to test whether the accused products embody the patented compositions or whether design-arounds are possible to avoid infringement. It is also fairly common for experts from each side to engage in a battle of experimental protocols.

Experts who conduct such experiments and wish to present the results as evidence must provide a written report that contains:

- a complete statement of all opinions the witness will express and the basis and reasons for the opinions;
- the facts or data considered by the witness in forming these opinions;
- any exhibits that will be used;
- the witness' qualifications;
- a list of all other cases in which the witness testified as an expert in the previous four years; and
- a statement of the compensation to be paid for the study and testimony.

(FRCP 26(a)(2)(B))

1.14 Discovery/Disclosure

In the US, the scope of discovery is generally wide. Parties may obtain discovery for any non-privileged matter that is relevant to any party's claim and is proportional to the needs of the case, taking into consideration:

- the importance of the issues at stake;
- the amount in controversy;
- the parties' 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 benefits.

(FRCP 26(b)(1))

There are several discovery tools that may be used – for example, requests for production of documents under FRCP 34 can be used to obtain documents or electronically stored information such as lab notebooks, emails, or data compilations. Document discovery is not limited by the type of document, but by the level of responsiveness to the discovery demand as supported by FRCP 26.

Parties may rely on interrogatories (FRCP 33) and requests for admission (FRCP 36), as well as individual and corporate fact witness depositions, in order to obtain discovery. Opposing parties may also take a testifying expert's deposition pursuant to FRCP 26(b)(4)(A).

Certain districts have local rules that provide for exchange of contentions in which parties explain their theories of infringement and invalidity. Particular procedures for discovery tools (such restrictions on the type or scope of discovery) may further vary depending on the district or judge.

1.15 Defences and Exceptions to Patent Infringement

There are several defences available in infringement actions.

Patent invalidity can be proven through multiple statutory avenues, such as:

- failing to provide a sufficient written description or failing to enable a person skilled in the art (35 USC § 112);
- anticipation by a single prior art reference (35 USC § 102);
- obviousness in light of one or more prior art references (35 USC § 103); and
- claiming patent ineligible subject matter (35 USC § 101).

Other doctrines that are judicially created, such as obviousness-type double patenting (where patent claims at issue are obvious variants of claims from a commonly owned reference patent), may also be raised.

Equitable doctrines may also render patents unenforceable as follows.

- "Unclean hands" – a defence that can be asserted to prevent a patent owner from being granted an equitable remedy because the patent owner acted unethically concerning the action at issue.
- Inequitable conduct – found when the patent owner materially deceived the US Patent and Trademark Office (USPTO) during patent prosecution. If inequitable conduct is found, all related patent claims may be rendered unenforceable.
- Equitable estoppel – proven by an accused infringer through three elements:
  - (a) the patentee's misleading conduct led the alleged infringer to reasonably infer that the patentee did not intend to enforce its patent against the alleged infringer;
  - (b) alleged infringer relied on that conduct; and
  - (c) owing to this reliance, the alleged infringer would be materially prejudiced if the patentee is allowed to proceed with its claim.

(AC Aukerman Co v RL Chaides Constr Co, 960 F.2d 1020, 1028 (Fed Cir 1992))

Another defence to accusations of patent infringement is prior use by the accused infringer, governed by 35 USC § 273. It applies to subject matter that consists of a process, machine, manufacture, or composition of matter in which:

- the commercial use of the subject matter in the US was in good faith; and
- the commercial use occurred at least one year before the earlier of either the effective filing date of the patent at issue or the date on which the claimed invention was disclosed to the public in a manner that qualified for the prior art exceptions under 35 USC § 102(b).

However, establishing prior use under § 273(g) is insufficient in itself to establish anticipation or obviousness.

1.16 Stays and Relevance of Parallel Proceedings

Patent proceedings can be stayed pending the outcomes of other proceedings before the US Patent Trial and Appeal Board (PTAB), including interferences, post-grant review, IPRs, and ex parte re-examination. Courts can grant motions to stay pending conclusion of a USPTO re-

examination (Ethicon, Inc v Quigg, 849 F.2d 1422, 1426–27 (Fed Cir 1998)).

District courts typically balance three factors in making stay determinations:

- the stage of the proceedings;
- the potential to simplify issues; and
- the undue prejudice to the non-movant or a clear advantage for the movant resulting from a stay.

(Murata Mach USA v Daifuku Co, Ltd, 830 F.3d 1357, 1359–60 (Fed Cir 2016))

Courts consider the outcomes of parallel proceedings for decisions to stay infringement and validity proceedings. Stays are justified when the outcomes of re-examinations would assist the court in determining patent issues (In re Cygnus Telecomms Tech, LLC, Pat Litig, 385 F Supp 2d 1022, 1023 (ND Cal 2005)).

Pursuant to 28 USC § 1659, district courts must stay district court litigation at the request of any respondent to an International Trade Commission (ITC) proceeding until a final decision, so long as the request is made within 30 days of the district court action's filing or after a party is named as a respondent in the ITC proceeding.

1.17 Patent Amendment

Patents can be amended during litigation. Certificates of correction arising from the USPTO's mistake are governed by 35 USC § 254. For more substantive changes to patent claims, one can file a request for reexamination (37 CFR § 1.510) or reissuance (35 USC § 251) of an application.

An application for reissuance of a patent that enlarges the scope of the claims of the original patent must be filed within two years of the original patent being granted (35 USC § 251(d)). Otherwise, new matter cannot be introduced, and claims can only be narrowed (35 USC § 251). Patents may also be amended during IPR proceedings upon motion by the patentee.

Requests for re-examination can be filed at any time (35 USC § 302). However, if a patent is involved in an ex parte or inter partes re-examination or becomes involved in litigation, the director of the USPTO can decide whether to suspend the ex parte (37 CFR § 1.565) or inter partes re-examination proceeding (37 CFR § 1.987).

Patentees may also seek certificates of correction, for instance, to correct mistakes. However, the Federal Circuit has held in one case, which involved a certificate of correction from the USPTO over an issued claim that was missing a limitation, that a "certificate of correction is only effective for causes of action arising after it was issued" (H-W Tech, LC v Overstock.com, Inc, 758 F.3d 1329, 1334 (Fed Cir 2014)).

1.18 Court Arbiter

In the US, recent court decisions have made forum shopping substantially more difficult. As in any US case, courts must have personal jurisdiction over defendants. Patent litigation has the same common-law principles and procedural rules as other types of civil litigation (SCA Hygiene Products Aktiebolag v First Quality Baby Products, LLC, 137 S Ct 954, 964 (2017)). Defendants must have minimum contacts with a forum state for personal jurisdiction to apply (Int'l Shoe Co v Washington, 326 US 310, 316 (1945)). Courts also analyse whether application of personal jurisdiction comports with due process by deciding whether:

- the defendant purposefully directed activities at residents of the forum state;
- the litigation results from those activities; and
- assertion of personal jurisdiction is reasonable and fair.

(New World Int'l, Inc v Ford Glob Techs, LLC, 859 F.3d 1032, 1037 (Fed Cir 2017))

In addition to establishing personal jurisdiction, patentees must also satisfy the venue requirement. For the purposes of identifying a proper venue, patent infringement actions may be brought where the defendant either:

- resides or is incorporated; or
- has committed acts of infringement and has a principal place of business.

(TC Heartland LLC v Kraft Foods Grp Brands LLC, 137 S Ct 1514, 1518–19 (2017))

Hatch-Waxman cases are typically tried before Federal District court judges. However, Hatch-Waxman cases may be tried before a jury if the accused product has been approved and has been launched at risk, thereby having harmed patentee(s). BPCIA litigation may proceed before a jury on request.

2. Generic Market Entry

2.1 Infringing Acts

The FD&C Act holds that it "shall be an act of infringement to submit" an ANDA under section 505(j) or a "paper" NDA as described in section 505(b)(2) for a drug (or its use), which is claimed in a patent, if the purpose of the submission "is to obtain approval… to engage in the commercial manufacture, use, or sale of a drug… claimed in a patent or the use of which is claimed in a patent" before the patent's expiration (35 USC § 271(e)(2)). Some courts have thus held that submission of the application is itself an act of technical infringement sufficient to establish jurisdiction for initiating an action.

Under the Hatch-Waxman framework, suits can be brought before the accused product has been approved or marketed. Given that an actual accused product may not exist at the time of suit, infringement inquiry under § 271(e)(2) considers "whether the probable ANDA product would infringe once it is made, used or sold" (Par Pharm, Inc v Eagle Pharms, Inc, 44 F.4th 1379, 1383 (Fed Cir 2022)).

If the FDA specification of the generic challenger defines the accused product in a manner that clearly resolves the question of infringement, then the specification controls the inquiry. Id. If a specification does not full resolve the question of infringement "clearly and directly", courts may consider "other relevant evidence, such as data or samples the ANDA filer has submitted to the FDA". Id.

A drug applicant may exclude a patented use from its label by submitting its proposed label to the FDA and "carving out" those methods of use which are claimed in patents (GlaxoSmithKline LLC v Teva Pharms USA, Inc, 7 F.4th 1320, 1327 (Fed Cir 2021); see 21 USC § 355(j)(2)(A)(viii)).

An applicant may also be liable for induced or contributory infringement under 35 USC § 271(b) and (c). To show induced infringement, a plaintiff must demonstrate that "the alleged infringer's actions induced infringing acts and that [they] knew or should have known [their] actions would induce actual infringements" (GlaxoSmithKline LLC v Teva Pharms USA, Inc, 7 F.4th 1320, 1327 (Fed Cir 2021)).

An ANDA applicant may be liable for contributory infringement if it sells or offers to sell a material or apparatus for use in a patented combination or process where the ANDA product is a material part of the patented invention and has no substantial non-infringing uses (see BTG Int'l Ltd v Amneal Pharms LLC, 352 F. Supp. 3d 352, 399 (D NJ 2018)).

An ANDA applicant's launch prior to conclusion of Hatch-Waxman litigation is sometimes referred to as an "at-risk" launch. In such cases, the applicant may be liable under 35 USC § 271(a).

2.2 Regulatory Data and Market Exclusivity

The FD&C Act and the Code of Federal Regulations set out the following categories of exclusivities available to pharmaceutical product applicants, with varying lengths and protections.

- New drug product exclusivity grants limited exclusivity for drug products with new chemical entities or approved active moieties that were subject to new and essential clinical investigations. This exclusivity bars the FDA from reviewing any NDA or ANDA for any drug containing the same active moiety for four years from the date of approval of the first-approved drug application if the NDA or ANDA contains a paragraph IV certification or for five years if it does not (21 CFR § 314.108(a)–(b)).
- New clinical investigation exclusivity confers three years from the date of approval of an NDA that includes investigations in humans with results that were not previously relied upon by the FDA to demonstrate substantial evidence of effectiveness for a previously approved drug product. Id.
- Orphan drug exclusivity confers seven years of exclusivity to drugs designated and approved to treat rare diseases – ie, those affecting under 200,000 people in the US – or drugs that have no reasonable expectation of recouping the costs of developing and making the drug available (21 USC § 360bb(a)(2). 21 USC § 360cc).
- Paediatric exclusivity confers six months of exclusivity to drugs when, in response to a written request from the FDA, a sponsor has submitted paediatric studies on the active moiety in their drug product (21 USC § 355a).
- 180-day exclusivity is conferred to the first ANDA applicant(s) seeking approval. The exclusivity generally begins after the first commercial marketing of the drug or after a court decision holding the patent invalid, unenforceable, or not infringed (21 USC § 355).

2.3 Acceptable Pre-launch Preparations

The Hatch-Waxman Act contains a safe harbour provision providing that it "shall not be an act of infringement to make, use, offer to sell, or sell… a patented invention… solely for uses reasonably related to the development and submission of information under a federal law [that] regulates the manufacture, use, or sale of drugs" (35 USC § 271(e)(1)). Such protection extends to not only drug products but also to medical devices and food or colour additives (Eli Lilly & Co v Medtronic, Inc, 496 US 661 (1990)).

However, only allegedly infringing activities subject to FDA pre-market approval that are "reasonably related" to submission of information qualify (Proveris Sci Corp v Innovasystems, Inc, 536 F.3d 1256, 1265–66 (Fed Cir 2008)). Such use includes not only preclinical studies but may also extend to scenarios where no data is actu-

ally submitted to the FDA (Merck KGaA v Integra Lifesciences I, Ltd, 545 US 193, 205–08 (2005)).

2.4 Publicly Available Drug and Patent Information

In the US, *The Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) provides a list of all approved prescription drug products with therapeutic equivalence evaluations, as well as patents identified by the drug sponsors as covering those products. It is updated with an Annual Edition and monthly Cumulative Supplement.

When seeking approval of a drug product, an ANDA applicant must certify to the FDA – for each patent listed in the Orange Book for that drug - a statement that:

- the patent information has not been filed;
- the patent has expired;
- the date on which the patent will expire; or
- the patent is invalid or not infringed by the manufacturer, use, or sale of the ANDA drug product.

(21 USC § 355(j)(2)(A)(vii))

If the applicant certifies that the patent will not be infringed or is invalid, the applicant must also give notice of such paragraph IV certification to the patent owner and the holder of an approved application under 21 USC § 355(b) for a drug that is claimed by the patent (21 USC § 355(j)(2)(B)). However, an ANDA applicant need not provide certifications for method-of-use patents claiming a use that the ANDA application does not seek approval to use (AstraZeneca Pharms LP v Apotex Corp, 669 F.3d 1370, 1374 (Fed Cir 2012)).

2.5 Reimbursement and Pricing/Linkage Markets

In the US, grant of marketing authorisation for pharmaceutical products is linked with patent status but only with regard to those patents listed in the Orange Book that:

- claim the drug substance (active ingredient) or drug product (formulation or composition); or
- claim a method of using the drug that has been sought or granted in the application.

Applicants may "carve out" certain methods of use from approval, thereby potentially avoiding method-of-use patents. As discussed further earlier, 505(b)(2) and 505(j) applicants must file certain certifications as to these patents. One such paragraph IV certification serves as notice to any patent owners - and holders of approved applications of drugs claimed by the patent – that the NDA filer alleges the related patents will not be infringed or are invalid.

The recipient of the paragraph IV certification has 45 days after receiving notice to file an action "for infringement of the patent that is the subject of the certification" (21 USC §§ 355(c)(3) and 355(j)(5)(B)). If such action is brought, approval of the NDA will become effective only after expiration of a 30-month period or upon a judicial decision that the patent is invalid or not infringed (21 USC §§ 355(c)(3) and 355(j)(5)(B)).

3. Biosimilar Market Entry

3.1 Infringing Acts

Biologic applicants operate under a different framework from ANDA applicants, with the former governed by the BPCIA. The BPCIA amended the Patent Act to provide that it "shall be an

act of infringement to submit… an application seeking approval of a biological product" with regard to patents that are or could be identified pursuant to section 351(l)(3) of the Public Health Service Act (21 USC § 271(e)(2)(C)).

If the applicant engages in the patent dance, the parties will negotiate a list of patents that are subject to immediate litigation. Only listed patents at this stage are subject to a declaratory action of infringement, validity or enforceability until the applicant provides notice to the patent owner that it will begin commercial marketing of the biosimilar in not less than 180 days 42 USC § 262(l)(9)(A). Although an aBLA applicant cannot be forced to engage in the patent dance (Amgen Inc v Sandoz Inc, 137 S Ct 1664 (2017)), failure to do so bars the applicant from initiating a declaratory judgment action – whereas the patent owner may immediately bring a declaratory judgment action for any patent claiming the biosimilar (42 USC § 262(l)(9)(C)).

3.2 Data and Regulatory Exclusivity

The BPCIA provides the following exclusivities for applicants.

- Reference product exclusivity grants to new biologics approved under a BLA a four-year exclusivity period, during which no aBLA may be filed on the product, and a 12-year period during which the FDA may not approve any biosimilar products (42 USC § 262(k)).
- Paediatric exclusivity confers an additional six months of exclusivity if the reference product conducted pediatric studies pursuant to the FD&C Act Section 505A (42 USC § 262(m)).
- Biosimilar applicant exclusivity grants a one-year period of exclusivity to the first biosimilar of a licensed biologic that is approved under the BPCIA, thereby preventing the FDA from approving any other biosimilars to the same reference biologic (42 USC § 262(k)(6)(A)).

3.3 Acceptable Pre-launch Preparations

The safe harbour provision of 35 USC § 271(e)(1) also shelters activities of biosimilar applicants conducted solely for the purpose of developing and submitting information under federal law.

3.4 Publicly Available Drug and Patent Information

The FDA maintains the Purple Book, or List of Licensed Biological Products, which contains biological products regulated by the Center for Drug Evaluation and Research. This includes not only reference products but also licensed biosimilars. The Purple Book includes the date of licensing for the product, the date of expiration for exclusivity periods, and certain patent information.

However, the Purple Book differs from the Orange Book in that BLA holders are only required to submit to the FDA the patent lists that they serve on biosimilar applicants during the patent dance (within 30 days of providing the biosimilar applicant with the list). The FDA updates the Purple Book every 30 days (42 USC § 262(k)(9)(A)).

As noted earlier, biosimilar applicants can choose whether to participate in the patent dance. If they choose to participate, biosimilar applicants must provide the patent owner a copy of their aBLA within 20 days of the FDA accepting the application. Thereafter, the patent owner and applicant negotiate what patents can be immediately asserted and which, if any, the RPS would be willing to license (42 USC § 262(l)). This includes exchanging statements detailing – on a claim-by-claim basis – each party's positions

regarding invalidity, enforceability and infringement for each patent. Id.

3.5 Reimbursement and Pricing/Linkage Markets

Unlike the Hatch-Waxman Act, the BPCIA:

- outlines an information-exchanging mechanism (ie, the patent dance);
- requires aBLA applicants to provide notice of commercial launch before launching;
- does not have the automatic 30-month stay; and
- has different exclusivities.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Under the Hatch-Waxman framework, patent term extension (PTE) is available for patents claiming drug products – and methods of use or manufacture of drug products – that are subject to regulatory review before commercial marketing or use (35 USC § 156(a)). In order to obtain PTE, the holder must submit an application for extension within 60 days of receiving permission from the FDA to market the product.

The PTE determination is made by the FDA and USPTO together. The FDA is responsible for initially calculating the length of the regulatory review for the product, which is published in the Federal Register (35 USC § 156(d)(2)(A)(ii)). After a chance for comment by interested parties, the USPTO calculates the final PTE length, which is capped at five years (35 USC § 156(g)(6)(A)).

Although biologics are also eligible for PTE, the rules applicable for granting PTE are less settled. This is due at least to the fact that biologics can present a difficult question of what is the relevant "active ingredient".

4.2 Paediatric Extensions

Paediatric exclusivity extensions exist for both small molecule drugs under the Hatch-Waxman framework and biologics under the BPCIA. Paediatric exclusivity under either is granted where a sponsor has submitted paediatric studies on the active moiety in their drug product – in response to a written request from the FDA – and confers on the applicant an additional six months of exclusivity for drug products containing the moiety (21 USC § 355a and 42 USC § 262(m)).

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

In the US, a PI may be granted before or during trial – or even pending appeal.

FRCP 65 dictates that a court may issue a PI only if the movant provides a bond sufficient to pay the costs and damages sustained by any party found to have been wrongfully enjoined as determined by the court.

A court may issue a PI only on actual notice to the adverse party – by personal service or otherwise – of the injunction, such that the patent owner gives the defendant sufficient advance notice in order to allow the accused infringer to prepare and present its defense.

If a court issues an injunction, enforcement is administered via its contempt authority. A party could move for contempt to sanction the party who fails to comply with the court order. Typical

contempt sanctions include a monetary fine or fee-shifting.

5.2 Final Injunctive Relief

A permanent injunction is a court order requiring a person to do or cease doing a specific action that is issued as a final judgment in a case. Unlike PIs, permanent injunctions generally do not require bonds. In ANDA actions, upon a finding of infringement, courts are required to order a permanent injunction such that the effective date of approval is not earlier than the patent expiration date (35 USC § 271(e)(4)). Likewise, upon a finding of infringement by an aBLA applicant, a court must order a permanent injunction prohibiting any further infringement of the patent until expiration of the infringed patent. Id.

If an ANDA is approved and the drug is already on the market, an injunction could be obtained under a four-factor test showing:

- the patent owner has suffered an irreparable injury;
- remedies, such as monetary damages, are inadequate;
- the balance of hardships favours the patent owner; and
- the permanent injunction would not hurt public interest.

(Weinberger v Romero-Barcelo, 456 US 305, 312 (1982))

A permanent injunction is ordinarily effective upon issue and, if not stayed, also effective pending appeal. When a party decides to appeal an issued injunction, a court also have the power to grant a stay.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

In the US, monetary damages and injunctions are not mutually exclusive – for example, a court may award monetary damages for past infringing acts, while issuing injunctions to prevent future infringement. However, in ANDA actions, monetary damages may be awarded only after the infringer launches at risk.

For certain pharmaceutical products, the public interest factor for injunctive relief could be especially important. A patent owner may argue for an injunction based on safety concerns, for example. An accused infringer, on the other hand, may argue that the court should not issue an injunction that takes life-saving drugs off the market if they cannot be substituted by another product.

5.4 Damages

Under 35 USC § 284, courts shall award the patent owner damages adequate to compensate for the infringement but in no event less than a reasonable royalty, together with interest and costs fixed by the court.

Two main types of damage awards are reasonable royalties and lost profits. A reasonable royalty is an estimation of the royalty that a licensee would pay for the rights to the claimed invention in a hypothetical negotiation. Lost profits are profits that a patent owner would have made if an infringer had not infringed. Damage awards may encompass both lost profits and a reasonable royalty.

To obtain lost profits, a patent owner must show that there is a reasonable probability that but, for the infringement, the patent owner would have made the infringer's sales. One useful, but non-exclusive, method to establish the entitlement to

lost profits is the Panduit test, which requires a patent owner to establish (Rite-Hite Corp v Kelley Co, 56 F.3d 1538, 1545 (Fed Cir 1995) (en banc)):

- demand for the patented product;
- absence of acceptable non-infringing alternatives;
- manufacturing and marketing capability to exploit the demand; and
- the amount of profit it would have made.

Determination of reasonable royalties could be based on established royalty rates, a hypothetical negotiation, or an analytical approach. Established royalty rates must come from pre-infringement licence agreements on comparable technology. In the absence of established royalty rates, a court may consider a hypothetical negotiation between a willing licensor and licensee to fix a royalty rate. A determination of the royalty stemming from a hypothetical negotiation is often made by assessing certain factors set forth in Georgia-Pacific Corp v US Plywood Corp, 318 F Supp 1116, 1120 (SD NY 1970). A district court may also use an analytical approach – obtaining the reasonable royalty by subtracting the industry standard profit margin from infringer's actual profit margin.

35 USC § 284 gives district courts discretion to award enhanced damages against infringers in egregious cases. Courts may also award pre-judgment interest on the compensatory portion of the damages award under this section, and post-judgment interest of the entire award under FRCP 37.

35 USCA § 286 limits the recovery of damages for past infringement to six years from the filing of the claim of infringement. Generally, there is no infringement liability for activities before a patent issues. However, provisional damages may begin after the publication date of the patent application if (35 USCA § 154(d)):

- the infringer had notice of the publication; and
- the asserted claims are substantially identical to the claims in the publication.

In jury trials, a district court has discretion to try damage-related issues together with – or separate from – other issues. As to the execution of judgment on damages, proceedings to enforce it are stayed for 30 days after its entry, unless the court orders otherwise (FRCP 62(a)).

If an accused infringer is wrongfully enjoined, the relief to the injured party is typically limited to the terms of the bond.

A party does not need to be the patent owner to claim damages in a patent litigation – for example, a party with all substantial rights to a patent may also claim damages against an infringer.

In the pharmaceutical industry, no monetary damage would result from filing an ANDA paragraph IV certification before commercial marketing. And the BPCIA limits a patent owner's damages to a reasonable royalty if an infringement suit is untimely filed. Patent owners can only seek PIs after receiving notice of commercial marketing. In both ANDA and BPCIA litigations, a company may decide to launch at risk, thereby making monetary damages possible if it is later found to have infringed a patent.

5.5 Legal Costs

Under the American Rule, each party in a litigation pays its own attorney's fees, unless the case is considered "exceptional" (35 USC § 285). District courts have discretion to award reasonable attorney fees to the prevailing party in excep-

tional cases. An exceptional case is one that stands out from others with regard to:

- the substantive strength of a party's litigation position; or
- the unreasonable manner in which the case was litigated.

(Octane Fitness, LLC v ICON Health & Fitness, Inc, 572 US 545, 554 (2014))

Not all legal costs can be shifted in a patent case. Even where attorney fees are shifted, for example, experts' fees generally still may not be shifted (Finjan, Inc v Juniper Networks, Inc, 2021 WL 3140716, at *5 (ND Cal 26 July 2021)).

5.6 Relevance of Claimant/Plaintiff Conduct on Relief

In the US, there are equitable doctrines that sanction patent owners' conduct in bad faith as follows:

- inequitable conduct could render a patent (and possibly a patent family) unenforceable (GS Cleantech Corp v Adkins Energy LLC, 951 F.3d 1310, 1325 (Fed Cir 2020));
- unclean hands could "close[] the doors of a court of equity to one tainted with inequitableness or bad faith" (Precision Instrument Mfg Co v Automotive Maintenance Machinery Co, 324 US 806, 814 (US 1945)); and
- asserting weak litigation positions may result in shifting the attorney's fees to the patent owners.

(Octane Fitness, LLC v ICON Health & Fitness, Inc, 572 US 545, 554 (2014))

6. Other IP Rights

6.1 Trade Marks

In the US, trade marks are protected by both statutory and common law. Trade mark disputes are not commonly adjudicated in the same action as patent disputes. In addition to exclusiveness, trade marks also provide other benefits to life sciences and pharmaceutical products by:

- helping consumers find their desired products;
- reducing medication errors; and
- incentivising investment in new medications.

Non-traditional trade marks, such as the colour of the drug, may provide additional protection. Since these non-traditional marks are not inherently distinctive, secondary meanings are usually required. Another concern regarding these non-traditional trade marks is that they may be deemed functional, which renders the marks not fit for trade mark protection.

6.2 Copyright

Copyright issues are uncommon in life sciences and pharmaceutical cases. In a lawsuit where copyright was at issue, for example, the Second Circuit held that the ANDA filer could not be liable for copyright infringement for copying verbatim the text used in the SmithKline users' guide because the labelling requirement under the Hatch-Waxman Act trumped the copyright concern (SmithKline Beecham Consumer Healthcare, LP v Watson Pharm, Inc, 211 F.3d 21, 29 (2d Cir 2000)).

6.3 Trade Secrets

A trade secret typically consists of (at least minimally) novel and commercially valuable information that is valuable because of its secrecy. Trade secrets disputes are not commonly adjudicated

in the same action as patent disputes in the life sciences and pharma sector, but may occasionally be adjudicated in the ITC.

7. Appeal

7.1 Timing to Appeal Decision

Parties to patent actions have a right to appeal, although the timing of such appeal varies as follows.

- A party appealing district court decisions must file its notice within 30 days following the judgment or order appealed against (28 USC § 2107).
- A party adversely affected by an ITC final determination must file its appeal notice within 60 days of the ITC decision becoming final (19 USC § 1337).
- A party seeking to appeal from a PTAB and the US Trademark Trial and Appeal Board (TTAB) proceedings must file such notice within 63 days of the date of the final Board decision (37 CFR § 90.3).

Under 28 USC § 1292, interlocutory appeals may be filed before the final decision.

7.2 Appeal Court(s) Arbiter

The Federal Circuit has nationwide and exclusive jurisdiction in a variety of subject areas, including patents, trade marks, and international trade. This means that the Federal Circuit handles all federal district court appeals regarding patent cases. The Federal Circuit also reviews certain administrative agency decisions, including those from the PTAB, TTAB and ITC.

The Federal Circuit's work begins after the Clerk's Office dockets a new appeal or petition and assigns a docket number. The parties to the cases prepare and file written briefs to present their arguments. The appeal is then randomly assigned to a panel comprising three randomly selected judges. There may be oral arguments, in which each side is typically allotted 15 minutes for argument. Parties may seek review of a Federal Circuit decision in the US Supreme Court.

7.3 Special Provisions

Generally, US district courts have broad discretion to streamline cases before them. Many district courts have local rules and, more specifically, patent rules. Such rules may govern claim construction proceedings, exchange of infringement and invalidity contentions, and procedures for pretrial and trial exchanges.

8. Other Relevant Forums/ Procedures

8.1 Other Relevant Forums/Procedures

US forums other than district courts (eg, the PTAB, TTAB and ITC) are also relevant to the pharmaceutical industry.

The PTAB generally conducts hearings such as IPR proceedings, hears appeals from adverse examiner decisions in patent applications and re-examination proceedings, and renders decisions in interferences.

The TTAB handles appeals involving applications to register marks, appeals from expungement or re-examination proceedings involving registrations, and trial cases of various types involving applications or registrations.

The ITC investigates and makes determinations in proceedings involving imports claimed to injure a domestic industry or violate US IP rights.

9. Alternative Dispute Resolution

9.1 ADR Options

Although court actions are more popular in the US compared with many other jurisdictions, there are other mechanisms for resolving disagreements between parties. Such ADR proceedings may result in faster and less expensive resolutions.

In mediations, for example, a neutral mediator may be used to discuss potential settlements. The mediator generally helps parties assess their legal positions. Even if parties do not reach an agreement, the mediation process facilitates exchange of information.

Although a mediation is normally not binding, an arbitration usually resolves the case on the merits. In an arbitration, parties present evidence and argue their positions before a neutral arbitrator. The procedural and evidentiary rules are usually set according to an arbitration agreement. If an arbitration is binding, for example, a party may not be able to reject the arbitration decision.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The Federal Trade Commission pays particular attention to settlements in life sciences litigation, and certain state laws may furthermore restrict the scope and content of settlements between such parties. NDA applicants are not permitted to "pay for delay" of generic drug entry, for example (FTC v Actavis, Inc, 570 US 136, 140 (2013)). Avoiding uncertainties and litigation costs, however, is permissible. Antitrust liabilities may also attach to patent misuse, inequitable conduct, and product hopping.

Kirkland & Ellis (Kirkland) has a patent litigation practice comprising 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. The firm's attorneys have extensive experience of pharmaceutical and biologics patent litigation, co-ordinating global IP disputes, post-grant proceedings before the US Patent and Trademark Office's Patent Trial and Appeal Board. In addition, Kirkland's lawyers have taken part in appeals of high-stakes cases before the US Court of Appeals for the Federal Circuit and the US Supreme Court, the Court of Appeal of England and Wales, and the UK Supreme Court.

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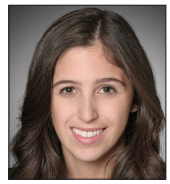

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Contents

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Parties to an Action for Infringement

In an action for infringement, the parties that must be involved are the patentee, the exclusive licensee, and the infringer. A patent can be granted to two or more patentees, the patentees shall be considered as joint owners and can both be parties to an action for patent litigation.

An action for infringement may be brought by an exclusive licensee and the exclusive licensee qualifies to commence court proceedings for infringement.

An exclusive licensee shall have the right to commence court proceedings against a person who is alleged to have infringed or is performing any act likely to cause an infringement of a patentee's right in a patent as under the Patents Act an exclusive licensee is recognised to enjoy the same rights as a patentee.

Rights of an Exclusive Licensee

These rights include the following:

- the right to exploit the patented invention and authorise the exploitation of the patented invention by others;
- where the patented invention is a product, to prevent any person, without the patentee's consent, from making, using, offering for sale, selling or importing the patented product; and
- where the patented invention is a process, to prevent any person, without the patentee's consent, from using, offering for sale, selling or importing the product obtained directly from the patented process.

Registration of Exclusive Licensee

The registration of a licence is required for an exclusive licensee to bring an action for infringement. Where a patentee grants a licence in respect of an invention, by way of a licence contract, such contract shall be signed by both parties and lodged with the Registrar for Patents and Companies Registration Agency.

A certificate of registration shall be issued and shall be prima facie evidence of any matter in respect of the licence contract.

Joinder of the Patentee

Unless the High Court orders otherwise, the exclusive licensee need not join the patentee as a plaintiff or as a defendant when bringing proceedings for any infringement of a patent in relation to which the patentee has concurrent rights of action.

An exclusive licensee may, if the patentee refuses or fails to commence court proceedings within three months after giving notice to the patentee to commence court proceedings, commence such proceedings in the licensee's own name, and the patentee may join in the proceedings at any time after commencement.

Revocation Action

The alleged infringer may, in proceedings for infringement, counterclaim for revocation of the patent, relying on any ground on which a patent may be revoked.

1.2 Defendants/Other Parties to an Action

Life sciences and pharma cases are rare in Zambia. However, hospitals and their associated doctors and other staff are usually sued in cases of professional/medical negligence.

1.3 Preliminary Injunction Proceedings

In Zambia, preliminary injunctions, which are known as interim injunctions, are available. In cases of extreme urgency, an interim injunction is ex parte, and such an application may be made by way of summons and affidavit either contemporaneously when filing court process or during the proceedings of the matter.

An ex parte application typically involves one party to the matter being heard, depending on the urgency of the matter. This may include applications for an interim injunction or applications for substituted service. Inter parte applications, on the other hand, involve all parties to the matter being heard, especially where the matter is contentious.

In situations of utmost urgency, interim injunctions are heard as soon as they are filed. The judge will issue a ruling as soon as the application has been heard, pending an inter partes hearing.

Principles Applicable for Granting an Interim Injunction

The power to grant interim injunctions is at the discretion of the court. The exercise of this discretion is based on sound legal principles. The following are the general principles which will be taken into consideration before an injunction can be granted.

Whether the plaintiff has raised a serious question to be determined at trial

The first consideration before granting an interim injunction is whether the plaintiff has raised a serious question to be determined at trial. That is to say, the claim must not be frivolous or vexatious. If the claim is frivolous or vexatious, the interim injunction will not be granted.

The adequacy of damages

If the plaintiff has established a serious question to be determined at trial, the court will then consider whether the plaintiff can be adequately compensated by an award of damages if judgment is awarded in favour of the plaintiff. If, in the court's view, an award of damages will suffice, the interim injunction ought to fail, however meritorious the claim may be.

If there is doubt as to the adequacy of damages and the ability of the defendant to pay them if the plaintiff were to succeed at trial, the court will proceed to the next stage, and consider the balance of convenience.

The balance of convenience

The balance of convenience test requires the court's assessment of whether the risk of injustice if the interim injunction is not granted, outweighs the risk of injustice if the injunction is granted.

Where the balance of convenience is even, the court will generally take such measures as may be necessary to preserve the status quo.

Requirements

An injunction is filed contemporaneously with the originating process. An application for an injunction is dependent upon there being a pre-existing cause of action against the defendant arising out of an invasion, actual or threatened by them of a legal or equitable right of the plaintiff. Therefore, before an application for an interim injunction can be filed, there must be a substantive cause of action.

Before applying for an interim injunction in a case involving a patent, the Registrar of Patents and Companies Agency must have either granted the patent, or made a decision with respect to

an opposition to the grant of a patent or a threat of infringement.

The earliest an interim injunction can be filed is contemporaneously when issuing court process.

Quia timet injunction
Quia timet relief is available in Zambia and the plaintiff must show a very strong probability of a future infringement, and that the ensuing damage will be of a most serious nature.

There are different acts which amount to a threat to infringe such as making, using, offering for sale, selling, or importing the patented product; and exploiting the patented invention.

Service
Ordinarily, the service is effected personally unless personal service is not feasible in the circumstances.

Injunctions are usually made ex parte. The defendant is brought to the attention of the said interim injunction upon being served with an ex parte order of the court pending an inter partes hearing in which the defendant/respondent is afforded an opportunity to be heard.

According to the rules governing service of process in Zambia, service must be personally effected; as such, the alleged infringer will have the court documents personally delivered to them, or, if it is a company, the documents will be served at the registered office where the company conducts its business.

The date of service will determine any subsequent deadlines because service may be delayed depending on the specifics of each case.

Evidence and submissions
Where an application for interim injunction is made ex parte, the alleged infringer does not have an opportunity to file evidence and submissions until the inter parte hearing. At the inter partes hearing, the alleged infringer is given an opportunity to file evidence and submissions in order to allow the judge to consider the evidence and submissions of all the parties before arriving at a decision.

Protective letters cannot be filed in Zambia; instead, an affidavit in opposition is filed, which is used to oppose an application filed by a party to an action.

Currently, the specific factors that originators, generic/biosimilar, or medical devices companies should take into account in considering the likelihood that an interim injunction will be granted are the same factors the court uses before granting an interim injunction as already discussed above.

1.4 Structure of Main Proceedings on Infringement/Validity

In Zambia, there is no separation between infringement and validity proceedings. If a question regarding the validity of the patent arises during the course of an action for infringement, the court will proceed to determine both issues. Validity is frequently raised as an issue in patent infringement proceedings, either as a defence or as a preliminary question.

1.5 Timing for Main Proceedings on Infringement/Validity

Statute of Limitations and Service

According to Section 79(5) of the Patents Act, infringement proceedings shall not be heard by the court unless the proceedings are commenced within a period of five years from the

date on which the facts giving rise to such proceedings became known to the patentee or an exclusive licensee, except that the court may, in its absolute discretion, allow proceedings to be commenced after five years.

According to Section 56 of the Patents Act, validity proceedings shall not be heard by the Registrar unless the proceedings are commenced within a period of three months from the date an application for the grant of a patent is advertised, or within such further period as the Registrar may allow, and before the sealing of the patent, by filing a written notice of opposition to the Registrar.

According to the rules governing service of process in Zambia, service must be personally effected; as such, the alleged infringer or patentee will have the court documents personally delivered to them, or, if it is a company, the documents will be served at the registered office where the company conducts its business.

The date of service will determine any subsequent deadlines and when requisite documents must be served.

Timeframes for Hearings and Decisions
The timeframes for hearings and interim steps are judge driven; therefore, the judge gives orders for directions with respect to the matter, ie, timelines for filing of requisite documents ancillary to the hearing.

At the conclusion of a hearing, the court may there and then pronounce its judgment or may reserve its judgement or ruling for a later date.

Where the court reserves its judgment or ruling, the court shall, in the case of a judgment, deliver the judgment within 180 days from the date set for filing of final submissions; in the case of a ruling, within 90 days after the conclusion of the hearing.

Interim Steps
The timeframes for interim steps are give by the court through orders for directions.

1.6 Requirements to Bring Infringement Action

Zambia does not recognise different types of patents except the utility patent.

The filing date of the application for the grant of the patent shall be the effective date of the patent. In this sense, a patent may be asserted without a grant, but an application for a grant of a patent must be submitted before a patent may be asserted.

The earliest a main infringement action can be filed is any time before the expiration of the statutory period of five years.

1.7 Pre-action Discovery/Disclosure

In Zambia, pre-action discovery, also referred to as discovery and inspection of documents, is available. There are no prerequisites for requesting the discovery and inspection of documents because it is a mandatory requirement for discovery and inspection of documents to be undertaken by the parties according to the Court Rules. However, as was discussed in **1.5 Timing for Main Proceedings on Infringement/Validity**, cases are judge-driven, therefore, the judge must issue orders for directions with respect to the discovery and inspection of documents within 30 days of the defence being filed.

It is possible to use materials obtained in other jurisdictions depending on what type of material it is. If the material in question is a document

executed outside Zambia, the document must be authenticated in Zambia before it can be used in the proceedings. This is in accordance with Section 3 of the Authentication of Documents Act Chapter 75 of the Laws of Zambia and the Judgment of the Supreme Court in the case of Lumus Agricultural Services Company Limited v Gwembe Valley Development Company Limited (In Receivership) 1999 ZR. If the document is a foreign judgment, the said judgment must be registered in Zambia before it can be given effect.

Cases from other jurisdictions can also be referred to. Foreign judgments, however, merely have persuasive authority and are not binding on Zambian Courts. Cases with high persuasive value are those which emanate from the Commonwealth.

1.8 Search and Seizure Orders

In Zambia, search orders are only available in criminal matters. Seizure orders, on the other hand, are available in civil matters.

Where a party to an action requires evidence from another party such as a document in the possession of the alleged infringer, the patentee or exclusive licensee may make an application to the court through summons and affidavit for an order requiring the alleged infringer to make an affidavit stating whether any document specified or described is, or has at any time been, in their possession, custody or power, and if/when they parted with it and what has become of it.

In relation to patent litigation, where a person has in their possession, custody or control, for commercial exploitation, a patented invention, a patentee or licensee may apply to the High Court for an order for delivery up, that the patented product or article be delivered to the patentee or licensee or to another person that the High Court specifies. This order operates as a seizure order.

1.9 Declaratory Relief

The Courts in Zambia are willing to grant a declaratory relief upon an application made by an interested person to the court. The only type of declaratory relief available in Zambia is a declaration of non-infringement.

According to Section 84(1) of the Patents Act, a person who is interested in a protected patent may apply to the High Court for a declaration, by the court, of the performance of a specific act, by the applicant, as not constituting an infringement of the patentee's right in the protected patent.

The requirements for the court to grant such relief are that the act to which the application relates must not be a subject of infringement proceedings; or the person making the application should satisfy the court that the person had previously written to the patentee, requesting a written acknowledgement of whether such act is infringing or non-infringing, and the patentee has failed or neglected to respond to such request within a reasonable period.

1.10 Doctrine of Equivalents

In Zambia, neither the doctrine of equivalence nor the concept of infringement by equivalence are applicable.

1.11 Clearing the Way

Zambia Medicines Regulatory Authority

The Zambia Medicines Regulatory Authority (the "Authority") is the statutory body established under the Medicines and Allied Substances Act No 3 of 2013 (MASA). This Act regulates the manufacture, importation, storage distribution, supply, sale and use of medicines and allied

substances. It also regulates the granting of pharmaceutical licences and marketing authorisations.

The Authority is mandated to ensure that pharmaceutical products being made available to the Zambian people meet the required standards of quality, safety and efficacy and that only qualified persons carry out relevant pharmaceutical practices.

Grant of a Licence

According to Section 33 of MASA, a person who intends to manufacture, distribute or deal in any medicine or allied substance shall apply to the Authority for a pharmaceutical licence in the prescribed manner and form upon payment of the prescribed fee.

Without a pharmaceutical licence, it is illegal to produce, sell or deal in any type of medication or allied substance. A pharmaceutical licence must be secured before the introduction of a new product.

Failure to obtain a licence amounts to an offence attracting a fine not exceeding two million penalty units, imprisonment not exceeding four years, or both.

Market Authorisation

According to Section 39 of MASA, a person who intends to place on the market, advertise, market, manufacture, sell, import, supply, administer or deal in any manner with any medicine or allied substance shall apply to the Authority for marketing authorisation in the prescribed manner and form.

Failure to obtain marketing authorisation amounts to an offence and, upon conviction, the court will impose a fine not exceeding two million penalty units or imprisonment for a period not exceeding four years, or both.

National Drug Quality Control Laboratory

An established National Laboratory, known as the National Drug Quality Control Laboratory (the "Laboratory"), is managed by the Authority. The Authority uses the Laboratory to verify the safety, quality and efficacy of medicines and allied substances which are manufactured or imported into the country by persons who are authorised or licensed to do so. After the Authority verifies the medicine or allied substances, a certificate of analysis is issued, thus allowing for the product's launch.

1.12 Experts

Although infringement and validity cases are rare in Zambia, it is common for the court to use evidence from experts in other cases. Currently, Zambia relies on the Rules of the Supreme Court, 1965 in relation to expert evidence. However, the proposed High Court (Amendment) Rules are underway and will soon become law.

The proposed High Court (Amendment) Rules, 2022 provide a detailed procedure on expert evidence and the form of such evidence. According to Order VI (2), a party may call an expert witness to give evidence on a specific issue. Additionally, the parties may agree to jointly instruct a single expert witness.

A party intending to call an expert witness shall file a witness statement, which shall refer to the report submitted by the expert witness.

According to Order VI Rule 37, the expert evidence shall be in the form of a report and shall state the academic and professional qualifications and experience by which the expert wit-

ness making the report has acquired specialised knowledge.

The report shall also state the questions which the expert witness has been asked to address, details of the literature or other materials, if any, which have been relied on in making the report, the name and qualifications of any person who carried out any examination, measurement, test or experiment which the expert witness used to make the report, and reasons for the expert's opinion.

Expert evidence is not binding on the court but merely aids the court in arriving at a decision, hence its significance will again depend on the circumstances of each case.

Although there are currently no special considerations that apply to experts testifying in court, it is common practice that experts should be objective when testifying because the rules of natural justice demand it. The proposed High Court (Amendment) Rules, 2022 place a duty on an expert witness to assist the court by giving an unbiased analysis on an issue in respect of which the witness has been called to testify.

The rules further require an expert report to contain a declaration that the expert witness who made the report understands that the witness's overriding duty is to the court and that the witness has complied with that duty.

Additionally, an expert should place before the court all the materials used by them in arriving at their opinion so that the court may weigh their relative significance. The principle is that the expert's opinion must not be substituted for the judgment of the court. It can only be a guide, albeit a very strong guide, to the court in arriving at its own conclusion on the evidence before it. This was the holding of the court in the case of Chuba v The People 1976 ZR 272.

Order VI Rule 33 allows the court to appoint a court-appointed expert witness. The court may, on its own motion or on an application by a party, appoint a court expert to inquire into and report on an issue other than an issue relating to a question of law or of construction of the law.

In deciding whether to appoint a court expert witness, the court shall consider the following: the complexity of the issue in relation to which the appointment is required; the impact of the appointment on the cost of the proceedings; the likelihood of the appointment expediting or delaying the trial of the case; the interests of justice; and any other factor which the court considers appropriate.

1.13 Use of Experiments

The court in Zambia has the power to issue orders for directions pursuant to Order XIX of the High Court Rules, SI No 58 of 2020. Amongst the directions that the court will issue is that the parties shall prepare a list of documents that the parties intend to rely on at trial. The parties will also be ordered to conduct discovery and inspection of documents and thereafter file a bundle of documents into court.

Therefore, the process of discovery and inspection of documents can be used to adduce results from experiments as the results will form part of the bundle of documents filed in court. However, an expert witness who prepares the results from the experiment will be required to testify in court. Please refer to **1.12 Experts**.

1.14 Discovery/Disclosure

Please refer to **1.13 Use of Experiments**.

1.15 Defences and Exceptions to Patent Infringement

Innocent Infringement

Section 83 of the Patents Act provides that in proceedings for infringement of a patent for an invention, damages shall not be awarded, and an order shall not be made for an account of profits, against a defendant who satisfies the High Court that, at the time of the infringement, the defendant was not aware, and had no reasonable grounds for supposing that the patent existed.

Non-infringement Acts

The following do not constitute an infringement of a patent:

- if the reproduction of the patented invention is done by a person for private and not commercial exploitation purposes;
- the reproduction of the patented invention is done by a person for the sole purpose of evaluation, analysis, research or teaching; or
- a person uses the results of an evaluation, analysis or research, which involves a patented invention, to create a different invention that complies with the requirements of Section 15 of the Patents Act.

Compulsory Licence

A compulsory licence is a licence granted by the Minister in accordance with and for the purposes stated in Section 99.

According to Section 99 of the Patents Act, a person may, after three years from the date of the grant of a patent, apply to the Minister for the grant of a compulsory licence on any of the following grounds, that:

- without reasonable cause, the patentee does not work the patented process in Zambia;
- the patented product or article is not available to the public in Zambia in sufficient quantity or at an affordable price;
- the refusal by the patentee to grant a contract licence, on reasonable terms, is prejudicial to the country's establishment and development of industries or commercial activities;
- the applicant for a contract licence has failed to obtain the patentee's consent for the use of the patented invention, under reasonable terms and conditions;
- the interest of public health or nutrition demand the commercial working of the patented invention in Zambia;
- there is a need to remedy the abuse of intellectual property rights or anti-competitive practices; or
- there is a national emergency which requires the use of the patented invention.

In proceedings for infringement, a compulsory licence may be used as a defence to infringement.

In addition to statutory defences, the person sued for infringement can challenge the validity of the patent on several grounds. Some of these grounds are as follows:

- the invention is not new, lacks novelty or is not useful; and
- the claim is defective, in that they do not sufficiently and clearly define the subject matter for which the protection is claimed.

Special Considerations for Life Sciences Cases

There are no special considerations that apply to life sciences cases; the defences are equally the same.

1.16 Stays and Relevance of Parallel Proceedings

Stay of Proceedings

As a rule, applicable to all litigation matters, a party can apply to stay proceedings if it is in the interests of justice that one matter be stayed to properly resolve the other matter. This is designed to avoid multiplicity in the administration of justice.

Any proceedings can form the basis of the stay, ie, infringement proceedings, validity proceedings, opposition proceedings or foreign proceedings.

There are no requirements or considerations to the grant of a stay of proceedings because such a grant is made in the discretion of the court. However, the court will stay proceedings if the proceedings ought not to be allowed to continue beyond all reasonable doubt.

Parallel Proceedings

Zambia does not recognise parallel proceedings because they are considered as forum shopping and an abuse of the court process.

1.17 Patent Amendment

Patents can be amended during litigation. Section 47 of the Patents Act No 40 of 2016 provides that the Registrar may, on request by an applicant, authorise the correction of a clerical error in a document filed with the Agency. Where a request for the correction of an error concerns the description, claim or drawings, the correction shall be obvious and immediately evident that nothing else is intended than what is offered as a correction. Such request for the correction of a clerical error is required to be made in the prescribed manner and on payment of the prescribed fee.

Where it is proposed by the Registrar that a correction be made, otherwise than upon a request, the Registrar shall give notice of the proposed correction to the applicant for the grant of a patent.

However, patent amendments are constrained to clerical errors concerning the description, claim or drawings.

1.18 Court Arbiter

Specialised Court

A commercial division of the High Court hears and determines commercial matters. There is, however, no specific court which determines intellectual property matters in Zambia. As such, any judge in the commercial division can decide pharma or life sciences cases.

Forum Shopping

Forum shopping is prohibited in Zambia.

2. Generic Market Entry

2.1 Infringing Acts

In Zambia, a right to bring an action for infringement will arise where a person infringes a patentee's rights, as discussed in **1.1 Claimants/ Plaintiffs to an Action**.

According to the Patents Act, the following will amount to infringing acts if done without the consent of the patentee:

- exploiting the patented invention and authorising the exploitation of the patented invention by others;
- where the patented invention is a product, preventing any person from making, using, offering for sale, selling or importing the patented product;

- where the patented invention is a process, preventing any person from using, offering for sale, selling or importing the product obtained directly from the patented process; and
- assigning, transmitting or licensing the patent.

An application for marketing authorisation is one of the stages that must be taken to clear the way for the launch of a new product, as has been explained under **1.11 Clearing the Way**. Unless the marketing is done in relation to a product that is covered by patent protection, it does not constitute an infringement act.

An application for reimbursement, pricing or listing, a submission or award of tender and an offer to supply after patent term expiry are not recognised in Zambia. Therefore, they cannot be considered as acts which amount to an infringement.

2.2 Regulatory Data and Market Exclusivity

Currently, there are no rules that apply to data and market exclusivity in Zambia.

2.3 Acceptable Pre-launch Preparations

It is not an infringement of a patentee's right in a patent if:

- the reproduction of the patented invention is done by a person for private and not commercial exploitation purposes;
- the reproduction of the patented invention is done by a person for the sole purpose of evaluation, analysis, research, or teaching; or
- a person uses the results of an evaluation, analysis or research, which involves a patented invention, to create a different invention that complies with the requirements of Section 15 of the Patents Act.

2.4 Publicly Available Drug and Patent Information

According to the Zambia National Formulary, which is a component of the Zambia National Medicines Policy, the Orange Book is accepted as a reliable guide for health workers for the prescription of medicines. Public information is not available on market authorisation applications and granted market authorisation applications. The applicable regulatory authority is the Zambia Medicines Regulatory Authority. Please refer to **1.11 Clearing the Way**.

2.5 Reimbursement and Pricing/Linkage Markets

The granting of Market Authorisation is not linked with patent status. A person who intends to advertise or market, manufacture, any medicine or allied substance may apply to the Authority for marketing authorisation. The granting of market authorisation is specifically related to the marketing of medicine and is not linked with the status of a patent.

3. Biosimilar Market Entry

3.1 Infringing Acts

Biosimilar market entry is not an option in this jurisdiction.

3.2 Data and Regulatory Exclusivity

Biosimilar market entry is not an option in this jurisdiction.

3.3 Acceptable Pre-launch Preparations

Biosimilar market entry is not an option in this jurisdiction.

3.4 Publicly Available Drug and Patent Information

Biosimilar market entry is not an option in this jurisdiction.

3.5 Reimbursement and Pricing/Linkage Markets

Biosimilar market entry is not an option in this jurisdiction.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Supplementary Protection Certificates and similar patent term extension instruments are not available in Zambia.

However, according to Section 67 of the Patents Act, a patentee or exclusive licensee may, six months before the expiry of the term of a patent, apply to the Registrar for an extension of the term of a patent for a further term not exceeding two years on the following grounds:

- where there are hostilities between Zambia or any country of the Commonwealth and any other country and the patentee has suffered loss or damage; or
- where an act of God occurs, and the patentee has not been able to work the patent.

4.2 Paediatric Extensions

Paediatric extensions are not available in Zambia.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

It is a condition for obtaining an injunction that a plaintiff (patentee) must give an undertaking to the court to pay any damages sustained by the defendant that the court considers the plaintiff should pay. The undertaking in damages is given to the court, not to the party against whom the interim order for the injunction is obtained.

Accordingly, any failure to comply with the undertaking is not a breach of contract but will be reproved by the court through the remedies available for contempt. However, the court cannot compel a party to give an undertaking; it will decline the application if a party refuses to provide an undertaking.

Undertakings as to damages remain in force until the inter partes hearing, where the injunction is heard inter partes. Life sciences cases are very rare in Zambia; therefore, a precise answer cannot be provided as to whether third parties can avail an undertaking as to damages.

Interim injunctions are enforceable immediately the court makes an order granting the injunction and upon service of such order.

Service

As to service, please refer to **1.3 Preliminary Injunction Proceedings**.

Enforcement

Interim injunctions are enforced by way of service of the court order granting the injunction. Disobedience of an interim injunction may lead to committal for contempt of court.

There is no requirement for the patentee to pay a bond, but the patentee must make an undertaking as to damages.

As discussed under **1.3 Preliminary Injunction Proceedings**, an injunction cannot stand on its own as there should be court action giving rise to an application for injunction. A patentee is required to commence an action for a preliminary injunction to be enforced or remain in force. The applicable timeframe for commencing such an action is within five years from the date on which the facts giving rise to such proceedings became known to the patentee.

A preliminary injunction cannot be stayed pending appeal. An application to discharge the injunction may, however, be filed.

5.2 Final Injunctive Relief

Please refer to **5.1 Preliminary Injunctive Relief**.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

The court has the discretion to consider whether the plaintiff will be adequately compensated by an award of damages. If the plaintiff can be adequately compensated, the interim injunction ought to fail, however meritorious the claim may be. Therefore, the court can award damages in lieu of an injunction where a plaintiff will be adequately compensated by an award for damages.

Life sciences and pharma patent litigation are not common in Zambia and, as such, public interest arguments have not been utilised to reduce the scope of injunctive relief in life sciences and patent litigation.

5.4 Damages

Calculation of Damages

The basis for the calculation of damages arising out of an infringement will be according to the loss of profits suffered by the patentee arising out of the infringing activities or by reference to a reasonable royalty rate.

A patentee or exclusive licensee cannot elect which method should be used as that is in the discretion of the judge or the deputy registrar.

Transfer Pricing

Transfer pricing does not play a role in the assessment of damages. However, the tax regulatory body in Zambia, the Zambia Revenue Authority, penalises corporate bodies for engaging in transfer pricing practices. In the case of Mopani Copper Mines v Zambia Revenue Authority Appeal No 24 of 2017, the Supreme Court agreed with the respondent (Zambia Revenue Authority) for penalising the appellant (Mopani Copper Mines) for engaging in transfer pricing practices with its shareholder Glencore International AG. The respondent was ordered to pay ZMW34,311,113,798.38 and ZMW140,891,939.89.

Assessment of Damages

It matters not whether the patentee has no competing product: the principle in Zambian courts on assessment of damages will follow the common law position, which is that damages for infringement or invalidity will be according to the loss of profits suffered by the patentee arising out of the infringing activities or by reference to a reasonable royalty rate.

There are special damages in Zambia, but they can only be specifically pleaded where the damages are quantified. In addition, there is a need

for satisfactory proof to be adduced before special damages can be awarded by the court.

Accrual of Damages and Interest on Damages

Damages accrue from the time when the infringing activities are undertaken by the alleged infringer.

Although courts have the discretion to award interest on any debt or damages claimed, the courts must exercise their discretion in accordance with the High Court Rules. Interest is payable from the date when the cause of action arose (or date of issuance of the writ of summons) to the date of judgment and thereafter from the date of judgment until the damages are paid pursuant to Section 4 of the Law Reform (Miscellaneous Provisions) Act and Section 2 of the Judgment Act.

The Supreme Court in the case of Kasote Singogo v Lafarge Zambia Plc Appeal No 33 of 2012 observed that Section 4 of the Law Reform (Miscellaneous Provisions) Act confers discretionary power on the court to award simple interest on debts and damages from the date that the cause of action arose up to the date of judgment.

The usual practice by the courts has been to peg this interest at the average short-term deposit rate from the date the action commences to the date of judgment. After judgment, the rate of interest imposed is at the current lending rate as determined by the Bank of Zambia.

Damages are assessed separately from the main trial.

Where judgment is given for damages to be assessed, the judge may elect to preside over the assessment or may refer the assessment to the deputy registrar. A judge at chambers and a deputy registrar exercise the same jurisdiction in relation to assessment of damages. Therefore, an appeal from the higher court concerning assessment of damages lies with the Court of Appeal.

The hearing of an assessment of damages constitutes a part or the continuation of the trial of the action. In this regard, it is vital to provide the court with sufficient evidence for the purpose of assessing the damages.

Damages for Wrongful Injunction

As a condition for obtaining an injunction, a plaintiff must give (unless the court orders otherwise) an undertaking to the court to pay any damages sustained by the defendant that the court considers the plaintiff should pay.

Order 27 Rule 6 of the High Court Rules Chapter 27 of the Laws of Zambia provides that a judge may, on an application or on their own motion, pursuant to an undertaking as to damages, order an assessment of damages arising out of a discharged injunction found to have been unjustified, and that the damages shall be assessed by the Registrar.

It is a condition precedent that before the judge makes an order as to such assessment, the defendant ought to demonstrate that they suffered damage as a result of the wrongful injunction.

5.5 Legal Costs

In Zambia, legal costs are recoverable as upheld by the court in the landmark case of Kuta Chambers (Sued as a Firm) v Sibulo (Suing as administratrix of the estate of the late Francis Sibulo), wherein the Supreme Court held that:

"The charges for legal services are called legal fees while the case costs, that is to say the expenses that legal practitioners incur on behalf of the instructing party (which include court filing fees, witnesses' travel expenses, photocopy charges, courier payments, etc) are called disbursements. The legal fees and disbursements together are what we understand as costs. Costs, therefore, are not confined to legal fees alone. This is consistent with the definition of costs given in section 2 of the Legal Practitioners' Act, Cap 30 of the laws of Zambia."

Costs are awarded at the court's discretion and no party to any proceedings shall be entitled to recover any of the costs of those proceedings from any other party to those proceedings except under an order of the court.

Assessment of Legal Costs

The assessment of legal costs in Zambia is known as taxation of costs. Taxation is the process of ascertaining the amount of litigation-related expenses that a party to proceedings is entitled to.

The taxation of costs is referred to a taxing officer who assesses the cost to be awarded to the party entitled to the costs, upon the party filing a bill of costs, which is an itemised list of litigation expenses incurred by the party claiming for costs.

A party entitled to receive taxed costs under an award for costs or to have the costs taxed by a taxing must commence taxation within three months of obtaining such order. There is no timeframe within which the taxation proceedings should be heard. However, a taxing officer has power to limit or extend the time for any proceedings before them, and to adjourn the same.

Following the taxing officer's preparation of the certificate of taxation, legal fees must be paid immediately.

Recovery of Costs

Cost recoveries include legal fees, court filing fees, witnesses' travel expenses, photocopy charges, courier payments and any expenses falling within such ambit.

Section 2 of the Legal Practitioners Act defines costs as fees, charges, disbursements, expenses, and remuneration. This is what forms the basis of legal costs and can be recoverable upon an order from the court after judgment.

5.6 Relevance of Claimant/Plaintiff Conduct on Relief

Penalisation of Costs

In Zambia, the High Court Rules provide that before a plaintiff to an action commences court process, a demand letter should be served on the defendant. This is done in order to prompt ex curia settlements in a bid to decongest the courts of unnecessary court actions and to further curb a backlog of cases. It is, therefore, mandatory for a demand letter to be issued before commencing court process.

Where the demand letter is not issued and served on the defendant, and the plaintiff proceeds to commence an action, the defendant may raise this at trial and the plaintiff may be penalised in costs.

6. Other IP Rights

6.1 Trade Marks

Trade mark disputes in the life sciences and pharma sector are not common in Zambia.

Sources of Law on Trade Marks

The Trade Marks Act Chapter 401 of the Laws of Zambia (the "Trade Marks Act") is the principal legislation governing trade marks in Zambia. The Trade Marks Act makes provision for the registration of trade marks and other purposes incidental thereto including but not limited to:

- actions for infringement of trade marks;
- validity of trade marks; and
- duration of trade marks and assignment and transmission of trade marks.

The Minister may, by statutory instrument, make regulations prescribing anything which is to be prescribed under the Act and for the better carrying out of the objects and purposes of the Act. These regulations may provide for:

- prohibiting the registration of any mark on grounds of morality, public policy, or any other sufficient reason; and
- securing and regulating the publishing and selling or distributing of copies of trade marks and other relevant documents, and regulating the practice under the Act.

The above pieces of legislation extend to pharmaceutical trade mark practice.

Restrictions on Naming

Under the Trade Marks Act, the term mark includes a device, brand, name, word, letter, numeral or any combination thereof. Therefore, the following are the restrictions on the naming of trade marks:

- a mark that would be disentitled to protection in a court of justice;
- a mark that would be contrary to law or morality;
- a scandalous design; service marks; a mark with the words "patent", "patented", "registered", "registered design", "copyright", "to counterfeit this is a forgery", or words with a similar effect;
- representations with armorial ensigns of Zambia or similar devices; and
- representations of the national flag of Zambia and representations of the President or any colourable imitations thereof.

6.2 Copyright

Copyright disputes in the life sciences and pharma sector are not common in Zambia.

The Copyright and Performance Rights Act Chapter 406 of the Laws of Zambia is the principal legislation that governs copyright in Zambia. The Act provides for copyright protection in literary, artistic and musical works, computer programs, audiovisual works, sound recordings, broadcasts, and cable programs. In addition, the Act provides for rights in performances and for any matters incidental to or connected with the foregoing.

The Minister may, by statutory instrument, make regulations for or with respect to any matter that by the Act is required to be permitted or to be prescribed, or that is necessary or convenient for carrying out or to give effect to the Act.

6.3 Trade Secrets

Trade secrets disputes in the life sciences and pharma sector are not common in Zambia, and Zambia does not currently have any laws governing trade secrets.

7. Appeal

7.1 Timing to Appeal Decision

Preliminary Injunctions

The position of the law in Zambia as held in the case of Afritec Asset Management v Gynae Antenatal Clinic Limited Appeal No 64 of 2015 is that where an injunction has been denied, the aggrieved party has the option to renew the application before the Court of Appeal. However, where an injunction has been granted, the aggrieved party can appeal the decision before the Court of Appeal within 30 days from the date of granting the injunction.

There is no timeframe for hearing an appeal on the decision of an injunction. The matter is not considered de novo. The Court of Appeal hears appeals on the record. This means that the appeal will be considered on the documents filed on the record of appeal pursuant to the Court of Appeal Rules SI No 65 of 2016.

Main Action Appeals

The timing to file an appeal against a first instance main action is within 30 days of the judgment appealed against. However, there is no timeframe for the hearing and decision of an appeal.

Appeals are not heard de novo; they are heard on the record and no further evidence can be adduced unless an application is made. Where a party appeals, it is a requirement, under the Court of Appeal Rules, that a party shall also file a record of appeal. The record of appeal shall include copies of proceedings in the High Court, a complete index of the evidence, a copy of the judgment appealed against and copies of documents in pleadings, so far as it is necessary for showing the matter decided and the nature of the appeal. Therefore, appeals are considered on the record of appeal.

There are further rights to appeal a decision of the Court of Appeal to the Supreme Court. However, in relation to the Supreme Court, there are certain conditions that must be met before leave to appeal is granted:

- the appeal raises a point of law of public importance;
- it is desirable and in the public interest that the appeal be determined by the Supreme Court; and
- the appeal would have reasonable prospects of success; or there is some other compelling reason for the appeal to be heard.

7.2 Appeal Court(s) Arbiter

Section 57 of the Patents Act No 40 of 2016 provides for the procedure to be followed where a patent is opposed. A person shall file with the Registrar a notice opposing the grant of a patent, which shall be accompanied by a statement of the particulars of the facts alleged in support of any of the stated grounds opposing the grant.

An opposition to the grant of a patent shall be heard and determined by the Registrar, and any person aggrieved with the decision of the Registrar with respect to an opposition to the grant of a patent may appeal to the High Court.

The High Court does not have specialised judges but a specialised division, which is the Commercial Division. Appeals to the High Court are heard by a single judge and not a panel of judges.

There is a Court of Appeal in Zambia, established pursuant to Article 130 of the Constitution of Zambia, Amendment Act No 2 of 2016. The Court of Appeal has jurisdiction to hear appeals

from the High Court. The Court of Appeal does not have any specialist judges. In this regard, patent litigation appeals from the High Court are heard by a panel of judges in the Court of Appeal constituted by an uneven number of not less than three judges.

7.3 Special Provisions

There are no specific procedural rules or guidance provisions for intellectual property claims. The procedural rules and provisions that apply to civil actions are the same as those applying to intellectual property claims.

8. Other Relevant Forums/ Procedures

8.1 Other Relevant Forums/Procedures

There are no specific procedures or forums relevant to life sciences litigations in Zambia.

9. Alternative Dispute Resolution

9.1 ADR Options

Alternative dispute resolutions are recognised by the judicial system in Zambia. Litigants have become more receptive to alternative dispute mechanisms rather than commencing court process because alternative dispute mechanisms have proved to be time efficient and more effective. In Zambia, there are two ADR mechanisms that are mostly practised and have a legal framework governing them: these are mediation and arbitration.

Court-Annexed Mediation

The High Court Act makes provision for court-annexed mediation. According to Order 31 Rule 4(1) of the High Court Rules, it is mandatory that at scheduling conference and before setting down an action for trial, a judge shall refer an action amenable to mediation to court-annexed mediation, except for a case involving a constitutional issue, the liberty of an individual, an injunction, or where the trial judge considers the case to be unsuitable for referral.

Arbitration

Arbitration in Zambia is governed by the Arbitration Act No 19 of 2000 (the "Arbitration Act"). According to Section 9 of the Arbitration Act, an arbitration agreement must be embodied in a contract or must take the form of a separate agreement. A court before which legal proceedings are brought in a matter which is subject to an arbitration agreement shall, if a party so requests at any stage of the proceedings and notwithstanding any written law, stay those proceedings and refer the parties to arbitration unless it finds that the agreement is null and void, inoperative or incapable of being performed.

In the case of Audrey Nyambe v Total Zambia Limited Appeal No 29 of 2011, it was held that "in determining whether a matter is amenable to arbitration or not, it is imperative that the wording used in the arbitration clause itself is closely studied".

Institute for Arbitration

The main institute for arbitration in Zambia is the Chartered Institute of Arbitration Zambia, which promotes ADR by making available to anyone seeking an arbitrator of a certain expertise a list and detailed background of arbitrators from which a party may choose.

In this regard, the two ADR mechanisms that would be available in the life sciences sector are mediation and arbitration.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

There are no specific settlement or antitrust considerations in this jurisdiction.

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