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IP Protection for Pharmaceuticals (Australia)

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A Practice Note on the Australian patent and regulatory framework for life sciences inventions. This Note addresses key patent issues for life sciences inventions, including patent subject matter eligibility, patent disclosure requirements, patent term extension, and patent litigation, and relevant regulatory provisions concerning certain life sciences inventions in Australia.

Australia has various laws to protect life sciences inventions, including both small molecule drugs and biologics. Because of the complexity of the patent and regulatory framework concerning life sciences inventions, counsel must understand the many issues that may arise when seeking to protect these inventions globally.

This Note explains the parameters of patent-eligible subject matter, patent disclosure requirements, patent term extension, and describes Australia's patent and regulatory framework for life sciences inventions. It describes intellectual property and regulatory protection for life sciences inventions, including any listing and notice requirements, market exclusivity, patent litigation, and their application to biosimilars inventions.

Key Australia Patent Requirements for Life Sciences Inventions

Australia includes several requirements that are important for life sciences inventions. These include:

- The patent must meet the requirement of patent subject matter eligibility.
- The specification must provide a clear enough and complete enough disclosure of the invention.
- The claims must be clear and succinct, and adequately supported by the description.

For more information on patents in Australia generally, see Practice Note, Patents.

Patent Subject Matter Eligibility

Life science-related technologies are of considerable importance to the Australian economy. The Australian patent system provides the possibility for obtaining a broad range of patents within the fields of human and animal health, including for small molecules, vaccines, monoclonal antibodies, polypeptides, stem cells, and their therapeutic uses. In Australia, one requisite for patentability is patent-eligible subject matter. The requirements for patent-eligible subject matter are:

- Governed by the construction and interpretation of "manner of manufacture," which is a term derived from section 6 of the English *Statute of Monopolies* of 1623 (Imp) (section 18(1), *Patents Act 1990*) (see Manner of Manufacture).
- Important when considering medical treatment and use claims (see Methods of Medical Treatment and Medical Use Claims).

Manner of Manufacture

The law relating to what constitutes patentable subject matter is everchanging in Australia, and although there is judicial guidance, there is no simple test to determine whether a claimed invention is a manner of manufacture. Patenting of human beings and the biological processes for their generation are expressly prohibited (section 18(2), *Patents Act 1990*). Otherwise, Australian law does not distinguish between whether the invention is implemented by software or other technical means, and it does not distinguish regarding the particular field of economic utility where the invention is applied.

The basis of the current legal conception of the term manner of manufacture was established by the High Court of Australia in the case of *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252. The Court endorsed an expansive definition of

manner of manufacture, where patentability is determined by reference to the policy intent of the legislation rather than by application of a strict definition. An invention meets this requirement if it is an "artificially created state of affairs" that belongs to the "useful arts" rather than "fine arts," and it must provide a material advantage in a field of economic endeavour. Judicial interpretation has also recognised several categories of subject matter that fail to satisfy the requirement. These include mere discoveries, ideas, scientific theories, and laws of nature.

More recently, the High Court in *D'Arcy v Myriad Genetics Inc* considered the patent eligibility of claims directed to naturally occurring genetic material ([2015] HCA 35). The High Court found that the legislative history, including the fact that the Australian government had not amended the patents legislation to expressly exclude genetic material, cannot be read as impliedly mandating the patent eligibility of claims for inventions relating to isolated nucleic acids coding for particular polypeptides.

Therefore, isolated naturally occurring genetic material is not eligible for patent protection in Australia. However, methods of genetic testing, diagnostic methods involving the practical application of "natural phenomena," and methods of medical treatment are eligible for patent protection. For more information, see Legal Update, Genes, genetic applications and patent eligibility: Australia continues to be a gene-patent friendly jurisdiction.

In general, Australian courts have indicated that, subject to other requirements and aside from particular exceptions, patents are available for:

- Products.
- Methods:
  - of making and using products; and
  - that otherwise result in a new and useful effect.

According to IP Australia's Patent Manual of Practice and Procedure, the assessment of whether an application defines patent-eligible subject matter is considered as to each claim. In general, Examiners approach the examination of manner of manufacture (patent-eligible subject matter) by:

- Construing the claim using the normal rules of construction. For more information on patent claim construction, see Practice Note, Patent claim construction.
- Identifying the substance of the claimed invention, based on:
  - the state of the art before the priority date;
  - the contribution to the art asserted by the specification;
  - the level of detail provided in the specification with regard to various aspects of the invention;
  - how the invention works;
  - the form of words, breadth, and emphasis of the claim;
  - the problem the invention addresses;
  - the claimed invention's actual or alleged advantages; and
  - the claimed invention's contribution to the state of the art on the priority date.
- Determining whether the substance of the claim lies within established principles of what does not constitute a patent-eligible invention (for example, where the substance is merely a scheme, plan, rules of gameplay, intellectual, or genetic information).
- If not, considering whether the substance of the claim otherwise lies outside of existing concepts of manner of manufacture and is to be treated as a "new class" of subject matter.

Methods of Medical Treatment and Medical Use Claims

In general, Australia offers a flexible approach to therapeutic claiming, with the ability to also include claims:

- Directed to:
  - a "method of medical treatment," specifically the administration of therapeutic drugs to humans;
  - a "product when used for purpose" (use-limited but construed essentially as a method claim); and
  - a "product for purpose" (limiting only to the extent that the product must be suitable for the purpose).
- In the "Swiss-type" format of "use of [compound] for the manufacture of a medicament for treating a [condition]." For more information on Swiss-type claims in Australia, see Legal Update, Holes in Australian Swiss claims - plugged in 2020.

"When used" claims in the form "product X when used for purpose Y" are allowable, and they are given a construction that is particular to Australian practice, that is, they are considered "disguised process claims," having essentially equivalent scope as a method claim directed to

the recited use (*Wellcome Foundation Ltd v Commissioner of Patents* [1980] HCA 21). As a result, claims in this form can confer novelty for a new use of a known product, including a therapeutic product in Australia.

EPC2000-style claims in the form "product X for [or for use in] purpose Y" are allowable and can be used to claim a therapeutic use. However, these claims are considered limiting only to the extent that the product must be "suitable for" the recited purpose. The effect of this is that if a drug is known, the claim directed to the drug "for" or "for use" in a particular therapeutic purpose is considered to lack novelty (as it is considered that the known drug was inherently suitable for the recited purpose). For more information on EPC2000-style and second medical use claims, see Legal Updates, EPO Board of Appeal interprets EPC 2000 transitional provisions and Determining if something is "substance or composition" for second medical use claims (European Patent Office).

In contrast to European practice, where "first medical use" claims are permissible and **all** medical uses of a known compound can be claimed on first recognition that the compound has at least one medical use, due to the particularities of Australian law regarding support and sufficiency, the current approach is that a use-limited product claim is only considered supported by the disclosures of a patent specification if it could reasonably be expected that the product would be effective for the recited purpose. In practice, this precludes claiming all possible medical uses of a compound, as these claims will be objected to for lack of support.

Patent Specification Requirements

The IP Laws Amendment (Raising the Bar) Act 2012 (IP Laws Amendment) came into effect on 15 April 2013 with the aim of raising Australian patentability standards and the requirements for patent specifications, which require:

- The specification provides a clear enough and complete enough disclosure of the claimed invention (see Sufficiency).
- The claims are adequately supported by the description (see Claim Support).

Often there is overlap between the sufficiency and claim support requirements (see Sufficiency and Support Overlap).

Sufficiency

The complete specification of an Australian patent must "disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art" (section 40(2)(a), *Patents Act 1990*). This is often referred to as sufficiency.

The Explanatory Memorandum to the IP Laws Amendment introducing this requirement states that the sufficiency requirement is to "be given, as close as is practicable, the same effect as the corresponding provisions of UK legislation and the European Patent Convention." Therefore, the complete specification must provide sufficient information to enable the skilled person to perform the invention over the whole width of the claims, without undue burden or the need for further invention.

For more information on sufficiency from a UK and EPC perspective, see Practice Note, Patent validity: sufficiency.

In essence, the test for sufficiency is one of undue burden and plausibility. The concept of plausibility was set out in detail in the UK Supreme Court decision *Warner-Lambert Co LLC v Generics (UK) Ltd (t/a Mylan)*, which held that it is a requirement that a "patent should disclose not just what the invention is and how to replicate it, but some reason for expecting that it will work" ([2018] UKSC 56 at [23]). If the person skilled in the art cannot perform the disclosed invention without prolonged research or tests that go beyond routine trial and error, that is considered to impose an "undue burden." When considering whether it is plausible that the invention can be worked across the full scope of the claim, a patent examiner considers whether there is a technically sound or credible basis for the principle of general application. If it is not plausible that the invention can be worked over the full scope of the claim, the disclosure is considered insufficient. If lack of plausibility is established, putting the invention into practice would inevitably require an undue burden.

The same sufficiency requirement also applies to priority claiming (section 43(2A)(b), *Patents Act 1990*; *TCT Group Pty Ltd v Polaris IP Pty Ltd* [2022] FCA 1493). An earlier (priority) application must provide a clear enough and complete enough disclosure of an invention claimed in a later (priority-claiming) application for the priority claim to be valid. For more information on priority claims from a US perspective, see Practice Note, Patent Prosecution: Domestic Benefit and Foreign Priority Claims.

Claim Support

The claim or claims of an Australian patent must also be clear and succinct and supported by matter disclosed in the specification (section 40(3), *Patents Act 1990*).

The Explanatory Memorandum to the IP Laws Amendment introducing the support requirement states that it is "intended to align the Australian requirement with overseas jurisdictions' requirements (such as the UK)." In practice, claims are considered to lack support where:

- They extend beyond the technical contribution to the art, that is, the claims are so broadly defined that they encompass embodiments beyond what the specification discloses.
- They omit essential features, that is, a claim is missing essential features that appear necessary for the described invention to work and to achieve its stated benefit.

The approach for determining whether the claims are supported by the specification is as follows (*CSR Building Products Limited v United States Gypsum Company* (2015) APO 72):

- Construe the claims to determine the scope of the invention as claimed.
- Construe the body of the specification to determine the technical contribution to the art.
- Decide whether the claims are supported by the technical contribution to the art.

The technical contribution to the art is not necessarily the same as inventive step. Rather, for a claim to a product or group of products, the technical contribution is the products themselves, and the disclosure in the specification should be sufficient to make substantially all embodiments, except for *de minimis* exceptions (*Merck Sharp & Dohme Corporation v Wyeth LLC (No 3)* [2020] FCA 1477).

Key claim support issues arise for:

- **Genus claims.** For genus claims to be supported over their whole scope, the body of the specification must provide sufficient information to enable the person skilled in the art to make every compound falling within the scope of the claims. Also, if the activity of the compound is a feature of the claim, the class of compounds must be such that the person skilled in the art would have a reasonable expectation that all of the class members will behave in the same way, in the context of the specification. Additionally, broad claim terms, such as "optionally substituted," where the substituents are not defined, are unlikely be considered supported over their entire scope on the basis that an undefined substituent encompasses a diverse range of possibilities and is not considered to represent an underlying principle of general application.
- **Pharmaceutical and medical treatment claims.** Claims to the use of known pharmaceutical compounds for a new therapeutic use are considered to lack support absent evidence of the idea working for the new use. Similarly, a claim to the therapeutic use of a new pharmaceutical compound with no other restriction lacks support if there is no evidence of the therapy working over the whole scope of the use as claimed. Where the claims are for methods of treatment, the description in the specification should not only identify a condition that may be treated but also demonstrate, by reference to tests, that the treatment is a reality and not just a possibility.

Sufficiency and Support Overlap

There is often an overlap between the grounds of sufficiency and support because both require the specification to provide an enabling disclosure of the claimed invention. However, the Federal Court has made clear that, although related, the grounds of support and sufficiency are distinct. As to sufficiency, the enabling disclosure must be found in the complete specification. In contrast, for support, the enabling disclosure supporting the claims must be found in the body of the specification (the description, any drawings, graphics, and photographs, and sequence listing). A claim that is broader than the technical contribution of the patent, even when it can be performed across its full scope, does not satisfy the support requirement even though it may satisfy the requirements of sufficiency.

Important Court and Australian Patent Office Life-Sciences Decisions

Important patent subject matter eligibility case decisions include those that address the patent eligibility of:

- Isolated naturally occurring genetic material (see Isolated Naturally Occurring Genetic Material).
- Methods of genetic testing (see Methods of Genetic Testing).
- Diagnostic methods (see Diagnostic Methods).
- Methods of medical treatment (see Methods of Medical Treatment).

The Australian Patent Office (APO) has also issued several important decisions affecting life-sciences inventions (see Patent Office Decisions).

Isolated Naturally Occurring Genetic Material

In *D'Arcy v Myriad Genetics Inc*, the High Court of Australia held that an isolated nucleic acid, coding for a BRCA1

protein, with specific variations from the norm that are indicative of susceptibility to breast cancer and ovarian cancer, was not patent-eligible subject matter ([2015] HCA 35). The High Court found that the essential element to the invention was the informational content of the claimed isolated genetic material. As the step of isolating the genetic material was known, the claims did not meet the threshold test for inventive step and so could not be considered to relate to subject matter eligible for patent protection.

If isolated biological products are modified to alter their function or activity for particular uses, this would nonetheless likely be considered to meet the patent-eligible subject matter threshold, in line with the approach set out by the High Court.

Methods of Genetic Testing

In an appeal from a pre-grant opposition to grant of an Australian patent for an invention for methods of identifying cattle having useful traits using genetic information from single nucleotide polymorphisms, the Federal Court of Australia confirmed that methods of genetic testing remain patent-eligible subject matter (*Meat & Livestock Australia Limited v Cargill, Inc.* [2018] FCA 51).

Diagnostic Methods

The Full Court of the Federal Court of Australia has confirmed that diagnostic methods involving the practical application of "natural phenomena" can be patent-eligible inventions in Australia (*Ariosa Diagnostics, Inc v Sequenom, Inc* [2021] FCAFC 101). Specifically, the invention in question related to a non-invasive method to determine fetal traits and malformations by performing diagnosis on cell-free foetal DNA (cffDNA). This is following the discovery that cell-free fractions of a pregnant woman's blood, which was historically discarded as medical waste, contain high levels of cffDNA.

Methods of Medical Treatment

The High Court has confirmed that methods of medical treatment are patent-eligible subject matter in Australia (*Apotex Pty Ltd v Sanofi-Aventis Australia Ply Ltd (*2013) 253 CLR 284). The case concerned Apotex's proposal to sell a generic version of Sanofi-Aventis' leflunomide drug covered by a patent that claimed a method of preventing or treating psoriasis using leflunomide.

Patent Office Decisions

The APO hearing decision in Evolva SA provided initial clarity on the level of detail required in a specification and highlighted the need for a specification to provide enough detail about an invention for a skilled person to plausibly work the invention ([2017] APO 57). Evolva SA filed for a patent for a new way to make sugar-based sweeteners (known as mogrosides) by use of an enzyme. The process involved contacting the starting materials with one of five specified enzymes or a polypeptide with "at least 90% sequence identity" to one of the specified enzymes, which during examination was deemed to be too broad and insufficiently supported.

One of the main considerations by the delegate (a type of patent examiner in Australia exercising the authority of the Commissioner of Patents) was whether a "research programme" would be required to assess whether a polypeptide, which was 90% identical to one of the specified polypeptides, would be effective in performing the invention. If so, then there would be insufficient support for the claims. In finding for the applicant, the delegate noted:

- It was plausible that the invention could be worked across the full scope of the claims, in that a principle of general application was set out in the specification.
- The claims were not unduly broad. They were not directed to every variant with 90% sequence homology, only those with a certain function (to catalyse the synthesis of mogrosides).

In Cargill Incorporated v Dow AgroSciences LLC, the polynucleotide encoding a codon-optimized sequence for the Δ9-desaturase gene was held to be patent-eligible subject matter, despite it coding for a naturally-occurring protein ([2016] APO 43). The reason for this was because the process of codon-optimization resulted in the production of the protein being increased over its production from the naturally occurring genomic sequence. Therefore, the substance of the claim was sufficiently "made," and the product of the claim (that is, increased production of Δ-9 desaturase) resulted in economic utility.

In *Academisch Ziekenhuis Leiden and BioMarin Technologies B.V.*, the APO expanded the patent eligibility of nucleic acid-based inventions under Australian practice ([2018] APO 49). The claims under consideration encompassed short forms of nucleic acids (oligonucleotides) that convert the mutated dystrophin gene in DMD to a form that can produce the partially functional dystrophin protein found in BMD patients, which prolongs the viability of muscle tissue. The delegate determined that the "contribution of the nucleotide sequence, on balance, weighs towards the substance of the claimed invention being a chemical compound", and therefore was patent-eligible subject matter.

Patent Term Extensions (PTE)

Australia offers patent term extensions (PTE) for pharmaceutical patents that claim pharmaceutical substances. In Australia, the standard patent term is 20 years from the date of filing. On grant of an extension of term, pharmaceutical patents can further benefit from an extension of up to five years. The Australian PTE regime is designed to compensate for delays beyond five years in obtaining registration of a therapeutic product on the Australian Register of Therapeutic Goods (ARTG). Until registration is obtained, a patentee has no practical ability to exploit a pharmaceutical product invention on the market in Australia.

Calculating PTE

A PTE can be obtained to extend the patent term for a period equal to the period beginning on the date of the patent and ending on the "earliest first regulatory approval date," less five years (section 77, *Patents Act 1990*). If the period between the two dates is five years or less, an application cannot be made for an extension of term. However, if the period between the two dates is ten or more years, this allows for the full five-year extension of term to be applied. Any period between five and ten years will be calculated, and an extension of term can be granted for between zero to five years.

Accordingly, on grant of an extension of term, pharmaceutical patents can further benefit from an extension of up to five years, meaning a maximum patent term of 25 years from the effective filing date (priority date) can be obtained. PTE can represent significant revenue for a patentee since the extension occurs after regulatory approval when a pharmaceutical product is generating income.

Eligibility

The legal requirements for obtaining a PTE in Australia are:

- The patent must relate to a pharmaceutical substance per se or a pharmaceutical substance when produced by recombinant DNA technology. The substance must be disclosed in the specification and must fall within the scope of the claims.
- The substance must be included on the ARTG before the 20-year term of the patent expires, and the entry must be current at the time of the application for an extension. The first inclusion on the Register is relevant and can be either a "listing" for export from Australia or a "registration" for marketing approval within Australia.
- At least five years must have elapsed between the effective filing date of the patent application and the first inclusion of the pharmaceutical substance on the ARTG.

"Pharmaceutical per se" means that only claims to compounds or pharmaceutical compositions qualify for a PTE. A pharmaceutical substance may encompass a mixture or compound of substances for therapeutic use whose application involves either:

- A chemical interaction, or physico-chemical interaction, with a human physiological system.
- Action on an infectious agent, or on a toxin or other poison, in a human body.

Importantly, PTE is available only for pharmaceutical substances for human use and not for pharmaceutical substances for veterinary or agricultural use.

A pharmaceutical substance that is produced by a particular method or process (product-by-process claims), or pharmaceutical substances used in a novel and inventive way for treatment, are not eligible for an extension of term unless the process by which the pharmaceutical substance is produced involves the use of recombinant DNA technology. Accordingly, claims that relate solely to uses of pharmaceutical substances, including second and later medical indications or their manufacture, are ineligible.

Where a novel and inventive pharmaceutical substance can only be defined by the process by which it was made, for example, if the exact chemical composition or structure of the substance is not fully characterised, it may then be possible to obtain an extension of term, when using claims in the format of "a pharmaceutical substance of X obtainable by the process or methods of Y" (*Zentaris AG* [2002] APO 14; *Pharmacia Italia SpA v Mayne Pharma Pty Ltd* [2006] FCA 305).

Patent Practice and PTE

On receipt of a request for PTE, the APO considers whether the claims are valid. If the examiner raises any validity objections, the APO does not progress the request and begins re-examination. For example, the examiner may consider the scope of corresponding patents in other jurisdictions and commence re-examination if they find those patents relevantly narrower. During re-examination, the PTE request is not invalidated but is only placed on hold.

The patentee must seek any post-acceptance amendments with sufficient time to ensure that they are allowed before the deadline for requesting PTE. The amendment procedure may take six months in the absence of opposition, and longer if opposed.

Strategic Considerations

Early consideration of a PTE strategy is critical, both during examination of a patent and then again before requesting any extension. Important points include:

- A PTE must be based on the first regulatory approval for a pharmaceutical substance.
- Only one PTE can be granted per patent.
- More than one patent can be extended based on a single regulatory approval.
- Once the PTE is granted, all claims in the patent are extended, although non-human and non-therapeutic uses are exceptions to infringement during the extension.

Because PTE must be based on the first regulatory approval of a pharmaceutical substance and only one PTE may be granted per patent, if a patent covers more than one potential clinical candidate, it is important to consider a divisional patent strategy to ensure that PTE is available for second or further clinical candidates (see Divisional Applications).

When a claim covers two or more pharmaceutical substances with different approval dates, the PTE request must be based on the earliest approved pharmaceutical substance (*Commissioner of Patents v Ono Pharmaceutical Co. Ltd* [2022] FCAFC 39; *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2022] FCAFC 40). This applies even if the earliest approval date relates to a competitor product or the approval occurred less than five years after the date of the patent, therefore rendering the patent ineligible for a PTE.

Accordingly, during patent prosecution, the applicant should carefully consider the likelihood of inclusion on the ARTG of more than one pharmaceutical substance that falls within the scope of the claims of a patent granted on the application.

Patent and Regulatory Framework for Life Sciences Inventions

The Australian pharmaceutical regulatory framework currently takes account of patent rights in a limited and indirect manner.

A sponsor applying to the Australian Therapeutic Goods Administration (TGA) for registration of a therapeutic good that relies on the safety or efficacy of an already approved product must provide a certificate under section 26B of the *Therapeutic Goods Act 1989*. The section 26B certificate must state either:

- The sponsor believes that the good would not infringe a valid claim of a granted patent.
- The sponsor has provided the proprietor of any relevant patent with notice of the application for inclusion on the ARTG.

Arguably, a patent notification scheme for generic and biosimilar medicines that is not qualified by reference to validity like the current section 26B certificate mechanism is necessary to comply with the Australia-United States Free Trade Agreement (AUSFTA). Article 17.10(4) of the AUSFTA requires notification to the patent owner if another party submits a medicine for marketing approval during the term of an existing patent. In 2019 and 2020, the TGA conducted consultations into the earlier notification of generic medicine and biosimilar applications to the patent owner. However, this effort has not been progressed. It is not clear when or even if the TGA will take up this issue again.

For more information on the Australian regulatory framework affecting life-sciences inventions, see Practice Note, Life Sciences Regulators: Overview (Australia).

Patent Listing

In Australia, there is currently no regulatory mechanism truly analogous to the Orange Book system in the USA, so it is not possible for patentees to list patents that protect pharmaceuticals and use indications. For more information on the Orange Book and the US Hatch-Waxman Act, see Practice Note, Hatch-Waxman Act: Overview.

Generic Drug Approval Application and Notice

Australia provides five years of data exclusivity for information filed in support of the first application to register a therapeutic good, whether it is a small molecule or a biological (section 25A, *Therapeutic Goods Act 1989*). It is not possible to make a generic drug approval application that relies on the safety or efficacy of an already approved product in Australia until the data exclusivity period has expired. Importantly, exclusivity is not provided for data relating to new dosage forms,

routes of administration, indications, or combinations with other known active ingredients.

The section 26B certificate (see Patent and Regulatory Framework for Life Sciences Inventions) is the regulatory mechanism for consideration of patent rights in generic drug approval applications. In practice, notice of a generic drug approval application may not be provided to the patent owner in accordance with the section 26B certificate mechanism in reliance on an opinion received by the applicant that any relevant patent claims are not valid and therefore not infringed, even if validity has not been challenged. As a result, patent owners may only become aware of the first generic or biosimilar products intended for the Australian market on their receipt of regulatory approval. In other words, they find out at the same time as the general public.

However, in many cases, the commercial launch of a generic pharmaceutical product in Australia depends on prior agreement from the Department of Health that it will subsidise the price of the product paid by patients through the Pharmaceutical Benefits Scheme. The Pharmaceutical Benefits Advisory Committee (PBAC) recommends which products should or should not be listed on the Pharmaceutical Benefits Scheme Schedule and for what indications. The PBAC does not consider patent rights.

An application to the PBAC for listing on the Pharmaceutical Benefits Scheme Schedule can be made during the TGA's safety and efficacy evaluation of the product, that is, before approval. The PBAC meets regularly to consider these applications. Applications for listing on the Pharmaceutical Benefits Scheme Schedule are made public before listing occurs because the PBAC publishes the agenda for its forthcoming meetings.

Accordingly, patent owners monitoring the PBAC's activities will get some notice of prospective launches.

Generic Sales Stay

A form of generic sales stay can be obtained in Australia by applying for an interlocutory (preliminary) injunction based on a claim for patent infringement. For more information on patent infringement, see Practice Note, Patent infringement.

Applying to the TGA for inclusion of a pharmaceutical or biosimilar on the ARTG is not an act of patent infringement. However, when a person applies to list a product on the Pharmaceutical Benefits Scheme Schedule, the applicant must guarantee that they can supply orders from pharmacists within a reasonable period after receiving the orders. So, while an application for listing does not constitute infringement, it communicates a present intention to sell the product, potentially giving the patentee a right to interim relief for threatened patent infringement. In addition, listing of a generic has an immediate effect on the "approved price to pharmacist" of the reference product, which is considered difficult to reverse.

In assessing whether an interlocutory injunction should be granted, the court considers whether the patentee has an arguable case for relief and the balance of convenience. If the patentee has a good argument that the patent is infringed, and the real issue is whether it is valid, the invalidity argument would have to be very compelling to undermine the existence of an arguable case.

Important influences on the balance of convenience include the state of the market at the time of the application and whether a launch or a restraint would cause damage that cannot be compensated by a monetary award. However, where the grant of an interlocutory injunction will effectively resolve the dispute (for example, by undermining the commercial viability of a respondent's product whatever the trial outcome), the court looks more closely at the merits of the infringement and invalidity arguments when assessing the balance of convenience.

Commonly, patentees have submitted in support of applications for an interlocutory injunction that the balance of convenience favours the grant of the injunction because, if the generic is listed on the Pharmaceutical Benefits Scheme Schedule, a potentially irreversible price reduction will result, and damages will be difficult or impossible to calculate.

However, these arguments now have considerably less force because there has been a shift in the court's position when it comes to assessing the balance of convenience, based on the reasoning that the calculation of compensation under an undertaking as to damages (for an incorrectly granted interlocutory injunction) can impose burdens and raise uncertainties that are far greater than the burdens and uncertainties involved in assessing damages for infringement (*Biogen International GmbH v Pharmacor Pty Ltd* [2021] FCA 1591). In practice, this has led to an increasing willingness of the court to expedite pharmaceutical patent litigation, including stricter case management, if it will avoid the court having to determine an application for an interlocutory injunction. This development, in particular, makes early strategic planning crucial in Australian pharmaceutical patent litigation.

For more information on patent litigation in Australia, see Patent Litigation: Case Management and Discovery (Australia).

Generic Marketing Exclusivity

There are currently no laws or regulations in Australia by which a generic drug manufacturer can obtain market exclusivity.

Important Patent Litigation Considerations for Life-Sciences Inventions

Cross-Undertakings as to Damages

When a court grants an interlocutory injunction preventing launch of a generic pharmaceutical or biosimilar, the patentee or exclusive licensee invariably agrees to give the "usual undertaking as to damages." The undertaking contemplates that other parties, such as the Department of Health, may be adversely affected by the interlocutory injunction and provides these persons with an entitlement to claim compensation.

Recently, the Department of Health has made claims under these undertakings in pharmaceutical cases. Those claims have involved extensive factual and expert evidence regarding the extra cost to the Department of Health of products whose price would have been reduced, but for the preliminary injunction preventing listing of a generic on the Pharmaceutical Benefits Scheme Schedule.

Discovery

Discovery is available and common in patent litigation in Australia. The court is, however, conscious of keeping discovery within a narrow range. Parties must apply for discovery, and it is not automatic. The approach of Australian courts to discovery in patent matters is more like that in the UK than in the US. For more information on the UK disclosure requirements, see Practice Note, Disclosure: an overview.

Discovery is typically by categories in patent litigation in Australia. For example, categories may comprise financial documents relating to particular products or communications in relation to a particular topic over a defined period of time. The categories of discoverable documents must be referable to specific matters in dispute.

Discovered documents are also subject to the implied *Harman* undertaking derived from UK law, which provides that the information obtained or produced under the compulsory processes of the court cannot be used for a "collateral or ulterior purpose" unrelated to the proceedings.

For more information on discovery in Australia, see Practice Note, Patent Litigation: Case Management and Discovery (Australia).

Limitations to Expert Evidence

Independent expert evidence is an essential component of patent litigation in Australia. While the court is responsible for construing the claims of a patent and determining the issues in dispute, evidence from experts in the field of the invention provides the court with the technical knowledge and background necessary to do so.

Until recently, there had been no clear guidance on the number of experts parties can call to give evidence in a particular area of technology. Owing to the significant time and cost associated with the preparation and delivery of expert evidence, the use of multiple experts may be inconsistent with the court's prerogative to facilitate justice in a manner which is efficient and cost effective.

The trial judge can limit the number of experts on which a party may rely (*Novartis AG v Pharmacor Pty Limited* [2022] FCAFC 58). The discretion is most likely to be exercised where a party adduces evidence from more than one expert in a single subject area, particularly if the witnesses have very similar expertise, are directed to respond to similar questions, or there is overlap in the evidence given. Therefore, when selecting an independent expert for patent litigation in Australia, it is important to carefully identify and engage the most appropriate witness for the relevant area of technology.

Biological Drugs and Biosimilars

Australia's biosimilar regulatory framework is closely aligned with Europe's. The TGA has adopted some European guidelines on the nonclinical and clinical data requirements specific to biosimilar medicines as well as the guidelines on the assessment of comparability of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

Applications for inclusion of biological products on the ARTG are made to the TGA, which assesses quality, safety, and efficacy. Information about applications for inclusion on the ARTG is not publicly available.

For a biosimilar to be included on the register, the reference medicine must:

- Already be approved in Australia based on full quality, safety, and efficacy data.
- Have been marketed in Australia for a "substantial period" and have a volume of marketed use so that there is likely to be a substantial body of acceptable data regarding the safety and efficacy for the approved indications. What amounts to a "substantial period" is considered on a casebycase basis.

Practical Considerations

Divisional Applications

Divisional patent applications can be filed before either:

- The acceptance deadline (12 months after the date of the first examination report).
- Up to three months after the acceptance of the parent application is formally advertised.

In general, maintaining a pending divisional application, even if a parent application has already been accepted or granted, provides flexibility to pursue protection that may be more robust or be found to be commercially advantageous in the future.

There is no limit to the number of divisional applications that can be filed. However, it is the position of the APO that third parties are not encumbered by the eternal pendency of divisional-upon-divisional-upon-divisional (that is, daisy chaining). Therefore, where an objection is raised in the first examination report on the divisional application for the same, or substantially the same, reason as an objection that was raised in the report on the parent or other ancestor, a Supervising Examiner may review the application and recommend case management or a hearing to achieve prompt resolution. That is, the APO expects applicants to actively prosecute divisional applications of this kind.

Grace Periods

For deciding whether an invention is novel or involves an inventive step, any information made publicly available by, the nominated person or the patentee, or their predecessor in title (in particular, including the inventor), with or without their consent, by publication or use of the invention within 12 months before the filing date of a complete application, must be disregarded (section 24(1), *Patents Act 1990*). This 12-month period is referred to as the "grace period." Recent decisions from the APO (*Rozenberg & Co Pty Ltd v Velin-Pharma A/S* [2017] APO 61 and *CNH Industrial Italia S.p.A.* [2020] APO 16) and the Federal Court (*Cytec Industries Inc. v Nalco Company* [2021] FCA 970), have confirmed that the grace period provisions apply to "whole of contents" disclosures, that is, earlier filed, later published patent applications.

Post-Grant Claim Amendments

Before commencing patent infringement proceedings, a patentee should consider whether the specification or claims of potentially enforceable patents need to be amended.

Applications to amend a patent are usually made to the APO. However, if a court proceeding relating to the patent is already pending, the patent can only be amended following an application to the court that is hearing the proceeding. These applications are commonly contested and involve significant additional expense and delay. The court also has a general discretion to refuse amendments and has done so recently on the basis that the patentee knew their claims were invalid and had the opportunity to amend before enforcement (*BlueScope Steel Limited v Dongkuk Steel Mill Co., Ltd (No 2)* [2019] FCA 2117). The APO does not have this discretion. Where the APO is satisfied that any amendments made are allowable (that is, they do not broaden the scope of the accepted claims or add new matter and comply with support and sufficiency requirements), and would if made, remove the grounds on which the patent is invalid, the APO must allow the amendments.

Standing and Proper Parties

In Australia, only patentees and "exclusive licensees" have standing to sue for patent infringement. For more information on patent licenses, see Practice Note, Patent Licence Agreements (Australia). Commonly, the patentee is a foreign parent company, and the Australian business is conducted by a local affiliate.

If an interlocutory (preliminary) injunction is not obtained, the infringer is not liable to pay compensation for damage suffered by anyone other than the patentee and any exclusive licensee. To qualify as an exclusive licensee, a licensee must be conferred a licence to all forms of "exploitation" of the claimed invention throughout Australia, to the exclusion of the patentee and all other persons (*Bristol-Myers Squibb Company v Apotex Pty Ltd*

[2015] FCAFC 2). Therefore, if a local affiliate would suffer damage as a result of the infringing conduct, then that damage is not recoverable unless the relevant entity is an exclusive licensee of the relevant patents and a named party in the infringement proceedings.