Pharmaceutical IP and competition law in Australia: overview

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A Q&A guide to pharmaceutical IP and competition law in Australia.

The Q&A gives a high level overview of key issues including patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, visit *Medicinal product regulation and product liability in Australia: overview*.

Patents

1. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

Australian patent law is governed by the Patents Act 1990 (Cth) (Patents Act). The Patents Act provides for the grant of two main types of patent:

- Standard, which is the traditional form of patent protection.
- Innovation, providing shorter term protection for inventions not meeting the inventive threshold requirement for a standard patent. The innovation patent has now been abolished and is being phased out (*see below, Abolition of innovation patents*).

Unless specifically referring to one type of patent, the following applies to both types of patents.

Significant reforms to Australian patent law introduced by the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Cth) (Raising the Bar Act) raised the bar for patentability.

Higher Raising the Bar Act patentability standards apply to patents and patent applications (New Patents and New Applications).

The "old" lower pre-Raising the Bar Act patentability standards still apply to (Old Patents and Old Applications):

- Standard patents granted before 15 April 2013 or innovation patents certified before 15 April 2013.
- Patent applications filed before 15 April 2013, for which examination was requested by 15 April 2013 or applications which the Commissioner of Patents decided to examine the before 15 April 2013 (innovation patent applications only).

For an invention to be protected by a patent, it must satisfy the requirements for a "patentable invention" under section 18 of the Patents Act. Before the Raising the Bar amendments, section 18 provided that a patentable invention is one that:

- Is a "manner of manufacture" (a threshold test requiring the invention to be the appropriate subject matter for the grant of a patent).
- Is novel relative to the prior art base.
- Involves an inventive step (standard patent) or an innovative step (innovation patent) relative to the prior art base.
- For a standard patent, the invention must not be obvious to a person skilled in the relevant art, assessed in light of "common general knowledge" and relevant "publicly available" information. Common general knowledge is limited to that existing in Australia before the priority date of the claim. Publicly available information is limited to that which a person skilled in the art could reasonably be expected to have ascertained, understood and regarded as relevant before the priority date.

- For an innovation patent, the invention must satisfy the "innovative step" requirement. This involves assessing whether the invention differs from the prior art in a way that makes a substantial contribution to the working of the invention. It does not consider whether the invention is obvious.
- Is useful, meaning that at least one embodiment of the invention must achieve the result promised in the specification (commonly known as the "utility" requirement).
- Has not been commercially exploited in secret by, or with the authority of, the patentee in Australia before the priority date of the patent.

To be valid, a patent must also satisfy section 40 of the Patents Act. Before the Raising the Bar amendments, this required that the complete specification:

- Describe the invention fully (known as "sufficiency"), including the best method known to the applicant (at the time of filing) of performing the invention (known as the "best method" requirement).
- For a standard patent, end with a claim or claims defining the invention. For an innovation patent, end with at least one and no more than five claims defining the invention.

The claims must:

- Be clear and succinct and fairly based on the matter described in the specification.
- Relate to one invention only.

The Raising the Bar Act made changes to the inventive step, utility, sufficiency and fair basis requirements for patentability as follows:

- Inventive step: the reforms removed the limitations described above with respect to the scope of "common general knowledge" and "publicly available" information, meaning that a greater breadth of prior art is considered in determining whether an invention involves an inventive step.
- Utility: an invention is not considered "useful" unless "a specific, substantial and credible use" for the invention is disclosed in the complete specification.
- Sufficiency: a specification must disclose the invention in a way that is sufficiently clear and complete for it to be performed by a person skilled in the relevant art.
- Fair basis: the fair basis requirement is replaced by a "support" requirement, to align with the law of other jurisdictions. An appropriate "basis" is required in the body of the specification for each claim. The scope of a claim must not exceed what is justified by the extent of the information provided to "support" that claim.

Abolition of innovation patents

In February 2020, the Australian Government passed the Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and the Other Measures) Act 2020, which phases out the innovation patent system. The last day that a new innovation patent can be filed is 25 August 2021. Existing innovation patents and innovation patents filed before 25 August 2021 will remain in force until their expiry.

Divisional innovation patent applications can still be filed after 25 August 2021, provided the parent application was filed on or before 25 August 2021.

Standard patent applications can still be converted to innovation patent applications after 25 August 2021, provided the standard application was filed on or before 25 August 2021.

As a result, the last innovation patents will expire in about 2028.

Scope of protection

Pharmaceutical and biotechnology products, processes and methods are generally patentable, provided they meet the conditions for patentability. This includes:

- Biological materials (such as chemical molecules, monoclonal antibodies, synthesised/modified isolated polypeptides, proteins and micro-organisms) and the processes for identifying, purifying and isolating them and methods of using them. However, isolated naturally occurring DNA or RNA (coding and non-coding, probes and primers, interfering RNA, isolated interfering/inhibitory nucleic acids and synthetic nucleic acids) are not patentable if they merely replicate the genetic information of naturally occurring organisms (*D'Arcy v Myriad Genetics Inc.& Anor [2015] HCA 35, High Court of Australia*).
- Medical devices.
- Methods of medical treatment involving a new use of a pharmaceutical product, as confirmed by the High Court of Australia in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd [2013] HCA 50*. However, methods of medical treatment not involving use of a pharmaceutical product, such as surgical and other physical procedures used by doctors to treat patients, may still fall outside the scope of patentable subject matter.
- Diagnostic methods were confirmed as patent-eligible subject matter by the Federal Court of Australia in *Sequenom, Inc. v Ariosa Diagnostics, Inc. [2019] FCA 1011*. This decision has been appealed to the Full Federal Court and the hearing occurred in June 2020 (though a final decision has not yet been issued).

Human beings, and the biological processes for their generation, are not patentable inventions (*section 18(2), Patents Act*).

Plants and animals, and the biological processes for their generation, are not patentable inventions for an innovation patent, unless the invention is a microbiological process or a product of such a process (*section 18(3), Patents Act*).

2. How is a patent obtained?

Application and guidance

Applications are made to IP Australia. IP Australia provides guidance on the application process at *www.ipaustralia.gov.au/patents*.

Applications should include:

- A title.
- A description to fully describe the invention, so that others can reproduce it from the information given and provide the best method of performing the invention.
- Up to five claims for innovation patents and any number of claims for standard patents. The claims should clearly define what patent protection is being sought, and must set out the essential features of the invention to establish its inventiveness.
- Drawings or figures (if applicable). These should help describe the invention and must be clearly labelled and described in the body of the specification.
- An abstract. A brief summary of the invention to identify the key features.
- Application forms and filing fee.

IP Australia's fees are available at *www.ipaustralia.gov.au/patents/understanding-patents/time-and-costs*.

Australia is also a contracting state of the Patent Co-operation Treaty (PCT). To obtain a patent in Australia, an applicant can file an international application under the PCT designating Australia, and then enter the National Phase in Australia within 31 months of the earliest priority date of the application.

Process and timing

The application process can begin by filing a complete application or a provisional application (in which case a complete application must be filed within 12 months to keep the priority date).

An application for a standard patent then proceeds as follows:

- The application is published about 18 months after the application's earliest priority date.
- A request for examination can be made by the applicant within five years of the filing date. If a request for examination has not been made by about 55 months from the earliest priority date, IP Australia will direct the applicant to request examination. The applicant will then have two months to request examination.
- Following the request for examination, the patent examiner can issue a notice that the standard patent application has been accepted, or an adverse report identifying any lawful grounds of objection. The applicant can respond to the adverse report. Further reports can be issued to which further responses can be filed. Once the patent examiner is satisfied that there are no outstanding issues, the application is accepted. For Old Applications, the application will lapse if it is not accepted within 21 months of the first adverse report. For New Applications, the application will lapse if it is not accepted within 12 months of the first adverse report.

After a complete application is accepted, interested third parties can oppose the grant on certain specified grounds, within three months of publication of acceptance of the application in the *Australian Official Journal of Patents* (AOJP).

If an opposition is made, both parties can file evidence (including expert evidence), and a hearing officer at IP Australia will hold a hearing with both parties to decide whether the opposition succeeds. If it does, the applicant

will usually be given an opportunity to amend the application to overcome any ground of opposition upheld, so that the patent may still be granted.

An appeal against an opposition decision must be made to the Federal Court of Australia.

If no opposition is filed or the opposition is unsuccessful, the accepted standard application is granted.

The current application process for an innovation patent is as follows:

- Within a couple of weeks of filing the application, IP Australia will conduct a simple formalities check to ensure the application is in order. IP Australia does not assess whether the patent is valid. If the application passes the formalities check, the innovation patent will be granted. However, an innovation patent cannot be enforced until it has been examined and certified.
- The unexamined innovation patent is then published at grant.
- The patentee or a competitor can request examination of the innovation patent.
- Following a request for examination, the patent examiner can issue a notice that the innovation patent has been certified or an adverse report. The patentee can respond to the adverse report. Further reports can be issued to which further responses can be filed. Once the patent examiner is satisfied that there are no outstanding issues, the innovation patent is certified. If the innovation patent is not certified within six months of the first report, it ceases.
- Once an innovation patent is certified, interested third parties can commence opposition proceedings and if successful, the innovation patent may be revoked.

An innovator may be able to delay or restrain a generic company from listing their product on the Pharmaceutic Benefits Scheme (PBS) and launching their product, after it has been granted regulatory approval, by obtaining an interlocutory injunction. The generic company's ability to list on the PBS and launch their product is subject to any patent proceedings to determine issues of potential infringement and invalidity.

3. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

The term of a standard patent from its effective filing date is either:

- 20 years.
- Up to 25 years for particular standard patents relating to pharmaceutical substances.

(*sections 67 and 70, Patents Act*.)

The term of an innovation patent is eight years from its effective filing date (*section 68, Patents Act*).

Annual renewal fees are payable from the fourth anniversary of the filing date for a standard patent, and from the second anniversary for an innovation patent. Renewal fees are detailed at *www.ipaustralia.gov.au/patents/understanding-patents/time-and-costs*.

Extending protection

A patentee can apply for an extension of up to five years of the term of a standard patent where the following conditions are satisfied (*section 70, Patents Act*):

- The patent includes at least one claim covering one or more pharmaceutical substances per se (as distinct from a pharmaceutical substance that forms part of a method or process), or one or more pharmaceutical substances when produced by a process involving the use of recombinant DNA technology.
- Goods containing, or consisting of, the pharmaceutical substance must be included in the ARTG.
- The first regulatory approval for the pharmaceutical substance must have occurred more than five years after the effective filing date of the patent.
- The term of the patent has not previously been extended.
- The term of a Swiss-form patent cannot be extended.

The term of the extension is the period between the effective filing date of the patent and the first regulatory approval date, reduced by five years. For example, if the date of the patent is 1 January 2010, and the first date of regulatory approval is 1 January 2017, the patent term extension would be two years.

No further extensions for a standard patent are possible.

The term of an innovation patent cannot be extended.

Early Notification Scheme

The Australian Government has proposed an earlier notification scheme as one of its new transparency measures for prescription medicines.

Under legislative changes which are likely to be introduced to Parliament in late 2020, applicants for the first generic or biosimilar of an originator product will have to notify the patentee when their application is accepted for evaluation by the Therapeutic Goods Administration (TGA). The intention behind this change is to encourage early negotiation and resolution of potential patent infringement and invalidity disputes before a generic of a biosimilar medicine is included on the PBS, to reduce litigation.

4. How can a patent be revoked?

After IP Australia examines and accepts an application, grant of a patent can be opposed by a third party (*see Question 2*).

After a patent is granted, it can be revoked in whole or in part by a prescribed court (usually the Federal Court of Australia) or the Commissioner of Patents. Any person can apply to a prescribed court for an order revoking a patent (*section 138, Patents Act*).

A defendant in infringement proceedings can file a counterclaim in the proceedings to revoke the asserted patent (*section 121, Patents Act*).

A patent can be revoked in whole or part by a prescribed court on any of the following grounds:

- The patentee is not entitled to the patent.
- The invention is not a patentable invention under section 18 of the Patents Act.
- The specification does not satisfy the requirements of section 40 of the Patents Act.
- The patent was obtained by fraud, false suggestion or misrepresentation.
- An amendment of the patent request or the complete specification was made or obtained by fraud, false suggestion or misrepresentation.

A person cannot apply to the court for an order revoking an innovation patent unless the innovation patent has been certified.

A standard patent can be revoked by the commissioner on receipt of an adverse report following re-examination (*section 101, Patents Act*). An innovation patent can be revoked by the commissioner on receipt of an adverse report following examination (*section 101F, Patents Act*) or re-examination (*section 101J, Patents Act*).

Old Patents (*see Question 1*) can be revoked in whole or part by the commissioner following re-examination on only limited grounds. Those grounds are that, when compared with the prior art base before the priority date, the invention either:

- Is not novel.
- Lacks an inventive step (standard patent).
- Lacks an innovative step (innovation patent).

A New Patent (*see Question 1*) can be revoked by the commissioner following re-examination on much broader grounds, including that:

- There is a lack of sufficiency or support (*sections 40(2) and (3), Patents Act*).
- The invention is not a manner of manufacture, is not novel or does not involve an inventive step (standard patent) or innovative step (innovation patent) compared to the prior art base before the priority date, or is not useful (*sections 18(1) and (1A), Patents Act*).
- The invention is not a patentable invention (*sections 18(2) and (3), Patents Act*).

Following the examination of an innovation patent, the commissioner must revoke the patent if he or she considers that a ground for revocation of the patent has been made out and that ground has not been removed (*section 101F, Patents Act*). The grounds on which the Commissioner can revoke an innovation patent following examination include, among other things (*section 101B, Patents Act*):

- The specification does not comply with sections 40(2) to (4) of the Patents Act.
- The invention is not a manner of manufacture.
- The invention is not novel when compared with the prior art base.
- The invention lacks an innovative step when compared with the prior art base.
- The invention is not a patentable invention (*sections 18(2) and (3), Patents Act*).
- The use of the invention would be contrary to law.

5. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

The Patents Act does not define infringement. However, a patentee is granted the exclusive right to exploit the patented invention and authorise another person to exploit that invention in Australia (*section 13, Patents Act*). Exploit is defined to include:

- Where the invention is a product:
    - making, hiring, selling or otherwise disposing of the product;
    - offering to make, sell, hire or otherwise dispose of the product;
    - using or importing the product; or
    - keeping the product for the purpose of doing any of those things.
- Where the invention is a method or process, using the method or process, or any action in the first bullet point above relating to a product resulting from the method or process.

Generally, a patent is infringed when a person exploits a patented invention or authorises another to do so in Australia without the licence or authority of the patentee. However, the exclusive rights of a patentee are limited during the extended term of a pharmaceutical patent to exploitation of the pharmaceutical substance per se for therapeutic use (*section 78, Patents Act*).

A patent claim can also be infringed indirectly or contributorily by supplying a product in circumstances where use of that product would infringe a patent (*section 117, Patents Act*).

A patent can be infringed by conduct after the publication date of the complete specification, although proceedings can only be brought after the patent has actually been granted (*section 57, Patents Act*).

The "old" pre-Raising the Bar Act included a "springboarding" provision that the "exploitation of an invention solely for the purpose of obtaining regulatory approval of goods intended for therapeutic use will not amount to infringement". The 2012 Raising the Bar Amendments introduced two additional exemptions to patent infringement:

- Widening the "springboarding" provision to any exploitation of a patent to obtain regulatory approval (not just of goods intended for therapeutic use) (*sections 119A and 119B, Patents Act*). This exemption is not intended to permit a person to manufacture the patented product for export to another country, or to stockpile the patented product for sale on expiry of the patent.
- An experimental exemption that carves out acts done predominantly for experimental purposes related to the subject matter of the invention (*section 119C, Patents Act*). These acts include tests, trials and procedures that a researcher or follow-on innovator may perform in testing principles or discovering new information. Market research on a patented invention to test the commercial demand of a product is not exempt under this section, as the purpose of such research is predominantly commercial.

The Patents Act also contains an exemption for prior use, being continuous exploitation of, or definite steps taken to exploit, the relevant product, method or process that occurred immediately before the priority date of the relevant claim (*section 119, Patents Act*).

Claim and remedies

Patent infringement proceedings can be commenced in any prescribed court but the Federal Court of Australia is the most common forum.

A first instance decision can be appealed to the Full Federal Court of Australia (usually comprised of three judges). There is a further right of appeal, with special leave, to the High Court of Australia.

A patent is infringed if the allegedly infringing product, process or method includes all of the essential features (integers) of the asserted claim. In assessing this, the court uses a purposive approach to construe the claim. Words are read in their proper context, having regard to the body of the patent specification.

Remedies available to a patentee include:

- Declarations of infringement by the court.
- Injunctions (including interlocutory injunctions pending final trial) and ancillary orders.
- Damages (which can include additional or exemplary) or an account of profits, at the election of the patentee.

- Additional damages at the court's discretion, having regard to a range of factors such as the flagrancy of the infringement, the need to deter similar infringements, any benefit obtained by the infringer and the infringer's conduct.
- Delivery up or destruction where the alleged infringer still has infringing goods in their possession.
- Legal costs.

A successful infringement claim, especially in the case of pharmaceutical patents, may deter others from entering the market before the expiry of the patent.

Dispute resolution and settlement

The Civil Dispute Resolution Act 2011 requires a party bringing a claim in the Federal Court to take "genuine steps" to resolve a dispute before bringing proceedings. When commencing proceedings, a claimant must file a Genuine Steps Statement, setting out the steps taken to resolve the dispute before commencing proceedings.

In a patent infringement dispute, this typically requires, at minimum, the patentee to write to the alleged infringer setting out the allegations of infringement and specifying the action required (such as providing undertakings to cease infringing conduct, and/or pay damages). However, even this step may not be required where proceedings are urgent.

The intention of this procedure is to encourage the parties to resolve their dispute without commencing proceedings.

Once proceedings are begun, the court can refer matters to mediation. The court will consider whether matters are suitable for mediation on a case-by-case basis. Mediation is typically conducted by a court registrar, or the parties can appoint an agreed private mediator.

The parties can also engage in settlement negotiations of their own accord at any time during the proceedings.

There are no specific rules or legislation on settlement agreements. Before 13 September 2019, certain conduct related to intellectual property rights was exempted from aspects of Australian competition law. This exemption no longer applies, so any settlement agreement will be subject to Australian competition law (*see below, IP and competition law issues*).

Relevant international patent instruments and processes

Australia is a party to the following international instruments:

- Paris Convention for the Protection of Industrial Property 1883 (Paris Convention). Under the Paris Convention, an applicant can file a patent application in Australia, claiming priority from an application filed within the previous 12 months in any other contracting state.
- Patent Cooperation Treaty 1970 (PCT), allowing applicants to seek patent protection in Australia by filing an international application under the PCT.
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977 (Budapest Treaty). Australia recognises micro-organism deposits made under the Budapest Treaty.

- Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS Agreement). Australia's patent laws meet the minimum requirements set out under the TRIPS Agreement.

6. Are there non-patent barriers to competition that protect an originator's monopoly over an authorised medicinal product?

A data exclusivity period protects particular medicinal products, under section 25A of the Therapeutic Goods Act 1989 (Cth) (TG Act). The Secretary of the Department of Health (Secretary) must not use protected information about another therapeutic good when evaluating a new therapeutic good for registration. Information is protected information if it meets the following criteria (*section 25A(2), TG Act*):

- It concerns an active component of a therapeutic good (not a therapeutic device) (new good), and was given to the Secretary in an application to register the new good.
- It is not in the public domain and the sponsor has not given written permission for the Secretary to use the information.
- When the application to register the new good was lodged, no goods containing that active component were (or had ever been) included in the ARTG.
- Five years have not passed since the day the new good became registered.

An active component is a substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods (*section 25A(3), TG Act*).

No additional data exclusivity periods are available, such as for information relating to a new indication.

Although Australia has an orphan drugs regime, it does not include a period of marketing exclusivity.

7. Are any restrictions placed on licensing or transferring patents to foreign parties? Are intellectual property transfers for inventions funded, or partially funded, by public investment restricted?

There are no specific legislative restrictions on licensing or transferring patents to foreign parties. However, certain acquisitions of interests in Australian businesses, or the assets of Australian businesses, may be subject to review under the Foreign Acquisitions and Takeovers Act 1975. Such a review is unlikely to be triggered unless the value of the transaction is very high (over AUD275 million). However, much lower thresholds apply in certain sectors, such as media and agribusiness.

There are also no legislative restrictions on transfers of publicly funded inventions.

Trade marks

8. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Legislation and scope of protection

Australian trade mark law is governed by the Trade Marks Act 1995 (Cth) (TM Act). To qualify as a trade mark, a "sign" must be used or intended to be used as a trade mark and must be capable of distinguishing goods or services dealt with or provided in the course of trade (*section 17, TM Act*). A sign includes a word, device, brand, aspect of packaging, label, shape, colour, sound, scent or any combination of these.

An application for a trade mark will be rejected if:

- The trade mark contains or consists of certain prohibited or prescribed signs (*section 39, TM Act*).
- The trade mark cannot be represented graphically (*section 40, TM Act*).
- The trade mark is not capable of distinguishing the applicant's goods or services for which the trade mark is sought from the goods or services of other persons (*section 41, TM Act*).
- The trade mark contains or consists of scandalous matter or its use would be contrary to law (*section 42, TM Act*).
- Use of the trade mark in relation to the goods or services for which it is sought would be likely to deceive or cause confusion because of some connotation of the trade mark (*section 43, TM Act*).
- The trade mark is substantially identical or deceptively similar to an earlier trade mark application or registration and the goods or services of both are the same, similar or closely related (*section 44, TM Act*).

There is no legislative protection for unregistered trade marks. However, where a trade mark owner has established a reputation in a trade mark, the owner may be able to take action against another party using the same or a similar trade mark, on any of the following grounds:

- The other party is passing off their goods as the goods of the trade mark owner.
- Use of the trade mark by the other party is misleading or deceptive conduct, or makes false representations prohibited under Australian consumer protection law.

Rights granted

The rights given by registration of a trade mark are (*section 20, TM Act*):

- The exclusive right to use the trade mark and to authorise other persons to use the trade mark.
- The right to obtain relief (including declaratory, injunctive and compensatory relief) under the TM Act if the trade mark has been infringed.

Trade mark rights are (on registration) backdated to the priority date (the date of the application). Where the trade mark is registered subject to conditions or limitations, the rights of the registered owner are restricted by those conditions or limitations.

General conditions and specific rules for naming medicines

For what can and cannot be registered as a trade mark generally, see above, *Conditions and legislation*. More specifically to medicinal products, the following can be registered, provided they satisfy the application requirements:

- A medicinal brand.
- The appearance of the medicinal product itself, including any distinctive shape or colour or colour combination of a tablet or capsule, or other delivery system such as a syringe or inhaler.
- The distinctive aspects of packaging.

The brand name of a medicinal product is likely to be rejected as a trade mark if:

- It is identical or deceptively similar to a notified International Non-proprietary Name (INN) or a notified INN stem and is therefore not distinctive.
- Use of the name would be misleading.

The Trade Mark Office has adopted a stricter stance on INN Name and INN Stem related objections in recent years.

9. How is a trade mark registered?

Application and guidance

Applications are made to IP Australia. Details on the application process are available at *www.ipaustralia.gov.au/trade-marks*.

IP Australia's fees are available at *www.ipaustralia.gov.au/get-the-right-ip/trade-marks/time-and-costs/fees*.

The authors are only aware of the TGA reviewing trade marks in the context of assessing additional trade names for prescription medicines. The TGA does not otherwise check trade mark applications filed with IP Australia.

Process and timing

Applications must be made in the prescribed form, which must specify the goods and/or services for which the applicant wishes to register the trade mark.

Applications are examined in order of filing. The period of time taken between filing and examination varies according to the number of applications lodged. Expedited examination is possible if there is good reason.

When the application is examined, it is assessed to determine whether it satisfies the TM Act. If it does, it will be accepted for registration. If not, a report is sent to the applicant setting out any requirements that need to be addressed.

The TM Act allows 15 months (extendable) from the date of the examiner's first report to meet any requirements set out by the examiner and to have the application accepted. If a trade mark application is not accepted and it runs out of time, it will lapse.

Trade mark applications are displayed online shortly after they are lodged, at *https://search.ipaustralia.gov.au/trademarks/search/quick*. Once a trade mark is accepted for registration, the details are advertised in the *Australian Official Journal of Trade Marks* (AOJTR).

Any person can oppose the registration within two months from the date of advertising of acceptance in the AOJTR. The registration can be opposed on any of the grounds on which an application for trade mark registration can be rejected, other than that it cannot be represented graphically.

Registration can also be opposed on the following grounds:

- The applicant is not the owner of the trade mark (*section 58, TM Act*).
- The opponent first used, and has continuously used, a substantially identical or deceptively similar trade mark for similar or closely related goods or services, before the applicant's first use (*section 58A, TM Act*). This ground is only available if the prior mark was cited by the registrar as an objection and the applicant overcame with evidence of prior continuous use.
- The applicant does not intend to use the mark (*section 59, TM Act*).
- Use of the mark may confuse or deceive due to another mark that has acquired a reputation in Australia (*section 60, TM Act*).
- The trade mark contains or consists of a false geographical indication (*section 61, TM Act*).
- The application or a document filed in support of it was amended contrary to the TM Act, or the registrar accepted the application based on evidence or representations that were false in material details (*section 62, TM Act*).
- The application was made in bad faith (*section 62A, TM Act*).

If no opposition is filed or the opposition is unsuccessful, the trade mark will be registered two months after it is advertised.

10. How long does trade mark protection typically last?

The initial registration period is ten years from the filing date. Registration of a trade mark can be renewed indefinitely for successive periods of ten years, on payment of a renewal fee. It is not necessary to provide evidence of trade mark use to renew a trade mark registration.

11. How can a trade mark be revoked?

A trade mark can be revoked by the registrar (*section 84A, TM Act*) or by a prescribed court (*sections 86-88, TM Act*).

The registrar can revoke the registration if the registrar believes "the trade mark should not have been registered" and it is reasonable to do so (*section 84A, TM Act*).

Applications to remove a trade mark from the Register for non-use, in relation to all or some of the goods or services for which the trade mark is registered, can be made on the grounds that the registered owner either:

- Had not used the trade mark in Australia or had not used it in Australia in good faith, and did not intend on the trade mark application date to, in good faith, use, authorise the use of, or assign the trade mark to a body corporate.
- Has not used the trade mark in Australia or has not used it in Australia in good faith, for a continuous period of three years ending one month before the day on which the non-use application was filed, providing it has been at least either:
    - five years since the filing date of the trade mark registration, if the trade mark was filed before 24 February 2019 (*sections 92 and 93, TM Act*); or
    - three years since the filing date of the trade mark registration, if the trade mark was filed after 24 February 2019 (*sections 92 and 93, TM Act*).

An aggrieved person can apply to a prescribed court (most revocation actions are commenced in the Federal Court of Australia) to rectify the register by cancelling or revoking the trade mark registration, or removing or amending an entry wrongly made in the register on various grounds, including:

- A condition or limitation entered in the register in relation to the trade mark has been breached (*section 86, TM Act*).

- The trade mark has become generic because it contains or consists of a sign that has become generally accepted in the relevant trade as the sign that:
    - describes or is the name of an article, substance or service; or
    - is the only commonly known way to describe or identify an article formerly exploited under a patent, or a service formerly provided as a patented process, where the patent has expired more than two years ago (*section 87, TM Act*).
- Any of the grounds on which the registration of the trade mark could have been opposed (*section 88, TM Act*).
- An amendment of the application for the registration was obtained due to fraud, false suggestion or misrepresentation (*section 88, TM Act*).
- Use of the mark is likely to deceive or cause confusion (*section 88, TM Act*).
- If the application relates to an entry in the register, the entry was made, or has been previously amended, due to fraud, false suggestion or misrepresentation (*section 88, TM Act*).

12. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions required to prove infringement

The rights of a registered trade mark owner are infringed if, without the owner's authorisation, another person uses, as a trade mark, a sign substantially identical or deceptively similar to the registered trade mark for (*section 120, TM Act*):

- Goods or services for which it is registered.
- Goods or services of the same description as those for which the mark is registered.
- Services closely related to goods for which the mark is registered.
- Goods closely related to services for which the mark is registered.
- Goods or services unrelated to those for which the mark is registered, if the mark is so well known that the alleged infringing mark is likely to indicate a connection with the owner of the well-known mark, and the owner's interests are likely to be adversely affected.

Claim and remedies

An action for infringement of a registered trade mark can be brought in a prescribed court. Most actions are commenced in the Federal Court of Australia, which can order:

- Declarations that a trade mark has been infringed.
- Injunctions (including interlocutory injunction orders pending final trial) and ancillary orders.
- Delivery up orders.
- Damages (which can include additional or exemplary) or an account of profits, at the election of the trade mark owner.
- Legal costs.

Dispute resolution and settlement

The considerations are similar to those for patents (*see Question 5, Dispute resolution and settlement*).

Relevant international trade mark instruments and processes

Australia is a party to the:

- Paris Convention. Under the Paris Convention, an applicant can file a trade mark application in Australia, claiming priority from an application filed in the previous six months in any other contracting state.
- The WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol). This allows applicants to seek trade mark protection in Australia by filing an international application under the Madrid system.
- The Nice Agreement. Australia follows the Nice classification for goods and services in trade mark applications.
- TRIPS Agreement. Australia's trade mark laws meet the minimum requirements set out under the TRIPS Agreement.

13. Outline the regulatory powers and enforcement action against counterfeiting in the pharmaceutical sector.

Enforcement of trade mark rights is usually carried out through civil actions. Police authorities, especially the Federal Police, can pursue criminal actions but they are rare. Suspected counterfeit medicines and medical devices can be reported to the TGA, which works with the relevant police department to investigate.

Owners of Australian registered trade marks can lodge a notice of objection with the Australian Border Force within the Australian Department of Home Affairs (Customs). Customs can seize suspected infringing or counterfeit goods imported through a border control point if a notice of objection is in place.

The importer can surrender the goods and this usually occurs in the case of counterfeit goods. If the importer seeks to have the seized goods released, Customs will issue a notice to the trade mark owner, who must then commence a civil action within ten days to prevent the goods from being released.

IP and competition law issues

> 14. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector. In particular, the competition authorities and their regulatory powers, key legislation, whether pharmaceutical investigations are common, key recent activity and case law.

Competition law

Australian competition/anti-trust laws are set out in the Competition and Consumer Act 2010 (Cth) (CCA). It is administered and enforced by an independent statutory authority, the *Australian Competition and Consumer Commission (ACCC)*.

The CCA's anti-competitive conduct prohibitions apply to virtually all businesses in Australia, including in the pharmaceutical sector. Most relevantly, the CCA regulates the following conduct:

- Mergers or acquisitions that have the effect of substantially lessening competition (*section 50, CCA*).
- Exclusive dealing, which is the imposition of various vertical restraint practices, and is prohibited if it has the purpose, or likely effect, of substantially lessening competition (*section 47, CCA*).
- Resale price maintenance, where a wholesaler specifies a minimum resale price to a retailer (*section 48, CCA*).
- Contracts, arrangements, understandings or concerted practices between corporations that have the purpose, or likely effect, of substantially lessening competition in a relevant market (*section 45, CCA*).
- A corporation with a substantial degree of market power engaging in conduct that has the purpose, or likely effect, of substantially lessening competition (*section 46, CCA*).
- Cartel behaviour, including price fixing, restricting outputs in the production and supply chain, market sharing and bid rigging (*section 45AD, CCA*).

In some circumstances, the CCA imposes criminal penalties for cartel behaviour, including jail terms for individuals.

Significant new risks

From 13 September 2019, with the repeal of the section 51(3) safe harbour exemption for licensing arrangements, all IP arrangements are subject to scrutiny for breach of the CCA, including cartel prohibitions.

There is no grandfathering of the repeal for existing IP licences. All IP licences made before or after the repeal are subject to the full operation of Australian competition law.

Licence conditions which breach competition law are void and unenforceable and expose the parties to heavy penalties.

Licensing arrangements in respect of patents, registered designs, copyright or eligible circuit layouts are now subject to the full operation of Australian competition law.

The following types of conditions in an IP licensing arrangement are now potentially subject to competition law:

- Exclusivity conditions which give only the licensee a sole or limited right to use IP.
- Restrictions on the licensee being able to supply in specific geographic areas, or to specific classes of customers or for specific uses.
- Restrictions on when the licensee can supply products under licence.
- Price restrictions for goods or services produced under licence.
- Restrictions on the licensee from acquiring goods or services form a third party.

More generally, any IP licence conditions that are either of the following are subject to the full scrutiny of the ACCC under the CCA:

- Having the purpose, effect or likely effect of substantially lessening competition in a market in Australia.
- Requiring the acquisition by the licensee of goods or services from specified third parties (to the extent such requirement has the purpose or likely effect of substantially lessening competition).

Cartel risk

There is now the risk that licensing arrangements between competitors may constitute cartel conduct.

If the parties to the licensing arrangement compete with each other, or would be competitors but for the term of the licensing arrangement, conditions which set prices, limit sales or allocate customers could constitute cartel conduct.

ACCC Guidelines

The ACCC has set out in guidelines six general principles that will inform its approach to enforcement of potentially anti-competitive licence conditions:

- IP rights and competition law are not in conflict. In particular, the ACCC acknowledges that IP rights confer exclusive rights on rights holders, and that the bare exercise of these exclusive rights will not have significant anti-competitive implications.

- IP rights do not always create substantial market power. Therefore, even where ownership of an IP right is a key determinant of a firm's market power, this will not of itself breach the CCA.
- Licensing or assignment of IP rights usually encourages competition, and enables IP to be exploited to a greater extent than would otherwise occur.
- Licensing arrangements can have the purpose, effect or likely effect of substantially lessening competition and breach the CCA. In assessing whether conduct substantially lessens competition, the ACCC focuses on the impact of the conduct on the competitive process.
- When assessing the effect or likely effect of conduct on competition, the ACCC will usually apply a with or without test. This test compares the likely state of competition with the relevant conduct to the likely state of competition without it (for example, comparing when a licence is in place to when there is no licence).
- The ACCC will assess whether conduct has the purpose, effect or likely effect of substantially lessening competition at the time the conduct occurs. For example, for the purposes of section 45 of the CCA, the ACCC will consider the purpose, effect or likely effect of a provision of contract, arrangement or understanding, both at the time it was made and at the time at which it was given effect.

Misuse of market power prohibition

Changes were made to the misuse of market power prohibition by the Competition and Consumer Amendment (Misuse of Market Power) Act 2017 (Cth). The changes were based on a competition policy review (Harper Review) concluded in 2015, which recommended bringing the misuse of market power prohibition into line with the other provisions in Part IV of the CCA.

The changes expand the reach of section 46 and make it easier to prove a breach. The three key changes are:

- Expanding section 46 to include the standard Part IV effects test (in addition to the existing purpose test). The ACCC asked for this change because it is difficult for it to prove the subjective purpose of an accused.
- Removing the "take advantage" limb. This makes it more difficult for a firm with market power to defend its actions. The taking advantage limb traditionally provided comfort to firms engaging in conduct that would be a rational business strategy even for a firm without substantial market power. The removal of this limb in favour of exclusive reliance on the standard Part IV substantial lessening of competition test expands the reach of the prohibition, and places significant importance on the interpretation of that test.
- Introducing the standard Part IV substantial lessening of competition test in place of proscribed anti-competitive purposes. A key issue is whether there is sufficient certainty when applying this test to misuse of market power. The Harper Review recommended requiring courts to have regard to specific factors that increase or lessen competition, including efficiency, innovation, product quality or price competitiveness. Although those factors were included in the first version of the Bill to implement the changes, they were removed during the parliamentary process. In the authors' view, the factors do not alter the nature of the test. Existing jurisprudence establishes that the test requires a comparison of the state of competition in the relevant market with and without the conduct, including pro-competitive and anti-competitive factors.

The ACCC released Guidelines on misuse of market power on 31 August 2018. The Guidelines include examples of conduct that the ACCC considers is likely to raise concerns under a substantial lessening of competition test. One

example involves the bundling of a competitive drug with a monopoly/patented drug. This signals that the ACCC may closely scrutinise the conduct of patent holders for pharmaceutical products under the new prohibition.

The ACCC has power to grant authorisation in relation to conduct under section 46, through changes introduced in the Competition and Consumer Amendment (Competition Policy Review) Act 2017 (Cth). The ACCC can authorise conduct to which the misuse of market power prohibition applies based on a public benefit test (which requires that public benefits outweigh public detriments, including any lessening of competition). This change standardises section 46 with other provisions of Part IV. However, the time and cost associated with an authorisation application means that significant forward planning and investment would be required by firms with substantial market power seeking to rely on authorisation to engage in conduct that could lessen competition.

On 6 December 2019, the ACCC commenced proceedings against Tasmanian Ports Corporation Pty Ltd in the Federal Court (the first proceedings brought under the amended section 46 prohibition).

15. Briefly outline the competition issues that can arise in relation to commercial contracts and other business arrangements relating to medicinal products? What compliance issues do parties to pharmaceutical technology licences and pharmaceutical distribution agreements need to consider?

Patent licensing conditions can trigger competition issues, especially where they restrict the commercial freedom of licensees. For example, competition law advice should be sought where licences, or particular favourable prices/terms of licences, are given in return for undertakings from the licensee that either:

- Could limit its ability to effectively compete with the licensor, in particular, imposing obligations or restrictions on the licensee relating to:
    - pricing;
    - the licensee's output (such as restricting the licensee's supply volumes for a particular product);
    - dividing the market (as between the licensee and licensor); and
    - rigging bids.
- Require the licensee to also purchase additional products or licences from the licensee or a third party.

Explicitly or constructively refusing to grant licences for essential products or technology can also trigger competition issues. Unlike the equivalent abuse of dominance legislation in the US, Australian law has not been used to provide access to patents where a patent owner refuses to grant a licence. The extent to which Australian competition law can be used in this way is debated. It is still a material risk to patents holders that should be factored into licence negotiations and patent strategy.

Competition issues may also arise if competitors for the supply of pharmaceutical products take steps to share competitively sensitive information with each other (such as details of pricing and customer information). Businesses should be aware of these risks when entering into commercial arrangements with each other.

When entering into supply and distribution arrangements, businesses should be aware that stopping resellers from advertising, displaying or selling goods from the supplier below a specified price may breach the CCA (though a supplier can provide a reseller with a recommended resale price (RRP) list).

16. Are there competition issues associated with the entry of generic pharmaceuticals in your jurisdiction?

On patent expiry and the entry of generics, previous patent holders must ensure that any commercial strategies to maintain market share, where they have significant market power, do not breach competition law.

In addition to misuse of market power and exclusive dealing issues concerning rebate programmes, other competition issues can arise from patent holders strategies to resist, or reduce incentives for, generic entry:

- **Patent settlements.** These include "pay-for-delay" strategies, where patent holders settle litigation with prospective generics over questionable patents, on terms including that generic manufacturers stay out of the relevant market. Though not yet considered by Australian courts, they are as likely to be found in breach of competition laws in Australia as they have in other jurisdictions. The Productivity Commission recommended in its Report on Australia's Intellectual Property Arrangements of 2016 a system for reporting and monitoring settlements between originator and generic pharmaceutical companies, to detect potential pay-for-delay agreements. It has received in principle support from the Australian Government.
- **Deals with manufacturers of precursor materials.** When patents expire, patent holders should ensure that any contracts with manufacturers of precursor materials do not lock up percentages of the market for that precursor material, so preventing a generic from entering the downstream market for the pharmaceutical.
- **Licensing of associated process patents.** Withholding patents associated with, or necessary for, manufacturing generic products after expiry of most core product patents may be considered a misuse of market power.

17. Have abuse of dominance issues arisen in the pharmaceutical sector in your jurisdiction?

To date, the *ACCC v Pfizer* (Pfizer) case is the only instance where abuse of dominance issues have arisen in proceedings brought by the ACCC concerning participants in Australian pharmaceuticals markets. No proceedings under the new abuse of dominance provision (section 46 of the CCA) (*see Question 14*) have been brought by the ACCC.

In *Pfizer*:

- The ACCC brought proceedings in the Federal Court of Australia against Pfizer Australia Pty Ltd, for alleged misuse of market power and exclusive dealing in relation to its supply of atorvastatin to pharmacies, in breach of sections 46 and 47 of the CCA.
- The ACCC alleged that Pfizer offered significant discounts and payment of rebates previously accrued on sales of Pfizer's Lipitor (Pfizer's originator brand of atorvastatin) conditional on pharmacies acquiring a minimum volume of up to 12 months' supply of Pfizer's generic atorvastatin product. The ACCC alleged that the offers were first made before Pfizer's loss of patent protection for the atorvastatin molecule in 2012.
- In February 2015, Justice Flick dismissed the ACCC's application. His Honour found that while Pfizer had taken advantage of its market power by engaging in the alleged conduct, Pfizer's market power was no longer "substantial" at the time the offers were made in January 2012. His Honour also found that the ACCC had failed to show that Pfizer had pursued its conduct for the proscribed purpose of deterring or preventing competitors from engaging in competitive conduct, or for the purpose of substantially lessening competition.
- In May 2018, the Full Court of the Federal Court of Australia dismissed the ACCC's appeal.
- In October 2018, the High Court dismissed the ACCC's application for special leave to appeal the Full Federal Court decision.

18. Have parallel imports of pharmaceuticals raised IP and competition law issues in your jurisdiction?

Parallel imports of pharmaceuticals have not raised IP and competition law issues in Australia. However, the ACCC has considered the parallel imports issue in a number of significant Australian competition law cases in the grocery and recorded music sectors. As such, the ACCC is familiar with the economic arguments and bringing cases to trial in the context of parallel imports.

19. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? Are there any formalities or other requirements that must be complied with to make the licence enforceable?

A patent or trade mark licence agreement and payment of royalties under it to a foreign licensor do not have to be approved or accepted by a government or regulatory body. However, the particulars of a licence can be recorded on the relevant IP Australia register.

There may be tax consequences for the remission of royalties and specific advice should be sought in this area.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, see *Medicinal product regulation and product liability in Australia: overview*.

Contributor profiles

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Areas of practice. Head of DLA Piper's Life Sciences practice across the Asia-Pacific and in Australia and leads DLA Piper's Life Sciences Intellectual Property and Regulatory practices in Australia; pharmaceutical, bioscience and medical technology patent litigation and advice; IP; pharmaceutical, bioscience and medical technology regulation; biotechnology and life sciences.

Recent transactions.

- Offers a level of experience unique to the Australian market, being both a US attorney and an Australian solicitor, advising and acting for many of the world's leading life sciences companies in those jurisdictions.
- Acting in Hatch-Waxman patent disputes in the US and in the Australian component of equivalent complex multi-jurisdictional patent disputes, including in patent disputes before trial courts, intermediate appeal courts (the US Court of Appeals for the Federal Circuit and the Full Federal Court of Australia) and final appeal courts (the US Supreme Court and the High Court of Australia).
- Has acted in some of the largest and most innovative life sciences disputes in Australia, for many of the world's largest innovator life sciences companies, including the first three cases to address claims on undertakings as to damages in pharmaceutical patent litigation by generic pharmaceutical companies, their suppliers and the Commonwealth of Australia, and the first biologic/biosimilar patent litigation in Australia, as well as in opposition proceedings for innovator life sciences companies before IP Australia.
- Has managed and co-ordinated multi-jurisdictional patent litigation for multinational innovator life sciences companies.

- Advising numerous life sciences companies in relation to patent issues, including international patent protection strategies and patent portfolio management.
- Advising life sciences companies on a broad range of regulatory issues including registration of pharmaceuticals and medical devices and technologies, promotion of products, compliance with industry codes, and clinical trials.
- Advising multinational life sciences companies on, and managing, the IP and life sciences regulatory aspects of multinational corporate transactions.
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Areas of practice. IP and litigation; pharmaceutical and medical device regulation; life sciences.

Recent transactions.

- Advising a medical devices company on establishing its operations in Australia, including in relation to the regulation, advertising and promotion of its medical devices and the regulation of health care professionals in Australia.
- Acting in pharmaceutical patent infringement and revocation proceedings before the Federal Court of Australia and in patent opposition proceedings before the Australian Patent Office, and the first litigation involving biosimilars in Australia.
- Advising on and overseeing the IP and life sciences regulatory aspects of international corporate transactions, including major acquisitions of multinational medical devices businesses.

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Areas of practice. Competition law advisory and litigation; class actions; cartel investigations and merger clearance.

Recent transactions.

- Advising on labelling and promotional activities to eliminate the risk of breaching the Australian Consumer Law.
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Areas of practice. Product liability; class actions and mass torts; insurance litigation; civil/commercial litigation.

Recent transactions.

- Currently acting for a global pharmaceutical company in a Federal Court class action relating to pelvic mesh devices.
- Currently acting for various global pharmaceutical companies and medical device companies in various pieces of litigation, claims and advisory work.
- Currently acting for a global food company in a Federal Court class action.
- Regularly acting for Australian, US and international companies on product related issues, be they product recalls, other regulatory issues or product liability claims.

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Areas of practice. Patent and trade mark litigation and disputes; infringement and freedom to operate advice; corporate advisory; patent licensing and strategy.

Recent transactions

- Advising on infringement and validity of patents and conducting infringement risk analysis.
- Acting for innovator companies in patent infringement and revocation proceedings involving pharmaceutical compositions, manufacture of biological materials and methods of medical treatment.
- Acting in Federal Court trade mark infringement proceedings, oppositions to trade mark registration before the Australian trade marks office and appeal of office proceedings.

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Areas of practice. Patent and trade mark litigation and disputes; infringement and freedom to operate advice; patent licensing and strategy.

Recent transactions.

- Acting in Federal Court and High Court patent infringement and revocation proceedings.
- Acting in Federal Court trade mark infringement proceedings, and oppositions to trade mark registration before the Australian trade marks office.
- Advising on infringement and validity of patents and conducting infringement risk analysis.

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Areas of practice. Competition and consumer law advisory and litigation; cartel investigations and merger clearance.

Recent transactions.

- Advising on labelling and promotional activities to eliminate the risk of breaching the Australian Consumer Law.
- Advising on pharmaceutical supply and distribution strategies.

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Areas of practice. IP and litigation; pharmaceutical and medical device regulation; life sciences; copyright; trade mark and domain name disputes.

Recent transactions.

- Acting in Federal Court patent infringement and revocation proceedings, and patent opposition proceedings before the Australian Patent Office.
- Advising multinational life science companies in relation to infringement and validity of Australian patents.
- Advising pharmaceutical, bioscience and medical device companies on Australian regulatory and compliance issues.

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Professional qualifications. Supreme Court of Victoria, 2012; Federal Court and High Court of Australia

Areas of practice. Patent, trade mark and copyright litigation and disputes; infringement and freedom to operate advice.

Recent transactions.

- Federal Court patent and trade mark infringement and revocation proceedings.
- Australian Patent Office opposition proceedings.
- Australian Trade Mark Office opposition proceedings.
- Advising on patent and trade mark infringement risks and assessments of patent validity.

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