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Pharmaceutical IP and competition law in Australia: overview

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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 in Australia:

- Standard, which is the traditional form of patent protection.
- Innovation, a second form of patent protection intended to provide protection for a shorter term to inventions that cannot satisfy the inventiveness requirement for a standard patent.

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

The most significant single set of reforms to Australian patent law in more than 20 years were introduced in 2013. The reforms, introduced by the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Raising the Bar Act) "raise the bar" for patentability.

However, the "old" lower pre-Raising the Bar Act patentability standards remain applicable to (Old Patents and Applications):

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

The "new" higher Raising the Bar Act patentability standards apply to standard and innovation patent applications for which examination was not requested, or innovation patent applications which the Commissioner of Patents decided not to examine, before 15 April 2013 (New Patents and Applications).

The Raising the Bar Act did not alter all of the "old" requirements for patentability.

Whichever standard applies to a patent or patent application will continue to apply to that patent or patent application throughout its entire lifespan.

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. Prior to 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. This assessment is made in light of the "common general knowledge", together with pertinent "publicly available" information. The relevant "common general knowledge" is limited to that which existed in Australia before the priority date of the claim, and "publicly available" information is limited to information that 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 an assessment of whether the invention differs from the prior art in a manner that makes a substantial contribution to the working of the invention. It does not consider whether the invention is obvious.
- Is useful (at least one embodiment of the invention must achieve the result promised in the specification).
- 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 the requirements of section 40 of the Patents Act. Prior to the Raising the Bar amendments, this required that the complete specification:

- Describe the invention fully, including the best method known to the applicant of performing the invention (known as "sufficiency").
- 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.

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The Raising the Bar Act made changes to the inventive step, usefulness, 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.
- Usefulness: an invention is not considered "useful" under the new law unless "a specific, substantial and credible use" for the invention is disclosed in the complete specification.
- Sufficiency: the new law requires that a specification disclose the invention in a manner that is clear and complete.
- Fair basis: the new law replaced the fair basis requirement with a "support" requirement. Therefore, in addition to requiring that there be appropriate "basis" in the body of the specification for each claim, the new law requires that the scope of a claim does not exceed what is justified by the extent of the information provided to support that claim.

Scope of protection

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

- Biological materials such as isolated or purified gene sequences, proteins and micro-organisms and the:
  - processes for identifying, purifying and isolating them; and
  - methods of using them.
- Medical devices.
- Methods of medical treatment.

Human beings, and the biological processes for their generation, are not patentable inventions (*section 18(2), Patents Act*). Also, plants and animals, and the biological processes for the generation of plants and animals, 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/get-the-right-ip/patents/apply-for-a-patent/*.

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

Process and timing

The application process can begin by filing either a complete application or a provisional application (in which case a complete application must be filed within 12 months).

An application for a standard patent then proceeds through the following process:

- 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 may issue either 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 pursued, a Hearing Officer at IP Australia will hold a hearing to decide whether or not the opposition succeeds.

An appeal against a decision of the Hearing Officer on an opposition 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 application process for an innovation patent is quite different and is as follows:

- Within a couple of weeks of the filing of an innovation patent 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 innovation patent 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 may issue either 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 then commence opposition proceedings and if successful, the innovation patent may be revoked.

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

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

The term of an innovation patent is eight years (*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/get-the-right-ip/patents/time-and-costs/fees/*.

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 that involves 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.

No further extensions for a standard patent are possible.

The term of an innovation patent cannot be extended.

4. How can a patent be revoked?

A patent 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*) or a defendant in infringement proceedings can file a counter-claim in the proceedings for the revocation of the asserted patent (*section 121, Patents Act*).

A patent can be revoked in whole or in 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 or it does not satisfy the requirements of section 40 of the Patents Act.

A standard patent can be revoked by the Commissioner on receipt of an adverse report following re-examination (*section 101, Patents Act*) and 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 can be revoked in whole or in part by the Commissioner following re-examination only on limited grounds. Those grounds are that, when compared with the prior art base as it existed 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 can be revoked by the Commissioner following re-examination on much broader grounds, including:

- 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) when compared with the prior art base existing 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 considers that a ground for the 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*):

- 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 to 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 doing any action mentioned immediately above in respect of the 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.

A patent claim can also be infringed indirectly or contributorily by a supplier (*section 117, Patents Act*).

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

The "old" lower pre-Raising the Bar Act included a "springboarding" provision, which provided 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 "new" Raising the Bar Amendments introduced two additional exceptions to patent infringement:

- An amendment that broadens the existing "springboarding" provision to any exploitation of a patent connected with obtaining regulatory approval (not just of goods intended for therapeutic use).

- An experimental exemption that carves out acts done for experimental purposes related to the subject matter of the exemption.

Claim and remedies

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

A first instance decision can be appealed to the Full Federal Court of Australia (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 whether the allegedly infringing product, process or method includes all of the essential integers of the asserted claim, the court employs a purposive approach to construing the claim.

Remedies available to a patentee include:

- Injunctions (including interlocutory injunctions pending final trial) and ancillary orders.
- Either damages (which can include additional or exemplary) or an account of profits at the election of the patentee.
- Legal costs.

6. Are there non-patent barriers to competition to protect medicinal products?

A period of data exclusivity to protect particular medicinal products exists under section 25A of the TG Act. Under that regime, the Secretary of the Department of Health and Ageing (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 being 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.

TRADE MARKS

7. 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?

Conditions and legislation

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 the following:

- Word.
- Device.
- Brand.
- Aspect of packaging.
- Shape.
- Colour.
- Sound or scent.
- Any combination of the above.

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 in respect of which the trade mark is sought to be registered 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 those goods or services in respect of which it is sought to be registered would be likely to deceive or cause confusion because of some connotation that the trade mark has (*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*).

Scope of protection

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

- A medicinal brand.
- The appearance, colour or colour combination of a tablet or capsule.
- The aspects of packaging.

The brand name of a medicinal product would likely be rejected as a trade mark, on the basis that it would be likely to deceive or cause confusion, if:

- It is substantially identical to a notified International Non-proprietary Name (INN) or a notified INN stem.
- The goods in relation to which trade mark registration is sought are not restricted to the particular substance identified by the INN or INN stem.

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

- The exclusive right to use the trade mark and to authorise other persons to use the trade mark (subject to any superior common law rights held by third parties).
- The right to obtain relief under the TM Act if the trade mark has been infringed.

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

8. 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/get-the-right-ip/trade-marks/trade-mark-application-process/*.

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

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 requirements of the TM Act. If the application satisfies all of the requirements, 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.

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 of the mark within two months from the date of advertisement of acceptance. The registration of a trade mark can be opposed on any of the grounds on which an application for the registration of a trade mark 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 of opposition 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 thereof was amended contrary to the TM Act or the Registrar accepted the application on the basis of 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 on payment of the registration fee.

9. 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.

10. 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 is entitled to revoke the registration of a trade mark 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 can be made to the Registrar on the grounds that the registered owner either:

- Has not used the trade mark in Australia and did not intend, on the trade mark application date, to use the trade mark.
- Has not used the trade mark in good faith in Australia, for a continuous period of three years ending one month before the day on which the non-use application is filed (*section 92, TM Act*).

An aggrieved person can apply to a prescribed court to rectify the Register by cancelling the registration of the trade mark, 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 contravened (*section 86, TM Act*).
- The trade mark contains or consists of a sign that has become generally accepted within 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 of the trade mark was obtained as a result of 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 is in respect of an entry in the Register, the entry was made, or has been previously amended, as a result of fraud, false suggestion or misrepresentation (*section 88, TM Act*).

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

Conditions

The rights of a registered proprietor of a trade mark are infringed if, without the proprietor's authorisation, another person uses as a trade mark a sign that is substantially identical or deceptively similar to the registered trade mark for:

- Goods or services for which it is registered.
- Goods or services of the same description as those in respect of which the mark is registered.
- Services which are closely related to goods for which the mark is registered.
- Goods which are 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 accordingly the interests of the registered owner are likely to be adversely affected (*section 120, TM Act*).

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 grant:

- Injunctions (including interlocutory injunctions orders pending final trial) and ancillary orders.
- Delivery up orders.
- Either damages (which can include additional or exemplary) or an account of profits at the election of the trade mark owner.
- Legal costs.

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

Enforcement of trade mark rights is carried out by way of civil action in the vast majority of cases. Police authorities, especially the Federal Police, can pursue criminal actions, but such actions are rare.

Owners of Australian registered trade marks can lodge a Notice of Objection with the Australian Customs Service (ACS). ACS can seize suspected infringing goods being imported through a border control point if a relevant Notice of Objection is in place. The importer can surrender the goods. Alternatively, if the importer seeks to have the seized goods released, ACS does not take any enforcement action itself but will issue a notice to the trade mark owner, who must then commence its own civil action within ten days to prevent the goods from being released.

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.*

IP AND COMPETITION LAW ISSUES

13. 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 in Australia

Australian competition/anti-trust laws are set out in the Competition and Consumer Act 2010 (Cth) (CCA), which is administered by an independent statutory authority, the Australian Competition and Consumer Commission (ACCC). The ACCC is the only national agency dealing generally with competition matters and the only agency with responsibility for enforcing the CCA.

The CCA's anti-competitive conduct prohibitions apply to virtually all businesses in Australia. This includes business 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. Generally this type of conditional dealing will only breach the CCA if it has the purpose, or likely effect, of substantially lessening competition in a relevant market in Australia (*section 47, CCA*).
- Resale price maintenance, where a wholesaler specifies a minimum resale price to a retailer (*section 48, CCA*).
- Contracts, arrangements or understandings 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 taking advantage of that market power for an anti-competitive purpose (*section 46, CCA*).
- Cartel behaviour, including price fixing, restricting outputs in the production and supply chain, market sharing and bid rigging (*section 44ZZRD, CCA*).

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

Regulatory focus

Each year the ACCC announce areas of commerce that will be a particular focus in the coming 12 months. These areas tend to be those where the ACCC has received large numbers of complaints over previous years, or where the ACCC has been given new powers of enforcement. The ACCC has not identified the life sciences sector as a sector of focus, however the ACCC has nominated "health and the medical sector" as a focus area. We consider that the breadth of the ACCC's focus on health will indirectly pick up the Life Sciences Sector.

Recent activity in the pharmaceutical sector

In February 2015, the Federal Court of Australia handed down its judgment in relation to the ACCC proceedings against Pfizer's Australian subsidiary, claiming that Pfizer contravened the CCA in two respects when it implemented a commercial strategy in 2012 to address projected loss of market share with the expiry of its Atorvastatin patent (a product marketed under its Lipitor brand).

The ACCC allege that in giving certain rebates to pharmacies on the condition that they pre-ordered at least 75% of their projected Atorvastatin requirements for between six and 12 months, Pfizer:

- Misused its market power for a proscribed anticompetitive purpose.
- Engaged in exclusive dealing with a purpose of substantially lessening competition.

The Federal Court held that Pfizer neither misused its market power nor engaged in exclusive dealing. A critical finding was that Pfizer did not have an anti-competitive purpose in developing and implementing its commercial strategy to deal with the loss of patent protection. The ACCC is appealing this decision. The key implications of this decision, if it is not overturned, for the life sciences sector are as follows:

- Originator manufacturers can vigorously compete and improve their ability to defend volume and price erosion after losing exclusivity (for example, rationalising the supply chain, offering rebates and discounts or bundling business products) where it is clear that the purpose is not to deter or prevent generic manufacturers from engaging in competitive conduct.
- When formulating and implement commercial strategies, clear contemporaneous business records should explain the business rationale to refute any subsequent allegation of an anti-competitive purpose.

Harper Review of competition law

The Australian Government has commissioned a "root and branch" review of Australian Competition Law and Policy. The review is chaired by Professor Harper who handed the committee's final report to the Australian Government on 31 March 2015. The Harper Review has three key implications for the Life Sciences Sector:

- Proposed amendments to section 46 (misuse of market power provisions).
- Repeal of the intellectual property licensing exemption to general competition law.
- Deregulation of community pharmacy location restrictions.

Align the misuse of market power prohibition

The Harper Review recommends bringing the misuse of market power prohibition into line with the other provisions in Part IV of the CCA. If implemented, these amendments would expand the reach of section 46 and make it easier to prove a contravention, primarily because of the removal of the "take advantage" limb and the addition of an "effects" test. The three key changes recommended by the Harper Review are:

- Expanding section 46 to encompass the standard Part IV effects test (in addition to the existing purpose test). If implemented, this would make it easier to prove contraventions of section 46. The ACCC has long advocated for this change on the basis that it is difficult for the ACCC to prove the subjective purpose of an accused.
- Removing the "take advantage" limb. If implemented, this would make it more difficult for a firm with market power to defend its actions. The taking advantage limb has traditionally provided comfort to firms engaging in conduct that would be a rational business strategy even for a firm without substantial market power. The Harper Review initially proposed including an express defence to this effect. The removal of this limb in favour of exclusive reliance on the standard Part IV substantial lessening of competition test would expand the reach of the prohibition and place significant importance on the interpretation of that test. The Harper Review recommends requiring courts to have regard to specific factors that increase or lessen competition including efficiency, innovation, product quality or price competitiveness.
- Introducing the standard Part IV substantial lessening of competition test in place of the existing proscribed anti-competitive purposes. If implemented, a key issue will be whether there is sufficient certainty associated with the application of this test in the context of misuse of market power. The Harper Review recommends requiring courts to have regard to specific factors that increase or lessen competition including efficiency, innovation, product quality or price competitiveness. In our view, the inclusion of those factors would 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 Harper Review also recommends allowing the ACCC to authorise conduct which satisfies a public benefit test (which requires that public benefits outweigh public detriments, including any lessening of competition). This change would standardise 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 as a basis to engage in conduct that could lessen competition.

If the recent matter of *ACCC v Pfizer* were to be decided under the new (amended) section 46, it is likely, in our view, that the Federal Court would reach the same outcome because:

- In relation to the allegation that Pfizer misused its market power, the Federal Court held that Pfizer had taken advantage of its market power but did not do so for an anti-competitive purpose.
- The ACCC did not to plead an anti-competitive effect (despite having the opportunity to do so in relation to its allegation that Pfizer engaged in exclusive dealing).
- On the Federal Court's findings, an argument that Pfizer's conduct had, or was likely to have had, the effect of substantially lessening competition in the Australian atorvastatin market is unlikely to succeed.

Repeal the intellectual property exception

The Panel recommends that an overarching review of Australia's intellectual property (IP) regime be undertaken, by way of a 12-month Productivity Commission inquiry. In the Panel's view, the review should address:

- Competition policy issues in IP arising from new developments in technology and markets.
- The principles underpinning the inclusion of IP provisions in international trade agreements (the Panel also recommends that a separate independent review should assess governmental processes for establishing negotiating mandates to include IP provisions in such agreements).

In addition, the Panel recommends that the IP exception in section 51(3) of the CCA be repealed. This recommendation is particularly relevant to IP rights holders and any party entering into licences or assignments involving IP rights. Currently, section 51(3) of the CCA provides a limited exception, for certain types of transactions involving IP rights, from the application of Part IV of the CCA. More specifically, the IP exception covers certain conditions in licences or assignments of IP rights in respect of patents, trade marks, registered designs, copyright and circuit layouts. However, the exception is limited, in that it does not extend to the prohibitions in Part IV against resale price maintenance (section 48) and the misuse of market power (section 46).

In the Panel's view, repealing the IP exception should not depend on, nor be delayed pending, the outcome of the proposed Productivity Commission inquiry. If the latter recommendation is implemented, transactions previously protected from regulatory

scrutiny by the operation of section 51(3) may give rise to material competition risks (for example, for originator manufacturers of pharmaceutical products) going forward. Importantly, however:

- The Panel recommends that IP licences and assignments should remain exempt from the cartel provisions of the CCA, consistent with the general position in respect of vertical supply arrangements.
- In the Panel's view, such vertical arrangements involving IP rights should only contravene the competition law if they have the purpose, effect, or likely effect, of substantially lessening competition.
- Competition law risks arising from the repeal of section 51(3) may be mitigated in circumstances where IP licensing or assignment arrangements produce offsetting public benefits, by applying for an exemption from the CCA through the usual notification or authorisation processes.

Deregulate pharmacy ownership and location rules

In the Panel's view, current restrictions on the ownership and location of pharmacies in Australia are unnecessary to ensure that pharmacies meet community expectations of safety, access and standard of care. By implication, those restrictions unduly restrict competition. The Panel recommends that such rules be repealed and replaced with regulations that effectively promote safety, access and standard of care but are less harmful to competition (and, in turn, less detrimental to the long-term interests of consumers). Likewise, we note that the recent National Commission of Audit (in its Phase One report) also recommended that pharmacy ownership and location rules be deregulated.

Importantly, due to the significant expected impact on the pharmacy sector, the Panel considers it likely that transitional arrangements will form an integral part of the reform process, and contends that negotiations for the next Community Pharmacy Agreement afford the Australian Government an opportunity to implement such transitional arrangements with a view to the eventual removal of location rules.

The Australian Government as at 1 June 2015 is yet to formally respond to the Harper Review's recommendations.

14. Briefly outline the competition issues that can arise on the licensing of technology and patents in a pharmaceutical context.

Competition issues are most likely to arise in Australia when pharmaceutical companies seeking to license their patents engage in the following conduct:

- Licensing conditions, especially where those conditions impose restrictions on 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; or
  - require the licensee to also purchase additional product or licences from the licensee or a third party.
- Explicitly or constructively refusing to grant licences to essential products or technology. Unlike the equivalent abuse of dominance legislation in the US, Australian law has not been used to provide access to patents in circumstances of a patent owner refusing to grant a licence. Though the extent to which Australian competition law can be used in this way is the subject of debate, it is still a material risk to patents holders that should be factored in to licence negotiations and patent strategy.

Further clarity in this area will follow the conclusion of the Australian *Apple v Samsung litigation (NSD 315 of 2013)*, in which Apple claim the terms on which Samsung offered to license to Apple certain standard essential patents constituted constructive refusal to license that technology, and as such breached Australian abuse of dominance legislation. Note the decision in that matter is not expected until 2015.

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

Patent expiry and the entry of generics is a time when previous patent holders must be vigilant to ensure that any commercial strategies to maintain market share, in circumstances where it is very likely they have built significant market power, do not breach competition law.

In addition to the misuse of market power and exclusive dealing issues concerning rebate programmes in the *ACCC v Pfizer* litigation (*see Question 13*), there are a number of other competition issues that could arise from strategies used by patent holders to resist, or reduce incentives for, generic entry. These are listed below:

- **Patent settlements.** These include "pay-for-delay" strategies where patent holders settle litigation with prospective generics over patents of questionable validity, 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 been in overseas jurisdictions.
- **Deals with manufacturers of precursor materials.** At the time that patents are to 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, to an extent that would prevent a generic from entering the downstream market for the relevant pharmaceutical.
- **Licensing of associated process patents.** Withholding patents that are associated with, or necessary for, manufacture of generic products after expiry of the majority of core product patents, may be considered a misuse of market power and invoke arguments similar to those raise by Apple in their case against Samsung (*see Question 13*).

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

To date the *ACCC v Pfizer* case (*see Question 13*) is the only instance where abuse of dominance issues have arisen in proceedings brought by the ACCC concerning participants in Australian pharmaceuticals markets.

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

No. However, the ACCC has considered the issue of parallel imports in a number of significant Australian competition law cases previously concerning the grocery and recorded music sectors. As such, the Australian regulator is familiar with the relevant economic arguments and with bringing cases to trial where the relevant offending conduct occurs in the context of parallel imports (or the threat of them).

18. Does a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? How is such a licence made 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 agreement can be recorded on the IP Australia Register.

There may be taxation 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, visit *Medicinal product regulation and product liability in Australia: overview*

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Areas of practice. Patents, copyright, trade marks and designs; pharmaceutical and medical device and technology regulation; biotechnology and life sciences.

Recent transactions

- Acting for a number of life sciences companies in connection with patent infringement and revocation proceedings involving pharmaceutical molecules, formulations, biologics and medical devices and technologies.
- Advising a number of life sciences companies on intellectual property management strategies including post patent strategies.
- Advising life sciences clients on a broad range of regulatory issues including registration of pharmaceuticals and medical devices and technologies, Pharmaceutical Benefits Scheme reimbursement, promotion of products, compliance with industry codes and product recalls.

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Areas of practice. Pharmaceutical, bioscience and medical technology patent litigation and advice; intellectual property; life sciences.

Recent transactions

- Acting or has acted in a number of Australia's and the United States' leading patent cases, including cases in the Federal Court of Australia, the United States Court of Appeals for the Federal Circuit and the Supreme Court of the United States.
- Advising and acting for, or has advised and acted for, many of the world's leading innovator life sciences companies in patent infringement and revocation litigation, often as a member of a global team working together to resolve complex, multi-jurisdictional patent issues and disputes.
- Advising or has advised numerous Australian and international pharmaceutical, bioscience and medical technology clients in relation to patent issues, including international patent protection strategies and patent portfolio management.

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

Recent transactions

- Advising on structuring distribution arrangements to eliminate risk of breach of cartel provisions, third line forcing and misuse of market power.
- Advising on levels of discounts to customers at which the risk of allegations of predatory pricing, misuse of market power and anti-competitive agreements are triggered.
- Advising on competition issues arising on cross licence arrangements in between competitors in respect of intellectual property rights.

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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.
- Currently acting for a supplier of a product that has been involved in a widespread product recall arising from fears of a Hepatitis A outbreak.
- Currently acting in Supreme Court of Victoria litigation arising from an AFL club's supplements programme.
- Currently acting in a Supreme Court of Victoria class action arising from the 2014 Mickleham bushfire.
- Recently acted in a Supreme Court of Victoria group proceeding involving more than 200 claims of equitable contribution arising from the manufacture of asbestos products (judgment pending).
- 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. Pharmaceutical patent litigation; product liability litigation; class actions; pharmaceutical and medical device regulation and compliance; commercial agreements for life sciences companies; contractual disputes.

Recent transactions

- Advising top ten innovator clients in relation to pharmaceutical patent revocation and infringement proceedings in the Federal Court of Australia.
- Advising medical device companies in relation to product registration and regulation, as well as litigation.
- Representing pharmaceutical and medical device clients defending product liability actions.
- Preparing commercial supply and distribution agreements for companies in the life sciences sector.

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Areas of practice. Brands and trade mark clearance, protection, and enforcement

Recent transactions

- Acting for pharmaceutical clients in trade mark clearance matters and brand protection advice.
- Acting for pharmaceutical clients in the prosecution of trade mark applications.
- Contentious trade mark matters including domain name disputes, oppositions, removal actions and infringement matters.

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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

- Advising on infringement and validity of patents and conducting infringement risk analysis.
- Acting for innovator and generic companies in patent infringement and revocation proceedings involving pharmaceutical compositions 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.