Australia
Australie
Australien

Report Q202

in the name of the Australian Group
by Carolyn HARRIS, Sarah MATHESON, Wayne CONDON and Ben STRATE

The impact of public health issues on exclusive patent rights

Questions

I) Analysis of current law and case law

1) Is a research or experimental use exception recognised under your patent law?

No express research or experimental use exception is available under the *Patents Act 1990* (Cth). Many believe that an implicit exception for experimental use would be found to exist were the question to come before an Australian court. This has not yet happened. Nevertheless, researchers tend to act on the assumption that an exception exists.

Whether a research exception exists and what its scope might be has been discussed in detail in recent years. The Australian Law Reform Commission (**ALRC**) released a report in 2004 recommending legislative clarification of the research exception. The Advisory Council on Intellectual Property (**ACIP**), an independent body established to provide policy advice to the Federal Government on issues relating to intellectual property, also recommended introduction of a statutory exception in 2005. Both groups discussed evidence supporting the existence of an experimental use exception, but in the absence of Australian court authority, neither could state with certainty whether the exception existed or what might be its scope.

The Commonwealth Government released a response in August 2007 stating that it would amend the patent legislation to include an experimental use exception, reflecting Australia's international obligations as closely as possible. The Government stated that the amendments will outline the research activities that can be done without infringing on a patent holder's rights, including determining how an invention works, verifying the validity of patent claims, or improving the invention. No such legislation has been introduced into parliament as yet.

Arguments supporting the exception tend to centre around definitions of the patentee's exclusive right under the Commonwealth Patents Act 1990 (**Patents Act**) to 'exploit' their invention. The Explanatory Memorandum states that this exclusive right was not intended to 'modify the present law relating to certain acts which have been held not to constitute infringement—for example, use of an invention for certain experimental or trial purposes'. ACIP supports this argument by observing that the fact that use for experimental or research purposes may not constitute an infringement is consistent with the scope and purpose of the Act as a whole.

There is also an old line of English authority, beginning with the 19th century case of *Frearson v Loe*,[1] which has not been overturned in Australia. The decision in that case suggested that acts might not constitute 'use' of an invention where there is no commercial purpose. It is possible that this exception would continue to apply to allow experimental use of patented products and methods.

[1] (1878) 9 ChD 48.

If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?

Given that the exception is not clearly defined, it is difficult to state precisely either the conditions in which the exception would operate or the scope of the exception. It seems that, whether the exception were found to be based on the definition of 'exploit' or on the principle in Frearson v Loe, use for commercial purposes would not be permitted.

2) *Is a Bolar-type exception recognised under your patent law?*

The *Patents Act* provides a Bolar-type exception for manufacturers of generic pharmaceutical products.

If so, under which conditions?

Rights in a 'pharmaceutical patent' are not infringed by a person exploiting an invention if the exploitation is solely for purposes connected with obtaining inclusion in the Australian Register of Therapeutic Goods or similar regulatory approval under a law of a foreign country. A 'pharmaceutical patent' is defined as a patent claiming a pharmaceutical substance or a method, use or product relating to a pharmaceutical substance. A method, use or product relating to a pharmaceutical substance includes:

– a method for producing a raw material needed to produce the substance;

– a product that is a raw material needed to produce the substance; and

– a product that is a pro-drug, metabolite or derivative of the substance.

The exception only applies for those seeking foreign regulatory approval if the patent in question has been extended beyond the normal twenty year period.

What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.?

According to the Explanatory Memorandum the definition of a 'pharmaceutical patent' is intended to cover 'all patents that a generic pharmaceutical company would need to exploit in order to seek inclusion of a good other than a medical device or a therapeutic device on the Australian Register of Therapeutic Goods'. The exception is not intended to allow the stockpiling of quantities for later sale or manufacturing of quantities of the product for export.

The scope of the exception is limited by the definition of a 'pharmaceutical substance'. A 'pharmaceutical substance' is defined as a substance, including a mixture or compound of substances, for therapeutic use:

– whose application involves a chemical interaction, or physico-chemical interaction, with a human physiological system; or

– action on an infectious agent, or on a toxin or other poison, in a human body.

The exception does not extend to 'medical devices' or 'therapeutic devices'. Accordingly, instruments, apparatus, appliances or materials used for medical or therapeutic purposes are not within the exception. In conjunction with the 'chemical interaction' requirement in the 'pharmaceutical substance' definition, this appears to limit the exception to drug patents.

If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?

3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions?*

Parallel imports of patented medicines or medical devices are not expressly permitted. The patentee's exclusive right to 'exploit' their invention includes the exclusive right to import it. There is no suggestion of a statutory exception for parallel importation. The Australian courts have not been required to consider the legality of parallel importation for some years.

However, the exhaustion of rights principle may prevent the patentee from claiming an exclusive right to import goods sold by the patentee to another party. Sale of patented goods without any restriction may give rise to an implied licence to do with imported goods as the purchaser wishes.[2] However, the patentee may use a licence agreement to impose conditions on what use may be made of patented goods after sale,[3] provided that the agreement does not prevent the purchaser from using or selling any product owned by any person other than the seller, or require the purchaser to acquire any product owned by any person other than the seller. Patentees who sell their products overseas may therefore make it a condition of sale that the purchaser may not import their goods into Australia. If they do not do so expressly, parallel importation may be permitted.

Do the same principles apply if the products originate from markets where they were made available under a compulsory license?

Apart from the limitations discussed in answer to Question 6, the Patents Act does not limit the conditions upon which a compulsory licence may be ordered. In general, a licensee is permitted to 'exploit' an invention, which includes the right to import it.

The objects of the compulsory licensing provisions include ensuring that Australian demand for the patented article could be reasonably met, whether from local production or from imports (see further answer to question 6 below). However, it is not clear whether the same reasoning would apply to import of goods made available under compulsory licences made in other markets.

4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

No exception for individual prescriptions is recognised under Australian patent law. The definition of the patentee's exclusive right to 'exploit' their invention includes the right to 'make' the patented product, or use the patented process to make a product. There is nothing to suggest a broad exception for syntheses by pharmacists or medical professionals of medications prescribed for an individual.

5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?*

Since the Full Court of the Federal Court of Australia's decisions in *Bristol-Myers Squibb Co v FH Faulding & Co Ltd*[4] (**Bristol-Myers**) and *Anaesthetic Supplies Pty Ltd v Rescare Ltd*,[5] methods of medical treatment have been considered patentable subject matter. However, Australian patent law does not provide for a medical treatment defence or similar exception to the patentee's exclusive rights. *Bristol-Myers* suggested that medical practitioners who

---

2 Interstate Parcel Express Co Pty Ltd (carrying on business as Angus & Robertson Bookshops) v Time-Life International (Nederlands) BV and Another (1977) 138 CLR 534; Avel Pty Ltd v Multicoin Amusements Pty Ltd (1990) 171 CLR 88.

3 Interstate Parcel Express Co Pty Ltd v Time-Life International (Nederlands) BV (1977) 138 CLR 534, 549; Transfield Pty Ltd v Arlo International Ltd (1980) 144 CLR 83.

4 (2000) 170 ALR 439.

5 (1994) 50 FCR 1.

wish to use patented methods of medical treatment should, although it is cumbersome and expensive, seek a compulsory licence (see further answer to question 6 below). Strong patent protection for methods of medical treatment, it is argued, encourages the great expense required to evaluate and investigate new medical processes and surgical methods.

6) *Are compulsory licenses available under your patent law?*

Compulsory licences are available under the Patents Act. An application for a compulsory licence may not be made until 3 years after the sealing of the relevant patent.

If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)?

The Federal Court may order a patentee to grant a licence to work a patented invention if:

- the applicant (for the compulsory licence) has tried for a reasonable period, but without success, to obtain from the patentee an authorization to work the invention on reasonable terms and conditions; and
- the reasonable requirements of the public with respect to the patented invention have not been satisfied; and
- the patentee has given no satisfactory reason for failing to exploit the patent; or
- the patentee has contravened or is contravening Part IV of the *Trade Practices Act 1974* in connection with the patent. This might include price-fixing, misuse of market power or exclusive dealing.

Reasonable requirements of the public are taken not to have been satisfied if:

- an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, in not reasonably met, because of the patentee's failure:
    - to manufacture the patented product to an adequate extent, and supply it on reasonable terms; or
    - to manufacture, to an adequate extent, a part of the patented product that is necessary for the efficient working of the product, and supply the part on reasonable terms; or
    - to carry on the patented process to a reasonable extent; or
    - to grant licences on reasonable terms; or
    - a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee to the purchase, hire or use of the patented product, the use or working of the patented process; or
    - if the patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia.

A compulsory licence must not give the licensee the exclusive right to work the patented invention, and a licence is to be assignable only in connection with an enterprise or goodwill in connection with which the licence is used.

Commentary on this aspect of Australian patent law reflects that the provisions of the legislation appear to provide significant opportunities for competitors adversely affected by the existence of all unworked patents to obtain relief. However, there are very few reported cases in which the provisions have been considered, and none that are directed to pharmaceutical inventions.

An examination of the circumstances set out [in the legislation] suggests that the objects of the compulsory licensing provision of the Act cover both (1) fostering Australian manufacturing industry to make the patented article or to use the patented process and (2) ensuring that the Australian demand for the patented article or articles made in accordance with the patented process should be reasonably met whether from local production or from imports. It could, therefore, be that the reasonable requirements of the public would not have been satisfied simply by the importation of enough patented articles to meet the Australian demand. The circumstance that to foster Australian manufacture is an object of the provisions as a whole might well dictate that in some circumstances a compulsory licence should be confined to the use of the invention for local manufacture and the sale of the products of such manufacture and should not afford the licensee the right to import and sell patented articles: *Fastening Supplies Pty Ltd v Olin Matheson Chemical Corp* (1969) 119 CLR 572.

If the patented invention (subject of the compulsory licence) cannot be worked by the applicant without infringing another patent, the Federal Court may only order a compulsory licence if it is satisfied that the patented invention involves an important technical advance of considerable economic significance on the invention to which the other patent relates. In conjunction with such an order, the Federal Court must order that the patentee of the other invention grant a licence to work the other invention insofar as is necessary to work the patented invention and must also order that the patentee of the other invention be granted a cross-licence to work the patented invention on reasonable terms. There are also prescribed conditions to account for assignment of a compulsory licence.

Subsequent to the grant of a compulsory licence, an interested person may apply to the Federal Court for an order revoking the patent if 2 years have expired since the grant of the first compulsory licence. The court may make such an order if satisfied that:

– both the reasonable requirements of the public with respect to the patented invention have not been satisfied and the patentee has given no satisfactory reason for failing to exploit the patent; or

– the patentee is contravening Part IV of the *Trade Practices Act 1974* or an application law in connection with the patent.

Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.

No compulsory licences have been granted in Australia for the domestic manufacture and supply of pharmaceutical products.

7) Has new Article 31bis TRIPS been ratified in your country?

Australia has accepted the changes to the TRIPS agreement regarding Article 31bis and notified the WTO of its acceptance on 12 September 2007.

Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003?

Acceptance of the new Article 31bis of TRIPS did not require amendment of Australian law - the obligation to avoid trade diversion of generic drugs is similar to other obligations in the TRIPS Agreement generally and is already adequately covered in Australian legislation.

Under the *Patents Act*, pharmaceutical products made under compulsory licence must be primarily for supply of the domestic market, ie, not for export. If Australia wishes to export drugs made under compulsory licence, amendments to the patents legislation will be required, consistent with the provisions of Article 31bis.

However, in discussions regarding the possible acceptance of the changes, it was suggested that Australia should accept the changes and then consider whether it was necessary to amend legislation to allow Australia to export patented pharmaceuticals and make them available for developing countries. The parliamentary committee that considered this issue stated:

The Committee supports acceptance of the Protocol, followed by any necessary amendments to the Patents Act 1990 to allow for compulsory licensing to enable export of cheaper versions of patented medicines needed to address public health problems to least-developed and developing countries. The Committee encourages the consultations to be coordinated by IP Australia later this year and urges the Government to actively support the provision of patented medicines to least developed and developing countries.

To date, no amendments to the existing legislation have been made. IP Australia is yet to commence consultation on possible legislative changes.

Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.

No compulsory licenses have been granted in Australia for the importation or exportation of pharmaceutical products.

8) Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?

Exploitation of patent applications and patents by the Crown is permitted under the *Patents Act*. The Crown may exploit an invention if the exploitation of the invention is necessary for the proper provision of those services within Australia.

The purpose of the provisions is to ensure that the Commonwealth and State governments have immediate access to inventions which are of benefit to the performance of their functions, without them having to wait until the term of a patent expires. The Australian provisions are based upon section 27 of the Patents, Designs and Trade Marks Act 1883 (UK) and are considered to represent a balance between the rights of the inventor and patentee and the rights of the Crown, representing the public interest. It is suggested that the Crown should not be prevented from acting in the public interest by patents which it has granted, especially in relation to matters such as those of national defence and public health. Furthermore, given that the Crown and its agencies are not normally engaged in commercial activities, but in the provision of public services, access to patent monopolies should be available where the public interest needs to be better served.

Where an invention is directly used by the Commonwealth or a State in performing its duties and functions, such a use will be regarded as falling within the provisions of the legislation. However, it is not clear that the legislative provisions are satisfied in circumstances where a patented article is acquired by Commonwealth or a State pursuant to the legislation and is then supplied to members of the public, possibly at a discounted rate and in competition with the patentee. This issue is yet to be authoritatively determined in Australia as in the two cases in which the question has been asked, the court has decided that the issue did not need to be determined.

A patentee is able to apply for a declaration that an invention has been exploited by the Commonwealth or a State or their authorities and authorized persons. The patentee is also entitled to compensation for such use. The Commonwealth and State are obliged, unless it appears contrary to the public interest to do so, to inform the applicant for a patent or patentee of the fact of exploitation of the invention, and to provide the applicant or patentee with such information as to that exploitation as he or she from time to time reasonably requires.

If the patentee and the Commonwealth or a State cannot agree on reasonable compensation, a court may be called upon to set terms and conditions for the exploitation.

9) Is the government allowed to expropriate a patent and, if so, under which conditions?

It is possible for the government to expropriate a patent application or a patent under the *Patents Act*. The Governor-General may make such a direction and all rights in respect of the patent or the invention are transferred to and vested in the Commonwealth. The Commonwealth must pay compensation as agreed between the Commonwealth and the compensable person, or in the absence of agreement, as is determined by the Court upon application by either party. There are no conditions specified in the legislation under which the government may expropriate a patent.

There have been no reported instances of the Commonwealth expropriating a patent.

10) If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.

When an extension of the term of a patent is granted, the rights of the patentee during the term of the extension are limited. This exception is peculiar to pharmaceuticals, as extensions may only be granted if a pharmaceutical substance *per se* is disclosed in the patent. The inclusion of the phrase *'per se'* means that , as a general proposition, claims for pharmaceutical substances produced by a particular process are ineligible for extension. To be eligible for extension, the claim must not be qualified by environmental, temporal or process components.

Exploitation of any form of the invention other than the specified pharmaceutical substances *per se* during the extension period does not constitute infringement. That is, once the extension period begins, the patent no longer gives the patentee the exclusive right to exploit anything claimed other than the pharmaceutical substance itself. For example, a manufacturing procedure used to produce the pharmaceutical substance will not continue to be protected under the extended patent.

II) Proposals for adoption of uniform rules

1) Should patent law provide for

- *research and experimental use exception;*
  The Australian Group considers that patent law should provide an exception for research and experimental use. Legislative clarification of the exception is appropriate, as it assists to provide certainty for researchers, even though any statutory exception will create issues of interpretation. Many countries already have an exception for research and experimental use, and harmonization is generally desirable.
- *Bolar exception;*
  The Australian Group considers that the current Australian exception is appropriate in balancing the interests of innovator and generic companies. The current springboarding provisions adequately address timely access to medicines by ensuring that cheaper generic medicines are available promptly following patent expiry.
- *parallel import of patented medicines;*
  While providing another means of accessing medicines, an express exception for parallel importation of patented medicines will limit the rights of patentees. Contractual constraints can, absent a legislative exception, limit importation, but can only go so far down a supply chain. The Australian group considers that such an exception could increase

access to patented medicines and should be considered as it does not unreasonably dilute the rights of the patentee. However, in Australia, the introduction of an exception for parallel importation of patented medicines would require careful consideration of the regulatory regime relating to medicines.

– *individual prescriptions exception;*
The Australian Group considers that any exception for individual prescriptions would need to be carefully defined. An exception may be appropriate for one-off, non-commercial prescriptions in cases of patient need.

– *medical treatment defence;*
Australia has no express exception for a medical treatment defence. Whilst the courts' view would be that a practitioner should seek a compulsory licence (see question 5), in general, the owner of a patent for a pharmaceutical is unlikely to sue a medical practitioner for using a pharmaceutical in a way that infringes a method claim, as the medical practitioner is ultimately the one who selects the medicine to be used. Thus, in a commercial context it is unlikely that a medical practitioner would be confronted by infringement action, even though there is no explicit defence. The introduction of a defence into Australian law could be argued to be desirable to protect medical practitioners, however, the corollary is the reduction of protection for companies who invest in research and development to improve medical treatments. On balance the Australian group is of the view that an explicit defence is unnecessary.

– *compulsory licensing;*
Australia has had no experience with compulsory licensing in relation to pharmaceuticals, so it is difficult to decide whether it is appropriate in practice. The Australian Group considers that compulsory licensing mechanisms will not always be helpful because of the long lead times for the production of medicines. Furthermore, the current requirements for a compulsory licence in Australia require that the licensee be able to fulfil production requirements. In the context of a pandemic, it may be that more than one licensee is required to provide sufficient product and hence the current provisions would not provide a satisfactory outcome.

– *expropriation;*
The circumstances in which expropriation may be desirable may be unpredictable, rendering legislative proscription of circumstances problematic. There is currently no articulation of the conditions in which expropriation could occur and the threshold criteria of 'the proper provision of those services' (see question 9) provides the government with broad latitude to exercise the right if necessary. The Australian Group considers that this breadth is acceptable because it allows for unpredictable circumstances to be encompassed, but still requires the Government to justify any decision it does make in this respect.

– *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*
It is the Australian Group's view that the above exceptions are sufficient to facilitate access to medicines. There is no need for further express measures.

2) *Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

The Australian Group considers that there are no ways other than those which would prove limitations on patent rights in which patent law might facilitate access to medicines.

3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised?*

The Australian Group considers that all of the exceptions discussed, including the research and experimental use exceptions, Bolar exception and individual prescriptions exception, should be harmonised to the extent possible. Harmonisation is useful for creating certainty for patentees and health organisations operating at an international level.

If so, how? If not, why not?

The Australian Group considers that harmonisation is best achieved through bilateral and multilateral treaties and through fora like AIPPI.

Summary

Australian law recognises several exceptions to the exclusivity of patentees' rights which may be relevant to public health issues. Australian legislation expressly provides for a Bolar-type exception, compulsory licensing provisions, and government use of patented inventions and expropriation of patents. An exception for experimental use may be implied, though no Australian court has considered this question. Parallel importation may be permitted where the patentee has not contracted to prevent it, though there is no express exception. Exceptions for individual prescriptions and medical treatment are not recognised.

The Australian Group considers that harmonisation of patent law is generally desirable. It is the Australian Group's view that patent law should expressly allow experimental use and parallel importation of patented inventions. The Australian Group considers that the scope of the Australian law's other exceptions strikes an appropriate balance between the rights of the patent holder and the interests of other parties.

Résumé

En droit australien, plusieurs exceptions sont reconnues dans le cadre de l'exclusivité des droits des titulaires de brevets pouvant concerner les problèmes de santé publique. Les lois australiennes prévoient expressément l'exception de type "Bolar", les dispositions relatives aux licences obligatoires et l'utilisation par le gouvernement d'inventions sous brevet et d'expropriation de brevets. Une exception pour utilisation à titre expérimental peut être implicite, bien qu'aucun tribunal australien n'ait pris cette option en considération. L'importation parallèle peut être permise lorsque le titulaire du brevet n'est partie à aucun contrat l'en empêchant, bien qu'il n'existe aucune exception expresse. Les exceptions pour les cas individuels de traitement médical et d'ordonnance de médicaments ne sont pas reconnues.

Le Groupe australien considère que l'harmonie est généralement désirable en matière de droit des brevets. Le Groupe australien pense fermement que le droit des brevets doit expressément permettre l'utilisation à titre expérimental et l'importation parallèle d'inventions sous brevet. Le Groupe australien considère que l'étendue des autres exceptions, en droit australien, apporte un équilibre approprié entre les droits du titulaire du brevet et les intérêts des autres parties.

Zusammenfassung

Das australische Recht erkennt mehrere Ausnahmen in Bezug auf die Exklusivität des Patentinhabers an, die in Bezug auf Fragen der öffentlichen Gesundheit relevant sein mögen. Die australische Gesetzgebung sieht ausdrücklich eine Ausnahme vom Bolar-Typ vor (der künftige Hersteller eines Generikums darf bereits vor Ablauf der Patentzeit des Originalprodukts Vorbereitungen für die Herstellung des Generikums treffen), Vorschriften über Zwangslizenzen und den Gebrauch patentierter Erfindungen durch die Regierung und die Enteignung von Patenten. Eine Ausnahme in

Bezug auf experimentelle Verwendung mag unausgesprochen enthalten sein, obschon sich bisher kein australisches Gericht zu dieser Frage aussprechen musste. Parallelimport mag gestattet sein, wenn der Patentinhaber keinen Vertrag abgeschlossen hat, um ihn zu verhindern; dies ist aber keine ausdrückliche Ausnahme. Ausnahmen für einzelne Verschreibungen und medizinische Behandlung werden nicht anerkannt.

Die australische Gruppe geht davon aus, dass die Harmonisierung des Patentrechts allgemein wünschenwert ist. Die australische Gruppe ist der Ansicht, dass das Patentgesetz ausdrücklich den experimentellen Gebrauch und den Parallelimport patentierter Erfindungen gestatten sollte. Die australische Gruppe ist der Ansicht, dass der Umfang der übrigen Ausnahmen des australischen Rechts einen angemessenen Ausgleich zwischen den Rechten des Patentinhabers und den Interessen anderer Parteien schafft.