Issues for pharmaceutical companies doing business in Australia

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The Australian pharmaceutical market is both highly competitive and highly regulated. There are a myriad of legal issues with which any pharmaceutical company conducting business in Australia must contend. Some of the current patent-related issues of relevance to pharmaceuticals in Australia are reviewed below.

Patent certification

In Australia, there is no linkage between the obtaining of marketing approval for pharmaceutical products and patents akin to the US Orange Book procedure. However, as a result of the Australia-US Free Trade Agreement, which took effect on 1st January 2005, an applicant applying for the listing or registration of a therapeutic good on the Australian Register of Therapeutic Goods (ARTG) must provide a certificate to the Australian Therapeutic Goods Administration (TGA) in relation to certain patent matters. Therapeutic goods are entered in the ARTG as either listed goods or registered goods, depending on their ingredients and intended purpose.

The listing or registration applicant must certify to the effect that either:

- Acting in good faith, it believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner or in circumstances that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods (a s 26B(1)(a) certificate); or
- A patent has been granted in relation to the therapeutic goods and the listing or registration applicant proposes to market the therapeutic goods before the end of the term of the patent, and the applicant has given to the patentee notice of the application for registration or listing of the therapeutic goods concerned (a s 26B(1)(b) certificate).

Subsequent amendments restricted these provisions only to listing or registration applicants which are required to submit safety or efficacy data as part of the application process, or which rely on the safety or efficacy data previously submitted to the TGA by another party in order to establish the safety of efficacy of other goods that have already been registered or listed. All applications for registration or listing of a medicine lodged on or after 3rd April 2006 must either notify the Secretary of Health that a patent certification is not required or provide a certificate.

If a certificate is required, it can be provided at any time prior to registration. However, the certificate is required once the evaluation of the safety, efficacy and quality of the goods has been completed by the TGA and a decision has been made to register the goods. At that stage, the listing or registration applicant will be notified in writing that the goods will be included in the ARTG once the applicant gives the certificate required or notifies where the certificate is not required in relation to the application.

In contrast to applications for the registration of therapeutic goods, the listing of medicines requires either a notification that a patent certificate is not required or the lodging of the certificate at the time of application. This is because the listing of goods occurs electronically and listing can be effected almost immediately.

If all other requirements for inclusion of the goods in the ARTG are met and the certificate has been provided by the registration or listing applicant, then the goods must be listed in the ARTG and there is no enquiry into the correctness of the certificate. The responsibility to ensure the correctness of the certificate rests with the registration or listing applicant.

Certificates required in relation to patent infringement proceedings

If the registration or listing applicant gives a certificate and the patentee (or an exclusive licensee) intends to commence proceedings against the registration or listing applicant for patent infringement, the patentee must itself provide a certificate prior to the commencement of those proceedings.

The certificate must be to the effect that the infringement proceedings are to be commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay.

If the patentee gives such a certificate which is false or misleading in any material particular or breaches the undertaking given in the certificate, then the registration or listing applicant can, with the leave of the court, apply to the Federal Court for an order that the patentee pay a pecuniary penalty. The maximum pecuniary penalty that can be imposed is A$10 million. The patentee may also be ordered by the court to pay compensation to the Commonwealth or State government for any loss sustained.

Requirements for interlocutory injunction applications

Before a patentee can commence proceedings seeking an interlocutory injunction against a registration or listing applicant which has given a s 26B(1)(b) certificate, the patentee must notify the attorney general of the Commonwealth or a State or Territory. If, in those circumstances, the patentee obtains an interlocutory injunction but subsequently discontinues the proceedings without the applicant's consent, or if the proceedings are dismissed and it is held that the patentee did not have reasonable grounds to believe it would be granted final relief for infringement of each of the asserted claims, the court may order the patentee to pay compensation to the registration or listing applicant. Compensation is in the form of an account of the gross profits of the patentee during the period of the injunction (without requiring the registration or listing applicant to establish or quantify any loss), as well as compensation to the Commonwealth or a State or Territory government for any loss that may have been sustained as a result of the grant of the interlocutory injunction.

Interlocutory injunctions in pharmaceutical patent cases

Prior to five years ago, there were very few examples in Australia of interlocutory (pre-final trial) injunction applications being made in respect of pharmaceutical patents. Since 2003, however, there has been a comparative explosion of such applications, with six cases having been decided since that time. The score currently stands at three cases in which interlocutory injunction applications have been refused and three in which they have been granted.

As with all of these cases, much depends on the facts; however, there are certain principles which can be usefully stated.

Principles governing interlocutory relief

The principles on which an application for an interlocutory injunction will be granted in Australia are well established:

- The applicant must establish that there is a serious question to be tried in respect of the infringement of the patent.
- The applicant must establish that, unless the injunction sought is granted, it will suffer irreparable harm for which damages cannot adequately compensate.
- The balance of convenience must favour the granting of the injunction sought.

Arguably, in the case of a pharmaceutical patent, where it is often asserted by the infringer that the patent is invalid, there is a fourth factor to be considered – the alleged infringer must establish a serious question to be tried on the alleged invalidity of the patent.

In most cases there is a sufficient argument as to the facts and the law to support a finding that there is an arguable case to be tried on infringement and invalidity. Most interlocutory injunction applications in Australia are therefore decided on the basis of whether the applicant would suffer irreparable harm if the injunction were not granted pending trial or on the balance of convenience factors, or both.

The PBS listing process

Once a therapeutic product has been registered or listed on the ARTG, the product sponsor can apply to the Pharmaceutical Benefits Advisory Committee for listing on the Pharmaceutical Benefits Scheme (BPS). If the product is listed on the PBS, the Commonwealth Government subsidises the medicine.

There have been a number of recent changes to the operation of the PBS which make the PBS a highly regulated and complex system of governmental subsidy for medicines. The complexity of the operation of the PBS has been an issue in all of the recent decisions relating to the grant of

interlocutory injunction applications in pharmaceutical patent cases.

Two recent cases

Two contrasting Australian Federal Court decisions handed down in 2007 emphasise the need to consider the impact of the PBS on pharmaceutical pricing in the context of interlocutory injunction applications in respect of pharmaceutical patents.

In the first of these, concerning the compound carvedilol, the alleged infringer had informed the market that it was proposing to sell carvedilol tablets commencing on 1st February 2007. The Australian Department of Health informed the alleged infringer that its products would be available under the PBS as from that date, and that the dispensed prices for the alleged infringer's products would be the same as the prices for the equivalent products sold by the patentee.

The patentee sued for patent infringement and sought an interlocutory injunction. The alleged infringer cross-claimed, alleging that the patent in suit was invalid. The court held that there was a serious question to be determined in relation to infringement. The patentee argued that it would suffer irrevocable harm if an interlocutory injunction were not granted. It relied on the following factors, among others:

- The possibility of a decrease in the price of its carvedilol products under the PBS (particularly given the then proposed changes to the PBS). On the facts, the court rejected the likelihood of this possibility.
- The patentee argued that it may elect to increase the price of its products in response to a generic listing in the expectation that lost sales will be made up by reason of a price increase. The patentee stated that it was impossible to say what effect that might have on market share. The court held that the market share consequences of an election to increase prices are measurable at any point by reference to lost sales, prices charged and margins earned. The patentee argued that it would be difficult to predict the dynamics of the market for the drugs in the price reference group which includes carvedilol under the PBS if there were additional competition from a generic entrant. The court held that this concern was speculative and the way to deal with it would be, if an injunction were refused, to reserve liberty to the patentee to apply again to the court if the postulated circumstances arose.
- The patentee also argued that the generic entrant could make an application to reduce the price of its carvedilol products at any time, thereby triggering an automatic price reduction under the PBS. The alleged infringer dealt with this concern by giving an undertaking to the court that it would not do so.

In this first case the Federal Court was not convinced by any of the arguments made by the patentee about the uncertainty of PBS pricing caused by the entry of a generic product into the market and refused to grant an interlocutory injunction.

The second decision was handed down late in 2007 in circumstances where the alleged infringer had first commenced an application in the Federal Court for revocation of a pharmaceutical patent. The patentee cross-claimed for infringement and sought an interlocutory injunction.

In granting the interlocutory injunction, the Federal Court considered the following factors to be important:

- The patent in suit was one which had been in force for some considerable time and had been commercially successful over that time.
- The alleged infringer had not commenced revocation proceedings within a timeframe so as to allow the issue of the validity of the patent to be considered in an orderly fashion, free of the complication occasioned by the impending launch of the alleged infringer's product.
- The judge was "much influenced" by the effects of disturbing the status quo, particularly as it related to the operation of the PBS. The court held that a new generic entrant into the field covered by the patent would have an effect which could be both unpredictable and irreversible, and that such a generic entry was likely to be an interference with the trade patterns of the patentee with its customers, at both wholesale and retail level, which may not be detectible or measurable in money terms.

It is also interesting to note that the alleged generic infringer argued that there was a public interest element in the encouragement of generic competition in pharmaceuticals. The judge was not impressed – he held that an organisation

engaged on a purely commercial enterprise wearing the cloak of public interest was something to be beware of.

Introduction of an experimental use exception to infringement

In August 2007 the then incumbent Australian Government issued its response to recommendations made by the Australian Advisory Council on Intellectual Property (ACIP) relating to patents and experimental use.

ACIP recommended that the Australian Patents Act be amended to establish an exception to patent infringement in the following terms:

"The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent.

Acts done for experimental purposes relating to the subject matter of the invention include:

- *determining how the invention works;*
- *determining the scope of the invention;*
- *determining the validity of the claims;*
- *seeking an improvement to the invention."*

The Government accepted, in principle, the recommendation to introduce an experimental use exception to patent infringement and stated that the exception will reflect, to the extent possible, the ACIP recommendation and as consistent with Australia's international treaty obligations.

However, no amendments were made to the Patents Act 1990 before the Federal Liberal Government was voted out of office. Although there seems to be no reason to suggest that the new Commonwealth Labour Government will deviate from the previous government's acceptance of ACIP's recommendation, it remains to be seen when and how this exception to patent infringement will be made part of Australia's law.

If the exception to infringement is enacted using the words of the recommendation, there will still be considerable room for debate as to how the provision will operate. For example, it is unclear whether the following would fall within the exception:

- The preparation of a patented compound for use in a comparative example to show relative efficacy.
- The manufacture of a patented compound to determine whether it can be prepared on a commercial scale; or
- The use of a patented receptor to find drugs that can block that receptor.

The enactment into Australian law of an experimental use exception to patent infringement may therefore only be the start of a long debate as to the extent of the exemption.

Wayne Condon practises in the area of intellectual property with an emphasis on patent litigation. He has more than 28 years' experience advising in relation to and conducting intellectual property litigation in Australia and other jurisdictions. Mr Condon's specific area of expertise is in the conduct of patent infringement and revocation proceedings, and he has been involved in a number of Australia's leading patent cases. His involvement in those cases has often been as part of a global team in multi-jurisdictional proceedings. He is therefore particularly experienced in dealing with the unique issues which arise in global litigation of this kind. He also has particular expertise in the pharmaceutical and biotechnology sector. Mr Condon is a prominent speaker on intellectual property matters and a proven author. having written extensively for a number of professional journals.

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