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Patent Opposition: Raising the Bar or Moving the Goalposts?

Australia's intellectual property laws will undergo major reform in April 2013, with the goal of better aligning the quality of granted patents with those of major trading partners, such as the USA and Europe. However, in some respects the reforms are selective, with the result that interested parties could, in the future, find themselves severely disadvantaged.

Less Time to Prepare Evidence

In a drive to reduce the overall length of the patent opposition process, the Patent Office is taking steps to make it more difficult to obtain extensions of time to file evidence.

Evidence in Australian patent oppositions usually takes the form of declarations from technical experts. The purpose of expert evidence is to attest to the state of the art, the common general knowledge and the teaching of prior art references. Under current practice the Patent Office will rarely consider any information that does not form part of expert evidence. Extension of time requests during opposition are, for the most part, a necessity associated with the difficulty in procuring expert evidence. This takes time, is expensive, and is typically not at the control of the patent applicant, the opponent or their respective representatives. Most experts have many other commitments.

Presently, it is not known how the tightening of extension of time requests will operate in practice. However, given the reliance on expert evidence, it is likely that both applicant and opponent will need to move far more quickly in order to formulate their respective positions. There may well be situations where a party is unable to properly assemble evidence due to a lack of time. This could lead, at worst, to the grant of patents of dubious validity or the rejection of patents that were possibly acceptable. There may be a bias towards parties with deep pockets.

Perhaps, as part of the current reforms, IP Australia missed an opportunity to implement a more far reaching measure by relaxing the reliance on expert evidence. This would have definitively addressed the length of opposition proceedings, their related cost, and met the overarching intention of the changes to bring Australian standards and practices in line with similar proceedings overseas.

Changing the Prior Art Base for Testing Inventive Step

A key element of the reforms is the change to the test for inventive step. The test will be altered to involve consideration of common general knowledge of the person skilled in the art anywhere in the world, not just in Australia. Furthermore, the requirement that prior art be 'ascertained, understood and regarded as relevant' will be abolished, thus broadening the range of documents that can be raised for inventive step.

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Congratulations to Watermark client **Bombora Wave Power Pty Ltd** on winning GE's Ecomagination ANZ Challenge prize of $100,000. The Challenge is a showcase of our region's clean technology and carbon reduction innovations. Watermark is proud to work with Bombora to provide Intellectual Asset Management services.

Recently, Watermark were proud sponsors of the LESANZ National Conference in Brisbane, and the AusBiotech BD Forum in Adelaide.

We are honoured to work side by side with such reputable organisations.

Patent Opposition – Raising the Bar or Moving the Goalposts?

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These changes mean that it will be harder to demonstrate an inventive step exists and accordingly the level of inventiveness required for a patent will increase.

These changes should bring Australia's inventive step test more in line with that of other major trading partners, and the new approach should be beneficial in opposition proceedings, where the validity of a patent claim is challenged.

A key focus of expert evidence in opposition is on inventive-step and common general knowledge. Since it will no longer be necessary to establish that a piece of prior art could have been 'ascertained, understood and regarded as relevant', reliance on expert declaratory evidence could be diminished. Patent attorneys and the Patent Office alike should be better placed to respectively submit and appraise a case for validity or invalidity in all but the most technically complex of cases. Such a change in practice would put the shorter timelines for opposition firmly in the hands of the applicant, the opponent and their representatives, resulting in much faster preparation of submissions.

Of course, this reflects the European approach to opposition practice, where the interested party's representatives generally make submissions in opposition.

Australia Should Adopt a More European Style Opposition Procedure

The Opposition Divisions and Technical Boards of Appeal of the European Patent Office decide opposition cases based on their own technical expertise. There is no requirement or necessary reliance on expert testimony. The law does allow the commission of an expert, if required. But in practice, the submission of evidence by appointing a technical expert is rarely ordered ex officio. However, the parties may present their own private experts, who may submit their analysis in writing.

IP Australia is raising the bar in respect of patent quality by modifying the test for inventive step to be more like that of major trading partners. It would seem appropriate to also modify opposition practice to relax the requirement for expert testimony in relation to common general knowledge and inventive step, and therefore align that aspect of opposition procedure with that of other major trading partners.

Alas, given the upheaval that the Australian patent system is undergoing, it seems unlikely that any further major reforms will occur in the near future. Therefore, interested parties will have to manage the shorter times frames within which to compile expert evidence as best they can. We await IP Australia's practice in regard to extensions of time with interest.

Dr Grant Jacobsen

Scoping an IP Due Diligence

Anyone involved in merger and acquisition (M&A) transactions will be familiar with due diligence investigations. Before buying a business, it makes sense for the vendor to investigate the target business to identify potential 'skeletons in the closet' that might affect value. In the context of a capital raising that requires a prospectus to be issued, the exercise of due diligence may afford a defence to liability if it turns out that the prospectus is defective.

For larger M&A transactions, the due diligence process is typically formalised by the use of a 'data room' (either physical or virtual) containing documents relevant to the business. Access to the data room is usually strictly controlled, and there will generally be a question and answer process by which bidders have the opportunity to ask questions of the target's management.

Balancing Risk and Cost

Thoroughly assessing the IP of a business can be a costly exercise, and a key issue which arises time and again for those undertaking due diligence investigations is how best to scope the investigations in a manner that appropriately balances risk and cost.

'Materiality thresholds' will generally govern what is to be reported to the bidder's management (or what is to be included in a prospectus) and they are the starting point for scoping any due diligence.

From an IP perspective, scoping a due diligence exercise can be particularly tricky. A typical IP due diligence will involve searches to ascertain what IP is owned by the target business. However, ownership searches alone do not provide any meaningful information in relation to the quality or validity of the relevant IP. For example, searches may show that a business has filed multiple patent applications. However, without further investigation it is not possible to draw any conclusion as to whether those applications are likely to result in granted patents, or whether the applications have any real value whatsoever.

Similarly, a typical IP due diligence - which involves compiling schedules of IP owned by the target business - will not reveal potential 'freedom to operate' risks, such as a key brand that is owned by another entity.

Five Key Areas of Enquiry

We suggest that the best way to scope an IP due diligence is to focus on what is of most value and potential value to the target business. For example, we suggest asking management the following questions:

1. What are the key product or service lines of the target business? Which product lines generate the most revenue for the business, or are most profitable? Do those product lines embody any IP (e.g. brand names, patents, designs), and if so, what is the breadth/strength of that protection? Patent and design expiration dates relevant to key product lines may provide an indication of when the business can expect to face additional competition.
2. What are the key markets in which the business operates? Which countries generate the most sales for the business? IP searches should be focussed on those countries.
3. Is capacity for expansion part of the perceived value of the business? For example, are there countries into which the business does not presently sell, but into which it might expand? Which brands and product lines would be sold in those countries? If expansion plans contribute to the perceived value in the business, it would be worthwhile checking that there are no issues with using key brands in those countries.
4. Are there particular manufacturing technologies or product features that are valuable to the business and which the business considers proprietary? Are those technologies protected by patents, or can they be protected as confidential information?
5. How is IP managed within the target business? The quality of a business's IP management systems may provide an insight into the likelihood of identifying hidden IP issues. How is IP managed in the business? Who within the business is responsible for identifying new IP and instructing attorneys? What systems/processes are in place for making decisions in relation to new filings and renewals? How much does the business spend annually on IP protection and enforcement?

Armed with the answers to these questions, it is possible to scope an IP due diligence that is focussed on what is material to the target business. A properly scoped and targeted IP due diligence is likely to provide information and insights that are useful to management, and will assist management to make quality decisions in relation to the proposed transaction.

Peter Hallett

Functional Ingredients: The Past May Come Back to Bite You!

A recent decision by the Full Bench of the Federal Court[1] may have far reaching impact on the food technology sector in Australia.

The case raises concerns for developers of food products having ingredients which impart beneficial functions other than supporting good nutrition.

Functional Ingredients in Baked Foodstuffs

The case involved a dispute between Danish biotech-based companies Novozymes and Danisco - two significant players in food technology globally. Core to the dispute is the manufacture of baked foodstuffs containing 'functional ingredients'.

The term 'functional ingredient' has different meanings depending on the context in which it is used. Danisco's patent, which was the focus of the dispute, broadly defines 'functional ingredient' as a constituent which performs a specific function in a foodstuff.

The process of Danisco's patent relies on an enzyme being able to produce two functional ingredients from constituents present in the starting food material prior to inactivation during the baking process. Common enzymes used in industry are proteins derived from microorganisms which are used as catalysts in biochemical reactions. Enzymes used as a processing aid during the production of foodstuffs, but which are ultimately inactivated during production, are not considered to be additives. Thus, there is a benefit for using enzymes in foodstuff production both from industry and consumer perspectives.

In the lower court[2], Danisco asserted infringement of their patent by virtue of the promotion and supply by Novozymes of Lipopan® Xtra for producing baked goods. Lipopan® Xtra is the trade mark given to a lipase enzyme which acts on fats found in animal and vegetable oils to produce lipids with emulsifying properties. These lipids can, for example, be used in dough to increase the softness of baked bread. Thus, in the context of Danisco's patent, the lipids produced by Lipopan® Xtra are considered to be functional ingredients.

In defence, Novozymes challenged the validity of Danisco's patent on several grounds. Of particular interest was the assertion that Danisco's invention lacked novelty over an earlier Novozymes patent. An example in that patent describes the use of an enzyme (a phospholipase also having lipase activity) as a bread improving agent. While the specification disclosed phospholipases as having dual activity, the invention was directed to improving bread by reducing phosphorous-containing components. The potential of the phospholipase to produce functional ingredients in the same manner that a lipase might was not known at the priority date of Novozymes' patent. Nevertheless, Novozymes submitted that use of the phospholipase according to the example would

inevitably result in the process of Danisco's patent. This argument was rejected, in part, because there was no disclosure or recognition of the production of functional ingredients in Novozymes' patent. The case was ultimately decided in Danisco's favour.

Invalidation of Danisco's Patent: Anticipation by Inevitable Outcome

The principle[3] concerning anticipation by inevitable outcome can be summarised as follows:

> If carrying out directions contained in a prior publication will inevitably result in something being made or done which would constitute an infringement of a claim, the claim has in fact been anticipated.

The Full Federal Court, in reconsidering Novozymes' earlier patent, rejected the primary judge's findings in relation to anticipation by inevitable outcome. It was considered that the primary judge had erred in interpreting the above principle, and in not fully appreciating expert testimony and evidence supporting the view that Novozymes' phospholipase, if used according to the method of Novozymes' patent, would have inevitably produced functional ingredients. It was therefore unnecessary that there be an explicit or implicit disclosure of the production of functional ingredients by phospholipase in Novozymes' patent to render Danisco's patent invalid.

Impact of This Case on the Food Sector

The food sector is highly competitive. Couple this with increasing demand from consumers for 'additive-free' food products and increasingly restrictive food labelling requirements, and manufacturers will be motivated to develop new cost effective processes for creating food products containing functional ingredients, irrespective of whether these ingredients perform 'functions' in foodstuff and/or provide health benefits in addition to supporting nutrition.

The present case highlights the importance of conducting detailed market and competitor analyses before driving innovation, particularly in existing market sectors.

Dr Chris Vindurampulle

[1] Novozymes A/S v Danisco A/S [2013] FCAFC 6

[2] Danisco A/S v Novozymes A/S (No 2) [2011] FCA 282 (29 March 2011)

[3] The General Tire and Rubber Co v The Firestone Tyre and Rubber Co Ltd [1972] RPC 457

Narrowing the 'ditch' between New Zealand and Australia

New Zealand and Australia have a close relationship, both culturally and in business. Australians often refer to New Zealand as the seventh state of Australia, and New Zealanders to Australia as their third, most westerly island. Historically, however, the two countries have had relatively independent patent laws and practice. This began to change in 1998 when both countries implemented laws allowing patent attorneys registered in one country to register in the other. This process of cooperation has continued with recent announcements by the Governments of each country of a Single Application Process and a Single Examination for applications filed in both countries.

The Single Application Process is an agreement that each country will allow for online filing of patent applications for the same invention in both countries in a single transaction. The reduced number of steps proposed to obtain the two patent applications has the potential to result in reduced overall costs to applicants. This, in turn, may lead to an increase in the number of patent filings in each country. It is important to note that it is intended that two separate applications are filed under the laws of each country, rather than a single cross-country application.

The Single Examination concept is intended to reduce duplication of examination for applications filed in both countries for the same invention. The aim is for a single examiner from one country to examine the two applications concurrently, thereby allowing for a more efficient examination of both applications. However, each application will be examined under the relevant country's law, albeit that they differ in certain respects, for example in regard to inventive step. Ultimately, the measure of success of the Single Examination concept will be whether the efficiency gained by only requiring a single examiner to be familiar with the subject matter of the two applications is greater than the complexity introduced by requiring examination to be undertaken in light of two different patent laws.

Before either system is introduced, it is understood that the New Zealand Parliament will have to pass the Patents Bill 2008 which updates New Zealand patent law and practice including the introduction of inventive step as a ground of examination.

Finally, although it is unlikely to occur for some time, there is also intent by the governments of Australia and New Zealand to merge the professions of the two countries, such that there will be a single body for the registration, training, and discipline of the patent professions.

Jeremy Robinson

Filing Belatedly For Patent Extension Of Term – Is It Possible?

In an appeal from a Patent Office decision to extend the time to file an application for extension of the term of a pharmaceutical patent, the Administrative Appeals Tribunal (AAT) recently upheld

- the power of the Patent Office to grant such an extension of time outside the prescribed period, and
- the use of the discretionary powers of the Patent Office to award a very long extension.

The decision is the most recent in the ongoing dispute between H Lundbeck A/S and several generic drug manufacturers over the correct expiry date of Australian Patent 623,144, covering Lundbeck's anti-depressant pharmaceutical escitalopram (+ citalopram), marketed as LEXAPRO™.

A request for a 121-month extension of time within which Lundbeck could request an extension of the term of the patent has been affirmed. Without the extension the LEXAPRO™ patent would have expired on 13 June 2009, but with the extension it expired on 9 December 2012. The extended term was important for both parties because the generic manufacturers had begun selling their own versions of LEXAPRO™ on or around 13 June 2009.

History of the Dispute

LEXAPRO™ was listed on the Australian Register of Therapeutic Goods (ARTG) on 16 September 2003 and the term of the patent covering it had been extended by the Patent Office until 13 June 2014 based on this date. This extension of term was revoked on 11 June 2009 by the Full Court of the Federal Court of Australia because

- CIPRAMIL™, a racemate mixture of (+) and (-) citalopram, contained (+) citalopram, and
- Lundbeck's extension of term application for LEXAPRO™ was not based on the first regulatory approval date of goods that contain or consist of (+) citalopram.

The Full Court also held that the LEXAPRO™ patent claims were valid and would be infringed by the respective generic products.

On 12 June 2009, one day before the LEXAPRO™ patent was to expire; Lundbeck filed an application for an extension of time to file an extension of term application based on its earlier ARTG listing of CIPRAMIL™. Nevertheless, the generic manufacturers went ahead and launched their own versions of LEXAPRO™, and opposed the extension of time request. These manufacturers took a calculated risk, given the likely damages award should the extension of time be granted and the term of the patent extended

AAT Review

The AAT had two questions to consider.

1. Does the legislation allow for an extension of time request for an extension of term of a patent?

The AAT held that if an application for an extension of term is made before the expiry date of the subject patent, the legislation makes available the discretion to grant an extension of time to satisfy all requirements of a patent term extension request. This is consistent with:

- the plain reading of the Patents Regulations and the Patents Act, and
- the interpretation adopted in the Patent Office Manual of Practice and Procedure.

2. If so, do the facts of this case justify a discretionary grant of an extension of time of over 10 years?

The justification for Lundbeck's extension of time request was an error in considering that the extension of term of the patent could be based only on the registration of LEXAPRO™ (and not CIPRAMIL™) because CIPRAMIL™ did not fall within the scope of the claims of the LEXAPRO™ patent. It therefore did not contemplate applying for an extension of term of the LEXAPRO™ patent based on the marketing approval of CIPRAMIL™.

It is a requirement that once an error or omission has been identified, an application for an extension of time be lodged without undue delay. The generic manufacturers argued that Lundbeck delayed its request for an extension of time, despite a suggestion to do so based on the CIPRAMIL ARTG date on 14 July 2005 from its Australian patent attorney and as a consequence, should not be entitled to the grant of a discretionary extension of time.

The AAT found that:

- It was reasonable for Lundbeck to believe that LEXAPRO™ had been accorded the correct and appropriate extension of term to 13 June 2014. (It was almost 10 years later that the basis for the extension of term was held to be incorrect in law). The reasonableness of Lundbeck's belief was supported by evidence that it was widely held among the Australian patent profession that the Federal Court was incorrect in finding that the CIPRAMIL ARTG listing date was the proper basis for an extension of the LEXAPRO™ patent term.
- In relation to undue delay, the patent attorney's 'letters setting out preliminary views, comments and possible strategic suggestions [did] not support a conclusion that the conduct of Lundbeck was in any way unreasonable in not making an application for an extension of time at that point'.

The decisions of the Patent Office and the AAT have been appealed to the Federal Court.

Dr Bruce Dowsing

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