



IAM: more than patents, beyond trade marks, way past IP. Fresh thinking from Watermark.

www.watermark.com.au

Should genes be patentable?

Patentability of gene sequences has been the focus of a number of Australian Government enquiries in the recent past as well as a matter of public interest and debate.

• See page 2



Watermark's world class IP professionals...

Congratulations to our Principal, **Roger Green** for his inclusion in Intellectual Asset Magazine's *Strategy 250 – The World's Leading IP Strategists*. Roger has been nominated as an individual who offers IP owners world-class strategic IP business advice.

Congratulations are also due to our Senior Associate and Lawyer, **Peter Hallett** for his inclusion in the *IAM Licensing 250 - The World's Leading Patent & Technology Licensing Lawyers*. Peter has been identified as one of the world's top lawyers in the area of patent and technology licensing.

Congratulations to Dr Chris Vindurampulle on his registration as a qualified Patent & Trade Marks Attorney.

Trans-Tasman Cooperation

Taking a look at the reforms needed to the intellectual property system in order to develop one process that accommodates two different sets of legislation and policies.

• See page 2

Watermark client wins second prestigious award

For the second year running SIPs Industries Australia Pty Ltd has won a GreenSmart Award, promoted by the Western Australian Housing Industry Association. This year SIPs Industries Australia won the 2011 Partnership Award and last year, the 2010 Product of the Year Award.

Structural Insulated Panels (SIPs) offer a green, energy and cost efficient solution to building construction. SIPs buildings are made with pre-manufactured panels that have outstanding strength and durability. The panels are heavily insulated providing thermal efficiency, critical in Australia's harsh climate. The core of insulation is sandwiched by two outer engineered timber boards

which can be used as floors, roofs, internal and external walls, replacing traditional wooden framing.

Using pre-manufactured composite panels speeds up the construction process considerably since panels are made to order before delivery to site. Typically the main structure of a building can be erected in days.

SIPs Industries specialises in all areas of building, including design, manufacture and on-site construction. Operating in the United Kingdom, South Africa and Australia, the sustainable product has demonstrable benefits to the environment.

Watermark's Perth office is currently helping SIPs Industries to protect and defend their intellectual property.

Cathy Hood



Providing award winning IP Strategy Development...

Watermark was selected by Corporate INTL Magazine to take out the 2010 Award for *IP Strategy Development Law Firm of the Year in Australia*.

Corporate INTL Magazine's independent research team reached its decision based on our service range, geographical location, operating procedures and the extensive expertise of our team.



Should genes be patentable?

While gene patents include within their scope human, animal and plant genes, the debate has largely centred on human genes and whether gene patents:

- advance technology by providing scientists with an incentive to create?
- hinder basic bench research via threat of litigation or actual litigation?
- allow those who control them to hinder clinical research and practice?

The Australian Senate Community Affairs Reference Committee handed down its report into Gene Patents in November 2010. The inquiry was set up to consider concerns raised over Australian patents directed to the BRCA1 and BRCA2 genes. Testing for these genes can identify a predisposition to developing breast or ovarian cancer. The owner of these patents has not enforced their patent rights in Australia, however, the impact of enforcement, should the patent owner choose to do so was central to the Committee's inquiry.

Following extensive consultation and submissions, the committee made 16 recommendations but did not recommend the patenting of genes be prohibited. It observed that the limited evidence it had did not show that gene patents are systematically leading to adverse impacts.

The committee also considered international developments and referred to the decision in the US District Court for the Southern District in New York (*Association of Medical Pathology and Others v The United States Patent*

and Trademark Office and Myriad Genetics, Inc and Others) in which Judge Sweet held that patent claims directed to isolated genetic materials are not patentable subject matter.

An equivalent challenge to the BRCA1 and BRCA2 gene patents in Australia was launched in the Federal Court in June 2010. It is unlikely that a decision in this case will be available this year as it is yet to be heard.

The Committee also referred to the Advisory Council on Intellectual Property's (ACIP) then current review on Patentable Subject Matter. ACIP's report issued in February 2011 and did not recommend that genetic material should be excluded from patentability. The ACIP report suggested that the existing exclusions from patentability should be retained (human beings and biological processes for their generation), but no new exclusions should be introduced.

The most recent development is the introduction into the Australian Federal Parliament of the Patent Amendment (Human Genes and Biological Materials) Bill 2010. It was introduced as a private members bill and thus does not have the endorsement of the major political parties. This Bill is intended to prevent the patenting of human genes and biological materials existing in nature. It proposes expressly excluding from patentability:

'biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature'

This Bill was referred to a specialized committee for review and this committee is expected to report to Parliament by a deferred deadline of 25 August 2011, with a focus on the specific terms of the proposed amendments and the implications of their implementation for human health and other potentially affected fields of innovation. The committee is also faced with the question of what 'substantially identical' is intended to mean.

With many different Australian and international forums currently considering the question of gene patents, it is hoped that a sensible outcome is reached that will continue to encourage research and development in Australia by allowing gene patenting and will also ensure that new medical diagnostics and treatments will be available to those in need.

Carolyn Harris

Trans-Tasman Cooperation

A high level of cooperation has existed for many years between the Australian and New Zealand governments with a commitment to create a seamless trans-Tasman business environment between the two countries.

In August 2009 the Australian and New Zealand governments announced a Single Economic Market ('SEM') outcomes framework between the two countries. One component of this framework is the integration of the intellectual property systems of the two countries to provide:

- one application process for patents,
- one examination process for patents,
- one trade mark regime,
- one plant variety right regime, and
- a single regulatory framework for patent attorneys.

Integration of Patent Examination between Australia and New Zealand

In February 2011 during bilateral talks on a number of topics, the next part of the SEM outcomes framework was outlined, including a commitment to establishing a joint patent examination system between the two countries.

According to the statement issued by the respective Australian and New Zealand intellectual property offices (<http://www.ipaustralia.gov.au/pdfs/news/>) this integrated patent system will be a world first. Two separate patent applications for the same invention filed in both Australia and New Zealand will be examined under the laws of the relevant country by one examiner located in either country. The intention is to reduce costs and to provide a faster examination process with a more consistent and high quality examination.

It is proposed Australia and New Zealand will operate as one integrated patent examination entity in practice but not in law. Examiners will grant or

refuse applications under each country's law. Both countries will however retain flexibility to implement legislation and policies.

The success of the integrated system will depend on examiners being trained in the laws of both countries and in understanding and applying both laws.

However significant differences currently exist between the Australian Patents Act 1990 and the New Zealand Patents Bill 2008 ('the NZ Bill'). Differences include the law on inventive step and statutory exclusions from patent protection in New Zealand (not Australia) that include methods for the medical treatment of humans by surgery or therapy and methods of diagnosis practiced on humans. Also the NZ Bill has recently been amended to exclude computer programs from patent protection.

The Australian Patent Office predicts it will be three years before a single patent examination process between the two countries is implemented, although this may be optimistic given some of the differences that exist.

A Single Regulatory Framework for Patent Attorneys in Australia and New Zealand

In April 2011 as a further part of the SEM outcomes framework, the Australian Patent Office and the Ministry of Economic Development in New Zealand issued a discussion paper for a single trans-Tasman patent attorney regulation.

The key reform proposed in this discussion paper is the establishment of a single trans-Tasman Government Board or body responsible for education, discipline and registration of patent attorneys. Again, there are differences between the two countries that will impact on the ultimate success of this integration.

The current Trans-Tasman Mutual Recognition Arrangement allows reciprocal registration for patent attorneys in each country. Watermark attorneys are registered and practice before the New Zealand Patent Office. Ultimately, if this new framework is implemented, Watermark will continue to assist in protecting and managing the intellectual assets of its clients in Australia and New Zealand.

Jill Newton



Does mere naming of a chemical compound destroy novelty?

It is well established in Australia that a claim will lack novelty if each essential feature is disclosed in a prior art document. What remains less clear, however, is the level of disclosure required to destroy novelty, particularly in chemical cases.

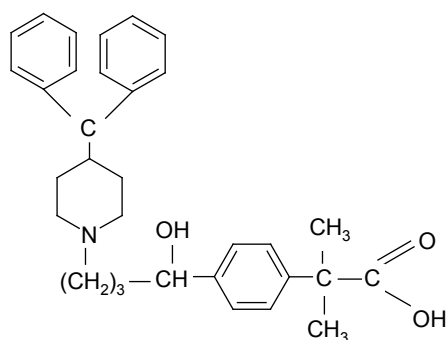
Enablement

Traditionally, the requirement that the disclosure 'enable' the skilled person to put the invention into practice was clear: 'the antecedent statement must be such that a person of ordinary knowledge of the subject would at once perceive, understand, and be able practically to apply the discovery without the necessity of making further experiments and gaining further information before the invention can be made useful' (English Court of Chancery in *Hill v Evans*¹, approved by the High Court, (the highest court in the Australian judicial system) (in *Olin Corporation v Super Cartridge*²).

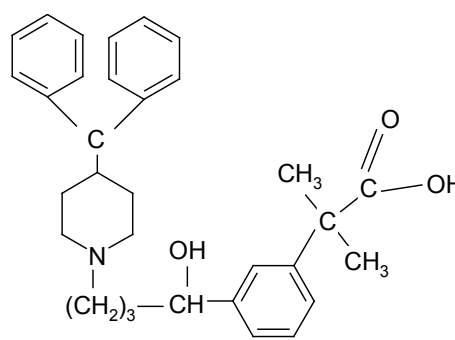
In more recent years, a potentially inconsistent line of authority has developed, which casts doubt on the enablement requirement where the relevant claim relates to a chemical compound: '[w]here the prior publication discloses exactly what is claimed, there is anticipation' (Full Court *obiter* in *H Lundbeck v Alphapharm*³, applied by the same judges in *Apotex v Sanofi-Aventis*⁴).

Albany Molecular Research v Alphapharm

The apparent tension between these lines of authority is set to again come under the judicial spotlight. Albany Molecular Research, Inc ('AMR') has recently filed a Notice of Appeal from the decision in *Albany Molecular Research v Alphapharm*⁵.



Fexofenadine (para regioisomer)



Corresponding meta regioisomer

The dispute centres on the isolated compound fexofenadine (shown above, left).

In the most significant aspect of the first instance decision, Jessup J considered whether claims to a substantially pure compound lack novelty. It was not in dispute that the closest prior art disclosed the isolated compound. However, Jessup J found that the prior art did not disclose an effective means of **preparing** the isolated compound. After extensive consideration of expert evidence, Jessup J was satisfied that following the instructions set out in the examples of the prior art would lead to a mixture of fexofenadine and the meta regioisomer (shown above, right), **not** isolated fexofenadine.

Validity of the relevant claims pivoted on whether, given these findings of fact, the claims were novel.

Jessup J felt he was bound by the law as expounded in *Lundbeck* and *Apotex*, notwithstanding the High Court decision in *Olin Corporation*. In siding with the closest factual precedent, Jessup J held that 'the disclosure of a compound by exact naming in the prior art is sufficient, of itself, to constitute anticipation'. It is not necessary to prove that the prior art enables the manufacture of the claimed compound. His Honour's reasoning leads to the unusual result that although the relevant claims are inventive, they lack novelty. Jessup J's orders revoking the relevant claims of AMR's patent have been stayed pending the appeal decision.

Patent Office Position

Interestingly, Australian patent examiners do not appear to be following the decisions in *Lundbeck*, *Apotex* and *AMR* as no reference is made to any of them in the relevant section of the examiner's manual⁶. The manual asserts that the definition of enabling disclosure in chemical situations is 'one sufficient in the case of a claim to a chemical compound to enable those skilled in the art to make the compound', citing the twentieth century English authority *Pall Corp v Commercial Hydraulics*⁷, which is consistent with the traditional *Hill v Evans* approach. It is not clear whether the absence of references to more recent Australian authority is deliberate, however, as the section of the manual has not been updated in five years.

Relevance to Pharmaceutical Patent Applicants

The AMR decision has particular relevance for chemical and pharmaceutical companies operating in Australia and has implications for the novelty of some chemical compound claims. As the law and Patent Office practice stand, originator companies with compound claims accepted by the Patent Office may find it difficult to defend third party novelty attacks in opposition or court proceedings, particularly where prior art enablement is at issue. It is likely to be a number of years before the available avenues of appeal from the first instance *AMR* decision are exhausted and a higher degree of legal certainty restored.

Geordie Oldfield

¹ *Hill v Evans* [1862] EngR 365.

² *Olin Corporation v Super Cartridge Co Pty Ltd* [1977] HCA 23.

³ *H Lundbeck A/S v Alphapharm Pty Ltd* [2009] FCAFC 70.

⁴ *Apotex Pty Ltd v Sanofi-Aventis* [2009] FCAFC 134.

⁵ *Albany Molecular Research Inc v Alphapharm Pty Ltd* [2010] FCA 120.

⁶ *Australian Patent Office Manual of Practice and Procedure Part 2.4.12.1.3.*

⁷ *Pall Corporation Commercial Hydraulics (Bedford) Ltd* [1990] FSR 329



Should I renew the trade mark I'm not using?

A trade mark is one of the most cost effective assets of a business.

The renewable term of a registered trade mark is almost universally 10 years, and when the cost of renewing is amortised across this term, it can come down to an investment of less than a couple of hundred dollars per year. Now that's value for money when you consider the value of a trade mark in brand positioning and protection of a product, service or even an entire business reputation.

A prudent owner of an intellectual asset, however, never spends money on it unless the cost of doing so is justified by the needs of the business in which it is used. If an asset such as a trade mark is not being used, it shouldn't be renewed, should it? Not so fast! It is true that a trade mark becomes vulnerable to removal from the Australian Trade Marks Register if it has not been used (as long as 5 years has passed since its date of registration). However, this is only one of several factors to be considered in taking a business decision about renewal.

The premise of the following suggestions is that, while a trade mark may have become vulnerable through non-use, this can be addressed by minimal, new and genuine use in commerce.

- Why is the trade mark unused right now? Is it because there are no products or services utilising the trade mark? Or is it that the company is still committed to the product or service, but actual sales or service delivery under the trade mark are not occurring because of other business factors such as the economic environment? Before abandoning the trade mark, a decision will need to be made about dropping or repositioning the product or service first. Perhaps the contributing circumstances will change. Don't throw out the proverbial baby with the bathwater.
- Is there value in reinvigorating the trade mark? If it was successful first time around, perhaps it can be used to stimulate new revenue streams. A great example of this strategy is the re-launch by Pacific Brands of the ANTZ PANTZ brand. The 'sick 'em Rex' campaign, successful when the brand was first launched,

was reintroduced about a decade later to achieve great market penetration of ANTZ PANTZ products a second time around.

- Is the trade mark of some value to another part of the business or to an external party? This is a particularly good question if a) there is a residual market reputation in the trade mark (despite the non-use), or b) quite some financial investment was required to achieve registration, or to originally build the brand in the market. Any decision to remove an intellectual asset from the books should be preceded by asking whether a last return on that investment can be obtained by divestment rather than abandonment.
- Does the trade mark have elements (words or figurative) in common with other company trade marks? If so, then keeping it alive may act as a defence to competitors strategically positioning their own trade marks closer to those other company trade marks in use (working assets). In other words, the trade mark may help keep a visual and aural distance between a company and its competitors. Remember, it's vulnerable to removal, not invalid. A competitor must take positive action to remove it. While it remains on the Register it creates at least a perception of a barrier to entry for competitors.
- Does the company want its competitors to have the advantage of that residual reputation mentioned above by being able to re register the trade mark in their name? Having abandoned a trade mark registration your company does not want to have to argue why a competitor's use is deceptive or misleading because the company still wants to claim that reputation, and realises too late that it is inextricably linked to the trade mark? Understand the full value of a trade mark, not just its cost.

The principles of good intellectual asset management apply equally to small and large investments. Sometimes the benefits of even a small spend on trade mark renewal can be counter intuitively vast, and the downsides of the 'saving' unexpected.

Karen Sinclair

Up to speed

Want the latest news? Subscribe to the RSS feed at the Fresh News desk at www.watermark.com.au



Meet Carla Cher

"The innovation of technology miniaturisation and miniature technology of our clients is changing the world. Although I can't see a lot of the technology I work with easily with the naked eye, the products it is ultimately put in to will be seen and used by millions of people. It's exciting helping our clients create something many will benefit from."



IAM

Part of your team

Carla Cher is a Patent and Trade Marks Attorney of Watermark. Contact Carla on c.cher@watermark.com.au

IAM: Keeping up to date

Intellectual Asset Management (IAM) is not simply about patents and trade marks. IAM is concerned with all aspects of the intellectual assets of a company while ensuring an approach that will suit your business and the future direction of the company. It is no longer just a matter of looking at your business in isolation, it is necessary to consider:

- Your competitors;
- How you can capitalise on your intellectual assets;
- What trends are occurring in the local and global market; and
- Where your industry and the technology that you use is headed.

Can't just think local any more

If you understand the global market and how it is affecting the local market, you can have a better understanding of what areas are likely to expand in your local market and conversely which areas are likely to diminish or in some other way, change.

Keeping in touch with technology

Likewise it is important to keep up to date with technology and what is occurring in your technology field. Our attorneys at Watermark are actively involved in a number of industry organisations. Knowing what factors may affect you and your business or how to capitalise on a specific area of the market is crucial. Being actively involved for almost 15 years within Engineers Australia, the peak engineering industry body in Australia, Carla Cher has networks in many sectors of the engineering community, particularly biomedical and micro and nanotechnology. Keeping up to date with trends and innovation in technology in this way is imperative, enabling us to advise our clients in a complete business focussed, IAM approach; rather than merely commenting on intellectual property matters, such as patent or trademark issues.

Carla Cher