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A dichotomy in legal outcomes makes for rocky roads ahead

Key Points -

- **The Full Federal Court of Australia (FFCA) has upheld the patent eligibility of Myriad's claims to the isolated BRCA genes, although leave to appeal this decision to the High Court has been sought.**
- **The FFCA decision contrasts the US Supreme Court's Myriad decision which found against the patent eligibility of the isolated BRCA genes.**
- **Australian patent law provides technology neutral safeguards against abusive monopolistic behaviour – there's no need to panic.**
- **US patent applicants seeking to patent isolated naturally occurring molecules should consider delaying prosecution until certainty around patent eligibility is restored.**

The controversial issue of gene patenting has hit the headlines, yet again, following the recent Full Federal Court of Australia ('FFCA') decision in *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 115.¹ The decision upholds an earlier² Federal Court finding that isolated gene molecules are patentable in Australia. These cases specifically relate to the BRCA patents which claim both breast cancer diagnostic methods and the BRCA gene molecules.

This FFCA decision contrasts that of the US Supreme Court³ ('USSC') in the parallel US Myriad litigation, where patent claims to the isolated BRCA gene molecules were invalidated on the ground that isolated DNA is a product of nature and therefore not patent eligible.

While the litigation in the US cannot be appealed any further, the FFCA decision may be appealed to the Australian High Court. In this regard, an application for leave to appeal to the High Court was

filed on 16 September 2014 but is yet to be decided.

Australia Got it Right

The FFCA, being expressly wary that oversimplification of the facts and underlying scientific principles can lead to incorrect conclusions, clarified that the isolation of DNA is more than just a mere discovery. The Court found that the BRCA gene molecule is not the same as its naturally occurring counterpart, there being both structural and functional differences which result from its isolation. Notably, the Court distinguished its reasoning from that of the USSC for reasons including that the USSC focussed on the nature of the information contained in the BRCA gene while the Australian Court focussed only on the nature of the physical molecule itself.

The FFCA decision concludes with comments which stress that it is not the role of the Court to comment on the

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wisdom of the patent system. Rather, the role of the Court is to apply the Australian law, as set out in the Patents Act 1990 (the Act) and as developed by the courts, and not to consider whether, for policy, moral or social reasons, gene molecules should be excluded from patentability.

On balance, the FFCA made a persuasive and clearly reasoned decision. Unsurprisingly, however, opponents to gene patenting have largely condemned the decision arguing, amongst other things, that the BRCA diagnostic test could become inaccessible and research could be stopped. Thus, there still remains a very serious disconnect between the public's understanding of the question of patentability and the decisions of the courts. For example, if isolated genes *per se* were found not to be patent eligible, this would have no impact on the existence of patent rights over a diagnostic test, which is separately

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patented. To this end, it is interesting to note that the Australian Myriad judicial proceedings did not challenge the validity of the BRCA diagnostic method claims and these claims remain in force. This situation therefore highlights the importance of the safeguards which are enshrined in legislation. For example, the Act contains Crown use and compulsory licensing provisions that provide a technology-neutral safety net which could be used to deal with abusive monopolistic behaviour in respect of patented DNA technologies.⁴ Still further, since 2012, certainty about the extent to which patent rights impinge on freedom to research has been provided by an experimental use exemption,⁵ which exempts from infringement work done for experimental purposes relating to the subject matter of an invention. Accordingly, the FFCA decision in the Myriad case does not impact on future access to the BRCA diagnostic test nor future research and development into improved or new tests.

On a more general note, it is pertinent to note that the FFCA decision has not changed the law in Australia but merely confirmed it. Within the context of this existing legal framework, to date there has never been a healthcare crisis in Australia due to an inability to access patented diagnostics or therapeutics.

But What Now for the US?

On 4 March 2014, the USPTO issued an updated examiner guideline⁶ which dramatically extended the application of the USSC decision beyond the exclusion of isolated genes to the exclusion of **all** 'naturally occurring products' from patent eligibility. Naturally occurring products are defined as substances found in or derived from nature including chemicals derived from natural sources, foods, metals, minerals, nucleic acids, organisms, proteins and the like.

The USPTO invited public commentary on this updated guideline and, not surprisingly, many⁷ have been critical of the Office's application of the law. The

guideline makes it nearly impossible for innovators to obtain an adequate scope of protection, particularly for biotechnological and pharmaceutical inventions involving natural products, and thus significantly undermines investment and innovation in these areas.

Until the USPTO alters its guidelines, or the US legislature clarifies the law, companies prosecuting patents in the US are recommended to pursue strategies to delay prosecution until certainty concerning patent eligible subject matter is restored.

**By Dr Tania Obranovich and
Dr Chris Vindurampulle**

Contact Tania:

t.obranovich@watermark.com.au

Contact Chris:

c.vindurampulle@watermark.com.au

¹ <http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/full/2014/2014fcafc0115>

² Cancer Voices Australia v Myriad Genetics Inc [2013] FCA 65 (15 February 2013); <http://www.austlii.edu.au/au/cases/cth/FCA/2013/65.html>.

³ Association for Molecular Pathology v Myriad Genetics, Inc. http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf [PDF, 146KB]

⁴ <http://intellectualassetmanagement.com.au/biotechnology/is-abolition-or-greater-control-of-gene-patents-still-on-the-australian-parliamentary-agenda.html>

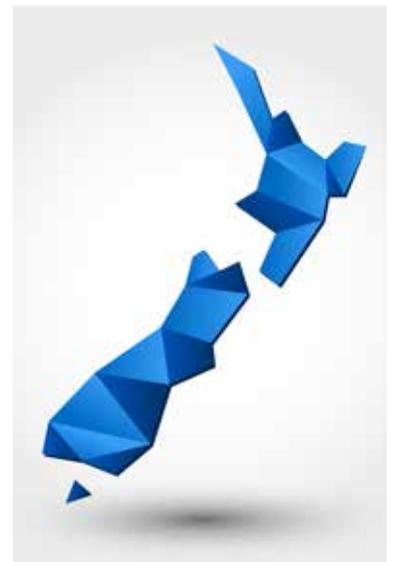
⁵ http://www.austlii.edu.au/au/legis/cth/consol_act/pa1990109/s119c.html

⁶ http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf [PDF, 198KB]

⁷ http://www.uspto.gov/patents/law/comments/myriad-mayo_guidance_comments.jsp

New Zealand Act – 5 take away points

- Examiners in New Zealand now have more tools at their disposal. Examination is made on an absolute standard of novelty, and inventive step is now a ground for examination. Applicants also now face reduced timeframes for responding to reports and obtaining acceptance.
- Computer software as such is no longer patentable. 'Software-type' applications filed in New Zealand will have to meet similar requirements for patentability as those filed in Europe.
- Applicants should be alert to the fact that divisional applications cannot be filed more than five years after the originating parent application, thereby putting a limit on daisy-chaining applications.
- Those with commercial interests in New Zealand now have more ways to challenge the validity of competitor patents and applications, from low cost observations during examination, medium cost re-examination options, through to higher cost opposition and revocation proceedings.
- The cost of maintaining patents and applications is now higher, with annual annuity payments now required.



By Jeremy Robinson

Contact Jeremy: j.robinson@watermark.com.au



Brand strategy: what's in a name[®]?

Key Points -

- **A surname can be a great brand because it personally connects you to your product.**
- **Registrable Trade Marks need to have a degree of uniqueness – surnames can fail at this hurdle.**
- **Commitment is required, but the legal hurdles to trade mark registration can be overcome through careful management.**



Many famous brands have their origin in the surname of a founder of the business: Selfridges®, Myer®, Givenchy® and Harrods® to name a few. These trade marks are now first and foremost associated with the businesses of the men who founded them, but once upon a time, Mr Selfridge and the others were just bright-eyed entrepreneurs, with no reputation, each trying to make an impression by using their name to distinguish their products and services in the market. History shows that these men were very successful, but it was a risky brand strategy to adopt!

The rules

It's fundamental to trade mark law that the 'origin' of a product or service can be associated with a particular trade mark. When applied to particular goods or services, if the trade mark has an element of uniqueness to it – known as 'distinctiveness' – then the owner of the trade mark can acquire the right to stop others using that trade mark on their similar products or services. It follows that if a trade mark is not distinctive for particular products or services, then no exclusionary right should be possible. Of course, what is distinctive is not always clear cut, and so the law has adapted to soften the hard edges of these rules.

A surname can be a 'good' brand

One factor in determining whether a trade mark is distinctive is whether other people might have a legitimate reason to adopt the same trade mark. Using your surname as your brand is a

very legitimate way of evoking the most personal and direct connection between your product and its origin. From a marketing perspective, this is a very good reason to use your surname as your brand.

But, when other people have the same surname, and are equally entitled to use their own name to indicate the origin of their product, the risk you run is that you will be unable to obtain the exclusionary protection afforded by trade mark law. Without that exclusionary protection, the competitive landscape is much rockier.

Knowing what you have to do

If you choose to adopt a surname as your brand, and you want to have all the benefits of trade mark law on your side, here are some factors you'll need to take into account:

- The Australian Trade Marks Office has a mechanism for determining just how distinctive a surname is. If a surname occurs on the Australian electoral roll more than 750 times, then it is questionable whether it is capable of being distinctive.
- If your product or service is a commonplace one – a café, clothing or retail outlet – then using a non-distinctive surname is going to be especially risky. If your product or service is more obscure, then the risks are much lower.
- If your surname is a common one, and your new business involves popular products or services – don't despair. You'll need to be really

committed, but if you can prove that, through heavy advertising and sales, your business has developed a strong reputation, i.e. the surname has become strongly associated with your business, then the protection of the law may be achievable.

- In the case of very common surnames, 'heavy' means many years of widespread and high volume use before you seek trade mark protection.
- If someone else in the past developed a strong reputation for their business using your surname, the residual power of that reputation might prevent you from starting your own business under the same name. Once a surname is recognised as a brand, the law can protect it well.

Talk to us early when you are strategising!

Surnames can become powerful and valuable brands. But getting the protection of trade mark law around them can be tricky – and expensive. The best approach? Talk to us early in your brand development process about ways to leverage a surname for long lasting success.

By Karen Sinclair

Contact Karen:

k.sinclair@watermark.com.au



Food for Thought – Innovation in the Food Industry

Key Points -

- **Global food demand is expected to increase 70 percent by 2050, with a concomitant increase in demand for premium food products in Australia's leading trading partners.**
- **Can Australia be the 'food bowl' of the Asia-Pacific, or should Australian companies be key drivers of food innovation focussing on the 'premium food sector'?**
- **Recent patent analysis suggest that Australian companies, in the food sector, demonstrate a 'positive technological specialisation'. This provides new opportunities for innovation and the development of 'premium products'.**

Global food demand is expected to increase 70 percent by 2050. The affluent middle class in Asia could reach 3 billion people by 2030. With abundant land, and suitable climatic conditions, it has been suggested that Australia should position itself as a ('food bowl' for the Asia-Pacific region. Practically speaking, however, as put by the Federal Government's Agriculture Minister, Mr Barnaby Joyce: 'We only produce about 1 percent of the agricultural product of the world ... and at the very best we feed about 60 million people now. If we doubled it – well, 120 million We couldn't even feed half of Indonesia'

Mr Joyce's view is that Australia should be an exporter of premium products.

At the Australia-China BusinessWeek Forum (held in August 2014) Mr Joyce's comments were echoed. Key speakers argued that Australian exporters need to think 'innovatively' at multiple levels not the least of which

is in the traditional areas of production, packaging and new product development (e.g. functional foods, vitamin enriched foods).

A recent report published by IP Australia (The Australian food industry: a patent analytics report 2014) ranked Australia 14th globally in patents relating to food - comparable to Canada and Sweden. It notes that Australia 'exhibits a positive technological specialisation in the food industry'. Around 45 percent of all Australian food inventions are cited by follow on inventors, with a significant degree of collaboration between applicants demonstrated by the fact that nearly 23 percent are co owned.

An analysis of Australian originating applications over the period 2000 to 2011, shows that the geographic distribution of patent applicants follows regional food and technology specialisation: wine and brewing from South Australia, meat processing

from Queensland, bakery from New South Wales and beverages from Victoria. Enhanced shelf life, improved production methods and functional/therapeutic foods are popular subject matter. Across the analysis period some sub-sectors have been sustained in popularity: cocoa/chocolate/confectionery, wine, dairy, packaging/food transport and therapeutic foods. These trends are not apparent in data from other countries, for example, Canada and Sweden.

The data backs up Mr Joyce: Australian companies do have unique products which should help create opportunities to secure entry into new markets. In an increasingly challenging domestic market, export of value added products is clearly indicated.

By Dr John Golding

Contact John:

j.golding@watermark.com.au

IAM: Watermark

Watermark congratulates:

Oxyzone Pty Ltd, in collaboration with Sydney Water, and Rip Buoy Holding Ltd were recognised at the Sydney Engineering Excellent Awards recently.

Oxyzone won in the category of 'Products, Manufacturing, Facilities and Processes'. Watermark helped with providing IP advice and an innovation patent.

Rip Buoy Holding was awarded the 'Innovations and Inventions, Highly Commended' Award.

Get to know Chris Vindurampulle:

Chris Vindurampulle, an Associate at Watermark believes that you can achieve anything if you want to.

Chris' PhD study in Microbiology and Immunology related to vaccine development and led to an interest in the field of biotechnology, in particular, bacteria-based technologies.

Prior to joining Watermark, Chris was a Research Fellow at the Center for Vaccine Development (CVD), at the University of Maryland, Baltimore, USA. When Chris returned to Australia, he worked as a Senior Research Fellow at the University of Melbourne contributing to research into a vaccine against streptococcus pneumoniae, a leading cause of morbidity in children under the age of 5.

