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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.

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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>

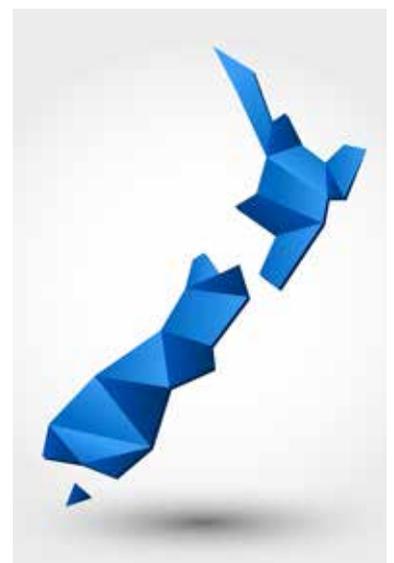
⁵ http://www.austlii.edu.au/au/legis/cth/consol_act/pa1990109/s119c.html

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

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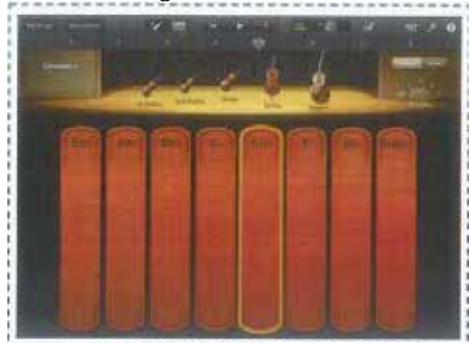


Design protection for transient display screens

Key Points -

- Design registrations for display screens on electronic products are being certified.
- Such certified designs have some commercial value, though enforceability remains uncertain.

Apple Inc's Australian Registered Design for 'Display Screen for an Electronic Device' (AU 345903) was substantively examined and certified in April 2013. This certification caused ripples because, previously, designs which are transient in nature were not considered certifiable. Other companies have since followed suit achieving certification of their transient designs.



AU 345903 in the name of Apple Inc for Display Screen for an Electronic Device

Protecting transient designs under the Australian Designs Act

Transient designs are designs which appear on a device, such as a display screen, when it is powered on, e.g. icons displayed on a computer screen, or a design displayed on some form of graphical user interface (GUI). These designs are usually generated by software.

Examination of an Australian Registered Design is not automatic and does not occur unless initiated by the applicant or a third party. If a design is a permanent feature of a product, then design protection is available under the Australian Designs Act 2003 (the Act). An Australian Registered Design is enforceable only after it passes substantive examination and is certified by the Australian Designs Office.

As the fate of registrations for transient

designs has been uncertain, the practice of companies keen on protecting transient designs in Australia has been to register their transient designs without requesting substantive examination. The Australian Designs Register is therefore replete with uncertified, and thus unenforceable, registrations of transient designs.

Enforcing registrations for transient designs

Although registrations of transient designs are being certified, their enforceability remains questionable.

The basic test for infringement of a registered design is whether the alleged infringer exploits a 'product' having a design identical/similar to the registered design without the design owner's permission. Importantly, the alleged infringing product needs to be the product for which the design is registered.

The Act defines a 'product' as a 'thing' that is manufactured or handmade. On its face, the Act does not exclude display screens.

However, the Australian Law Reform Commission's (ALRC) report No. 74 which preceded the current Act stated that a 'screen display' should not be regarded as a product. The ALRC report recommended that:

Screen displays should **not** be able to be protected as designs.

It is **not** necessary to include any special provision in the new designs legislation to confirm this.

The Government accepted this recommendation. As a consequence, no provision was included in the Act to expressly exclude protection for 'screen displays'.



In view of the Government's acceptance of the ALRC recommendation, the current practice of the Designs Office is to require that a 'product' be non-transient. The Examiner's Manual of Practice and Procedure explains that a product is a 'thing', the features of which must be assessed when it is 'at rest', rather than 'in use', e.g. an electronic device not connected to a power supply. In view of this guidance, the basis for certifying designs relating to 'screen displays' is uncertain. Possibly, examiners are unable to conclude, based only on the filed representations, and accompanying statement of newness and distinctiveness, that the registered design is transient rather than permanent in nature.

Determining infringement of transient designs

When assessing infringement of a registration for a transient design, it will likely be imperative to ascertain – what is the product? And is it protectable under the Act?

An answer to these questions will likely only become clear when – and if – they are considered by a court.

In the meantime, we recommend that prospective applicants bear in mind that 'display screens' can be registered **and** certified in Australia. However, whether such registration can be successfully enforced in court remains uncertain.

By Shirraj Takle

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Protecting Your Brand: The Justice League Way

Key Points -

- **Warner Bros. and DC Comics continue evergreening strategy for trade marks in preparation for movie release**
- **The development of IP is critical to establishing and protecting valuable exclusive rights**
- **What comes first? Domain names or trade marks?**

It may be over 18 months until the release of the highly anticipated Batman V Superman movie, but Warner Bros. (WB) and DC Comics have already begun evergreening their IP rights through the registration of new trade marks and domain names.

Building an IP portfolio

Warner Bros. began in mid-2013 by registering the domain names BatmanVsSuperman.com, SupermanVsBatman.com and BatmanVsSupermanMovie.com, giving fans their first insight into possible movie titles. However, they also quickly threw the market off the scent by registering several Man of Steel titles, suggesting that there may be a sequel of the original Man of Steel feature.

Fast forward to July 2014, and unbeknown to the 6,000 cheering fans at San Diego Comic Con, DC Comics had filed trade marks across Australia¹ for the movie title, "Batman V Superman: Dawn of Justice". Each of these marks has now been accepted in goods and services classes 9 and 41, which relate

to motion pictures and entertainment services, respectively.

Trade Mark filing strategy

WB and DC Comics are no stranger to protecting their brands in the market, like most international companies, the development of IP is critical to establishing and protecting valuable exclusive rights. The 'Dawn of Justice' trade mark adds to a list of over 100 marks in Australia, including the ubiquitous Superman shield (Trade Mark Nos. 426045 & 728445) and variations of the Batman logo (Trade Marks Nos. 1513455 and 1517824).

For companies like WB or DC Comics, it is extremely important to file for marks and domains when an idea is conceived, preventing domain-squatters and those capitalising from marks yet to be registered. In this particular case, a 'footprint' of the brand was established several months after the initial announcement of 'a movie' in 2013 with the registration of domain names. However, DC Comics left the filing of trade marks, for the movie title, until 7



Australian Trade Mark Application
No. 1643438

weeks after the release of the name.

Why was the trade mark filing left so late in Australia?

Those familiar with Australian trade mark law would understand that ownership of a trade mark is established by being the 'first to use' it.² DC Comics has an extensive and well-established portfolio of Superman and Batman marks, dating back to the 1940s. Therefore any applicant that dared to file for the 'Batman V Superman: Dawn of Justice' mark or similar, would have been denied by General Zed the Trade Marks Registrar on the grounds of section 43 of the Trade Marks Act 1995 'likely to deceive or cause confusion' or section 44 'marks that are substantially identical or deceptively similar'. Alternatively though, domain names and social media accounts are not governed by similar laws and hence 'Flash' speed is required to secure these marketing avenues.

By Dr Renee White

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¹ Australian Trade Mark No. 1633098

² Australia Trade Marks Act 1995 s 58A

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.

