Inspire!

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Editorial

Adrian Crooks, Partner

Welcome to the December edition of *Inspire!*

As 2015 draws to a close, we would like to wish you season's greetings and a very happy new year. The past 12 months have been significant for the POF Group with a move to our new premises at 333 Collins Street, Melbourne, and Dr Mark Wickham and Dr Scott Whitmore joining the POF Partnership along with a number of other senior appointments. Looking ahead to next year, the recent focus on the importance of innovation to Australia's future promises exciting times in the area of intellectual property.

Our final *Inspire!* for 2015 looks at two important decisions of Australia's highest Court. Mark Wickham assesses the implications of *D'Arcy v Myriad Genetics Inc.*, a case which received a significant amount of media attention due to its association with genetic testing for predisposition to breast and ovarian cancer. Ultimately, the High Court held that claims to isolated nucleic acids defined by reference to naturally occurring genetic mutations were not patentable subject matter. The decision itself relates to a narrow class of claims, however its ongoing impact may be broader and IP Australia is still refining how it proposes to implement the decision at an examination level.

In *AstraZeneca AB v Apotex Pty Ltd*, the High Court further clarified aspects of the inventive step test under Australian Law. Magda Bramante analyses the Court's consideration of when and how prior art information can be used to answer the obviousness question.

Staying in the realm of genetics, Dr Leigh Guerin contemplates advances in plant gene technology. What will the patent landscape mean for research and commercialisation in this field, and will new techniques alter public perception of genetically edited crops?

Also in this edition, Mark Williams provides some tips on IP protection for health apps, Daniel McKinley reviews the intellectual property aspects of the Trans-Pacific Partnership, Michelle Betschart discusses foreign trade mark filing strategies, and Annette Rubinstein asks the question "Is personal training fun?"

We hope you enjoy this edition of *Inspire!*, and look forward to working with you in 2016.

D'Arcy v Myriad Genetics Inc.

Dr Mark Wickham, Partner

On 7 October 2015, the High Court of Australia unanimously allowed Ms D'Arcy's appeal from the Full Federal Court decision in *D'Arcy v Myriad Genetics Inc (2014) 224 FCR 479* ('D'Arcy'), holding that Myriad's claims to isolated nucleic acids were not patentable subject matter.

The decision relates to Australian Patent 686004, which includes claims to methods of diagnosing a predisposition for breast and ovarian cancer, as well as claims to isolated nucleic acids related to those methods. The claims to the methods, probes, cloning and expression vectors, and host cells, were not in issue. The High Court, whose decision relates to whether under Australian law, claims directed to isolated nucleic acids were a "manner of manufacture", and therefore patentable subject matter.

Prior to the High Court decision, a Full Federal Court had held that isolated nucleic acids were different to the gene comprising the nucleic acid sequence as it exists in nature, and that the isolation of the nucleic acid lead to an economically useful result – the treatment of breast and ovarian cancers. The Full Court concluded that the isolated nucleic acid, including cDNA, was an artificially created state of affairs of economic benefit, and was therefore patentable.

While the patent expired on 11 August 2015 at the end of its term, the High Court held that the invention claimed in the relevant claims (a nucleic acid coding for a BCRA1 protein with one or more specified variations indicative of susceptibility to breast cancer and ovarian cancer) did not fall within the concept of a manner of manufacture.

In making this finding the Court focussed on the significance of the genetic information in the nucleotides of the claims rather than the isolated nucleotides being a tangible product per se, stating:

> 'Despite the formulation of the claimed invention as a class of product, its substance is information embodied in arrangements of nucleotides. The information is not "made" by human action. It is discerned. That feature of the claims raises a question about how they fit within the concept of a "manner of manufacture". As appears from s 6 of the Statute of Monopolies, an invention is something which involves "making". It must reside in something. It may be a product. It may be a process. It may be an outcome which can be characterised, in the language of NRDC, as an "artificially created state of affairs". Whatever it is, it must be something brought about by human action.'

Consideration was also given to whether the isolated nucleic acids were an 'artificially created state of affairs', in relation to which the Court commented:

> 'Ms D'Arcy also engaged with the finding by the Full Court that the isolated nucleic acids were patentable as "an artificially created state of affairs". Engaging with that criterion in this case places the question of patentability in too narrow a frame. It invites debates about the application of categories such as "products of nature" versus "artificially created products" which may be distracting from the central issue, that is whether an essential integer of the claims, the genetic information, takes them outside the category of that which can be "made". But even if the criterion of an "artificially created state of affairs" were to define the area of discourse in this case, the fact of the existence of the requisite mutations or polymorphisms is a matter of chance. It is not something "made". It is not "artificially created".'

The Court held that while the invention claimed might strictly be classified as a product of human action, it was the existence of the information stored in the relevant sequences that was an essential element of the invention as claimed:

> 'Although it may be said in a formal sense that the invention as claimed, referring to isolated nucleic acids, embodies a product created by human action, that is not sufficient to support its characterisation as

a manner of manufacture. The substance of the invention as claimed and the considerations flowing from its substance militate against that characterisation. To include it within the scope of a "manner of manufacture" involves an extension of that concept, which is not appropriate for judicial determination.'

The finding that the features of the claims and their 'substance as an invention', related to 'sequence information', led to the conclusion that patentability would not serve the purposes of the concept of "manner of manufacture". The Court also attached the same informational characteristics to cDNA.

It was initially unclear whether the decision would have a broad or narrow impact on the biotechnology industry.

On 16 October 2015, IP Australia issued their proposed practice for applying Myriad for public consultation.

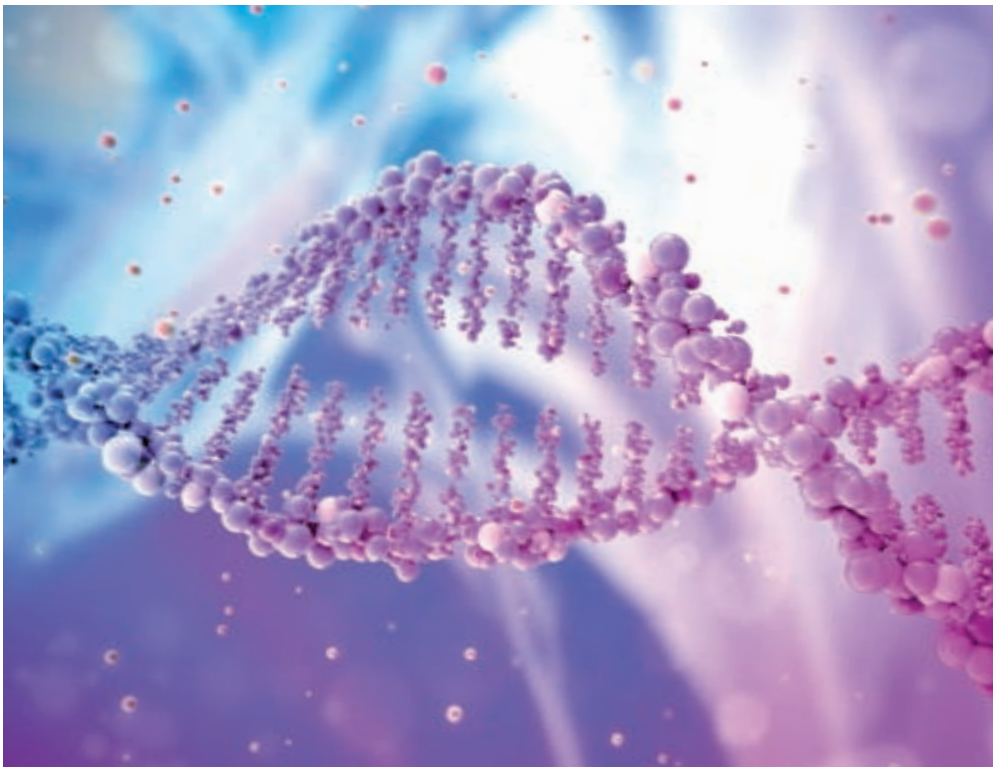
The proposed practice indicates that on the basis of the decision, the Commissioner considers the following are not patent eligible and will not accept claims for:

- Naturally occurring (human or non-human) nucleic acid sequences encoding polypeptides or functional fragments thereof – either isolated or synthesised cDNA
- Naturally occurring human and non-human coding RNA – either isolated or synthesised.

The Commissioner proposes the following remain patent eligible on the basis that they do not merely represent information coding for a polypeptide:

- Naturally occurring isolated regulatory DNA (e.g. promoters, enhancers, inhibitors, intergenic DNA)
- Isolated non-coding (e.g. "Junk") DNA and isolated non-coding RNA (e.g. miRNA)
- Naturally occurring isolated bacteria
- Naturally occurring isolated virus
- Isolated polypeptides, including isolated polyclonal antibodies
- Synthesised/modified polypeptides
- Chemical molecules purified from natural sources (e.g. new chemical entities, antibiotics, small molecules)
- Isolated cells, including isolated stem cells
- Probes
- Primers
- Isolated interfering/inhibitory nucleic acids (e.g. antisense, ribozymes)
- Monoclonal antibodies
- Fusion/chimeric nucleic acids
- Transgenes comprising naturally occurring gene sequences
- Vectors/microorganisms/animals/plants comprising a transgene.

Given the practice is focused on nucleic acids that merely represent information coding for a polypeptide, the practical impact of the decision is likely to be less of a concern to the Biotechnology sector than some feared.



Consultation on the proposed practice closed on Friday 6 November 2015, and we are awaiting issuance of the final practice.

Interim measures

IP Australia has also begun issuing correspondence in relation to patent applications with claims to isolated nucleic acids that are under examination.

For applications approaching their acceptance deadline with claims to isolated nucleic acids, the Commissioner has indicated that she is still considering how the technology is impacted by the decision of the High Court, and depending on the outcome of this consideration it may be necessary to raise an objection to these claims. The correspondence proposes options for the applicant to consider in the interim:

> '… file amendments to the application to clearly remove any subject matter of concern,
>
> allow the application to remain pending in its present form (noting that the application will lapse if the final date for acceptance is reached), or
>
> file a divisional application in order to keep this matter pending and the applicant may consider applying for fee waivers for such applications.'

Oppositions

In the case of Oppositions to grant involving applications with claims to isolated nucleic acids, IP Australia have been issuing correspondence indicating that the High Court decision in D'Arcy may be relevant to the determination of the opposition and inviting both parties to provide written submissions on the relevance of the decision to the claims. The correspondence indicates the hearing officer will take into consideration any submissions made in coming to a decision. We are yet to have any opposition decisions issue on such claims following the decision in D'Arcy.

Interestingly, the Office has also begun citing D'Arcy in support of the approach taken in *Research Affiliates LLC v Commissioner of Patents [2014]* FCAFC 150, of examining the 'substance of the invention' in considering the patentability of a scheme or abstract idea implemented on a computer (see *General Electric Company v Ausrail Technologies Pty Ltd [2015] APO 67* at paragraph 103):

> 'The Full Court decided that the implementation of a scheme or abstract idea, which itself would not be considered to be patentable subject matter, would not be rendered patentable subject matter through implementation on a computer. The substance of the invention is determined not as a matter of form but involves an analysis of the alleged inventive step compared to the prior art. This approach of examining the 'substance' of the invention was also mentioned in D'Arcy …'.

It appears that examination of the substance of the invention, rather than just the form of the claims, will be an important part of considering whether an invention as claimed can be characterised as a manner of manufacture.

Dr Mark Wickham *BSc(Hons) MCommrclLaw PhD* is a Patent and Trade Marks Attorney with extensive experience in biologics, pharmaceuticals and agricultural biotechnology. Mark majored in genetics and biochemistry, and his PhD focussed on the molecular and cell biology of malaria. His postdoctoral work focussed on inflammatory bowel disease and gastrointestinal bacterial infections.
mark.wickham@pof.com.au

Trans-Pacific Partnership (TPP) Agreement – Intellectual Property provisions

Daniel McKinley, Senior Associate

The Trans Pacific Partnership (TPP) Agreement was finally concluded on 5 October, 2015 with the full text of the Agreement made public on 5 November. The Agreement is yet to be ratified by signatory countries, although at this stage there is nothing to suggest that ratification will not take place. Signatories to the TPP include Brunei, Chile, New Zealand, Singapore, Australia, Canada, Japan, Malaysia, Mexico, Peru, United States and Vietnam.

The main aims of the TPP are to lower trade barriers such as tariffs and also to help establish a common framework for intellectual property laws amongst the member countries.

PCT and Madrid Protocol

The TPP requires that signatories join the Patent Cooperation Treaty (PCT) for International Patent Applications, and the Madrid Protocol for the International Registration of Trade Marks. All of the TPP countries are already PCT member countries. However, Brunei, Chile, Canada, Malaysia and Peru will need to become Madrid Protocol members. This should make obtaining trade mark registrations in these jurisdictions simpler and more cost-effective.

Grace period for patents

The TPP specifies that a grace period will be afforded to patentees for any self-disclosure within the 12 months prior to filing a patent application in a signatory country. The US, Australia and Canada already offer such a grace period, however other TPP countries, notably Japan, Singapore and Vietnam, will have to expand their grace period provisions to include any prior self-disclosure within the 12-month period.

Patentable subject matter and innovation patents

The TPP includes a requirement regarding patentable subject matter which provides that subject matter that may be excluded under national laws includes: plants, animals, diagnostic, therapeutic and surgical methods as well as biological processes for the generation of plants and animals. There is nothing in the TPP to suggest that Australia will need to alter the *Patents Act* to cater to the patentable subject matter requirements.

Pharmaceuticals and biologics

The TPP requires signatories to adopt a regulatory review exception that permits generic pharmaceutical manufacturers to make small batches of a patented pharmaceutical to apply for marketing approval before the patent expires without risk of liability for infringement. This provision allows for what is known as 'springboarding', enabling generics to enter the market immediately upon the expiry of the relevant patent, preventing a de facto extension of term. Australia already has these provisions.

It is understood that the US pushed for changes to the rules regarding IP protection for biologics, which are a type of medicine comprised of complex molecules such as proteins isolated from plants, animals and micro-organisms. They can include vaccines, oncology medications and other therapies such as insulin. Biologics are not always patentable because they can include naturally occurring products such as insulin or other blood components. As such, another form of regulatory protection available for biologics is known as 'data exclusivity'.

Data exclusivity refers to the protection of clinical trial data submitted to regulatory agencies from use by competitors, which is a different type of monopoly protection to patents. The TPP requires that signatories establish data exclusivity provisions. The TPP requires that signatories should provide 5 years of data exclusivity from the date of marketing approval in the relevant country. An equivalent period of data exclusivity is already provided for in Australia in the *Therapeutic Goods Act*, pursuant to Australia's FTA with the US, so no change to Australian law should be required. There is some doubt as to whether the TPP may enable the term to be renegotiated in the future as there is a provision for review in 10 years. It is understood that the US pushed for the 'data exclusivity' term to be extended to, perhaps eight years or more. However, the text of the TPP suggests only a minimum five-year term, meaning no change to Australia's current law in the area.

The TPP also requires that signatories institute a 'Patent Linkage' procedure whereby patent holders must be notified prior to the marketing of a competing product so that they can decide whether to assert their patent rights and perhaps, seek an injunction. Australia already has such a provision.

Copyright

The term of copyright in Australia for films and sound recordings is 70 years from the year in which the recording or film was first published. For literary, dramatic and musical works published during the lifetime of the author, copyright lasts for 70 years from the end of the year in which the author died. The previous terms were generally 50 years and were altered as a result of Australia's accession to the Australia-US FTA in 2005. The 70-year terms now part of Australian Copyright law are also mandated by the TPP. A number of signatory countries may be required to amend their copyright laws to extend the term of copyright protection to be equivalent to the terms applicable in Australia and the US.

Enforcement

According to the Department of Foreign Affairs and Trade, the TPP agreement requires parties to introduce strong enforcement systems including civil procedures, provisional measures, border (customs) measures and criminal procedures and penalties for commercial scale trade mark counterfeiting and copyright or related rights piracy. TPP parties will be required to institute legal procedures for the prevention of stealing of trade secrets and establish criminal procedures and penalties for trade secret theft including by way of cyber-theft.

Conclusion

The TPP agreement's provisions regarding intellectual property appear to be an attempt to mould the IP laws of signatory countries in the image of the US's IP laws. Having already been through a process of negotiating and ratifying an FTA with the US in 2005, Australia's IP laws already reflect the IP provisions of the TPP. The most significant changes to IP laws resulting from the TPP will be in other countries which, at least to some extent, should make international IP protection and enforcement a simpler and cheaper proposition for Australian clients.

Daniel McKinley *BMedSc LLB MIP FIPTA* is a Lawyer and Patent and Trade Marks Attorney specialising in manufactured products for building and construction, household and consumer products as well as business methods, back-end and eCommerce software, remote sensor monitoring and signal processing. He also works with clients in the medical technology fields of orthopaedic devices and implants, prosthetics, surgical instruments, drug delivery, diagnostics, audiology and methods of medical treatment.
daniel.mckinley@pof.com.au

Considerations when developing a foreign trade mark filing strategy

Michelle Betschart, Associate

Trade mark rights are granted on a national basis, making it necessary to register in each country or region in which protection is required. In light of separate registrations being necessary in each country of interest, filing and maintenance costs can escalate quickly if there are a number of jurisdictions where protection is sought.

In adopting a foreign filing strategy, there are a number of timing and cost factors that trade mark owners need to consider. These factors will, to a large extent, depend on the countries where protection is sought. Although a trade mark owner might ideally seek to protect their trade mark across the globe, filing and ongoing costs mean that in practice, trade mark owners may need to take a pragmatic approach to the selection of countries where protection is sought. As a starting point, trade mark owners need to consider which countries they have a real and genuine intention to use their trade mark in relation to the manufacture or sale of their goods or services, within the next few years.

'First to file' versus 'first to use'

Once the countries of interest have been selected, an important consideration will be whether those countries are 'first to file' or 'first to use'. Many countries follow a first to file trade mark system. This means that the person who files a trade mark application and obtains registration will have priority, even if another party can show prior use of the trade mark. Accordingly, in first to file countries, it is important to file trade mark applications as early as possible to minimise the likelihood an unscrupulous party will obtain rights to the mark. On the other hand, some countries, including Australia, follow a common law system whereby the first person to use a trade mark will have priority over a person who files a trade mark application at a later date.

For Australian trade mark owners, China and the United States provide good examples of how, whether a country is 'first to file' or 'first to use', might determine where that country sits in a trade mark owners' foreign filing strategy. China, for example, is a 'first to file' country so we recommend that if a trade mark owner is using, or is intending to use their trade mark in China in the near future, they should seek protection in China early. On the other hand, the United States is a 'first to use' country. This means that if a trade mark owner starts using their trade mark in the United States in commerce, and a third party subsequently files an application for the same mark, the trade mark owner who used the mark first will

ultimately have stronger rights in the trade mark. Whether a country is 'first to file' or 'first to use' is only one determinant of where that country might sit in a trade mark owner's foreign filing strategy.

In the United States for example, trade mark owners should keep in mind that actual use of a trade mark in the United States, is critical to obtaining registration and/or maintaining a registration. Trade mark owners filing applications in the US need to consider whether they expect to be able to demonstrate use of their trade mark in commerce in the United States, within a three to five year period depending on the basis upon which the US application is filed.

Costs of foreign filing

Other factors for determining where a country sits in a trade mark owner's foreign filing strategy are the application filing costs and the costs of maintaining a registration. For example, in some Middle Eastern countries, the application costs can be as much as ten times the cost of filing an application in Australia. If there is only expected to be limited use of a mark in a country with significant filing and maintenance costs, obtaining trade mark protection in that country might be prioritised behind a country with lower costs, where there is expected to be heavy use.

If your business is expanding into countries outside of Australia, we recommend you speak to your attorney about developing a tailored, foreign filing strategy which ensures you are covered for key jurisdictions.

Michelle Betschart *LLB/LP(Hons) BSc LLM (IP)* is a Trade Marks Attorney who advises both local and overseas clients on all aspects of trade mark registerability and protection. Prior to joining POF, Michelle worked as a lawyer for a large medical institute as well as the South Australian Government. Michelle recently completed her Master of Laws at the University of Melbourne.
michelle.betschart@pof.com.au

Will breakthroughs in genetic technology make genetic engineered crops more palatable?

Leigh Guerin, Patent Attorney

From the hand of nature to the hand of man

Humans have been tinkering with the genetic make-up of plants and animals for almost 10,000 years through selective breeding. Throughout this period, humans have selected plants and animals that have spontaneously mutated to possess desirable features. This has turned the Wolf into Great Danes and Pomeranians, and turned corn cobs shorter than your thumb into the corn cobs we buy today. But this process takes time. Cross breeding plants to produce hybrids has sped up the process, but all too often this led to plants with unforeseen or undesirable traits. Furthermore, this process was limited by the availability of closely related plant species with desirable traits.

In 1863, an Austrian scientist name Gregor Mendel performed an experiment which became the foundation for modern genetics. However, despite Mendel's ground-breaking work, we still didn't understand how traits were passed between generations, or indeed how they originated in the first place.

It's all in the genes

In the 20th century this began to change. Throughout the 1920s and 1930s, experiments pointed to the source of inheritable traits as being large molecules that were susceptible to alteration by x-rays. In 1943 a team of scientists led by the American Oswald Avery, discovered that by transferring DNA from a first type of bacteria to a second type, the second type could be made to possess the physical traits of the first. In this process, Avery not only founded our modern understanding of DNA as the source of inheritable traits, but arguably also created the first human genetically manipulated organism.

Despite this breakthrough, the first genetically modified organism (GMO) was not generated for another 30 years. In 1972, a genetically modified (GM) bacterium was created, and in 1973 the first GM animal was created. It took another decade before the first GM plants were created, and another 13 years until they were commercialised in 1996. The first two GM crops had genes introduced from bacteria to produce plants that were tolerant to weed killer and plants that produced their own pesticide. GM crops were rapidly adopted, and by 2010, 20% of all planted cropland were GM crops.

Despite the proliferation of GM crops, their development and implementation is highly controversial. Many questions have arisen regarding the long-term effects on the environment and human health, while the intellectual property rights associated with GM crops have spawned a myriad of ethical and moral debates.

A move away from GM

Recent advances in the tools available for genetic engineering may help to solve some of the problems associated with GM plants. These tools are offering the potential for a new type of genetic alteration of plants, one more akin to natural selection and hybridisation, albeit with greater specificity and predictability. A process known as genetic, or genome, editing may help address many of regulatory and public hurdles to adoption of GM crops.

Traditional genetic modification transfers whole genes from a distantly related, or unrelated, organism into a plant. However, genetic editing makes precise breaks at pre-determined points in the plant genome allowing the removal or replication of parts of that genome. In this way, genes can be tweaked to function better or can be turned off completely. In essence, genetically edited crops, unlike GM crops, contain no foreign DNA.

The three main new technologies that allow for this new form of genetic editing are zinc-finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs) and clustered regularly interspaced short palindromic repeats (CRISPR) nucleases. These clumsily named tools provide scientists with an unprecedented ability to precisely manipulate genes in plants. This has already led to the development of new crops such as mildew-resistant wheat and herbicide-tolerant canola.

Possibilities, pitfalls and patents

The uptake and utilisation of GM crops has largely depended on government regulations and public perception. In countries like the US, GM crops have been widely adopted by farmers. However, the European Union which has strict approval and regulation processes for GM plants and foods, has a considerably lower percentage of GM crops. Locally, South Australia, Tasmania and the ACT have moratoriums on all commercial GM crop production.

However, genetically edited crops, by virtue of containing no foreign DNA, are not currently covered by many of the existing government regulations. The US department of agriculture has decided that since genetically edited crops are virtually indistinguishable from crops that have naturally changed, or are a product of selective breeding, they do not fall under the umbrella of genetically modified organisms (GMOs), and therefore bypass GMO regulations. A similar approach has been taken in Canada, where the first commercial genetically edited crop is currently growing. Whether the EU and countries like Australia will take the same approach is yet to be known.

The approach used in genetic editing is more like natural selection than traditional genetic modification; however, will this difference be enough to convince an already sceptical public who may view these crops as 'Frankenfoods'. Public perception of genetically edited crops will depend on the ability of the

food industry and scientists to communicate the technology and inform the public of any need for such foods. In any event, a large determinant of the success of genetically edited plants will be based on the public's willingness to embrace them.

Issues of intellectual property

One consistent issue that genetically engineered crops will share with GM crops will be that of intellectual property. The controversy surrounding patents on new forms of GM crops and the limitations that these place on farmers, especially in developing nations, has been at the forefront of the ethical debate about GM crops. It is unlikely that this will change with GE crops. In fact, the intellectual property picture is more complex than ever before.

Many of the technologies used to perform genetic engineering, such as CRISPR, ZFNs and TALENs are new discoveries. Unlike the mid-1990s when the first GM crops came onto the market, genetically edited crops are following hot on the heels of innovations in the tools for genetic engineering, and like most new discoveries, these tools are protected by patents.

CRISPR (recently labelled 'the biggest biotech discovery of the century') alone is already covered at least 11 granted US patents and the subject of over a 100 more applications, despite only being discovered in mid-2012. Additionally, at least seven companies are actively commercialising this technology. While the technology around ZFNs and TALENs may not be as hotly contested, there are over 24 US patents covering ZFNs, and at least four US patents covering TALENs. All in all, the number of patents simply covering the tools for genetically editing crops will be a maze that will have to be traversed before a product can be generated and commercialised.

With this rapid and disruptive change, there are opportunities for companies and countries willing to accept this technology. The willingness of the US to embrace GM crops in the 1990s, led to the development of a significant local industry. With the lessons learnt from the last 20 years of GM crops, countries like Australia can now make an informed assessment of the possible impacts of this new technology. If willing, Australia could use this new approach to agriculture to improve our ability to produce food, while developing intellectual property which can be exported alongside our world-leading produce to build on our rich history of agriculture.

Dr Leigh Guerin *BMedPharmBiotech(Hons) PhD MIP* is a Patent Attorney who completed his undergraduate degree in Medical and Pharmaceutical Biotechnology at the University of South Australia, graduating with first-class honours. His PhD in Medicine from the University of Adelaide focussed on mechanisms of immune tolerance. Leigh was subsequently employed as a postdoctoral researcher at Harvard University before returning to Australia.
leigh.guerin@pof.com.au

High Court clarifies test for inventive step over prior art

Magda Bramante, Associate

In the recent case *AstraZeneca AB v Apotex Pty Ltd & Ors* [2015] HCA 30, the High Court unanimously found that AstraZeneca's patent for its cholesterol lowering drug rosuvastatin lacked inventive step and was therefore invalid.

AstraZeneca's patent was directed at low dosage levels of rosuvastatin, a commercially successful product marketed under the brand Crestor®. Generic pharmaceutical suppliers Apotex, Watson Pharma (now Actavis Pharma) and Ascent Pharma challenged the validity of the patent.

Subsections 7(2) and 7(3) of the *Patents Act 1990* (Cth) were central to the High Court's decision. These subsections provide that an invention does not involve an inventive step if it would have been obvious to a person skilled in the art in light of the following before the priority date of the patent:

(a) the common general knowledge considered alone; or

(b) the common general knowledge considered together with prior art information publicly available in a single document. The single document is to contain prior art information which could reasonably be expected to have been "ascertained, understood and regarded as relevant" by the skilled person.

It was not disputed that rosuvastatin did not form part of the common general knowledge. However, its existence was disclosed in two documents, a European patent which claimed the invention of the compound rosuvastatin and methods of preparing it, and a journal article referred to as the 'Watanabe Article'.

Both the primary judge and the Full Federal Court considered that the invention lacked inventive step by reference to the common general knowledge considered with either of the two prior publications.

AstraZeneca raised two primary contentions on the inventiveness test, each of which was rejected by the High Court.

(1) AstraZeneca argued that the two prior art documents had not been shown to satisfy the requirement of relevance. AstraZeneca said that the test for assessing relevance required that each of the documents must be considered separately. The evidence of the expert witnesses regarding identification of the European patent and the Watanabe Article involved a comparison of those documents with a number of other documents in a prior art search which AstraZeneca said was not permissible.

The High Court rejected this argument, and found that in assessing whether any particular document satisfied the test as to relevance, it was permissible to consider a number of sources of information to determine whether any one of those documents satisfied the test.

(2) AstraZeneca also argued that even if the documents were considered relevant, obviousness was not made out as there existed additional documents which identified other compounds as being of interest. AstraZeneca's contention was that a person skilled in the art was confronted with a choice between compounds and the experts did not explain what they would do in this situation.

The High Court rejected this approach, and found that the question is not whether it would have been obvious to the skilled addressee to choose rosuvastatin over other compounds. Rather, it is whether a person skilled in the art would, in light of the common general knowledge plus *either* the European patent or the Watanabe article, have been directly led as a matter of course to try rosuvastatin in the expectation that it might produce a solution.

Notably, Chief Justice French also stated that there was a tendency in AstraZeneca's arguments to confer upon the person skilled in the art "more human characteristics of volitional and purposive action than are necessary".

The High Court decision clarifies that in assessing whether a particular piece of prior art information would be "regarded as relevant", there is no requirement that the information be considered in isolation. The decision also establishes that the inventive step test does not involve a question of whether it was obvious to choose one piece of prior art information over another.

Magda Bramante *BSc LLB LLM* is a Lawyer and Patent and Trade Marks Attorney who has a wide range of experience in all aspects of IP including patent, design, trade mark, copyright and trade practices issues. Magda is also experienced in Federal Court matters and opposition proceedings before the Patent and Trade Mark Office.
magda.bramante@pof.com.au

IP protection for digital health apps in Australia

Mark Williams, Senior Associate

The Apple App store has over a million apps. Tens of thousands of these apps relate to health, and many are downloadable for a small fee. A question we are often asked is, "how do you protect your app against competitors?".

Should you bother?

In deciding whether or not it's worth pursuing IP protection, thought should be given to factors such as:

> the lifespan of the app (as patents can take a number of years to obtain)
> whether the app contains patentable subject matter
> whether the app is simply a front end to a process or system which operates as a 'black box' in the cloud, and
> whether the app is associated with a piece of expensive hardware which is protected by patent.

Australian patents

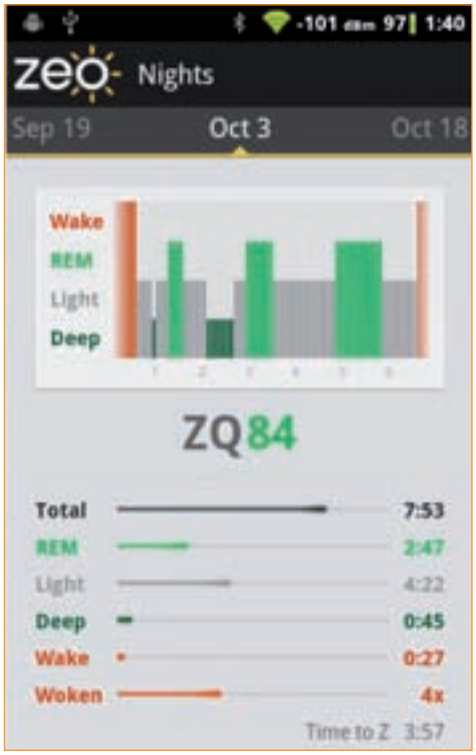
The patent system provides the best protection for apps since it protects the functionality of the app – rather than the specific expression of the idea like copyright does. Copyright in the computer code exists automatically, but is of limited value since an app developer is unlikely to infringe copyright in the computer code if they independently code another app with the same functionality.

In order to obtain patent protection, the app must:

1. be novel or new (i.e. are there existing apps, patent applications or other information already published anywhere in the world that disclose the app's functionality?),
2. involve an inventive step (i.e. is not obvious), and
3. be directed to patentable subject matter.

Many apps will fall foul of (2) and (3). In Australia, an *innovation* patent may be filed (which lasts for a reduced term of eight years) which replaces the test at (2) with a lower threshold *'innovative step'* test. This type of application can be suitable for many apps since they are relatively fast to obtain and set a lower hurdle to achieve a patent.

With regard to patentable subject matter – it essentially comes down to whether or not technology is sufficiently embedded in the functionality of the app to justify the grant of a patent. Simply performing a known manual method on an app using processing power alone is unlikely to be patentable subject matter, there needs to be a technical problem that is solved or a technical advance made. Apps that integrate with or use signals and sensors in the hardware of the device (such as accelerometers or GPS) or interact with external hardware tend to be the sort of subject matter that passes muster with regard to patentability. For example, the Zeo Sleep app would likely be patentable subject matter since it interacts with sensors and or a gyroscope in the phone to determine whether or not you've had a good night's sleep or not.



The Zeo Sleep app

Australian designs

Designs protect the *visual features* of the app such as the Graphical User Interface (GUI). Although the validity of registered designs for "GUIs" is untested by the Australian courts, Australian law does allow for the registration and certification of designs for screen displays. Designs may be filed where a patent is not possible, or even in addition to patent protection. Many mobile phone manufacturers are registering designs for screen displays and this strategy has also extended into the digital health space. Janssen Pharmaceutica NV recently filed a number of design registrations for the GUI of their mobile health management app, care4today™.

Trade marks and domain names

Trade marks are another way to protect an app since they can prevent competitors from calling their app by the same or a similar name.

The care4today™ app

While there are any number of imitation Angry Birds apps available – none of them may be listed as Angry Birds. The owner of the Angry Birds app, Rovio Entertainment Ltd, has trade marks around the world for the name ANGRY

BIRDS and even the characters within the Angry Birds game to protect its brand. Domain names for the app should also be secured even if the domain name simply points to the app on the app store.

Characters from the Angry Birds game

Consider filing for patent protection and/or design protection in Australia before you launch your app on the app store. While Australian patent law has a grace period for public disclosures, the same does not apply for designs.

POF has a dedicated Electronic, Physics and IT team with patent and trade marks attorneys with considerable experience and expertise in software, mobile devices, business methods and electronic devices.

If you have any questions relating to apps and IP protection, please contact us.

Mark Williams *BCSE(Hons) MIP FIPTA* is a Patent and Trade Marks Attorney with over 13 years' experience in drafting and prosecuting patent applications. He specialises in the fields of electronic devices, electronic gaming machines, online transactions and payment systems, anti-virus software, business methods and mobile 3GPP/LTE standards.
mark.williams@pof.com.au

Congratulations to our newly qualified Trade Marks Attorney, Michelle Blythe

Michelle Blythe has recently joined the ranks of registered attorneys, becoming a Trade Marks Attorney in early October 2015.

Michelle joined POF in January 2014 after completing a Bachelor of Biomedicine and a Master of Engineering (Biomedical), at the University of Melbourne. Michelle is currently completing her Master of Intellectual Property Law also at the University of Melbourne.

During Michelle's Master's degree she studied specialist subject areas including tissue and metabolic engineering, forensic biomechanics, medical imaging, biomaterials and clinical engineering. She completed her industry project with the Bionics Institute at St Vincent's Hospital in Melbourne, focusing on image processing to improve methods of automated neuron counting.

Prior to joining POF, Michelle held a position as a Biomedical Engineer at St Vincent's Hospital, where she coordinated the roll-out of new infusion devices across the hospital and developed her skills in medical device repair.

Michelle is a valuable member of POF's Electronics, Physics and IT team, with experience drafting patent applications for a range of medical devices, and prosecuting patent applications for Australian and foreign applicants. Michelle is an enthusiastic IP advocate, providing an annual IP lecture to Melbourne University engineer undergraduates.

Michelle is currently undertaking her final subjects to become a registered patent attorney.

We congratulate Michelle on this significant achievement.

POF hosts Anti-Counterfeiting seminar and workshop in partnership with REACT

On Thursday 15 October, POF hosted a one-day seminar and counterfeit identification workshop at our Melbourne Office. The event was organised in conjunction with REACT, a leading anti-counterfeiting organisation headquartered in Europe.

It was the first event of its kind run for Australian Customs. The morning consisted of a half-day seminar where we were fortunate to be joined by an impressive line-up of speakers including The Hon Jane Garrett MP, the Victorian Minister for Consumer Affairs, Gaming & Liquor Regulation, and representatives from Hong Kong Customs, Australian Border Force and NSW Fair Trading. Each speaker presented on their respective roles and actions in relation to anti-counterfeiting and the event provided a platform for the exchange of best practices in the fight against counterfeiting.

The afternoon session was run as a training workshop designed to inform customs authorities on current counterfeiting trends and critical risk indicators to assist them in identifying counterfeit goods. More than 25 companies from various industries were represented at the event and it attracted some well-known corporates from various industries including pharmaceuticals, toys, automotive, fashion and consumer electronics.

The event was a great success, and we received some very positive feedback from attendees who found the day informative and engaging.

If you would like to find out more about the event, or if you have any issues in relation to anti-counterfeiting, please contact Marine Guillou – marine.guillou@pof.com.au

Serendipity in science – a patenting perspective

Dr Neil Ireland, Partner

Research by its nature can be inexact, and a serendipitous discovery made during a research programme may be of greater value than the result initially intended. In the pharmaceutical industry there are many instances where a chance observation or 'side effect' observed during clinical trials has led to a commercially important product.

The ability of an organisation to recognise these opportunities and take advantage of them can turn a failed research project into a significant revenue stream. This requires not only the ability of the organisation to recognise the potential commercial applications of any observed 'side effect', but also requires astute use of the patent system to ensure that second generation patents are filed to protect the commercially important new application.

The Sildenafil story

In 1991, Pfizer researchers were working on compounds for the treatment of hypertension, and were particularly interested in pyrazolopyrimidones. They synthesised a number of compounds in this class including UK-92,480 (the number given to sildenafil), and subsequently filed a patent application covering the compounds and their use in the treatment of cardiovascular disease in 1992.

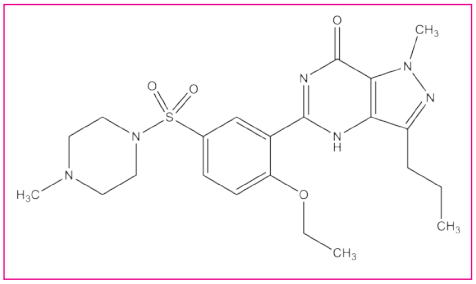


Figure 1 The structure of Sildenafil

As luck would have it, during clinical trials it was found that the drug had little or none of the desired effects and was therefore found to be ineffective for the treatment of angina (the initial purpose of the drug). They did, however, notice a side effect that the drug could improve and sustain a man's penile erection. In what was surely an example of amazing flexibility in the decision making tree for a company of that size, Pfizer almost immediately stopped research into the use of sildenafil as a heart medication, and initiated investigations into its use in the area of male erectile dysfunction. As a result of this research, Pfizer filed a second patent application directed towards the use of sildenafil to treat erectile dysfunction in 1994. This was clearly a success for the company given that sales of Viagra ranged between 1.5 US billion and 2.1 US billion per annum for each year from 2003 until 2014.

The Minoxidil story

Minoxidil was first developed by the Upjohn Company in the late 1950's, and was intended to be used for the treatment of ulcers. Unfortunately the drug was found to be relatively ineffective as a cure for that condition, but was found in 1965 to be an effective vasodilator that could be used as a treatment for hypertension. The company obtained a patent for the drug in 1967 and received market approval in 1979. The drug was then marketed under the trade name Loniten for the treatment of hypertension.

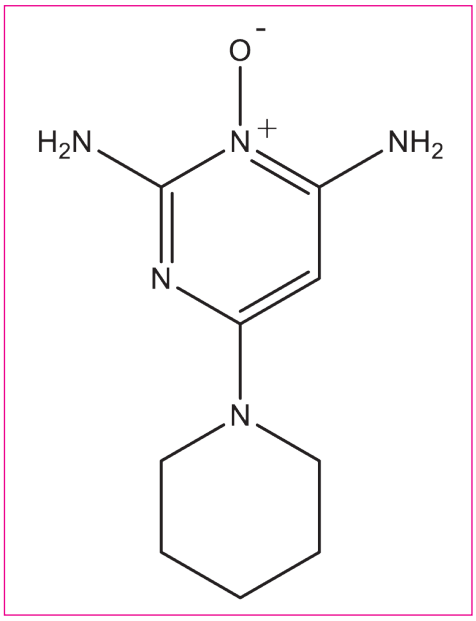


Figure 2 The structure of Minoxidil

During the clinical trials into Minoxidil, clinicians observed unexpected hair growth on the faces and shoulders of some subjects, and some men reported hair regrowth on their heads. As a result of the observation, a second patent application was filed in 1971 directed towards hair regrowth using Minoxidil. The sales of the active agent under the trade mark Rogaine turned into a significant income earner for the company, complementing sales of the compound as a hypertensive.

The Bimatoprost story

Bimatoprost was first developed to lower intraocular pressure in patients suffering from chronic glaucoma or ocular hypertension, and patent applications were first filed covering the molecule in 1992. In 2001, approval was given by the FDA for its use in lowering intraocular pressure and the drug entered the market.

During clinical trials it was observed that patients treated with the drug noticed an increase in diameter, density and length of eyelashes. As a result of this observation, in 2002 Allergan filed patent applications directed towards the use of the compound to treat hair loss, and in particular for stimulating eyelash growth. Allergan were able to obtain patents and subsequent regulatory approval for the cosmetic use of darkening and lengthening eyelashes, and the active agent is now sold under the trade name Latisse. Given the number of potential users of the active agent for cosmetic purposes far outnumber the patients who need to be treated for high intraocular pressure, this observation has significantly increased the sale potential of this drug for the company.

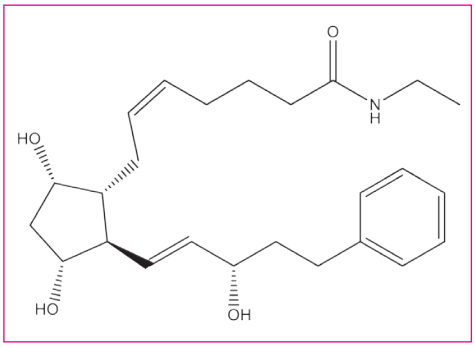


Figure 3 The structure of Bimatoprost

In addition, the second generation patent directed towards the cosmetic use will expire almost 10 years after the original molecule patent. The net effect of this is that Allergan will be able to derive a significant income stream from their original research long after the expiry of the original compound patent.

Summary

As illustrated by these case studies, quite often a research project does not provide the original desired results, and the initial patented use of a compound may not turn out to be a successful commercial product. Nevertheless, diligent observation of patients during the clinical trial phase may reveal 'side effects' that can be turned into very successful products, which in some instances may be more valuable than those the initial research was intended to provide.

Neil Ireland *BSc(Hons) GDipIPLaw LLB(Hons) PhD MRACI CChem FIPTA* is a Patent and Trade Marks Attorney with 18 years' experience across a wide range of chemical technologies, with particular expertise in small molecules, polymers and nanotechnology. Neil completed a PhD in synthetic organic chemistry, which was followed by three years' research experience in the food industry where his research focussed on flavour development in dairy products.
neil.ireland@pof.com.au

Is Personal Training fun?

Annette Rubinstein, General Counsel

One of the joys of being a lawyer is that your friends ask your advice on every legal issue from parking tickets to extradition, regardless of your area of practice. Recently a friend asked me whether he should sign an agreement with his personal trainer, which excluded liability for everything I could think of and some things that would never have crossed my mind. My friend is a fan of the ABC program *The Checkout*, which provides entertaining and accurate information about consumer rights, and thought that this could not be legal. Was he right?

The Australian Consumer Law (ACL) sets out consumer guarantees, which apply to most goods and services that are acquired for personal or domestic use, or which have a price of no more than $40,000. The consumer guarantee for services requires the services to be provided with due care and skill, and reasonably fit for any purpose specified by the consumer. If my hairdresser uses the wrong dye and turns my hair green when I asked for ash blonde, he would have breached these consumer guarantees. The ACL states that these consumer guarantees cannot be excluded by agreement.

However, providers of 'recreational services' are allowed to exclude liability under these consumer guarantees. This exception is not in the ACL itself, but in the legislation which implements the ACL as Commonwealth, State and Territory legislation. This exception was inserted as a result of concerns that insurance for providers of high risk activities such as hang-gliding and horse riding was unaffordable or unobtainable, given the high levels of compensation awarded for catastrophic accidents.

Section 139A of the Commonwealth legislation (the *Competition and Consumer Act 2010*) defines recreational services as services that consist of participation in:

a) a sporting activity or similar leisure time pursuit; or
b) any other activity that:
   i. involves a significant degree of physical exertion of physical risk; and
   ii. is undertaken for the purposes of recreation, enjoyment or leisure.

"Well" I said, "I don't think personal training is a sporting activity or even a similar pursuit to a sporting activity. I will happily agree that personal training involves a significant (or indeed excessive) degree of physical exertion or risk or both, but you could force me to do a hundred crunches and I would still refuse to admit that it could possibly be undertaken for recreation, enjoyment or leisure. After all, the treadmill was a method of punishing prisoners in the nineteenth century and the music played in gyms breaches the international convention against torture".

In any case, even if personal training were a recreational service, the clause in question was not permitted by section 139A of the *Competition and Consumer Act*. This section only permits clauses that limit or exclude liability for personal injury or death only. The clause my friend had been asked to sign also excluded liability for loss or damage to property. Why a recreational service provider should be able to exclude liability for blinding a client, but not for breaking her glasses, is a question I am not qualified to answer.

"Further" I said, "since your personal trainer is in Victoria, they have to comply with both the Commonwealth Competition and Consumer Act and the Victorian Australian Consumer Law and Fair Trading Act. The recreational services exception in the Victorian Act is not identical to the one in Commonwealth Act, and sets out wording that must be used to warn the consumer that they are signing away rights to compensation for personal injury or death". The document my friend had been asked to sign did not include the magic words.

Finally, the personal trainer may well have contravened section 18 of the ACL which prohibits misleading deceptive conduct in trade or commerce, by leading clients to believe that they had signed away their rights to compensation when this was not the case. Sometimes there isn't a simple answer to a simple question, but you will never know if you don't ask.

Annette Rubinstein is General Counsel of the Phillips Ormonde Fitzpatrick Group. Her favourite leisure time activity is lying on the couch reading trashy novels and eating chocolates. Phillips Ormonde Fitzpatrick Lawyers can advise on limitation of liability clauses and the Australian Consumer Law generally.

IP Australia and the European Patent Office to increase collaboration

Dr Neil Ireland, Partner

On 7 October 2015, IP Australia announced that they had signed a memorandum of understanding (MoU) with the European patent office (EPO) to increase bilateral cooperation between the two offices with the aim of delivering benefits to users of the patent systems in both Australia and the European community.

The areas of potential collaboration between the two patent offices are wide ranging, including the reciprocal access to patent information and the establishment of a Patent Prosecution Highway (PPH) pilot program. These two initiatives are both likely to provide significant benefit to Australian patent applicants.

Patent prosecution highway

In previous editions of *Inspire!*, we have reported on the global patent prosecution highway (GPPH) that exists between Australia, Canada, Denmark, Hungary, Iceland, Israel, Finland, Japan, Korea, the Nordic Patent institute, Norway, Portugal, Russia, Spain, Sweden, The United kingdom and the United states of America. Under the global patent prosecution highway, applicants can utilise the results of examination in one jurisdiction to request expedited examination of their application in another GPPH country which increases prosecution speed and facilitates early patent grant.

Unfortunately the European patent office is not a member of the GPPH and so Australian patent applicants have not yet been able to take advantage of the results of examination in Australia to expedite the prosecution of their European applications. Following the signing of the MoU, the two patent offices are now working towards establishing the framework to implement a Patent Prosecution Highway. The details of how the Patent Prosecution Highway will be implemented are still being discussed by the two offices, and it is anticipated that users of the system will not be able to take advantage of this development until midway through calendar year 2016. Nevertheless, once the system is in place there will be the opportunity for innovators in both jurisdictions to accelerate the prosecution of their patent applications. We will provide more information as soon as details of the process are finalised.

Information sharing

The other anticipated benefit to innovators from the increased collaboration between IP Australia and the EPO will be in the area of information sharing between the two offices. The MoU encompasses a pilot project which will allow IP Australia to gain experience with using the Cooperative Patent Classification (CPC) system. The CPC is the result of an initiative between the USPTO and the EPO to develop a common internationally agreed upon classification system for technical documents which should facilitate faster and more accurate patent searching and lead to better examination outcomes.

Finally, the information sharing will lead to improvements in the Global Patent Dossier project which provides a platform for the sharing of patent examination information between patent offices. The sharing of such information typically leads to faster examination of patent applications throughout the world and should enable IP Australia to reduce their already impressive turn-around time between the date of filing of an examination request and the date of receipt of an examination report.

Summary

Whilst IP Australia and the EPO are still working through the details of how to implement all the agreed upon actions from the MoU, the initiatives that flow from it are likely to lead to faster, more efficient examination in Australia and provide Australian innovators with the ability to use the grant of an Australian patent to expedite examination in the European patent office.

If you have any questions on any of these initiatives please contact your POF attorney.

Neil Ireland *BSc(Hons) GDipIPLaw LLB(Hons) PhD MRACI CChem FIPTA* is a Patent and Trade Marks Attorney with 18 years' experience across a wide range of chemical technologies, with particular expertise in small molecules, polymers and nanotechnology. Neil completed a PhD in synthetic organic chemistry, which was followed by three years' research experience in the food industry where his research focussed on flavour development in dairy products.
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