K&L GATES

2016 PATENT & PLANT BREEDER'S RIGHTS YEAR IN REVIEW

Intellectual Property in the age of the "Ideas Boom"

WELCOME

Welcome to the first edition of K&L Gates Australia, Patent and Plant Breeder's Rights Year in Review in which we examine the significant judgments, developments and events effecting patents and plant breeder's rights in Australia.

2016 proved to be the year of the unexpected. Once and for all, we learned to treat polls with a grain of salt as we saw Britain voting to leave the European Union and Donald Trump winning the U.S. Presidency. We also saw the boundaries of literature redefined when Bob Dylan, the once radical musician, was awarded the Nobel Prize. And amongst significant change, there seemed to be change for change's sake. Most notably, Apple dropped the headphone jack on its iPhone.

But did 2016 deliver a significant shift for Australian patent and plant breeder's rights? Perhaps not on the same scale as other world events, but it certainly did hand us some surprises and, I am pleased to say, many were pleasant.

Some critical and defining themes, shaping the landscape of patent enforcement include:

- In 2015, the High Court's decision in *D'Arcy v Myriad Genetics Inc*, cast gloom on the biotech industry. However, 2016 has buoyed industries' hope with the Australian Patent Office refusing to adopt an overly broad interpretation of *Myriad*. In fact, the Australian Patent Office has confirmed that nucleic acids are patentable in Australia.
- The Courts had to consider whether an Australian affiliate of an international pharmaceutical company was an exclusive licensee for the purposes of the Patents Act and, consequently, whether it had standing to sue. This appears to be one of the strong themes that emerged in 2016 in the context of pharmaceutical patent litigation. If you are a licensee, it would be prudent to consider your current license arrangement as this battleground is unlikely to go away anytime soon.
- The allegation of unjustified threats, typically thrown into any response to an allegation of infringement (usually in the penultimate paragraph) has, in 2016, emerged as a solo act. It serves as a reminder that one should be prepared to advance its allegations.
- Software and computer implemented business method patents continued to attract attention in 2016. Although there has been pessimism surrounding the patentability of inventions relating to software and business methods (with the number of filings sharply decreasing over the past few years), a closer look at such patents shows that an increasing number of applications are in fact proceeding to grant. These statistics alone should buoy patentees; together with the Productivity Commission's failure to proceed with its recommendation to exclude software patents from patent eligible subject matter.

We hope you find this publication both informative and enjoyable reading.

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With thanks to Bronte Richardson & Wendy Mansell - Summer Clerks 2016/17

IN THIS ISSUE

We are pleased to present you with our inaugural K&L Gates Australia, Patent and Plant Breeder's Rights Year in Review. In this publication, we reflect on key decisions published by the Federal Court and the Australian Patent Office, as well as policy developments and proposed reforms to patent law which may impact you in 2017 and beyond.

2016 - ON A PAGE

DECISIONS:

90 AUSTRALIAN PATENT OFFICE

14 FEDERAL COURT OF AUSTRALIA

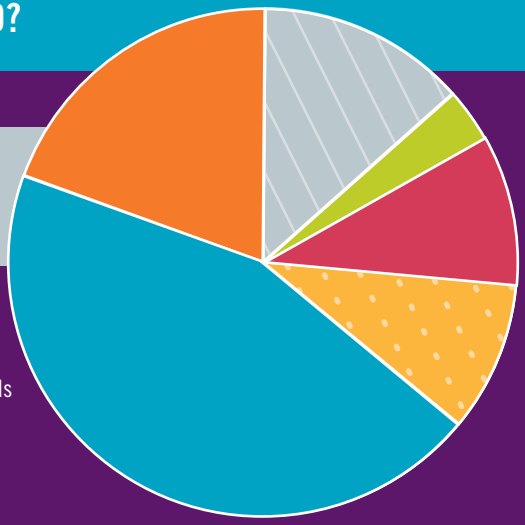
(of which 3 were Appeals from Decisions of the APO)

11 FULL FEDERAL COURT OF AUSTRALIA

0 HIGH COURT OF AUSTRALIA

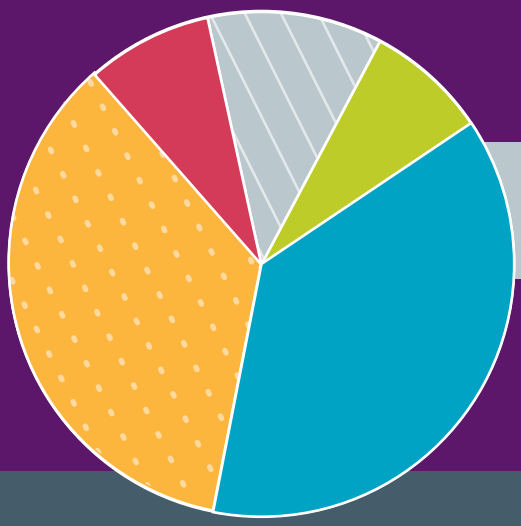
WHAT TYPE OF PATENTS ARE BEING LITIGATED?

APO DECISIONS BY SUBJECT MATTER



- Medical Devices
- Chemical
- Engineering/Electrical
- Pharmaceutical (human and animal)
- Biotech
- Computer-implemented/Business Methods

FEDERAL COURT AND FULL FEDERAL COURT CASES BY SUBJECT MATTER



- Medical Devices
- Biotech
- Engineering/Electrical
- Computer-implemented/Business Methods
- Pharmaceutical (human and animal)

OF THESE MATTERS...

- Standard Patents
- Innovation Patent Matters

Figure 1.

LITIGATION RISKS IN THE LIFE SCIENCES SPACE

In late 2015, the Full Federal Court delivered their judgment in *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)* [2015] FCAFC 172. This matter required the Full Federal Court (Court) to consider whether the Commonwealth of Australia was precluded, as a matter of law, from recovering compensation pursuant to any of the Undertakings as to Damages (proffered by various patent owners in order to secure interlocutory injunctions in a number of different proceedings) by reason of the certification process set out under Chapter 3, Part 3-2, Division 2 of the *Therapeutic Goods Act 1989* (Cth) (**Therapeutic Goods Act**).

The certification process was introduced into the Therapeutic Goods Act in response to requirements stemming from the Australian-United States Free Trade Agreement. The provisions impose a number of obligations on both applicants who seek to register a product on the Australian Register of Therapeutic Goods (**ARTG**), while relying on safety and efficacy data previously submitted by a third party and patentees/exclusive licensees who intend to sue such applicants for patent infringement. The provisions also provide a number of mechanisms by which the Commonwealth of Australia may seek compensation in relation to patent infringement proceedings where a party has given a false or misleading certificate or breached an undertaking given pursuant to a certificate.

In exercising its discretion to grant an interlocutory injunction, the Court generally requires an applicant to provide the "usual undertaking as to damages". The "usual" undertaking extends to submitting to pay compensation to anyone affected by the operation of the interlocutory order. In these proceedings, the Commonwealth sought to rely on such an undertaking in order to seek compensation from Sanofi and a number of patentees in circumstances where the entry of generic products to the Australian market was delayed by interlocutory injunctions in patent proceedings and where the patents were ultimately found to be invalid.

It was argued by Sanofi (and the other patentees) that the compensatory provisions under the Therapeutic Goods Act certification process should operate as the sole source of the

> The "**usual undertaking as to damages**" if given to the Court in relation to any interlocutory order made by it or any interlocutory undertaking given to it, is an undertaking:
>
> a. to submit to such order (if any) as the Court may consider to be just for the payment of compensation, (to be assessed by the Court or as it may direct), to any person, (whether or not that person is a party), affected by the operation of the order or undertaking or any continuation (with or without variation) of the order or undertaking; and
>
> b. to pay the compensation referred to in (a) to the person affected by the operation of the order or undertaking.
>
> *Paragraph 2.2 of the* ***Usual Undertaking as to Damages Practice Note*** *(GPN-UNDR)*

Commonwealth's claim to any damages. This approach was rejected by the Court who found that the legislation in no way curtailed the Court's power to extract undertakings and/or tailor those undertakings when granting an interlocutory injunction.

Unsurprisingly, Sanofi (and the other patentees) sought special leave to appeal this decision to the High Court. On 12 May 2016, the High Court dismissed the application for special leave.

This case serves as a warning to parties to fully consider the scope of interlocutory orders in patent proceedings, including the suite of potential litigants (in addition to those directly involved in the suit) who may try to recover damages by relying on an undertaking that may have been hastily given. As noted by Justice Dowsett:

"Any limitations upon the undertakings ought to have been sought at the time at which they were given. The Court would then have had to consider whether such limited undertakings were sufficient to justify the grant of the interlocutory injunctions. The Commonwealth has not put its case in that way. However, in any event, I see no basis for limiting the Commonwealth's right to seek to enforce the undertakings to the extent that it benefits under them.[1]"

RELYING ON THE CLASSICS

It is a fundamental principle of modern patent law that in exchange for a time-limited monopoly, a patentee must sufficiently disclose the invention. This is captured by sections 40(2)(a) and (aa) of the *Patents Act 1990* (Cth) which require a complete specification to:

(a) disclose the invention in a manner which is clear enough and complete enough for a the invention to be performed by a person skilled in the relevant art; and

(aa) disclose the best method known to the applicant of performing the invention.

In March 2016, the Full Federal Court delivered their judgement in *Les Laboratoires Servier v Apotex Pty Ltd* [2016] FCAFC 27. The patent in this matter related to a new salt of perindopril, a compound known especially for the treatment of arterial hypertension and heart failure. The arginine salt is identified as providing greater stability than other, more commonly utilised pharmaceutically acceptable salts.

The Full Federal Court found that the patent was liable to be revoked as it did not disclose the best method known to the applicant of performing the invention. This result was based on a finding that the phrase "classical method of salification" was imprecise and that the patent should have identified the specific method used, rather than a class of methods.

The matter also dealt with the Court's discretion to allow a patentee to seek to amend a patent pursuant to section 105. In this case, the Court did not permit the patentee to amend and the Full Court noted in their judgment that:

"… it will not always be possible to overcome a ground of revocation by an amendment."

The facts of the case provide a compelling reminder that international applicants should ensure that they take heed of advice from their Australian patent attorneys and advisors when it comes to filing patents in this jurisdiction. The Court noted that Servier's patent director had relied on her knowledge of international jurisdictions and ignored a recommendation from an Australian patent attorney to include further details about the method of manufacture *"even if the manufacturing method is well known in the art.[2]"*

WHEN DOES A LICENSEE HAVE STANDING TO SUE FOR PATENT INFRINGEMENT?

An *exclusive licensee* of a patent is able to commence patent infringement proceedings pursuant to section 120(1) of the Patents Act. While at first glance this seems like a relatively straightforward provision of the Act, it is shaping up to be one of the key battlegrounds in patent litigation proceedings.

exploit, in relation to an invention, includes:

a. where the invention is a product—make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or

b. where the invention is a method or process—use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.

In *Actavis Pty Ltd v Orion Corporation* [2016] FCAFC 121 the Full Federal Court found that for a party to be an exclusive licensee they must be able to engage in all activities that are comprehended within the definition of "exploit" under the Patents Act. As such, it is not possible to divide up the bundle of rights and have one party with an exclusive right to manufacture a product and one with an exclusive right to sell the product and claim that both parties are exclusive licensees.

In the most recent decision relating to the ongoing dispute between H Lundbeck A/S, Lundbeck Australia Pty Ltd and a number of generic companies in relation to the Lexapro patent for citalopram, *H Lundbeck A/S v Alphapharm Pty Ltd* [2016] FCA 1232, Justice Jagot found that the generic parties were not estopped from raising the issue of whether Lundbeck Australia Pty Ltd was the exclusive licensee during the relevant period. Justice Jagot also found that raising the issue so late in the proceedings was not an abuse of process.

A CAUTIONARY TALE – THE CONSEQUENCES OF MAKING UNJUSTIFIED THREATS

While taking pro-active steps to protect your patent rights is important, the case of *NSL Engineering Pte Ltd v Australian Mobile Mining Equipment Systems and Accessories Pty Ltd* [2016] FCA 614 serves as a reminder that it is important to ensure that patent owners (and/or exclusive licensees) are prepared to advance an argument in relation to unjustified threats in the event that a court ultimately finds that a product or process does not infringe their patent.

In the absence of any argument from Australian Mobile Mining Equipment Systems and Accessories Pty Ltd as to why sending correspondence alleging that the RAM Revolver product infringed Australian Patent 2013100396 and threatening infringement proceedings was justified, Justice Jessup, on finding that the product did not infringe the patent also found that the letters constituted unjustified threats under section 128 of the *Patents Act*. His Honour also found that correspondence sent to third parties who sold the product contained representations that were misleading within the meaning of section 18 of the *Australian Consumer Law*. While these findings did not ultimately lead to an award of damages (as the applicant in the matter advised the Court that they would not be pursuing a damages claim),[3] Justice Jessup's findings establish an interesting precedent and potentially set the scene for substantial damages claims in the future.

[1] Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis) [2015] FCAFC 172, [20].

[2] Les Laboratoires Servier v Apotex Pty Ltd [2016] FCAFC 27, [248].

[3] NSL Engineering Pte Ltd v Australian Mobile Mining Equipment Systems and Accessories Pty Limited (No 2) [2016] FCA 1187.

POST-*MYRIAD*-IAN

In October 2015, the High Court of Australia stunned the biotech industry by overturning the 5:0 decision of the Full Federal Court and ruling that certain isolated nucleic acids were not patentable subject matter.

To condense what was a long and complex decision, the High Court in *D'Arcy v Myriad Genetics Inc* [2015] HCA 35 (**Myriad**) found that the "substance" of the disputed claims was genetic information, even though the claims themselves were drafted as product claims. Since that information was the same as that which occurs in nature, the High Court considered that the information had not been "made" by human action and could not be the subject of a valid claim. The High Court also noted the considerable breadth of the claims and the potential "chilling effect" that such claims could have on further innovation.

Although the High Court clearly stated that it would not be concerning itself with "gene patenting" generally, a number of the principles set out in *Myriad* warranted concern given their potential to have far-reaching impact on biological inventions more broadly. The High Court's elevation of substance over form when construing the disputed claims was concerning considering all biological inventions will include some element of natural occurrence. The apparent regard paid by the High Court to claim scope and sufficiency when dealing with a question of manner of manufacture also raises issues for those operating in new fields of research where discoveries are more likely to be foundational, and claims based on such discoveries, duly broad. Fuelling concern was the apparent knee-jerk reaction from Australian Patent Examiners who, in the immediate aftermath of *Myriad,* began objecting to almost any claim directed to an isolated nucleic acid.

Yet despite this gloomy outlook, 2016 proved to be a year of optimism for the biotech industry as the Patent Office took a narrow view of *Myriad* and confirmed that nucleic acids can still be patented in Australia.

Arrowhead Research Corporation [2016] APO 70 concerned claims directed to interfering RNA compositions capable of reducing the expression of spleen tyrosine kinase. In determining the "substance" of the claimed invention, the Delegate gave consideration to the description of the specification, observing that the manner in which the invention worked was not solely dependent on the sequence of nucleotides in the interfering RNA. The Delegate found that the informational, structural and chemical content of the interfering RNA molecules were all essential elements of the claimed invention and, as such, the substance of the invention encompassed all of those elements, not merely the genetic information conveyed by the molecule.

In *Cargill Incorporated v Dow AgroSciences LLC* [2016] APO 43, the Patent Office once again allowed a claim directed to a nucleic acid, this time on the basis that the nucleic acid sequence did not exist in nature. The disputed claim in that case defined a codon-optimised polynucleotide encoding a naturally occurring fungal enzyme. The Delegate found that the substance of the claim was not merely naturally occurring information, but information that had been modified to enhance the expression of the fungal enzyme in plants. This modification was found to provide economic utility and render the polynucleotide a manner of manufacture.

Similar reasoning was applied in *Commonwealth Scientific and Industrial Research Organisation v BASF Plant Sciences GmbH* [2016] APO 83 which also concerned claims directed to a codon-optimised nucleic acid. In addition, the disputed application included claims defining a single recombinant nucleic acid molecule made up of a series of naturally occurring coding sequences. Although each coding sequence on its own occurred in nature, the combination of coding sequences did not exist naturally on the same nucleic acid molecule. On that basis, the Delegate found that the genetic information conveyed by the claimed nucleic acid had been "made" and therefore represented patentable subject matter.

In contrast, nucleic acid sequences which are merely isolated from nature can no longer be the subject of a valid claim. In *Meat & Livestock Australia Limited and Dairy Australia Limited v Cargill, Inc. and Branhaven LLC* [2016] APO 26, the disputed application included a claim defining an isolated polynucleotide having a sequence identical to that which occurs in nature. Noting that such a claim would not define a manner of manufacture, the Delegate stated that *"if information in an isolated nucleic acid is the same as that contained in the DNA of the subject from which the nucleic acid was isolated, then the isolated polynucleotide is not patent eligible"*.

There is no doubt that the range of biological material that can be patented has eroded since the High Court handed down its decision in October 2015. The act of isolating, purifying or synthesising is no longer sufficient to render a nucleic acid patentable subject matter. cDNA, once regarded as patentable on the basis that it does not exist without the technical intervention of man, is no longer patentable on that basis alone. But 2016 has seen the Patent Office take a narrow view of *Myriad* and the decisions issued so far confirm that nucleic acids, in many different forms, can still be patented in Australia. Nucleic acids which have a sequence that does not occur in nature can still be the subject of a valid claim. Other human-made modifications that have a material effect on the function of the nucleic acid can also contribute to its patentability.

The impact of *Myriad* on the biotech industry is therefore not likely to be as damaging as many had first thought. After the initial knee-jerk reaction from examiners at the Patent Office, it is clear that the pendulum has already begun to swing the other way. A recent study published in *Nature Biotechnology* found that, in the three years since the US Supreme Court's equivalent decision in *Associate for Molecular Pathology v Myriad Genetics, Inc.*,[4] the rate of "gene patenting" in the US has only modestly slowed.[5] If 2016 is anything to go by, it is likely that only modest effects will be observed in Australia too.

[4] 133 S. Ct. 2107 (2013).

[5] Aboy, M. et al. Nature Biotechnology 34, 1119-1123 (2016).

SOFTWARE AND COMPUTER IMPLEMENTED BUSINESS METHODS – THE CURRENT STATE OF PLAY

Pundits hoping for another chapter in the long running journey of RPL Central's patent application covering a computer implemented method of evidence gathering for recognition of prior learning were left disappointed when RPL's special leave application was dismissed by the High Court in May 2016.[6] After much anticipation, the dismissal was somewhat anticlimactic, with the High Court simply stating that the decision of the Full Federal Court[7] "was plainly correct".

The High Court's rejection of RPL Central's application to appeal occurred just one month shy of the two year anniversary of the U.S. Supreme Court's ruling in *Alice Corporation Pty Ltd v CLS Bank International* 573 US 134 S. Ct. 2347 (2014) - a decision widely regarded as being responsible for the demise of software patents or patents on software for business methods. However, despite the concerns, an analysis of the Australian Patent Office database indicates that the number of software and business method patents granted in Australia have in fact tended to increase since 2014 (see Figure 2 below). Paradoxically, over the same period of time, there has been a rapid and significant decline in the number of software patents or patents on software for business methods filed in Australia. Figure 2 below is based on an analysis we have conducted of the number of applications filed with the Australian Patent Office over the past six years showing the dramatic fall in patent filings in these fields of technology since *Alice*.

There can be no doubt that the U.S. Supreme Court's *Alice* decision and the decisions of the Australian Federal Court in *RPL Central and Research Affiliates,* have created a great deal of debate over the fate of software patents and patents for computer implemented business methods. However, a closer look at the hard data suggests that it is well worth taking a 'first principles' approach following the High Court's analysis in the NRDC case[8] and *Myriad* in considering whether any particular invention in these fields is patentable subject matter.

The outcome of two decisions of the Australian Patent Office is illustrative of this point. Both decisions related to electronic gaming machines (colloquially referred to as 'poker machines') and arose following hearings to determine objections raised during examination that the respective claims were not directed to patent eligible subject matter. While both cases involved the question of whether the relevant computer-implemented features of the poker machines could properly be characterised as a 'manner of manufacture', they each produced a different outcome.

In *Aristocrat Technologies Australia Pty Limited* [2016] APO 49, it was found that the claims were directed to patent eligible subject matter. The claims describe an improved display and user interface of the electronic gaming machine which allows users to view multiple different games, as well as associated stake denominations, on a single screen. It was argued by the examiner

that the substance of the claimed invention was "games characterised by rules for the progress of game play" such that the "utility of the invention lies merely in the possibility of more interesting game play". It was thus argued that the part of the computer was merely to act as the intermediary to carry out the method of allowing users to select the different games and denominations, "without adding anything to the substance of the invention of rules for the progress of game play". Despite finding that the claimed invention "appears to require only generic computer implementation", the Hearing Officer nevertheless considered that on the facts of the case (at the priority date) gaming machines were not configured as claimed and as such, "the contribution is technical in nature, and achieves a practical and useful result".

In contrast, the claims of the patent applications in *Konami Gaming, Inc* [2016] APO 46 were rejected on the basis that they were solely directed towards new rules in a virtual gaming machine. The virtual gaming machines were described as being configured to adjust the payout depending on the outcome from free games awarded or from combinations of patterns across multiple frames shown on the display. The Hearing Officer found that the substance of Konami's invention lay in the rules of a game and not to any new and unconventional implementation of those rules in the gaming machine.

The simplest point which arises from these different outcomes is that, ultimately, whether a patent application involves patent eligible subject matter will turn on the identification of the invention. That said, as computer functions become more commonplace yet increasingly sophisticated, identifying the substance of a high-tech invention will undoubtedly raise new complexities.

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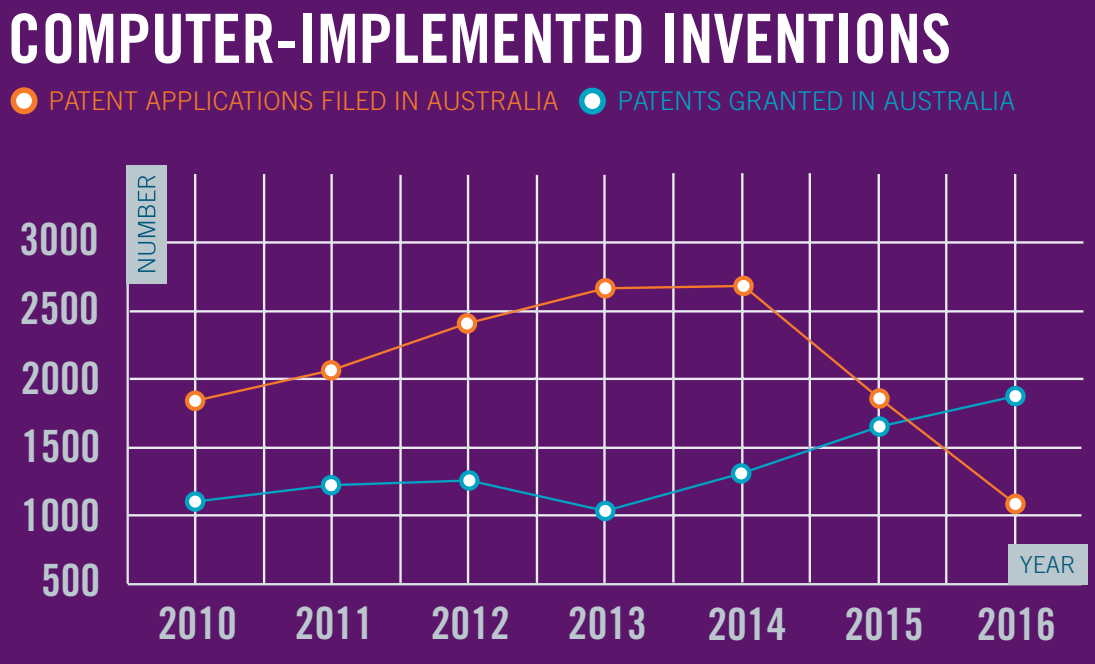
[6] RPL Central Pty Ltd v Commissioner of Patents [2016] HCASL 84.

[7] Commissioner of Patents v RPL Central Ltd *[2015] FCAFC 177.*

[8] National Research Development Corporation v Commissioner of Patents [1959] HCA 67; *(1959) 102 CLR 252.*

Figure 2.



PLANT BREEDER'S RIGHTS

First revocation decision handed down by the PBR Office

2016 saw the Australian Plant Breeder's Rights (**PBR**) Office publish its first substantive decision in a revocation proceeding under the *Plant Breeders Rights Act 1994* (Cth) (**PBR Act**). It is appropriate then that we provide a brief primer on PBR and on the decision in *Majestic Selections Pty Ltd v Bushland Flora* [2016] APBRO 1.

In Australia, new plant varieties can be protected by PBR or patents, or both. Compared to patents, PBR are generally cheaper and simpler to obtain. However, the scope of protection afforded by PBR is more limited, generally relating to propagating material of the variety and including the exclusive right to:

- produce or reproduce the material;
- condition the material for the purpose of propagation;
- offer the material for sale;
- sell, import or export the material; or
- stock the material for any of the above purposes.

PBR can also extend to so called "dependent varieties" and "essentially derived varieties". "Dependent varieties" include plants that can only be reproduced by the repeated use of the protected variety, whereas 'essentially derived varieties' include those varieties which are predominantly derived from the protected variety, retain its essential characteristics, and do not exhibit any important (as distinct from cosmetic) features that differentiate it from the protected variety. In certain circumstances, PBR can also extend to material harvested from the protected propagating material and products made from them.

To be eligible for PBR, a plant variety must be new, or only recently exploited. In addition, it must meet the so called "DUS" requirements; that is, it must be *distinct* from any other variety whose existence is a matter of common knowledge, it must be *uniform* across siblings, and it must be *stable* across generations.

The term of a PBR is 25 years for trees and vines or 20 years for all other varieties. Section 50(1) of the PBR Act provides that the Secretary must revoke PBR in a plant variety if the Secretary becomes satisfied that facts existed that, if known before the grant of the right, would have resulted in the refusal to grant that right. The PBR Act also provides that a person whose interests are affected by the grant of PBR in a plant variety may apply to the Secretary, in writing, for the revocation of the right.[9]

PLANT BREEDER'S RIGHTS APPLICATION PROCESS

FILING - PART 1

- Prima facie case for distinctness and breeding
- Acceptance of application
- Provisional protection

MAJESTIC SELECTIONS PTY LTD V BUSHLAND FLORA [2016] APBRO 1

Majestic Selections Pty Ltd v Bushland Flora [2016] APBRO 1 concerned a variety of *Lomandra* named "Lime Tuff" for which Bushland Flora (**Bushland**) had been granted PBR in 2011. Majestic Selections Pty Ltd (**Majestic**) sought revocation of the PBR on several grounds, including that Lime Tuff was not distinct from any other variety of whose existence is a matter of common knowledge. Majestic provided evidence in the form of phenotypic and genotypic data from a number of *Lomandra* plants which it considered to be indistinguishable from Lime Tuff. One of those plants, the so called "Kuranga" variety, was found growing in the yards of a local primary school.

While accepting that genetic data may be used to support an argument that the two plants are indistinguishable, the Delegate stated that "in itself it is not sufficient to draw conclusions about the phenotypic distinctness or otherwise of the material tested".[10] The Delegate therefore placed much greater weight on the phenotypic evidence. In that regard, Majestic's expert witness claimed that only slight differences existed between Lime Tuff and Kuranga, and that such differences could not render Lime Tuff a distinct variety. Bushland's expert witness on the other hand considered the differences to be "conclusive that the plants differ".[11] Accepting that phenotypic differences existed between Lime Tuff and Kuranga, the Delegate considered those differences to be subtle and based on plants that had been grown in different locations rather than under trial conditions.[12] Since the phenotypes in question were quantitative and environmentally influenced, the Delegate was not convinced that Lime Tuff was distinct from Kuranga.

Having concluded that Kuranga was not distinct from Lime Tuff, the Delegate then had to consider whether Kuranga was "a variety of common knowledge". Given the broad meaning ascribed to this phrase under the PBR Act the Delegate looked for guidance from the International Convention for the Protection of New Plant Varieties, which provides a number of reasons why a variety may be considered "common knowledge," including that the variety had been commercialised. Since Kuranga had been sold to a local primary school several years before the PBR application for Lime Tuff had been filed, the Delegate concluded that Lime Tuff did not meet the requirement that it be distinct from any other variety whose existence is a matter of common knowledge at the time of filing. The PBR for Kuranga was accordingly revoked.

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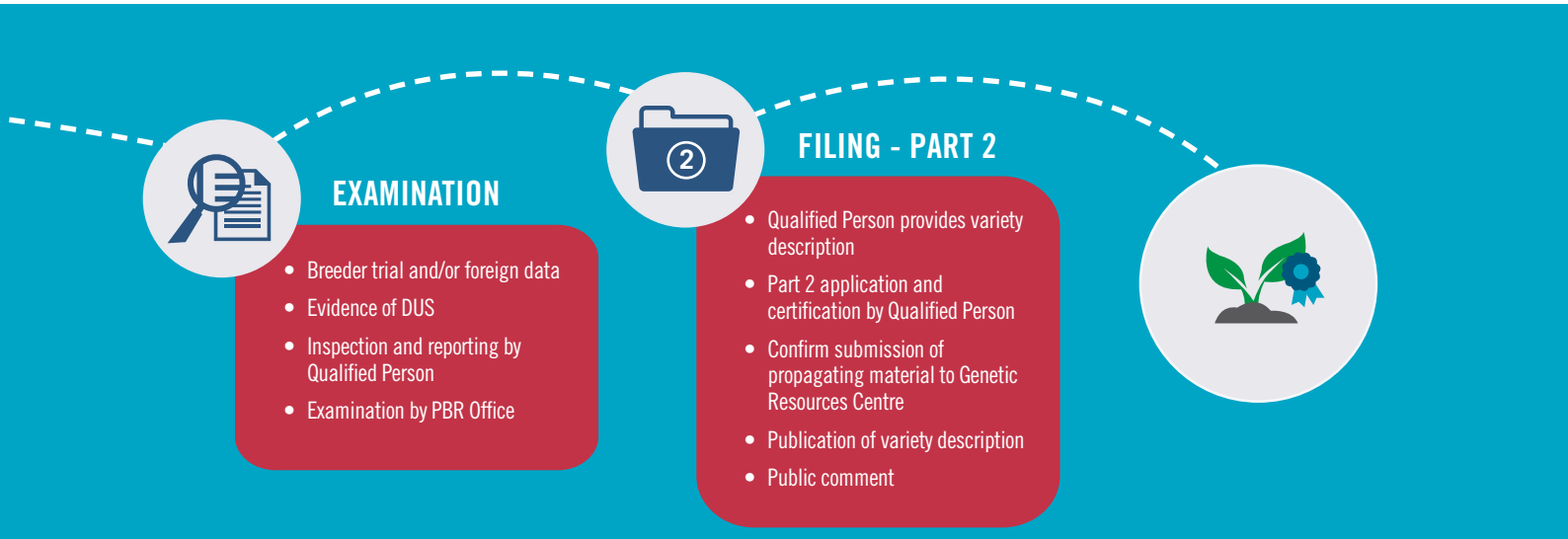
[9] PBR Act s 50(8).

[10] Majestic Selections Pty Ltd v Bushland Flora [2016] APBRO 1, [23].

[11] Majestic Selections Pty Ltd v Bushland Flora [2016] APBRO 1, [31].

[12] Majestic Selections Pty Ltd v Bushland Flora [2016] APBRO 1, [32].



TOWARDS 2017: PRODUCTIVITY COMMISSION'S "INTELLECTUAL PROPERTY ARRANGEMENTS" INQUIRY REPORT

In late December, the Federal Government released the Productivity Commission's final "Intellectual Property Arrangements" Inquiry Report. The Inquiry is the latest in a long line of Australian Council on Intellectual Property, Australian Law Reform Commission, Senate Committee and Productivity Commission reviews into the intellectual property system. Its recommendations have been widely criticised by industry and the legal profession concerned by the "weakening" effects on Australia's patent system.

The Commission details seven major recommendations for change to Australia's patent law.

INTRODUCTION OF AN OBJECTS CLAUSE

Recommendation 7.1

The Australian Government should incorporate an objects clause into the *Patents Act 1990* (Cth). The objects clause should describe the purpose of the legislation as enhancing the wellbeing of Australians by promoting technological innovation and the transfer and dissemination of technology. In so doing, the patent system should balance over time the interests of producers, owners and users of technology.

To combat an apparent high volume of "low-value" patents which are said to be stifling innovation and competition, the Commission has recommended that the *Patents Act 1990* (Cth) (**Act**) be amended to include an 'objects clause' which would provide clear objectives to ensure that public interest is protected and considered in the granting of patent rights. The application of an 'objects clause' would in effect require a patent to pass a test of social utility before it may be granted.

While there would seem to be nothing wrong with applying a test that reflects the principles of a well-functioning patent system, it is difficult to see how principles underpinning the social and public value of innovation can be crystallised into a definitive 'objects' statement, particularly when there is a broad spectrum of views on where the right balance of those principles lies.

CHANGES TO THE INVENTIVE STEP

Recommendation 7.2

The Australian Government should amend ss. 7(2) and 7(3) of the *Patents Act 1990* (Cth) such that an invention is taken to involve an inventive step if, having regard to the prior art base, it is not obvious to a person skilled in the relevant art. The Explanatory Memorandum should state:

- a 'scintilla' of invention, or a scenario where the skilled person would not 'directly be led as a matter of course', are insufficient thresholds for meeting the inventive step
- the 'obvious to try' test applied in Europe would in some instances be a suitable test.

REVIEW

KEY LEGISLATIVE REFORM

DECEMBER 1994

Patents (World Trade Organization Amendments) Act 1994

- Standard patent terms were extended from 16 to 20 years.
- Extension of term for pharmaceutical substances abolished.

AUGUST 1995

Advisory Council on Industrial Property
Review of the Petty Patent System

JULY 1998

Intellectual Property Laws Amendment Act 1998

- Extension of term for patents for pharmaceutical substances used for therapeutic purposes reintroduced.

MARCH 1999

Advisory Council on Industrial Property
Review of Enforcement of Industrial Property Rights

SEPTEMBER 2000

Intellectual Property and Competition Review Committee
Review of intellectual property legislation under the Competition Principles Agreement

NOVEMBER 2000

Patents Amendment (Innovation Patents) Act 2000

- It took nearly 5 years for any of the recommendations from the Petty Patent System review to be adopted and implemented.

OCTOBER 2001

Patents Amendment Act 2001

- Public oral disclosures anywhere in the world become part of the "prior art base".
- In determining inventive step, combinations of more than one piece of prior art could be considered where they existed before the priority date, would have been considered relevant by the person skilled in the art and would have been combined together.

FEBRUARY 2004

Advisory Council on Intellectual Property
Report on a Review of the Patenting of Business Systems

AUGUST 2004

Australian Law Reform Commission
Genes and Ingenuity Report: Gene Patenting and Human Health

AUGUST 2004

US Free Trade Agreement Implementation Act 2004

NOVEMBER 2004

Advisory Council on Intellectual Property
Should plant and animal subject matter be excluded from protection by the innovation patent?

NOVEMBER 2005

Australian Council on Intellectual Property
Patents and Experimental Use

DECEMBER 2005

Advisory Council on Intellectual Property
Review of Crown Use Provisions for Patents and Designs

SEPTEMBER 2006

Intellectual Property Laws Amendment Act 2006

- Some of the recommendations from the "Review of intellectual property legislation under the Competition Principles Agreement" and "Review of the Enforcement of Industrial Property Rights" were implemented by this amendment.
- This included broadening the spring boarding exception relating to pharmaceutical products to patent infringement.

JANUARY 2010

Advisory Council on Intellectual Property
Review of enforcement of Plant Breeder's Rights (PBR)

NOVEMBER 2010

Senate Inquiry
Gene Patents

FEBRUARY 2011

Advisory Council on Intellectual Property
Review of Patentable Subject Matter

APRIL 2012

Intellectual Property Laws Amendment (Raising the Bar) Act 2012

- The inventive step threshold was raised again, meaning that all prior art, anywhere in the world may be considered whether or not the inventor should or could have known about it; sources of prior art may be freely combined; and the relevant common general knowledge is based on a global standard.
- An experimental use exemption to patent infringement was introduced by this reform.
- Acts required to gain regulatory approval also became and exemption to patent infringement (essentially broadening the "spring boarding" provisions to encompass other industries).

MAY 2013

Parliamentary Review
Pharmaceutical Patent Review

JUNE 2014

Advisory Council on Intellectual Property
Review of the Innovation Patent System

DECEMBER 2016

Productivity Commission
Productivity Commission Inquiry Report – Intellectual Property Arrangements

IP Australia should update the Australian Patent Office Manual of Practice and Procedure such that it will consider the technical features of an invention for the purpose of the inventive step and novelty tests.

Recommendation 7.3

IP Australia should reform its patent filing processes to require applicants to identify the technical features of the invention in the set of claims.

The Commission seeks to further raise the bar on the inventive step requirement. It suggests that the current obviousness test is ineffective and recommends that the threshold for inventive step needs to be raised so as to ensure a greater advance over the prior art. In raising this threshold the Commission argues that the test will be more in line with the qualitative approach utilised in the European Union and will result in superior quality patents.

RESTRUCTURE OF PATENT FEES

Recommendation 7.4

The Australian Government and IP Australia should set patent fees to promote broader intellectual property policy objectives, rather than the current primary objective of achieving cost recovery. To this end, the Australian Government, with input from IP Australia, should:

- restructure patent renewal fees such that they rise each year at an increasing rate (including years in which patents receive an extension of term) — fees later in the life of a patent would well exceed current levels
- reduce the initial threshold for claim fees, and increase claim fees for applications with a large number of claims.

As a measure to deter the maintenance of the life of "low value" patents the Commission has recommended a restructure of patent renewal fees, whereby those fees rise each year at an increasing rate, and also an increase in claim fees for applications with a large number of claims.

ABOLISHING INNOVATION PATENTS

Recommendation 8.1

The Australian Government should abolish the innovation patent system.

The Commission recommends the innovation patent system be abolished. It views the "second-tier patents" as redundant despite the vital role that they play in many important areas of technological innovation and development.

REFORM FOR PHARMACEUTICAL PATENTS

Recommendation 10.1

The Australian Government should reform extensions of patent term for pharmaceuticals such that they are only:

i. available for patents covering an active pharmaceutical ingredient, and

ii. calculated based on the time taken by the Therapeutic Goods Administration for regulatory approval over and above 255 working days (one year).

The Australian Government should reform s. 76A of the *Patents Act 1990* (Cth) to improve data collection requirements for extensions of term, drawing on the model applied in Canada. Thereafter no extensions of term should be granted until data is received in a satisfactory form.

In relation to pharmaceuticals the Commission also suggests that the extension of term is excessive and that it should be wound back. It has also been recommended that more stringent data collection requirements be implemented for extensions of term.

Recommendation 10.2

The Australian Government should introduce a system for transparent reporting and monitoring of settlements between originator and generic pharmaceutical companies to detect potential pay for delay agreements. This system

should be based on the model used in the United States, administered by the Australian Competition and Consumer Commission, and include guidelines on the approach to monitoring as part of the broader guidance on the application of the *Competition and Consumer Act 2010* (Cth) to intellectual property (recommendation 15.1).

The monitoring should operate for a period of five years. Following this period, the Australian Government should review the regulation of pay for delay agreements (and other potentially anticompetitive arrangements specific to the pharmaceutical sector).

The Commission has recommended that a system be implemented to monitor "pay for delay" settlements between originator and generic pharmaceutical companies. Irrespective of whether this recommendation is incorporated into any legislative reform implemented by the Government, it is likely that there will be an increased focus by the ACCC on patent settlements given the competition regulator's interest in competition issues in the life sciences sector.

REPRIEVE FOR SOFTWARE PATENT AND PATENTS FOR COMPUTER IMPLEMENTED BUSINESS METHODS

The Commission has decided not to proceed with its recommendation introduced in its earlier draft report to exclude software patents as patentable eligible subject matter. The Commission has instead recommended a "wait and see approach" by monitoring software patents issued in Australia. It has also recommended that IP Australia publish more detailed information on cases where the manner of manufacture test is considered, in order to educate the community and allow policy makers to assess if future reform is required.

INTELLECTUAL PROPERTY LAWS AMENDMENT BILL 2017

In November 2016 a draft bill of amendments and regulations was released. These amendments contained within the *Intellectual Property Laws Amendment Bill 2017* provide us with a more tangible view as to what we can expect, at least in the shorter term, for the future of patent law. The proposed Bill seeks to introduce provisions aimed at rectifying administrative inconsistencies within the laws, streamlining processes and reducing regulatory costs. The Bill does not incorporate any of the recommendations from the Commission and it will be interesting to see whether it will be passed in its current form, or whether further amendments will be made to avoid successive waves of reform.

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