

INTRODUCTION –

This is a submission to the *IP Australia* addressed to the Commissioner of Patents in answer to the invited public consultation¹ on the proposed examination practice change following the High Court decision in *D'Arcy v Myriad Genetics Inc. [2015]*², hereinafter *D'Arcy*. The intention is to highlight some relevant issues that will affect patent procedure for biological inventions³, specifically genes patentability, in the future, if *IP Australia* alters scientific parameters related to the patentable subject matter in order to become narrower, and harsher on inventors. Limiting patent claims will not keep biological inventions away from court scrutiny, thus a long and extenuating process applied on a case-by-case basis. The issue belongs to the law-making realm, as patentability regarding genes is not fully prescribed in the *Patents Act 1990*, section 18, (2)⁴, its reach remaining unclear.

This submission considers that changing the patentability of subject matter may result in a narrower interpretation of innovative inventions. The *IP Australia* must take into consideration that:

- a) Myriad patents granted by the *United States Patent and Trademark Office*, hereinafter *USPTO*, are not identical in claims and specifications to the Australian patent application presented to the *IP Australia*⁵;
- b) In the United States, Myriad patents validity was reviewed at the district court⁶, a motion was granted, following an appeal to the Federal Circuit⁷, then by a *writ of certiorari* reached the United States Supreme Court.⁸ Myriad patents were held valid but reversed in part concerning the isolation of genes and the creation of cDNA. There was a concurrent opinion of Justice Scalia, who in a remarkable observation stated that courts are unable to affirm knowledge “into fine details of molecular biology”.⁹ Common sense dictates that the separation of functions in the scientific labour is the realm of the *USPTO*, which also applies to the *IP Australia*;
- c) The harmonisation of patent law practice is necessary in light of Australian free trade agreements and treaties.¹⁰ Having said that, it is not necessarily true that court opinions of our partners in trade in such topics as biotechnology involving human genes must be

¹ See, Australian Government IP Australia, About us, Public Consultations, *Consultation on our proposed examination practice following the High Court decision in D'Arcy v Myriad Genetics Inc. (23/10/2015)* <<http://www.ipaustralia.gov.au/about-us/public-consultations/Consultation-on-our-proposed-examination-practice-following-the-High-Court-decision-D'ArcyvMyriad-Genetics-Inc/>>.

² See, *D'Arcy v Myriad* [2015] HCA 35.

³ See, Australian Government IP Australia, Get the right IP, Patents, About Patents, *What can be patented*, Patents for biological inventions, (03/04/2014) <<http://www.ipaustralia.gov.au/get-the-right-ip/patents/about-patents/what-can-be-patented/patents-for-biological-inventions/>>.

⁴ See, *Patents Act 1990* (Cth) section 18, (2).

⁵ See, *D'Arcy v Myriad Genetics Inc.* [2014] FCAFC 115 [132].

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

⁶ See, *Association for Molecular Pathology v United States PTO*, 2010 U.S. Dist. LEXIS 35418 (NY, 2010).

⁷ See, *Association for Molecular Pathology v United States PTO*, 2010 U.S. App. LEXIS 17077 (2nd Circuit, 2010). See also *Association for Molecular Pathology v United States PTO*, 689 F. 3d 1303 (NY, 2012) (Shepard's® subsequent analysis indicate that some district courts followed the decision, others explained it, and others distinguished this opinion, which means there is not an unified jurisprudential understanding before and after the U.S. Supreme Court handed their decision).

⁸ See, *Association for Molecular Pathology v Myriad Genetics, Inc.*, 2013 U.S. LEXIS 4540 (Thomas J) (2013).

⁹ See, *Association for Molecular Pathology v Myriad Genetics, Inc.*, 2013 U.S. LEXIS 4540 (Scalia J) (2013).

¹⁰ See, Australia-United States Free Trade Agreement, *Chapter Seventeen – Intellectual Property Rights*, Article 17.1.: General Provisions. 17.9: Patents, <http://www.austlii.edu.au/au/other/dfat/treaties/2005/1/chapter_17.html>.

followed narrowly on a case-by-case *modus operandi*. Jurisprudence can change in the future;

- d) The issue of whether a concept of discovery¹¹ versus law of the nature debate was not fully scrutinized by the High Court of Australia, and thus ignored in their decision;
- e) If changes to the patent subject matter concerning patent eligibility are made to the naturally occurring isolated bacteria, naturally occurring isolated virus, or isolated biological material capable of economic result or being useful¹², uncertainty in the future for Australian innovative industry can occur. *IP Australia* must fulfil its function to the best of their patent examiners and Commissioner of Patents abilities, altering its police of patentability will not be a long-term solution;
- f) Jurisprudence is crucial to guide us in statutory interpretation throughout acceptable social order, but it cannot automatically perform a law-making duty. This is particularly true in topics where the Legislature must act positively to give a plain and straightforward meaning of intellectual property, specifically in patents of biological material involving human genes;
- g) Biological material claims and its patentability or non-patentability must be scrutinized from the perspective of those professionals trained and educated to perform that occupation. By default courts should restrict their task to review issues according to the legislation applicable. In this case, the *Patents Act 1990*, section 18, (2)¹³ possess a past legislative history of ambiguity that should be taken into account for an efficient statutory interpretation¹⁴;
- h) A new legislative instrument or further clarification in an amendment to section 18 (2) is crucial to clarify about biological inventions involving genetic material and its patentability boundaries.

Therefore, we will delve into these issues below.

A) A brief Patent history: a Legislative Background in granting patents

IP Australia is a Commonwealth entity that evolved from the Australian Patent Office created in 1904¹⁵, by force of the *Patents Act of 1903*.¹⁶ It is crucial to understand that the independence bestowed to *IP Australia* to act and perform acts was given so that the patent procedure can be finalised with a refusal or acceptance of a patent. Exceptions may apply, but the general rule is that a standard patent or an innovation patent application must be subject to scientific analysis necessary to evaluate whether an invention has been presented or not until the grant.

¹¹ See, *D'Arcy v Myriad* [2015] HCA 35 (Gageler, Nettle JJ) 147.

¹² See, Australian Government IP Australia, About us, Public Consultations, *Consultation on our proposed examination practice following the High Court decision in D'Arcy v Myriad Genetics Inc.* (23/10/2015) <<http://www.ipaustralia.gov.au/about-us/public-consultations/Consultation-on-our-proposed-examination-practice-following-the-High-Court-decision-D'ArcyvMyriad-Genetics-Inc/>>

¹³ See, *Patents Act 1990* (Cth) section 18, (2).

¹⁴ See, Australian Law Reform Commission, Publications, *Genes and Ingenuity: Gene patenting and human health* (ALRC Report 99), 15. Stem Cell Technologies, Legislative history of s 18(2) of the Patents Act, <<http://www.alrc.gov.au/publications/15-stem-cell-technologies/application-patent-law-stem-cell-technologies>>.

¹⁵ See, Australian Government IP Australia, About us, *What we do*, Our history, (31/07/2015) <<http://www.ipaustralia.gov.au/about-us/what-we-do/our-history/>>.

¹⁶ See, An Act relating to Patents of Inventions n. 21 of 1903, Part II – Administration, Division 1 – The Minister, The Commissioner, and the Patent Office, section 12.

- **Jefferson and the U.S. patent system**

Appointed as Washington's first Secretary of State, a scientist as well as a politician, Thomas Jefferson, was also the first appointed Patent Officer of the United States.¹⁷ Jefferson shaped the American patent procedure including extensions for patents from the very beginning, including appropriate procedures for review of decisions.¹⁸ Refused patents were sent to the U.S. Congress to be reviewed in the eyes' of public scrutiny with Jefferson's presence, and of the interested inventors, seldom a pleasant encounter. Working in a small team, for managing and preparing reports to clarify the reasons for a refused invention by the Board of Arts before the U.S. Congress, overloaded Jefferson. His Jeffersonian test was reduced to one question addressed to the inventors applying of the patent grant: is this an invention useful or theoretical work?¹⁹

This question is remarkably similar to the one inferred from *D'Arcy* to the High Court of Australia as well.²⁰

In line with his test, Jefferson had rejected the desalination of seawater invention lodged by Jacob Isaacks circa 1791.²¹ The event was a natural phenomenon with no human intervention, a truly phenomenon of nature. Isaacks appealed to the U.S. Congress, so that Jefferson was summoned to deliver his reasons for Isaacks' patent application rejection. This was one of the uncountable lengthy sessions at the U.S. Congress that Jefferson, the Commissioner, had to attend. US inventors enjoyed a democratic system that allowed them to challenge patent decisions contrary to his interests, polarising the 1790-1793 U.S. Congress.²² Because of these turbulent years, *The Patents Act of 1793*²³ was penned by Jefferson²⁴ to clarify tests for patentability, novelty and non-obviousness.

- **Some court decisions that challenged the *status quo* of patent law in the United States**

In *Lowell v. Lewis*²⁵, the court was asked to define what was novelty, what was a clear claim description and what the invention claimed for a monopoly should be. Justice Joseph Story observed that obscure terms may contaminate the patent specifications, and consequently render a patent application invalid. Equally important was the theory of beneficial utility developed by Justice Story, which is contained in this passage:

¹⁷ See, Ana Penteadó, *International Intellectual Property and International Environmental Law: A Study of Ownership of Indigenous Peoples' Intellectual Property Rights*, (PhD Thesis, Macquarie University, 2008).

¹⁸ See, Ana Penteadó, *International Intellectual Property and International Environmental Law: A Study of Ownership of Indigenous Peoples' Intellectual Property Rights*, (PhD Thesis, Macquarie University, 2008).

¹⁹ See, Ana Penteadó, *International Intellectual Property and International Environmental Law: A Study of Ownership of Indigenous Peoples' Intellectual Property Rights*, (PhD Thesis, Macquarie University, 2008).

²⁰ See, generally, *Cancer Voices Australia v D'Arcy* [2013] FCA 65 [76]. See, specifically, *D'Arcy v Myriad* [2015] HCA 35 (Gageler, Nettle, Gordon JJ) [124], [241].

²¹ See, Ana Penteadó, *International Intellectual Property and International Environmental Law: A Study of Ownership of Indigenous Peoples' Intellectual Property Rights*, (PhD Thesis, Macquarie University, 2008).

²² See, Ana Penteadó, *International Intellectual Property and International Environmental Law: A Study of Ownership of Indigenous Peoples' Intellectual Property Rights*, (PhD Thesis, Macquarie University, 2008).

²³ See, *Patent Act of 1793*, Chapter 11, Statute 318-323 (21st February of 1793).

<http://ipmall.info/hosted_resources/lipa/patents/Patent_Act_of_1793.pdf.>

²⁴ See, Ana Penteadó, *International Intellectual Property and International Environmental Law: A Study of Ownership of Indigenous Peoples' Intellectual Property Rights*, (PhD Thesis, Macquarie University, 2008).

²⁵ See, *Lowell v Lewis* 15 F. Cas 1018 (C.C.D. Ma 1817). See, Robert Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* (Lexis and Nexis, 3rd, 2002) 217-219. See also Ana Penteadó, *International Intellectual Property and International Environmental Law: A Study of Ownership of Indigenous Peoples' Intellectual Property Rights*, (PhD Thesis, Macquarie University, 2008).

"In my judgment the [defendant's] argument is utterly without foundation. All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sounds morals of society. The word "useful", therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention."²⁶

Indeed, what a long way we walked from the beneficial utility to technology morality. Take the example of artillery patentability subject matter. For instance, weapons are manufactured exclusively to exterminate human beings or to neutralise targets, and generally are patentable. The Gatling gun²⁷, a rapid-fire assault gun, was granted a patent in 1893.²⁸ Today guns are independently operated weapons, some with a hybrid drive for use as normal handgun or automatic weapon²⁹, which a non-expert like myself assumes is the state-of-the-art for this industry. Amazingly, no one questions whether the economics of patentability are amoral, which is an entirely different matter, but the beneficial utility is unquestionable missing here.

The politics of morality transformed patent subject matter, changing what is of economic value; gambling and weapons illustrate my point, not to mention the tobacco and alcohol industries. It is not my objective to inquire whether these industries are justifiable for patentability purposes, but rather to show that technologies that were once considered immoral are currently acceptable patent subject matter (gambling machines, cigarettes and alcohol). The point is that social norms are reshaped in our perception from time to time. Therefore, one assumes that the borderline of morality parameters in genes patentable subject matter can change, perhaps be restricted or prohibited altogether. Indeed, these complex issues must be dealt by statutory amendment.

In *Parker-Davis & Co v H. K. Mulford Co*³⁰ the patent claimed the process of isolation of a purified substance of medical and economic importance, the final product being called Adrenalin. First, the patent applicant claimed the obtained active principle itself, including process and product, which the Examiner rejected entirely. Subsequently, the claims were changed in the amendment provided by the applicant, so that the Examiner reported the claims as being broader than the claims originally stated. Moreover, a similar product was sold in the market called Adrin, which Adrenalin as a product infringed, allowing the question of novelty to be presented before the Court. *Parker-Davis* is considered a landmark for allowing patents on DNA sequences.³¹ In *Association for Molecular Pathology, Et Al v. United States Patent and Trademark Office*³² the issue was that the

²⁶ See, Robert Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* (Lexis and Nexis, 3rd, 2002) 217.

²⁷ See, Wikipedia, Gatling gun, with an extensive verbatim. <https://en.wikipedia.org/wiki/Gatling_gun>

²⁸ See, United States Patent and Trademark Office, Patent: US000502185, Inventor: R.J.

Gatling <<http://pdfpiw.uspto.gov/.piw?Docid=00502185>>.

²⁹ See, The World Intellectual Property Organization, *Patentscope*, Search International and National Patent Collections, (WO2010102727) "Externally and Also Independently Operated Weapon", Inventor: Hubert Schneider, International Filing Date: 26/02/2010

<<https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2010102727>>

³⁰ See, Robert Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* (Lexis and Nexis, 3rd, 2002) 97-104. See also Ana Penteadó, *International Intellectual Property and International Environmental Law: A Study of Ownership of Indigenous Peoples' Intellectual Property Rights*, (PhD Thesis, Macquarie University, 2008).

³¹ See, Robert Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* (Lexis and Nexis, 3rd, 2002) 103.

³² See, *Association for Molecular Pathology v United States Patent and Trademark Office*, U.S. District LEXIS 35418, 17 (Sweet J) (2010).

gene was intact in its composition performing similar functions. Consider this passage by District Justice Hand in *Parker-Davis* where he observed the absence of statutory provision:

“But even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it available for any use by removing it from the other gland-tissue in which was found (...). The line between different substances and degrees of the same substance is to be drawn rather from the common usages of men than from nice considerations of dialectic...”³³

Now compare with this passage in *Association for Molecular Pathology v USPTO*³⁴ relevant for this submission:

“Plaintiff’s challenge to the validity of these claims, and the arguments presented by the parties and amici, have presented a unique and challenging question:

Are isolated human genes and the comparison of their sequences patentable?”³⁵

Two complicated areas of science and law are involved: molecular biology and patent law. The task is to seek the governing principles in each and to determine the essential elements of the claimed biological compositions and processes and their relationship to the laws of nature. The resolution of these issues presented to this Court deeply concerns breast cancer patients, medical professionals, researchers, caregivers, advocacy groups, existing gene patent holders and their inventors, and those seeking to advance public health. The claims-in-suit directed to “isolated DNA” containing human BRCA1/2 gene sequences reflect the USPTO’s practice of granting patents on DNA sequences so long as those sequences are claimed in the form of “isolated DNA.”

This practice is premised on the view that DNA should be treated no differently from any other chemical compound, and that its purification from the body, using well-known techniques, renders it patentable by transforming it into something distinctly different in character. *Many, however, including scientists in the fields of molecular biology and genomics, have considered this practice a “lawyer’s trick” that circumvents the prohibitions of the direct patenting of the DNA in our bodies but which, in practice, reaches the same result.*(...) It is concluded that DNA’s existence in an “isolated” form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to “isolated DNA” containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. para 101.”³⁶

Interestingly enough, in *the United States Code Title 35, Patents*, 35 U.S.C. 101³⁷ an amendment to include *Public Law 112-29*³⁸, section 33 (a) provides a clear limitation on the issuance of patents **towards any claim directed to or encompassing a human organism**. The Second Circuit decided *Association* in August 16 in 2010 and the amendment to the relevant 35 U.S.C. is of September 16 in

³³ See, See, Robert Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* (Lexis and Nexis, 3rd, 2002) 99.

³⁴ See, *Association for Molecular Pathology v United States Patent and Trademark Office*, U.S. District LEXIS 35418, 1 (Sweet J) (2010).

³⁵ See, *Association for Molecular Pathology v United States Patent and Trademark Office*, U.S. District LEXIS 35418, 1 (Sweet J) (2010).

³⁶ See, *Association for Molecular Pathology v United States Patent and Trademark Office*, U.S. District LEXIS 35418, 1 (Sweet J) (2010).

³⁷ See, The United States Patent and Trademark Office, *Patents, Patents Laws, Regulations, Policies & Procedures, Manual of Patent Examining Procedure, Appendix L – Patent Laws*, <<http://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#d0e302310>>

³⁸ See, The United States Patent and Trademark Office, *Patents, Patents Laws, Regulations, Policies & Procedures, Manual of Patent Examining Procedure, Appendix L – Patent Laws, AIA para 33 (Related to 35 U.S.C. 101) – Limitation on issuance of patents*, <<http://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#aiasec33limitonissuance>>

2011. It appears that *Association*³⁹ influenced the amendment *supra* mentioned. Nonetheless, the point to be made is that statutory amendment were provided to support the findings of *Association for Molecular Pathology v United States PTO*.⁴⁰ One can infer that is not the case in *D'Arcy* as Australian legislation is unclear regarding the limitations on biological material accrued from human genes subject to patentability.

The *Statute of Monopolies*, section 6⁴¹ does not clarify that a product extracted from its natural surroundings is not a patentable subject matter. It is not disproportionate to have lower expectations about this archaic piece of law, as centuries ago it would be unlikely that His Majesty could predict the evolutionary pattern of biotechnology in our days. Let alone to legislate about genes. Notwithstanding that, the High Court of Australia indicates that *The Patents Act 1952* (Cth)⁴² may help the inquiry of whether a proper subject of letter patent possesses a quality of inventiveness. According to the High Court, this shall be an “artificial state of affairs and economic utility”⁴³, which Myriad invention does not possess, as it is an unaltered gene discovery.⁴⁴ *The Patent Act 1990*, section 18 (1) (a)⁴⁵ must follow guidance on prior legislation and jurisprudence to restrict genes patentability. The section consists of a single sentence that applies limitations in the general sense to non-patentability to human biological extract and generation.⁴⁶

Could one assume that the section expressly prohibits biotechnology associated to “encode” and not to “coding”?⁴⁷ What about mutations and polymorphism concepts?⁴⁸ The Full Court⁴⁹ and the High Court of Australia⁵⁰ stated in their opinions, there is no definition to “coding”⁵¹ in the Australian patent law, therefore, it is not far from reasonable to admit that *the Patent Act 1990*, section 18 (2) falls short on the prescribed norm for coding, mutations and polymorphisms⁵², which are not semantics here. Perhaps I will safely adopt Justice Scalia rationale; I do not have knowledge in molecular biology to support a conclusion for or against it.⁵³

³⁹ See, *Association for Molecular Pathology v United States PTO*, 2010 U.S. App. LEXIS 17077 (2nd Circuit, 2010).

⁴⁰ See, *Association for Molecular Pathology v United States PTO*, 2010 U.S. App. LEXIS 17077 (2nd Circuit, 2010), See, *Association for Molecular Pathology v United States PTO*, 2010 U.S. Dist. LEXIS 35418 (NY, 2010).

⁴¹ See, The National Archives, legislation.gov.uk, browse legislation, *Statute of Monopolies 1623*, 1623 Chapter 3 21 Ja 1, section VI, An Act concerning Monopolies and Dispensations with penal Lawes and the Forfeiture thereof,

<<http://www.legislation.gov.uk/aep/Ja1/21/3/section/VI>>

⁴² See, *D'Arcy v Myriad* [2015] HCA 35 (Gageler, Nettle JJ) [125]- [127].

⁴³ See, *D'Arcy v Myriad* [2015] HCA 35 (Gageler, Nettle JJ) [125].

⁴⁴ See, *D'Arcy v Myriad* [2015] HCA 35 (Gageler, Nettle JJ) [128], [130], [131], [134], [136], [137], [139], [141].

⁴⁵ See, *Patents Act 1990*, section 18, (2) (“Human beings, and the biological processes for their generation, are not patentable inventions.”).

⁴⁶ See, *Patents Act 1990*, section 18, (2) (“Human beings, and the biological processes for their generation, are not patentable inventions.”).

⁴⁷ See, *Patents Act 1990*, section 18, (2). See especially, *D'Arcy v Myriad* [2015] HCA 35 (7 October 2015) (Gordon J) [245]-[246]. See also *D'Arcy v Myriad* [2014] 224 FCR 479, [175]. See also, *Cancer Voices Australia v D'Arcy* [2013] FCA 65, [71].

Cancer Voices Australia v D'Arcy [2013] FCA 65, [63].

⁴⁸ See, *D'Arcy v Myriad* [2015] HCA 35 (7 October 2015) (Gordon J) [190].

⁴⁹ See, *Cancer Voices Australia v D'Arcy* [2013] FCA 65, [62].

⁵⁰ See, *D'Arcy v Myriad* [2015] HCA 35 (7 October 2015) (Gordon J) [245]-[246].

⁵¹ See, *D'Arcy v Myriad* [2015] HCA 35 (7 October 2015) (Gordon J) [245].

⁵² See, *D'Arcy v Myriad* [2015] HCA 35 (7 October 2015) (Gordon J) [190].

⁵³ See, *Association for Molecular Pathology v Myriad Genetics* 2013 LEXIS 4540 (June 13, 2013) (Scalia J).

In *Funk Bros. Seed Co v Kalo Inoculant Co.*,⁵⁴ a patent infringement case, a bacteria was found to produce “manifestations of laws of nature”⁵⁵ so the Supreme Court decided that “If there is to be invention from such discovery, it must come from the application of the law of nature to a new and useful end.”⁵⁶ Nonetheless, the claim to the new product was rejected:

“But we think that that aggregation of species fell short of invention within the meaning of the patent statutes. Discovery of the fact that certain strain of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. (...) No species acquires a different use.”⁵⁷

Some decades have passed after *Funk* and the question of discovery surfaced in *Diamond v. Chakrabarty*⁵⁸, with opposite results for “a bacteria containing two or more different energy-generating plasmids”⁵⁹ not occurring in nature, qualified for an invention. In *Chakrabarty*, the Supreme Court refers to *Funk* case, in which opinion they stated that:

“Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility.”⁶⁰

Professor Merges wisely reflects on *Diamond* and *Funk* results for patentable subject matter comparing their decisions:

“What distinguishes these two cases? One possible answer is that the Court is drawing a line between discovery and invention. In *Chakrabarty*, the Court emphasizes the transformation that the inventor makes on the admittedly natural raw materials of the invention. But in *Funk Bros.*, the Court emphasizes that the bacteria, though combined in a novel way, still perform their same old natural function.”⁶¹

Moreover Professor Merges observes that *the United States Code Title 35, Patents*, section 35 U.S.C. 100⁶² provides inventions with two meanings of both “invention” and “discovery”⁶³, which differs

⁵⁴ See, Robert Merges, Peter Menell, Mark Lemley and Thomas Jorde, *Intellectual Property in the New Technological Age* (Aspen Law & Business, 1997) 144-147.

⁵⁵ See, Robert Merges, Peter Menell, Mark Lemley and Thomas Jorde, *Intellectual Property in the New Technological Age* (Aspen Law & Business, 1997) 145.

⁵⁶ See, Robert Merges, Peter Menell, Mark Lemley and Thomas Jorde, *Intellectual Property in the New Technological Age* (Aspen Law & Business, 1997) 145.

⁵⁷ See, Robert Merges, Peter Menell, Mark Lemley and Thomas Jorde, *Intellectual Property in the New Technological Age* (Aspen Law & Business, 1997) 146.

⁵⁸ See, See, Robert Merges, Peter Menell, Mark Lemley and Thomas Jorde, *Intellectual Property in the New Technological Age* (Aspen Law & Business, 1997) 136-144.

⁵⁹ See, Robert Patrick Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* (LexisNexis, 3rd ed., 2002) 67 note 3.

⁶⁰ See, Robert Patrick Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Material*(LexisNexis, 3rd ed., 2002) 139.

⁶¹ See, Robert Patrick Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* (LexisNexis, 3rd ed., 2002) 147.

⁶² See, United States Patent and Trademark Office, Appendix L, Patent Laws, United States Code Title 35, Patents, Part II – PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS, Chapter 10, Patentability of Inventions, 35 U.S.C. 100 Definitions, (1), (a) <http://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#al_d1d917_1bef1_2b>.

⁶³ See, United States Patent and Trademark Office, Appendix L, Patent Laws, United States Code Title 35, Patents, Part II – PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS, Chapter 10, Patentability of Inventions, 35 U.S.C. 100 Definitions, (1), (a) <http://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#al_d1d917_1bef1_2b>.

dramatically from the *Patent Act 1990 (Cth)*, section 18, (1) and (1 A).⁶⁴ The *Patent Act 1990 (Cth)* does not provide any further definition on section 18, (2) to encompass or to make a restriction to genes. This can be subsequently interpreted as a narrow scope to include any biological subject matter to be apparently not patentable, which is really a conservative interpretation of the *Statute of Monopolies* and further patent legislation.

Looking at the legislative history of the *Patent Act 1990*, section 18 (1) (a), it was originally proposed by senator Brian Harradine during parliamentary debates⁶⁵ that inventions involving “ human life forms, genetic manipulations of human species, trans-species procedures involving human cells and human embryonic cells”⁶⁶ should be of concern.⁶⁷ At that time, the *Senate Standing Committee on Science, Industry and Technology* was also concerned about section 18 (2) for: “the proposal’s apparent breath and ambiguity.”⁶⁸ Subsequently to its enactment, the *IP Australia Manual of Practice and Procedure* indicated a narrower interpretation of the section 18 (2) scope, excluding human beings which result from biological processes (naturally fertilised or otherwise).⁶⁹

I am afraid I fail to see where in the High Court of Australia’s decision this piece of information on legislative history behind *Patent Act 1990*, section 18 (2) enactment was taken into consideration to reach its opinion.⁷⁰ Assuming this is a fact, more should be said clearly and unambiguously about an in-existent provision limiting claims directed to or to include a gene non-patentability in Australian patent law. The *Australian Law Reform Commission* appears to have reached the same conclusion regarding section 18 (2): that given its ambiguity, it does not exclude many inventions involving genetic materials and technologies from patentability.⁷¹

In line with my observation above, a pertinent issue raised by Professor Merges is relevant here:

⁶⁴ See, *Patent Act 1990*, section 18, (1), (1A).

<http://www.austlii.edu.au/au/legis/cth/consol_act/pa1990109/s18.html>

⁶⁵ See, Australian Law Reform Commission, Publications, *Genes and Ingenuity: Gene patenting and human health* (ALRC Report 99), 15. Stem Cell Technologies, Legislative history of s 18(2) of the Patents Act, <<http://www.alrc.gov.au/publications/15-stem-cell-technologies/application-patent-law-stem-cell-technologies>>.

⁶⁶ See, above note 65. (‘ Senator Harradine indicated that he was concerned that insufficient consideration was being given by Parliament to ‘the possibility of patenting new forms of animal life and that the Australian Patents Office (as it then was) might grant patents on a human or a genetically-modified human.’)

⁶⁷ See, Australian Law Reform Commission, Publications, *Genes and Ingenuity: Gene patenting and human health* (ALRC Report 99), 15. Stem Cell Technologies, Legislative history of s 18 (2) of the Patents Act <<http://www.alrc.gov.au/publications/15-stem-cell-technologies/application-patent-law-stem-cell-technologies>>

⁶⁸ See, Australian Law Reform Commission, Publications, *Genes and Ingenuity: Gene patenting and human health* (ALRC Report 99), 15. Stem Cell Technologies, Legislative history of s 18 (2) of the Patents Act <<http://www.alrc.gov.au/publications/15-stem-cell-technologies/application-patent-law-stem-cell-technologies>>.

⁶⁹ See, Australian Law Reform Commission, Publications, *Genes and Ingenuity: Gene patenting and human health* (ALRC Report 99), 15. Stem Cell Technologies, Legislative history of s 18 (2) of the Patents Act <<http://www.alrc.gov.au/publications/15-stem-cell-technologies/application-patent-law-stem-cell-technologies>>.

⁷⁰ But see, *Cancer Voices Australia v D’Arcy* [2013] FCA 65, (Nicholas J) [111]-[119].

⁷¹ See, Australian Law Reform Commission, Publications, *Genes and Ingenuity: Gene patenting and human health* (ALRC Report 99), 7. Exclusions from Patentability, 7. Exclusions from Patentability, Human beings and the biological processes for their generation, 7.7. <<http://www.alrc.gov.au/publications/7-exclusions-patentability/existing-exclusions-patentability>>.

“Is there any difference in the *degree* of human intervention required to make these two inventions?”⁷²

The American law has updated the patent legislation with the *1952 Patent Act*⁷³ and further updates of limitation on issuance of patents.⁷⁴ Professor Merges suggested that prior to the *1952 Patent Act*⁷⁵, the standard of patentability became harsher whenever the U.S. courts would apply tests of non-obviousness to patentable subject matter such as the “flash of genius”⁷⁶ case of *Cuno Engineering Corp v Automatic Devices Corp.*⁷⁷

When I read and consider the result in *D’Arcy* and what that means to innovative technology for diseases and improvements of screening and prevention in Australia, I have serious concerns on how future patent inventions in the realm of biotechnology will be tested against this jurisprudence. It is unhealthy to abstain from checks and balances on government institutions, whether the branch is the Judiciary or the Executive. Further, the consequences of what a unified genes patent policy – Judiciary and *IP Australia* – means for patentable subject matter on biotechnology inventions, I am afraid the future looks unclear.

As for the impact on stakeholders, including the ones that provide screening tests and clinical trials for non-profit purposes, it does not look encouraging either. Any research project needs intellectual capital as well as venture capital. For future inventors in start-ups, in research laboratories, in the universities to have funds for biotechnology research in Australia, it may be a hardship. Venture capitalists will certainly divert their interest to other less ambiguous portfolios, or to trade secrets practice, which entails contractual base arrangements like confidentiality agreements between parties. Trade secrets are costly to run, but are efficient.

It is necessary to have a little bit of legislative ingenuity to draft an amendment to the current patent legislation, ratifying that in the case of stakeholders such as non-profit organizations, including universities and research institutes, a new solution will be proposed. A proper compulsory license to should be considered. In Canada, for instance, ovarian and breast cancer tests can be performed for “a third of Myriad’s cost”⁷⁸ because the government decided to move away from any obligation to comply with the validity of Myriad’s patents.⁷⁹ It is a dangerous approach.

⁷² See, Robert Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* (LexisNexis, 3rd edition, 2002) 107.

⁷³ See, United States Patent and Trademark Office, *Appendix L, Patent Laws*, United States Code Title 35, Patents, Part II – PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS, Chapter 10, Patentability of Inventions, 35 U.S.C. 100 Definitions, (1), (a). <<http://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#d0e302310>>.

⁷⁴ See, United States Patent and Trademark Office, *Appendix L, Patent Laws*, United States Code Title 35, Patents, Part II – PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS, Chapter 10, Patentability of Inventions, 35 U.S.C. 100 Definitions, (1), (a), AIA para 33 (Related to 35 U.S.C. 101) Limitation on issuance of patents <<http://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#aiasec33limitonissuance>>

⁷⁵ See, Title 35 – Patents, enacted by act July 19, 1952, Chapter 950, para 1, 66 Statute 792, <<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title35/pdf/USCODE-2011-title35.pdf>>.

⁷⁶ See, Robert Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* (LexisNexis, 3rd edition, 2002) 108.

⁷⁷ See, *Cuno Engineering Corporation v Automatic Devices* 313 U.S. 553 (1941). See especially, Robert Merges and John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* (LexisNexis, 3rd edition, 2002) 108.

⁷⁸ See, *Association for Molecular Pathology v United States Patent and Trademark Office* 2010 U.S. District LEXIS 35418, 17.

⁷⁹ See, Nathaniel Lipkus, Just Biotech, Mining Biotech Gold, Should Diseases be Patentable? Gene Patents in Canada: A Myriad of Possibilities <<http://www.justbiotech.ca/gene-patents-in-canada-a-myriad-of-possibilities/>>.

While I acknowledge that for some areas in government, such as healthcare, it is paramount to have access to new technologies, I disagree entirely on submitting the scientific parameters designed by *IP Australia* to be narrower in the interpretation of patentability subject matter due to *D'Arcy*. Again, as I stated, narrower interpretation on patentability will reverse accessibility to resources, as private investment will possibly be unavailable or unwilling to commit to intangible assets. Some argue that there will be a significant number of competitors to choose from for breast and ovarian cancer tests after *Association* was decided in the United States Supreme Court⁸⁰, which I doubt as potential infringement claims (and lawsuits) will adversely influence competitors' decision to confront the compliance of policies to avoid unnecessary risks.

If a solution can be proposed to these circumstances, it could be in the form of a compulsory license inspired by the 2001 *Doha Declaration*⁸¹, designed for non-profit and research organizations, to be proposed as an amendment to the *Patents Act 1990*, section 18, (2). That would be a better strategy for all stakeholders involved. Much like in the crooner Sinatra's tune, *something's got to give* in order to have public order.

- **Genes patentability in Australia and in the United States – some issues**

Unlike the Federal Court in *Cancer Voices Australia v. Myriad Genetics Inc.*⁸², the High Court of Australia did not entertain the question that the patent claims presented are described in a different way as they were presented in the U.S. Supreme Court.⁸³ I have to turn to the degree of patentability, which is crucial here. Whether it is the degree of human intervention and ingenuity of an inventor (most likely a team of inventors), or a refusal of those talents to be considered in the High Court of Australia's decision, or the past legislative history not contemplated.⁸⁴ I am not in a position to comment, nonetheless, the legislative history behind section 18 (2) does not confirm that the Australian legislation avoided the topic altogether, but made an effort to leave less ambiguity.⁸⁵

As *D'Arcy* decision stands now, both *IP Australia* and the courts, possibly with confusing results, will perform the scrutiny for the degree of patentability. *IP Australia* has a distinct role in granting patents or finding patentability for new subject matter, so that implies that courts will be called upon to validate patents granted by the *IP Australia*, whenever a Jacob Isaacks⁸⁶ presents himself. I expect that *IP Australia* patent examiners will guide themselves with tests such as novelty, non-obviousness and useful arts, not with a narrow interpretation of manufacturing elements according to the *Statute of Monopolies* or an unclear *Patents Act 1990*, section 18 (2). It will be appalling for

⁸⁰ See, Robert Langreth and Shannon Pettypiece, 'Myriad Gene Patent Ruling Triggers Race for Cancer Tests', *BloombergBusiness* (online), (15 June 2013 6:12AM) <<http://www.bloomberg.com/news/articles/2013-06-14/myriad-gene-patent-ruling-triggers-race-for-cancer-tests>>.

⁸¹ But see, The World Health Organization, Programmes, *Bulletin of the World Health Organization*, Access to AIDS medicines stumbles on trade rules, (5 May in 2006) <<http://www.who.int/bulletin/volumes/84/5/news10506/en/>>.

⁸² See, *Cancer Voices Australia v D'Arcy* [2013] FCA. See also *D'Arcy v Myriad* [2014] FCAFC 115, [132]-[133].

⁸³ See, *D'Arcy v Myriad* [2015] HCA 35 (French, Kiefel, Bell, Keane JJ) [79]-[80]. See also, *D'Arcy v Myriad* [2014] FCAFC 115, [132].

⁸⁴ See, *D'Arcy v Myriad* [2015] HCA 35 (French, Kiefel, Bell, Keane JJ) [36]-[37].

⁸⁵ See, Australian Law Reform Commission, Publications, Genes and Ingenuity: Gene patenting and human health (ALRC Report 99), 15. Stem Cell Technologies, Legislative history of s 18 (2) of the Patents Act <<http://www.alrc.gov.au/publications/15-stem-cell-technologies/application-patent-law-stem-cell-technologies>>.

⁸⁶ See, Ana Penteadó, *International Intellectual Property and International Environmental Law: A Study of Ownership of Indigenous Peoples' Intellectual Property Rights*, (PhD Thesis, Macquarie University, 2008).

future patent applications on biotechnology material, to guide themselves on a case-by-case court decision only, because patent protection is conferred in a narrow interpretation of patentability.⁸⁷

Although more debate is necessary as the *Australian Law Reform Commission* suggests, excludable subject matter is more important than innovation as it stands now. Whether the Australian legislator will propose amendments to the *Patents Act 1990*, section 18, (2) and when the Australian Parliament decides to debate the topic to clarify a more friendly policy towards innovation, this caveat of what is or not permissible is open. It will not improve to make the *IP Australia* examination process narrower and harsher for inventors at the cost of less freedom from influence of what is considered a very controversial High Court decision.

DISCLAIMERS

I would like to state that I am interested in presenting my concerns as a legal researcher of patent law, specifically American patent law compared to the Australian patent law. My arguments are anchored on Professor Robert Merges' scholarship, one of the most recognized scholars in this area, a respected IP authority worldwide, who I learnt my first IP lessons at University of California at Berkeley. Professor Merges has been invited to many Congressional hearings since 1987 concerning intellectual property, especially patents.⁸⁸

My argumentative line in the discovery concept, patent specifications due diligence and biological material patentability are supported from my own investigation in jurisprudence selected in his books and articles, as well as his lectures. Most of the investigation I have developed here is presented in a condensed form, representing some extracts of my doctorate thesis. My opinions and arguments reflected in this submission are solely due to my own legal rationale studying the topic. My intention is to collaborate to the discourse and to the best outcome between the recent High Court of Australia decision in *D'Arcy* and the interested stakeholders, especially *IP Australia*.

On a personal note, I had an opportunity to investigate many aspects of patent policy in Australia and overseas towards the concept of discovery and invention in my doctorate. My topic of interest was Traditional Knowledge and further benefit sharing due to discoveries and association of biological information in patents. Comparing things and facts is the best manner to act upon any information gained or acquired.

Regarding conflict of interests, I declare that I am not a patent attorney and I have no clients in the biotechnology industry, therefore, my submission is devoid of any economic gain and represent my own views.

A.P.

⁸⁷ See, *D'Arcy v Myriad* [2015] HCA 35 (French, Kiefel, Bell, Keane JJ). ("The legislative history cannot be read as implicitly mandating the patentability of claims for inventions relating to isolated nucleic acids coding for particular polypeptides. The legislative history does not assist the Court in answering the question posed in this appeal.").

⁸⁸ See, Professor Robert Patrick Merges, U.C. Berkeley (Boalt Hall) School of Law, faculty CV, <<https://www.law.berkeley.edu/php-programs/faculty/facultyCVPDF.php?facID=297..>>