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The Empire of Cancer: Gene Patents and Cancer Voices

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The Empire of Cancer: Gene Patents and Cancer Voices

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‘The empire of cancer spread / across the wrinkled sheets.’

Derek Walcott, Omeros1

In his book, The Emperor of All Maladies, Siddhartha Mukherjee writes a history of cancer — ‘It is a chronicle of an ancient disease — once a clandestine, “whispered-about” illness — that has metamorphosed into a lethal shape-shifting entity imbued with such penetrating metaphorical, medical, scientific, and political potency that cancer is often described as the defining plague of our generation’.2

Increasingly, an important theme in the history of cancer is the role of law, particularly in the field of intellectual property law. It is striking that a number of contemporary policy debates over intellectual property and public health have concerned cancer research, diagnosis, and treatment.3 In the area of access to essential medicines, there has been much debate over Novartis’ patent application in respect of Glivec, a treatment for leukaemia.4 India’s Supreme Court held that the Swiss company’s patent application violated a safeguard provision in India’s patent law designed to stop evergreening.5 In the field of tobacco control, the Australian Government introduced plain

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1 Derek Walcott, Omeros, (Noonday Press, 1992).


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packaging for tobacco products in order to address the health burdens associated with the tobacco epidemic. This regime was successfully defended in the High Court of Australia. In the area of intellectual property and biotechnology, there have been significant disputes over the Utah biotechnology company Myriad Genetics and its patents in respect of genetic testing for BRCA1 and BRCA2, which are related to breast cancer and ovarian cancer. The Federal Court of Australia handed down a decision on the validity of Myriad Genetics’ patent in respect of genetic testing for BRCA1 in February 2013. The Supreme Court of the United States heard a challenge to the validity of Myriad Genetics’ patents in this area in April 2013, and handed down a judgment in July 2013. Such disputes have involved tensions between intellectual property rights, and public health.

This article focuses upon one of these important test cases involving intellectual property, public health, and cancer research. In June 2010, Cancer Voices Australia and Yvonne D’Arcy brought an action in the Federal Court of Australia against the validity of a BRCA1 patent — held by Myriad Genetics Inc, the Centre de Recherche du Chul, the Cancer Institute of Japan and Genetic Technologies Limited. Yvonne D’Arcy — a Brisbane woman who has had treatment for breast cancer — maintained: ‘I believe that what they are doing is morally and ethically corrupt and that big companies should

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6 Tobacco Plain Packaging Act 2011 (Cth).
9 Materials associated with the case are documented here: Association for Molecular Pathology v Myriad Genetics Inc (2013), the Supreme Court of the United States, 12-398 <http://www.scotusblog.com/case-files/cases/association-for-molecular-pathology-v-myriad-genetics-inc>; and the judgment is here: Association for Molecular Pathology v Myriad Genetics, Inc, 133 S Ct 2107 (2013).
not control any parts of the human body.’\textsuperscript{13} She observed: ‘For my daughter, I’ve had her have [sic] mammograms, etc, because of me but I would still like her to be able to have the test to see if the mutation gene is in there from me.’\textsuperscript{14}

The applicants made the following arguments:

Genes and the information represented by human gene sequences are products of nature universally present in each individual, and the information content of a human gene sequence is fixed. Genetic variations or mutations are products of nature. The isolation of the BRCA1 gene mutation from the human body constitutes no more than a medical or scientific discovery of a naturally occurring phenomenon and does not give rise to a patentable invention.\textsuperscript{15}

The applicants also argued that ‘the alleged invention is not a patentable invention in that, so far as claimed in claims 1–3, it is not a manner of manufacture within the meaning of s 6 of the Statute of Monopolies’.\textsuperscript{16} The applicants suggested that ‘the alleged invention is a mere discovery’.\textsuperscript{17} Moreover, the applicants contended that ‘the alleged invention of each of claims 1–3 is not a patentable invention because they are claims for biological processes for the generation of human beings’.\textsuperscript{18} The applicants, though, later dropped the argument that the patent claims related to biological processes for the generation of human beings.

In February 2013, Nicholas J of the Federal Court of Australia considered the case brought by Cancer Voices Australia and Yvonne D’Arcy against Myriad Genetics. The judge presented the issues in the case, as follows:

The issue that arises in this case is of considerable importance. It relates to the patentability of genes, or gene sequences, and the practice of “gene patenting”. Briefly stated, the issue to be decided is whether under the Patents Act 1990 (Cth) a valid patent may be granted for a claim that covers naturally occurring nucleic acid — either deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) — that has been “isolated”. In this context, the word “isolated” implies that naturally occurring nucleic acid found in the cells of the human body, whether it be DNA or RNA, has


\textsuperscript{14} Ibid.

\textsuperscript{15} Cancer Voices Australia \textit{et al} \textit{v} Myriad Genetics Inc \textit{et al} (2010), Federal Court of Australia, Statement of Claim, 8 June.

\textsuperscript{16} Ibid.

\textsuperscript{17} Ibid.

\textsuperscript{18} Ibid.
been removed from the cellular environment in which it naturally exists and separated from other cellular components also found there.

The genes found in the human body are made of nucleic acid. The particular gene with which the patent in suit is concerned (BRCA1) is a human breast and ovarian cancer disposing gene. Various mutations that may be present in this gene have been linked to various forms of cancer including breast cancer and ovarian cancer.19

The judge held in this particular case that Myriad Genetics’ patent claims were a ‘manner of manufacture’ under s 6 of the Statute of Monopolies and s 18(1)(a) of the Patents Act 1990 (Cth). The matter is currently under appeal in the Full Court of the Federal Court of Australia.20

This article interprets the dispute over Myriad Genetics in light of the scholarly work of Nobel Laureate Professor Joseph Stiglitz on inequality.21 Such work has significant explanatory power in the context of intellectual property and biotechnology. First, Stiglitz has contended that ‘societal inequality was a result not just of the laws of economics, but also of how we shape the economy — through politics, including through almost every aspect of our legal system’.22 Stiglitz is concerned that ‘our intellectual property regime … contributes needlessly to the gravest form of inequality.’23 He maintains: ‘The right to life should not be contingent on the ability to pay.’24 Second, Stiglitz worries that ‘some of the most iniquitous aspects of inequality creation within our economic system are a result of “rent-seeking”: profits, and inequality, generated by manipulating social or political conditions to get a larger share of the economic pie, rather than increasing the size of that pie’.25 He observes that ‘the most iniquitous aspect of this wealth appropriation arises when the wealth that goes to the top comes at the expense of the bottom.’26 Third, Stiglitz comments: ‘When the legal regime

23 Ibid.
24 Ibid.
25 Ibid.
26 Ibid.
governing intellectual property rights is designed poorly, it facilitates rent-seeking’ and ‘the result is that there is actually less innovation and more inequality.’\textsuperscript{27} He is concerned that intellectual property regimes ‘create monopoly rents that impede access to health both create inequality and hamper growth more generally.’\textsuperscript{28} Finally, Stiglitz has recommended: ‘Government-financed research, foundations, and the prize system ... are alternatives, with major advantages, and without the inequality-increasing disadvantages of the current intellectual property rights system.’\textsuperscript{29}

This article provides a critical analysis of the Australian litigation and debate surrounding Myriad Genetics’ patents in respect of genetic testing for BRCA1. First, it considers the ruling of Nicholas J in the Federal Court of Australia that Myriad Genetics’ patent was a manner of manufacture as it related to an artificially created state of affairs, and not mere products of nature. Second, it examines the policy debate over gene patents in Australia, and its relevance to the litigation involving Myriad Genetics. Third, it examines comparative law, and contrasts the ruling by Nicholas J in the Federal Court of Australia with developments in the United States, Canada, and the European Union. Fourth, this piece considers the reaction to the decision of Nicholas at first instance in Australia. Fifth, the article assesses the prospects of an appeal to the Full Federal Court of Australia over the Myriad Genetics’ patents. Finally, this article observes that, whatever happens in respect of litigation against Myriad Genetics, there remains controversy over Genetic Technologies Limited. The Melbourne firm has been aggressively licensing and enforcing its related patents on non-coding DNA and genomic mapping.

1 The Metaphysics of a Manner of Manufacture

In the case of Cancer Voices Australia \textit{v} Myriad Genetics Inc, the Federal Court of Australia considered a test case in respect of gene patents.\textsuperscript{30} The presiding judge was Nicholas J who has considerable expertise in intellectual property law and policy. The then Solicitor-General Stephen Gageler — now a judge of the High Court of Australia — commented on Nicholas J’s ability in this area on his appointment: ‘Your Honour was known at the bar for your expertise in intellectual property, having appeared in some of the most significant intellectual property cases in the Federal Court and in the High Court in recent decades.’\textsuperscript{31} The judgment of Nicholas J is careful, diligent, and circumspect in dealing with questions of patentability under Australian law.

\textsuperscript{27} Ibid.
\textsuperscript{28} Ibid.
\textsuperscript{29} Ibid.
\textsuperscript{30} Cancer Voices Australia \textit{v} Myriad Genetics Inc [2013] FCA 65.
\textsuperscript{31} Stephen Gageler, Ceremonial Sitting of the Full Court to Welcome the Honourable Justice Nicholas (18 November 2009) The Federal Court of Australia
Nicholas J stressed that ‘whether or not a valid patent may be granted for a claim to naturally occurring “isolated” nucleic acid depends on whether such a substance is “a manner of manufacture” within the meaning of s 6 of the Statute of Monopolies: see s 18(1)(a) of the Act’. The judge applied the precedent of the High Court of Australia in National Research Development Corporation v Commissioner of Patents on patentable subject matter. Nicholas J noted that ‘[t]he case was described by Barwick CJ in Joos v Commissioner of Patents as a “watershed” in this area of law, and in Grain Pool of Western Australia v Commonwealth of Australia Gleson CJ, Gaudron, McHugh, Gummow, Hayne and Callinan JJ referred to it as a “celebrated judgment”. Nicholas J stressed that ‘[w]hether or not a composition of matter (including a micro-organism) is a “manner of manufacture” must be decided in accordance with the principles set out in the NRDC case’. The judge emphasised ‘that a composition of matter may constitute patentable subject matter if it consists of an artificial state of affairs, that has some discernible effect, and that is of utility in a field of economic endeavour’.

Nicholas J emphasised the need for human intervention in respect of the creation of an ‘artificial state of affairs’:

It goes without saying that the relevant state of affairs must be the result of some human intervention. After all, it is the element of human intervention that allows one to both characterise the relevant state of affairs as being artificial and to identify one or more inventors who, one way or another, must have brought such a state of affairs into existence in the first place. The real problem lies in knowing, or rather not knowing, what degree of human intervention is necessary before it can be concluded that the requisite artificial state of affairs exists. It is an especially difficult problem in the present case, not so much because the

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34 Joos v Commissioner of Patents (1972) 126 CLR 611, 616.
35 Grain Pool of Western Australia v Commonwealth of Australia (2000) 202 CLR 479, [45].
37 Ibid [101].
38 Ibid.
authorities provide no clear solution to it, but because the problem has an almost metaphysical dimension to it.\textsuperscript{39}

His Honour squarely recognises here the difficulty and complexity of applying the test of a ‘manner of manufacture’ to the facts of the case. Nicholas J observes that such considerations about the relationship between an inventor and an invention are similar to a question of metaphysics, because it involves explanations of the fundamental nature of being and the world.

Nicholas J also makes two further points about the interpretation of \textit{National Research Development Corporation v Commissioner of Patents} on patentable subject matter.\textsuperscript{40} First, his Honour stressed that ‘it is important to note that NRDC does not require the Court to ask whether a composition of matter is a “product of nature” for the purpose of deciding whether or not it constitutes patentable subject matter.’\textsuperscript{41} Nicholas J observes: ‘NRDC recognises that it may be unhelpful to approach the problem in this way.\textsuperscript{42}’ Nicholas J commented: ‘I think this is especially so in the field of biotechnology in which micro-organisms play a critical role in the development, manufacture and use of diagnostic and therapeutic products and techniques.’\textsuperscript{43} Second, his Honour emphasised: ‘NRDC does not require the Court to ask whether a micro-organism is “markedly different” to something that already exists in nature for the purpose of deciding whether it constitutes patentable subject matter.’\textsuperscript{44}

Finally, the judge states his conclusion that the disputed patent claims are valid in terms of being a manner of manufacture:

There is no doubt that naturally occurring DNA and RNA as they exist inside the cells of the human body cannot be the subject of a valid patent. However, the disputed claims do not cover naturally occurring DNA and RNA as they exist inside such cells. The disputed claims extend only to naturally occurring DNA and RNA which have been extracted from cells obtained from the human body and purged of other biological materials with which they were associated.

The applicants contended that each of the disputed claims was invalid on the sole ground that it was not a claim to a manner of manufacture and therefore did not comply with the requirements

\textsuperscript{39} Ibid [102].

\textsuperscript{40} \textit{National Research Development Corporation v Commissioner of Patents} (1959) 102 CLR 252.

\textsuperscript{41} \textit{Cancer Voices Australia v Myriad Genetics Inc} [2013] FCA 65, [103].

\textsuperscript{42} Ibid.

\textsuperscript{43} Ibid.

\textsuperscript{44} Ibid.
of s 18(1)(a) of the Act. That contention should be rejected for the reasons previously given. In my opinion each of the claims is to a manner of manufacture as that expression should now be understood. My reasons have nothing to say about the possible invalidity of the disputed claims on any other ground.\textsuperscript{45}

Intriguingly, the judge noted that the ‘reasons have nothing to say about the possible invalidity of the disputed claims on any other ground.’\textsuperscript{46} There does seem to be an indication here that the judge would have preferred to have heard alternative arguments in respect of the challenge to the patents of Myriad Genetics.

2 \textit{Raising the Bar: The Australian Debate Over Gene Patents}

The judge, Nicholas J, considered the Australian policy debate over gene patents and recent amendments to patent law.\textsuperscript{47}

2.1 The Australian Law Reform Commission

As a result of multiple controversies over Myriad Genetics Inc, Genetic Technology Ltd, and other companies, the Australian Law Reform Commission (ALRC) undertook a review of intellectual property rights over genes and genetic and related technologies, with a particular focus on human health issues. The Commission released an issues paper in July 2003, a discussion paper in January 2004, and a final report, which was tabled in Parliament in August 2004.\textsuperscript{48} The Commission was of the view that patentable subject matter in Australia included biotechnology:

\begin{quote}
It is clear that the processes for identifying, isolating and purifying naturally occurring materials, including biological material such as genetic sequences, should be patentable when those processes satisfy the other requirements of patentability — namely, when they are novel, inventive, useful and fully disclosed. However, legitimate concerns have been raised about the patenting of
\end{quote}

\textsuperscript{45} Ibid [136]-[137].
\textsuperscript{46} Ibid.
\textsuperscript{47} Cancer Voices Australia v Myriad Genetics Inc [2013] FCA 65.
biological materials that occur in nature, but have been isolated and purified by humans. Isolated biological materials may, in some cases, replicate exactly the composition and characteristics of material that occurs in nature. Although one cannot deny the legitimacy of patenting processes for isolating and purifying naturally occurring materials, or the legitimacy of patenting new chemical substances that are the product of human ingenuity, there are attractive arguments for the view that such materials should not have been treated as patentable subject matter.

However, the time for taking this approach to the patenting of products and materials has long since passed. For decades, naturally occurring chemicals have been regarded by patent offices in many jurisdictions as patentable subject matter, when they are isolated and purified. This principle has been applied by analogy to biological materials, including genetic sequences, on the basis that they are ‘merely’ complex organic compounds. This development was certainly not foreseen when the modern patent system was established, and a different approach might have been available when the issue first arose for consideration.49

In his judgment, Nicholas J was heedful of the recommendations of the inquiry, and the response of the Australian Government: ‘The Australian Government Response specifically accepted the ALRC’s recommendation that the Act not be amended to exclude (inter alia) genetic materials and technologies from patentable subject matter.’50

2.2 The Parliamentary Debate

Nicholas J was also conscious of the failed efforts to pass prohibitions on gene patents in the Australian Parliament.

In November 2010, the Senate Community Affairs Reference Committee released its long awaited report on gene patents.51 As the executive summary indicates, the report focused upon gene patents in relation to health and medicine.52 The majority of the committee were reluctant to impose a prohibition on patents being granted in the field of biotechnology, observing that it ‘heard conflicting evidence as to whether a prohibition on the patenting

49 Australian Law Reform Commission, Genes and Ingenuity: Gene Patenting and Human Health, 130, above n 48, [6.51]-[6.52].
50 Cancer Voices Australia v Myriad Genetics Inc [2013] FCA 65 [119].
52 Ibid xi.
of genes and other biological materials (a) would be effective and (b) would not lead to unforeseen consequences in other fields of technology, particularly biotechnology research and development.\(^{53}\)

A private members’ bill was introduced into the Australian Parliament, entitled the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (Cth). The sponsors included the Liberal Party members, Senators Heffernan and Coonan; Greens Senator Rachel Siewert; and Independent Senator Nick Xenophon. The Bill proposed a broad prohibition on biotechnology patents in s 18 (2):

The following are not patentable inventions: (a) human beings, and the biological processes for their generation; and (b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.’

In my view, such a provision was ambiguous, uncertain and indeterminate in its breadth and scope. There was no accompanying definition of ‘biological materials’. As a result, the major parties were wary of supporting the proposed prohibition in respect of ‘biological materials’.

There has been substantive debate over the topic in the committee and the Parliament.\(^{54}\) The Bill was not supported by the Australian Parliament. Reviewing such developments, Nicholas J noted: ‘The Bill was referred to the Legal and Constitutional Affairs Legislation Committee for inquiry and its report was tabled in the Senate on 21 September 2011’.\(^{55}\) His Honour observed: ‘In its report the LCAC recommended (by majority) that the Senate not pass the Bill which eventually lapsed.’\(^{56}\) Without the support of the main political parties of the Australian Labor Party and the Coalition, it is doubtful that such a broad prohibition on biotechnology patents would ever pass through the Australian Parliament.

### 2.3 Raising the Bar

In his judgment, Nicolas J emphasised that the Australian Government has sought to respond to concerns about gene patents with the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Cth). His Honour commented:

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53 Ibid.
55 Cancer Voices Australia v Myriad Genetics Inc [2013] FCA 65, [118].
56 Ibid.
Many of the recommendations that were accepted in the Australian Government Response were implemented by the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Cth) (the Amendment Act). In particular, the Amendment Act introduced into the Act a new experimental use defence, which took effect on 16 April 2012 (see now s 119C of the Act) and a new definition of “useful” which will take effect from 15 April 2013 (which will be s 7A of the Act).

Section 119C is significant in the present context. This is because one of the main arguments that has been advanced against the patentability of isolated DNA sequences (as well as other biological materials) is the impact that patents for such materials may have on future research into previously undiscovered genetic mutations and research and the development of new diagnostic and therapeutic technologies that may only take place using patented biological materials.

The introduction of s 7A is also significant in the present context. Section 7A will make it more difficult for patent applicants to obtain patent protection for expressed sequence tags (ESTs). ESTs are short nucleotide sequences that represent a fragment of a cDNA “clone” that have proven especially controversial in circumstances where their principal use is as a research or experimental tool.\(^57\)

The judge makes the sound point here that the Australian Patent Office and the courts can use the utility requirement to provide rigorous examination of gene patents, as has been the favoured approach in the United States.\(^58\) Moreover, the defence of experimental use will certainly provide protection for scientists and researchers working in the field of biotechnology against claims of patent infringement.\(^59\) The judge commented: ‘I think it is important to recognise that the recent and imminent changes to the Act address at least some of the problems that opponents of the Australian Patent Office’s long standing practice have previously identified.’\(^60\)

In 2012, there was a renewed push for a prohibition on gene patents led by Melissa Parke MP, the ALP member for Fremantle. With a background in law, human rights, and international politics, Parke has been an eloquent advocate for tightening the rules on patentability. She argued:

\(^57\) Ibid [120]-[122].


\(^60\) Cancer Voices Australia v Myriad Genetics Inc [2013] FCA 65, [123].
The problem with [the Raising the Bar Bill] was that it did not address the issue of patentable subject matter. It did not cover gene patents. And that’s an omission that needs to be rectified. And so I am intending to introduce a private member’s bill to ban gene patents that I hope will have the support of the Government and also widespread support within the Parliament.61

Melissa Parke has been concerned about,

the consequences of [gene patents] in restricting science and health research, as well as the cost not only in human lives and quality of life but also in the massive expense to the taxpayer through additional impost on the health system, including the Pharmaceutical Benefits Scheme (PBS).62

She lamented that Cancer Voices Australia and Yvonne D’Arcy had been forced to take litigation because of inaction by the Australian Patent Office and the Australian Parliament: ‘It is shameful that cancer patients have been forced into this action because of the facilitation of gene patents by IP Australia and inaction by successive governments.’63 Parke contended that the Supreme Court of the United States ruling in Mayo v Prometheus64 required a reconsideration of the patentability of biotechnology — both in the United States and Australia:

In the course of its judgment in Prometheus, the Supreme Court made the important point that “monopolisation of natural phenomena through the grant of a patent might tend to impede innovation more than it would tend to promote it”, and this is the key reason why we must challenge the claim by the biotechnology industry that a ban on gene patents would mean the end of investment in genetic research.65

63 Ibid.
64 Mayo Collaborative Services v Prometheus Laboratories Inc 132 S Ct 1289 (2012).
65 Parke, above n 62.
2.4 The Productivity Commission

The Productivity Commission has been conducting an inquiry into compulsory licensing and crown use. In its draft report, the Productivity Commission recommended that compulsory licensing provisions in Australian patent law should be reformed. The Commission recommended that ‘when a patent is used to engage in unlawful anticompetitive conduct, a compulsory licence should only be available under the Competition and Consumer Act 2010 (Cth).’ It submitted that ‘[a] public interest test should replace existing criteria based on the “reasonable requirements of the public” in the Patents Act 1990 (Cth).’ In its view, ‘[f]or cases other than those relating to unlawful anticompetitive conduct, this would provide an access regime when greater use of a patented invention would deliver a net benefit to the community.’ The Productivity Commission recommended:

To reduce uncertainty about the scope of Crown use, the Patents Act should be amended to make it clear that Crown use can be invoked for the provision of a service that the Australian, State and/or Territory Governments have primary responsibility for providing or funding.

The Productivity Commission was of the view that such reforms would be of assistance in dealing with issues, such as those that arose in respect of gene patents and biotechnology. The final report of the Productivity Commission strongly called for the modernisation of Australia’s patent laws regarding crown use and compulsory licensing.

2.5 The Intellectual Property Laws Amendment Bill 2013 (Cth)

After the judgment of Nicholas J, in 2013, the Federal Government introduced the Intellectual Property Laws Amendment Bill 2013 (Cth). Introducing the Bill,
the Honourable Yvette D’Ath, Member for Petrie and Parliamentary Secretary for Climate Change, Industry and Innovation emphasised that proposed reforms to crown use would be of assistance in dealing with gene patents:

Crown use is an important, but rarely used, safeguard that allows governments to access patented inventions without the consent of the owner. It is necessary for a government to have the power to be able to make use of patented inventions to serve the interests of the community.

Similarly, a patent holder should not be able to indefinitely frustrate the needs of the community, for example, by denying access to an important health technology. This bill will amend the Patents Act to clarify the scope of Crown use and its operation. It adopts recommendations of the Productivity Commission inquiry report into compulsory licensing of patents, which found there was uncertainty around the scope of current Crown use provisions, particularly in the context of health care.

The review was one element of the government’s strategy to monitor the impact of gene patents in the community and to make sure that such patents do not lead to Australians being denied reasonable access to essential healthcare technologies.73

In its report, the House of Representatives Standing Committee on Social Policy and Legal Affairs supported reforms to Crown use: ‘The Committee is aware there have been difficulties with the existing Crown use provisions and believes that maintaining the status-quo could result in continued uncertainty about when Crown use could be invoked.’74 The committee also ‘welcomes the idea that its use is clarified so that in future, where necessary, the provision can be used with more certainty.’75

Melissa Parke gave the strongest speech on the Bill in the Australian Parliament. She noted that ‘Crown use can be exercised when a government

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75 Ibid.
has the primary responsibility for providing or funding the provision of the service’. In her view,

This means that governments can intervene to address unreasonable patent holder conduct that could result in patients being denied reasonable access to health care, such as occurred with Genetic Technologies unreasonably refusing to allow Australian laboratories to test for breast cancer.

Melissa Parke commented on the utility of crown use:

I hope that it would also deal with a situation that was highlighted in the Senate Community Affairs References Committee inquiry into gene patents. During that inquiry the Peter MacCallum Cancer Centre gave evidence that its research into breast and ovarian cancer had been delayed by two years and ended up costing three times as much because gene or patent holders Myriad and Genetic Technologies refused to grant it permission to use the genes in its research. To the extent that there may have been uncertainty in the operation and scope of the Crown use provisions in the Patents Act, with this amendment there will now be no impediment to governments in Australia, state and federal, taking action in the public interest to prevent despicable behaviour by corporations like Genetic Technologies and Myriad that have demonstrated repeatedly that they are motivated only by greed and self-interest.

Nonetheless, Parke insisted that there was a need for further legislative action in respect of gene patents. She called for a prohibition in respect of gene patents: ‘The patenting of human genes is fundamentally flawed, because knowledge about human genes should not be private property but rather should belong to everyone.’ Parke was also hopeful that the decision of the Supreme Court of the United States in Association for Molecular Pathology v Myriad Genetics, Inc would be an influence upon the Full Court of the Federal Court.

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77 Ibid.

78 Ibid.

79 Ibid.

80 Association for Molecular Pathology v Myriad Genetics, Inc, 133 S Ct 2107 (2013).
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The legislation passed the House of Representatives 72-68. However, debate in the Senate was adjourned, before the Bill could pass. As a result, the legislation has lapsed, with Parliament rising for the Australian election in September 2013.

In 2013, in the Australian Senate, Senator Richard di Natale and Senator Rachel Siewert of the Australian Greens and Senator Bill Heffernan of the Liberal Party argued:

that the Senate — (a) notes the recent ruling by the United States Supreme Court that human genes are not eligible for patent protection; (b) recognises that this ruling is a significant development in the debate over gene patenting and the future of medical research; and (c) urges the Australian Government to consider the implications of this for the \textit{Patents Act 1990}.\footnote{Senate, ‘Resolution on Health-Gene Patents’, Hansard, Senate, Australian Parliament, 25 June 2013, \<http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fjournals%2F20130625_SJ152%2F0018%22>.}

\section{The International Controversy over Myriad Genetics Inc}

The judge in the Australian case examines the comparative situation in the European Union and the United States in respect of gene patents.\footnote{Cancer Voices Australia \textit{v} Myriad Genetics Inc [2013] FCA 65.}
The Australian case was considered at an interregnum — at a point time at which superior courts around the world have been reconsidering the patentability of biotechnology inventions. As such, Nicholas J was in quite a difficult predicament, writing about gene patents, at a time when the state of the law internationally was in a mercurial state of flux and uncertainty.\footnote{In particular, the judge handed down his decision prior to the ruling of the Supreme Court of the United States in \textit{Association for Molecular Pathology \textit{v} Myriad Genetics, Inc, 133 S Ct 2107 (2013)}.}
3.1 The European Union

After reviewing the European Union Biotechnology Directive 1998 and United Kingdom patent law, Nicholas J comments: ‘It is clear from these provisions that in the UK, as in many other parts of Europe, isolated DNA and isolated RNA may be patentable even though they are identical in their chemical composition to DNA and RNA found in the cell.’

The history of opposition to Myriad Genetics’ patents in respect of BRCA1 and BRCA2 perhaps deserved closer attention. The Institut Curie, the AP-HP (Paris Public Hospitals), and the Institut Gustave-Roussy — in addition to the Institut National du Cancer and other European institutions — have contested the patent claims of Myriad Genetics Inc and later the University of Utah in respect of BRCA1 and BRCA2. E Richard Gold and Julia Carbone have provided a good overview of the protracted conflict over patent law and genetic testing in the European Patent Office. The authors observed that oppositions limited the scope of the patent protection:

Oppositions were generally successful in limiting Myriad’s patents (assigned to the University of Utah around the time the opposition procedures were launched). On May 18, 2004, an opposition division of the EPO revoked Myriad’s patent on the diagnostic test (EP 699 754). In January 2005, an opposition division limited Myriad’s patent over mutations of BRCA1 (EP 705 903) to specific mutations. Appeals from these two decisions were heard and decisions rendered in November 2008. First, instead of revoking EP 699 754, the Technical Board of Appeal restricted the patent to certain mutations of the BRCA1 gene and to diagnostic methods for their identification. With respect to EP 705 903, the Technical Board of Appeal expanded the opposition division’s amendments to cover methods for identifying mutation 185delAG, a deletion of two nucleotides.

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86 Cancer Voices Australia v Myriad Genetics Inc [2013] FCA 65 [128].


With respect to the patent over BRCA1 itself, the opposition division maintained the patent, in amended form, in January 2005. On September 27, 2007, the Technical Board of Appeal upheld the opposition division’s decision. Finally, in 2005, an opposition division of the EPO also ruled that Myriad’s patent over BRCA2 in amended form—limited to the detection of the 6174delT mutation in people of Ashkenazi descent—was valid. Although the opposition division only focused on technical matters, as opposed to policy arguments, the scope of Myriad’s patents have nonetheless been significantly reduced.90

There have been a number of appeals to the Boards of Appeal to the European Patent Office by the University of Utah.91 The approach of the European Patent Office has been to restrict the scope of the controversial patents relating to genetic testing in respect of BRCA1 and BRCA2.

The judge did not consider the Nuffield Council of Bioethics report on gene patents,92 or the Danish Council of Ethics report on gene patents93 — but that seems entirely understandable, given that such policy inquiries have become dated, written as they were after the Human Genome Project.

There has been much more activity in respect of the European Biotechnology Directive in respect of stem cell patents. In the case of Oliver Brüstle v Greenpeace eV, the European Court of Justice ruled on the application of the European Biotechnology Directive.94 First, the court held:

90 Ibid 45.
94 Oliver Brüstle v Greenpeace eV (European Court of Justice, C-34/10, 18 October 2011) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX%3A62010CJ0034%3AEN%3AHTML>. 

EAP 18
Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions must be interpreted as meaning that: any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a “human embryo”; it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a “human embryo” within the meaning of Article 6(2)(c) of Directive 98/44.95

Second, the court ruled:

The exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6(2)(c) of Directive 98/44 also covers the use of human embryos for purposes of scientific research, only use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable.96

Third, the court held:

Article 6(2)(c) of Directive 98/44 excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.97

3.2 The United States

Nicholas J reviewed the recent litigation over Myriad’s patents in the United States District Court for the Southern District of New York98 and the United States Court of Appeals for the Federal Circuit.99 His Honour noted that the

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95 Ibid, Operative Part.
96 Ibid.
97 Ibid.
three judges in the dispute adopted quite different reasoning. Nicholas J noted that the law in the United States would remain unsettled until the resolution of the dispute in the Supreme Court of the United States:

On 30 November 2012, the US Supreme Court announced that it would hear an appeal in the *Myriad* case. The US law in relation to the patentability is therefore not likely to be settled until the Supreme Court reaches its own decision on the issue.\(^\text{100}\)

The judge sought to distinguish the Australia litigation from its United States counterpart: ‘In any event, it seems to me that the *Myriad* decision does not provide any direct assistance to either side in the present case.’\(^\text{101}\) First, the judge emphasised that ‘the law in Australia is different’ — particularly given the precedent of the *NRDC*.\(^\text{102}\) Nicholas J\(^\text{103}\) noted that there were significant differences in constitutional law between the two countries on matters of intellectual property:

> It must also be recognised, especially as the *Myriad* case heads to the US Supreme Court, that the constitutional setting in which patent legislation operates in the US is quite different to that in which patent legislation operates in this country: *Grain Pool of Western Australia v Commonwealth of Australia*.\(^\text{104}\)

Secondly, the judge emphasised that ‘the evidence in the *Myriad* case was not the same as the evidence in the present cast’.\(^\text{105}\) His Honour stressed: ‘And at least in relation to the matter of covalent bonds, I have taken a different view of the facts to that taken by Judge Lourie’.\(^\text{106}\)

Subsequent to the decision of Nicholas J, the Supreme Court of the United States handed down its decision in *Association for Molecular Pathology v Myriad Genetics, Inc.*\(^\text{107}\) Summarising the case, Thomas J commented:

> Respondent Myriad Genetics, Inc. (Myriad), discovered the precise location and sequence of two human genes, mutations of which can substantially increase the risks of breast and ovarian cancer. Myriad obtained a number of patents based upon its

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\(^\text{100}\) *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65, [134].

\(^\text{101}\) Ibid [135].

\(^\text{102}\) Ibid.

\(^\text{103}\) Ibid.

\(^\text{104}\) *Grain Pool of Western Australia v Commonwealth of Australia* (2000) 202 CLR 479, [28]-[32].

\(^\text{105}\) *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65, [135].

\(^\text{106}\) Ibid.

\(^\text{107}\) *Association for Molecular Pathology v Myriad Genetics Inc*, 133 S Ct 2107 (2013).
discovery. This case involves claims from three of them and requires us to resolve whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent eligible under 35 USC § 101 by virtue of its isolation from the rest of the human genome. We also address the patent eligibility of synthetically created DNA known as complementary DNA (cDNA), which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins.\textsuperscript{108}

The judge held: ‘We hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.’\textsuperscript{109}

The relationship between the jurisprudence of Australia and the United States is a complicated one. There have certainly been intellectual property cases, in which the High Court of Australia has declined to follow the Supreme Court of the United States. In the case of\textit{IceTV Pty Limited v Nine Network Australia Pty Limited}, for instance, the High Court of Australia took a different approach to the question of originality, partly because of comparative constitutional questions.\textsuperscript{110} Notwithstanding the comments of Nicholas J, there have been a number of patent cases in which Australian courts have approved of, or followed, United States authorities on patentable subject matter. In the case of\textit{Grain Pool of Western Australia v Commonwealth of Australia}, the High Court of Australia approved of the ruling of the Supreme Court of the United States in\textit{Diamond v Chakrabarty}.\textsuperscript{111} Australian courts\textsuperscript{112} have followed the United States Court of Appeals for the Federal Circuit ruling in\textit{State Street Bank}\textsuperscript{113} (even though it has since been discredited by the Supreme Court of the United States in the\textit{Bilski v Kappos} case).\textsuperscript{114} There has been much discussion of United States precedent on methods of human treatment in Australian cases as well.\textsuperscript{115} The relationship between Australian

\textsuperscript{108} Ibid 2110-11.
\textsuperscript{109} Ibid 2111.
\textsuperscript{110} IceTV Pty Limited v Nine Network Australia Pty Limited [2009] HCA 14 (22 April 2009).
\textsuperscript{111} Grain Pool of Western Australia v Commonwealth of Australia (2000) 202 CLR 479, [28]-[32].
\textsuperscript{113} State Street Bank & Trust Co v Signature Financial Group, 149 F 3d 1368 (1998).
\textsuperscript{115} Anaesthetic Supplies Pty Limited v Rescare Limited [1994] FCA 1065.
and United States intellectual property law has been further reinforced by intellectual property obligations under trade agreements — such as the Australia-United States Free Trade Agreement 2004.

3.3 Canada

E Richard Gold and Julia Carbone have written a comparative study of the various conflicts over Myriad Genetics and its patents. The authors stressed that provincial governments in Canada resisted Myriad Genetics’ demands in relation to patent law and clinical testing. Gold and Carbone noted that the government of Ontario even raised such concerns in *Monsanto Canada Inc v Schmeiser* before the Supreme Court of Canada.

The provincial Government of Ontario was also a party to the case because of its concerns about the impact of gene patents on biomedical research and health care. The province was sensitive to the issue because it had been threatened in the past with legal action for patent infringement by the Utah biotechnology firm, Myriad Genetics. Dianne Dougall, the legal director of the Ontario Ministry of Health, commented: ‘It is crucial that these issues be discussed with regard to the potential impact on the health-care system’. In the course of oral argument in *Monsanto Inc v Schmeiser*, Sara Blake, on behalf, the Attorney-General of Ontario, sought to bring the Supreme Court of Canada’s attention to the impact of gene patents in the health care field. She expressed concern that a ruling in *Monsanto Inc v Schmeiser* could have an inadvertent and unforeseen impact upon health care. Blake observed that gene patents were distinctive from other kinds of patents. First of all, the lawyer observed that gene patents dealt with living subject matter, which could reproduce. Second, Blake commented that DNA had a dual nature in that it covered both an active molecule and was a source of information. Third, the lawyer observed that gene patents had much broader claims than, say, drug patents because they covered genes, diagnostic tests, and even genetic diseases. Blake argued that gene patents of uncertain scope were a public nuisance. She claimed that there needed to be a purposive approach taken to the interpretation of the claims of gene patents, so that there was certainty as to the scope of the claims and fairness to both patent applicants and the public.

116 Gold and Carbone, above n 89.


However, Gold and Carbone observed: ‘This intervention was not very successful as the majority of the Court did not address Ontario’s concerns in its judgment.’\textsuperscript{121}

There was much debate about the significance of the Supreme Court of the United States decision in 2013. Professor Richard Gold of McGill University commented:

> The major outcome of this decision for Canadians is that we face the worst of all worlds. Which investor will assume that the Canadian courts — which have never confronted this issue — will offer patent protection where the U.S. does not? Which cash-strapped hospital or public laboratory will assume that Canadian patents are invalid? Both investors and hospitals will assume the worst, leaving Canada in a precarious position of short-term decreases in investment with no compensating increased use by hospitals and laboratories.\textsuperscript{122}

Gold argued that ‘Canada needs to resolve the uncertainty’.\textsuperscript{123} He observed: ‘The patent office — the branch of government with the most expertise in the area — has been gutted by court decisions of any policy-making role’.\textsuperscript{124} Moreover, Gold noted: ‘Courts can only rule on the issue if presented with a case’.\textsuperscript{125} He stressed: ‘Since public hospitals and labs have few resources to defend against a threat of patent infringement, they have simply stayed away.’\textsuperscript{126} Gold maintained that ‘Parliament has been shy in updating our patent laws to deal with the new realities of biomedical research’.\textsuperscript{127}

4 ‘We Were Doing This For Future Generations’: Gene Patents, Human Rights, and Intergenerational Justice

There was a spectrum of opinions and views over the ruling of Nicholas J in the Myriad case, and the surrounding policy debate over gene patents.\textsuperscript{128} The

\textsuperscript{121} Gold and Carbone, above n 89, 553.


\textsuperscript{123} Ibid.

\textsuperscript{124} Ibid.

\textsuperscript{125} Ibid.

\textsuperscript{126} Ibid.

\textsuperscript{127} Ibid.

\textsuperscript{128} Sunanda Creagh and Will Mumford, ‘Historic Ruling Allows Private Firms to Patent Human Genetic Material’, \textit{The Conversation} (15 February 2013)
responses ranged from emotional, heartfelt concerns over gene patents; to cool, intellectual analysis of the decision; to political posturing in various different directions. E Richard Gold and Julia Carbone have observed that Myriad Genetics has been the focal point of much controversy in a range of jurisdictions:

Myriad is certainly guilty of many mistakes: it failed to fully understand and perhaps even respect the nature of public health care; it allowed hostile attitudes to persist in the scientific community without seriously attempting to correct the public record; and it too quickly attributed hostile motivations to those working in government. However, Myriad was caught up in a debate inspired and sustained by much broader concerns than those relating to it alone including, general hostility to human gene patents, concern about the sustainability of public health systems, and anxiety at the apparent demise of “open science.” Myriad became a lightning rod for these debates: a necessary foil for an already assembled opposition.

Gold and Carbone make the good point that the dispute over Myriad Genetics cannot merely be comprehended or explained as dispute over legal rules. It raises larger questions about healthcare, human rights, and the biotechnology industry. Gold and Carbone comment: ‘It is perhaps because of the high profile of breast cancer that this test, patented by Myriad, struck a chord among politicians and the public.’

4.1 Yvonne D’Arcy and Cancer Voices

One of the plaintiffs, Yvonne D’Arcy, said: ‘To tell the truth I’m very disappointed. We were doing this for future generations, and I’m just so disappointed.’ It is striking how D’Arcy portrays the issue of gene patents as one of bodily integrity, human rights, women’s rights, and intergenerational justice. Such an approach echoes that taken by the

129 Gold and Carbone, above n 89, S58.
130 Ibid.
American Civil Liberties Union, which has highlighted the voices of cancer patients and sufferers in the Supreme Court of the United States dispute involving Myriad Genetics.\(^{133}\)

Rebecca Gilsenan, the principal lawyer at Maurice Blackburn, observed: ‘We argued that isolated genetic material is not an invention but is naturally occurring. The ruling ... has far reaching consequences for future medical research and genetic testing.’\(^{134}\)

Sally Crossing, the spokesperson for Cancer Voices Australia commented:

> We are extremely disappointed and it has far ranging impacts for people with cancer and researchers who want to be able to use these genes that have been patented. The more we restrict use and allow ownership of human genes to particular commercial interests, the more difficult and costly it is to undertake research finding is in relation to one breast cancer gene mutation, BRCA1, but it could be applied to a patent over any human gene.\(^{135}\)

### 4.2 Cancer Council Australia

The Cancer Council Australia CEO, Professor Ian Olver, observed the case showed patent law should be changed ‘to protect the community from gene monopolies.’\(^{136}\) He complained that ‘discovering and isolating genetic materials is not inventive, yet the current law gives licence to biotechnology companies to claim ownership of naturally occurring substances.’\(^{137}\)

A campaigner against gene patents, Luigi Palombi said the case had far-reaching consequences: ‘Effectively, everything in the human body can be considered patentable, the human body is now a commodity. It’s components are a commodity.’\(^{138}\) He complained: ‘I’m just appalled by the decision and I’m hoping now that the government, or that politicians within the parliament will try and address this.’\(^{139}\) Such a stance seems an overly strong and emotional response. There is nothing particularly appalling about the judgment. Nicholas J handed down a carefully considered decision, which

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\(^{134}\) Corderoy, above n 20.

\(^{135}\) Creagh and Mumford, above n 128.

\(^{136}\) Ibid.

\(^{137}\) Ibid.

\(^{138}\) Ibid.

\(^{139}\) Ibid.
certainly took into account the long jurisprudence of patent law, comparative law, and policy debates.

James Flanagan, Breast Cancer Campaign Scientific Fellow at Imperial College London, lamented: ‘Clearly, this is a terrible decision for breast cancer patients and breast cancer researchers in Australia and around the world.’ He commented that ‘it is often forgotten that these genes are also involved in ovarian cancer risk and other tumour types as well.’ He argued: ‘With current whole genome sequencing technologies, it is now so very cheap to sequence these genes, the costs that Myriad charge to sequence them are unjustified.’

4.3 Patent Attorneys

Patent attorneys, though, were broadly supportive of the decision of Nicholas J. Vaughan Barlow, a partner of Pizzeys Patent and Trade Mark Attorneys observed: ‘Patent applicants seeking to claim genetic and other biological materials should be assured that such subject matter has been strongly affirmed as being patentable under Australian law.’ He commented:

In combination with the recent defeat of proposed legislative amendments to ban patenting of such subject matter, this first decision by the Australian Federal Court on the patentability of genetic material consolidates the position adopted for many years by the Australian patent office and therefore provides greater certainty to patent applicants.

Mark Summerfield, a patent attorney at Watermark, complained that the action was misconceived: ‘The challenge to the Myriad BRCA1 gene patent claims was based on a doomed technical ground because the true reason for objection — genuine concern about the propriety of government-sanctioned monopolies over human genetic material — is not a recognised basis for

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141 Ibid.

142 Ibid.


144 Ibid.
denying a patent under our law.’" The patent attorney profession, though, does have a tendency to take a partisan approach in policy debates in patent law, and demand that a broad range of patentable subject matter be protected. Such a position fails to take account of efforts by superior courts to draw limits and boundaries in respect of eligible patentable subject matter.

4.4 Academic Commentary

In a measured response, Professor Dianne Nicol from the University of Tasmania observed that the judge ‘has given a broad reading of the “invention” requirement in Australian law (referred to as manner of manufacture).’" She observed:

Using the language from a 1959 case, he says that what is required is an “artificially created state of affairs” and that without human intervention an isolated DNA sequence does not exist outside the cell. This approach was clearly open to the judge to take based on prior cases.

Nicol was concerned, though, that patentable subject matter may not have clear limits: ‘It is difficult to think of the circumstances where an artificially created state of affairs would not exist whenever there is some form of human intervention.’

5 Appeal to the Full Court of the Federal Court of Australia

Cancer Voices Australia and Yvonne D’Arcy decided to appeal the decision of Nicholas J. Rebecca Gilsenan, principal lawyer, observed:

Our appeal is directed towards saying that having held that the gene is not relevantly different inside or outside the body, it was then an error to say that when it is outside the body it constitutes an artificial state of affairs that is therefore patentable subject matter.

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146 Creagh and Mumford, above n 128.

147 Ibid.

148 Ibid.

149 Corderoy, above n 20.

150 Ibid.
The appeal to the Full Court of the Federal Court of Australia was heard in August 2013. In light of the decisive loss at first instance, the appellants have reframed their arguments. The Full Federal Court of Australia may have greater scope for judicial creativity than a trial judge.

5.1 The Plain Packaging Decision

First, the appellants may find worthwhile considering the High Court of Australia’s ruling on plain packaging of tobacco products. The decision contains significant and important language about the need to take into account the public policy objectives of intellectual property — such as patent law. French CJ emphasised: ‘There are and always have been purposive elements reflecting public policy considerations which inform the statutory creation of intellectual property rights.’ Considering patent law, the judge stressed that ‘the objectives [of patent law] were the encouragement of industry, employment and growth, rather than justice to the “inventor” for his intellectual percipience.’ The decision highlights the need for courts to take into account the public purposes of intellectual property — including the promotion of public health. The High Court of Australia referred to the language in Article 8(1) of the TRIPS Agreement 1994:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

5.2 Emerging Technologies

Second, the appellants could argue that Australian law in respect of patentable subject matter should be modernised, particularly in light of emerging technologies in the fields of biotechnology, medicine, information...
technology, nanotechnology, and stem cell research. The rather abstract distinction between products of nature and an artificial state of affairs does not necessarily provide a clear-cut distinction between what is in the intellectual commons, and what is in the public domain.

5.3 Policy Debate

Third, the appellants could dispute the significance of Australian policy debate about gene patents to the case. The murky and turbulent history of law reform in respect of patent law and biotechnology has been contentious, and open to a variety of different readings.

5.4 Comparative Law

Fourth, there has been a push to review the Federal Court of Australia decision in light of new developments in comparative law. The Age has editorialised that a ‘modern look at genome patents is timely’. The Age has argued that the decision of the Supreme Court of the United States ‘should provide impetus for our courts and Parliament to fix a growing problem exacerbated by a recent Federal Court ruling.’

The appellants have emphasised the significance of comparative law in respect of gene patents and the related fields of medicine and biotechnology. Rebecca Gilsenan observed: ‘We’ve taken a lot of confidence from the unanimous decision of the US Supreme Court.’ In particular, there has been an exploration of the Supreme Court of the United States’ rulings in *Bilski v Kappos*, *Mayo v Prometheus*, and the case of *Association for Molecular Pathology v Myriad Genetics Inc.*

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157 ‘Modern Look at Genome Patents is Timely’, *The Age* (Melbourne) 15 June 2013.
158 Ibid.
159 Wells, above n 151.
160 *Bilski v Kappos* 545 F 3d 943 (2010); Lemley et al, above n 114; and Eisenberg, above n 114.
161 *Mayo Collaborative Services v Prometheus Laboratories Inc*, 132 S Ct 1289 (2012).
The reasoning of the Supreme Court of the United States in the case of
Association for Molecular Pathology v Myriad Genetics Inc\(^ {163}\) will no doubt receive
close inspection. Thomas J held in his judgment:

> We have “long held that this provision contains an important
> implicit exception[:] Laws of nature, natural phenomena, and
> abstract ideas are not patentable.” Rather, “they are the basic
tools of scientific and technological work” that lie beyond the
domain of patent protection. As the Court has explained, without
this exception, there would be considerable danger that the grant
of patents would “tie up” the use of such tools and thereby
“inhibit future innovation premised upon them.” This would be
at odds with the very point of patents, which exist to promote
creation.\(^ {164}\)

His Honour emphasised: ‘As we have recognised before, patent protection
strikes a delicate balance between creating “incentives that lead to creation,
invention, and discovery” and “imped[ing] the flow of information that might
permit, indeed spur, invention.’\(^ {165}\) Applying this formula, Thomas J held:
‘Myriad did not create anything’.\(^ {166}\) His Honour stressed: ‘To be sure, it found
an important and useful gene, but separating that gene from its surrounding
genetic material is not an act of invention.’\(^ {167}\) Thomas J noted:
‘Groundbreaking, innovative, or even brilliant discovery does not by itself
satisfy the § 101 inquiry. Myriad found the location of the BRCA1 and BRCA2
genes, but that discovery, by itself, does not render the BRCA genes “new ...
composition[s] of matter,’ § 101, that are patent eligible.’\(^ {168}\)

Nonetheless, Thomas J stressed that cDNA would be patent eligible under
United States patent law:

> cDNA does not present the same obstacles to patentability as
> naturally occurring, isolated DNA segments. As already
> explained, creation of a cDNA sequence from mRNA results in
> an exons-only molecule that is not naturally occurring ... The lab
> technician unquestionably creates something new when cDNA is
> made. cDNA retains the naturally occurring exons of DNA, but it
> is distinct from the DNA from which it was derived. As a result,
cDNA is not a “product of nature” and is patent eligible under

\(^ {163}\) Association for Molecular Pathology v Myriad Genetics Inc, 133 S Ct 2107 (2013).
\(^ {164}\) Ibid 2116.
\(^ {165}\) Ibid.
\(^ {166}\) Ibid.
\(^ {167}\) Ibid.
\(^ {168}\) Ibid.
§ 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. ¹⁶⁹

Thomas J made a number of important reservations and caveats about the scope of the decision. The judge stressed that ‘there are no method claims before this Court’. ¹⁷⁰ His Honour noted: ‘Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method’. ¹⁷¹ Thomas J insisted that ‘this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes’. ¹⁷²

Moreover, the judge held:

Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of § 101 to such endeavors. We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material. ¹⁷³

Thomas J thus laid down a number of important limitations and caveats to the decision of the Supreme Court of the United States.

There was much media commentary on the decision of the Supreme Court of the United States. ¹⁷⁴ The geneticist and public researcher, Mary-Claire King, was interviewed about the Supreme Court of the United States ruling in the Myriad case on gene patents. She commented:

I am delighted. This is a fabulous result for patients, physicians, scientists and common sense. When I was working on it from 1974 to 1994, it did not cross my mind that a legal case that would end up in the Supreme Court would be the consequence of my work. But it did and sometimes that’s what happens when you start in a new area of science. It is a relief to have a decision

¹⁶⁹ Ibid 2118.
¹⁷⁰ Ibid 2119.
¹⁷¹ Ibid 2120.
¹⁷² Ibid.
¹⁷³ Ibid.
after so many years, and I’m so gratified that it was a unanimous decision.\textsuperscript{175}

There was also been a significant pushback by the biotechnology industry. First, Myriad Genetics stressed that the Supreme Court of the United States had upheld its cDNA patent claims.\textsuperscript{176} Second, Myriad Genetics has sued two of its competitors — Ambry Genetics and Gene by Gene — arguing that their genetic testing infringed other patent claims, which have been unaffected by the Supreme Court of the United States decision.\textsuperscript{177} Third, peak bodies such as BIO and PhRMA have considered political lobbying on the topic of patentable subject matter.\textsuperscript{178} Furthermore, such industry associations have argued for higher standards of intellectual property protection for biotechnology in free trade negotiations such as the Trans-Pacific Partnership.\textsuperscript{179}

\section*{5.5 Other Patent Criteria}

Finally, the appellants in the Australian case could, in future, pursue alternative actions against Myriad Genetics Inc. Nicholas J indicated in his first decision that it may well have been worthwhile considering other grounds of challenge — particularly, in respect, of threshold standards, such as novelty, inventive step, utility, and written description. Indeed, in the European Union, there has been close attention to such issues in patent oppositions to the Myriad Genetics’ patents in respect of BRCA1 and BRCA2.

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{175} Sarah Reardon, ‘Court Ruling on Genes is a Victory for Common Sense’ (18 June 2013) 2922 \textit{The New Scientist} <http://www.newscientist.com/article/dn23708-court-ruling-on-genes-is-a-victory-for-common-sense.html>.


\item \textsuperscript{179} Ibid.
\end{itemize}
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6 Genetic Technologies Limited

A weakness of the Australian litigation in respect of genetic testing has been the failure to address underlying foundational patents held by Melbourne firm, Genetic Technologies Limited (GTG).\(^{180}\) Professor Ian Olver from Cancer Council Australia observed: ‘The catalyst for this case was the attempt by Genetic Technologies in 2008 to monopolise tests for BRCA1 and BRCA2 genetic mutations, including demands that public hospitals cease providing the tests.’\(^{181}\) He observed: ‘Following community outrage, the company withdrew its demands’.\(^{182}\) Olver commented: ‘But there was — and still is — nothing in the law to prevent such a demand being made in the future.’\(^{183}\) If GTG is such a concern, it seems to be a strategic mistake that Cancer Voices have not also challenged the patents in respect of non-coding DNA and genomic mapping.

There has been longstanding controversy over GTG — which is the owner of patents related to genomic mapping and non-coding DNA, as well as being the exclusive licensee of a range of patents held by Myriad Genetics for Australia and New Zealand.\(^{184}\)

6.1 The GTG Patents

GTG obtained broad patents on a range of scientific inventions arising out of the work of Malcolm Simons. Most significantly, the USPTO awarded US Patent No 5,612,179 to GTG for an invention entitled, ‘Intron sequence analysis method for detection of adjacent and remote locus alleles as haplotypes,’\(^ {185}\) and US Patent No 5,851,762 to GTG for an invention entitled ‘Genomic Mapping Method by Direct Haplotyping Using Intron Sequence Analysis’.\(^ {186}\) GTG obtained licenses in Australasia to Myriad’s patents in

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\(^{182}\) Ibid.

\(^{183}\) Ibid.


respect of genetic testing. In 2008, GTG announced that the company would enforce its rights in respect of these patents against public, as well as private, providers of genetic testing.\textsuperscript{187} Its press release sought to explain the motivations behind this: ‘Given that Genetic Technologies now offers an excellent service and has considerable excess capacity, the Company has made a commercial decision to enforce the exclusive rights granted to it by Myriad Genetics to perform diagnostic testing of the BRCA1 and BRCA2 genes in Australia and New Zealand’.\textsuperscript{188} Westmead Hospital and the Peter McCallum Laboratory received legal letters from GTG demanding they cease all testing for the BRCA1 and BRCA2 genes in women. In response to a public outcry over the issue, GTG withdrew its legal demands in respect of genetic testing for breast cancer and ovarian cancer. Its press release observed: ‘The Company looks forward to working positively with all its partners, including other public and private testing laboratories, to continue providing these world class testing services.’\textsuperscript{189}

### 6.2 Corporate Governance

There has been significant controversy over the corporate governance of Genetic Technologies Limited. In 2008, the Australian Securities and Investments Commission (ASIC) banned Rocco Musumeci of Bell Potter Securities Limited from providing financial services for four years, after it was found he had engaged in market manipulation by trading shares in Genetic Technologies Limited.\textsuperscript{190} In 2008, ASIC brought action against founder and major shareholder, Mervyn Jacobson in the Melbourne Magistrate’s court, alleging 319 counts of market manipulation through his involvement in the trading of company shares.\textsuperscript{191} Jacobson relinquished his position in December 2008 — but has remained a major shareholder in Genetic Technologies Limited. In 2010, Geoffrey Newing — who had been chief operating officer for Genetic Technologies Limited — pleaded guilty to five counts of market


\textsuperscript{188} Ibid.


manipulation. In 2011, the daughter of Mervyn Jacobson and husband of Geoffrey Newing — Tamara Newing — was sentenced to a term of 21 months imprisonment following a guilty plea to 10 counts of market manipulation. Newing was ordered to be released on a recognisance release order. There has been much turmoil in the board of Genetic Technologies Limited. In November 2012, Chief Executive Officer Paul MacLeman and other key personnel resigned, after the directors Mel Bridges and Huw Jones were not re-appointed by shareholders (dominated by Mervyn Jacobson).

6.3 The GTG Patent Enforcement

Notwithstanding such corporate turmoil and disorder, Genetic Technologies Limited has continued to be active in the enforcement of its family of patents. In 2010, GTG filed a patent infringement suit in respect of its non-coding DNA technologies against nine parties in the United States District Court, Western District of Wisconsin. The parties included Beckman Coulter Inc, Orchid Cellmark Inc, Gen-Probe Inc, Interleukin Genetics Inc, Molecular Pathology Laboratory Network Inc, Monsanto Inc, PIC USA Inc, Sunrise Medical Laboratories and Pioneer Hi-Bred International Inc. In 2011, GTG filed a lawsuit in the United States District Court for the Western District of Wisconsin against a number of clinical pathology laboratories associated with Sonic Healthcare Limited.


In late December 2012, Genetic Technologies Limited filed a lawsuit against LabCorp and 23andMe Inc., alleging infringement of a United States patent, which relates to methods for analyzing the ACTN3 gene to predict athletic performance. In its complaint, Genetic Technologies Limited alleges that LabCorp performs ACTN3 testing through the National Genetics Institute. Patients purchase these testing kits through 23andMe Inc. GTG has sought an injunction and damages against LabCorp and 23andMe Inc. A commentator wondered whether this patent raised questions about patentable subject matter in light of the Supreme Court of the United States ruling in Mayo v Prometheus and the hearing of the case of Association of Molecular Pathology v Myriad Genetics.

In March 2013, Genetic Technologies Limited announced further litigation in the United States and the European Union. The company commented that it was involved in ongoing patent litigation against Agilent Technologies, Inc, Bristol-Myers Squibb Company, GlaxoSmithKline PLC, Merial LLC and Pfizer Inc. The Company has also filed law suits in the United States against Genesis Genetics Institute, Medical Diagnostic Laboratories LLC, Reproductive Genetics Institute, Inc, Reprogenetics LLC, Genetics & IVF Institute Inc, Prevention Genetics, the Genelex Corporation, Natera Inc, HistoGenetics LLC, and General Genetics Corporation.

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200 ‘Genetic Technologies Limited Sues LabCorp and 23andMe for Patent Infringement’, above n 199.
201 Mayo Collaborative Services Prometheus Laboratories Inc, 132 S Ct 1289 (2012).
202 Association for Molecular Pathology v Myriad Genetics Inc, 133 S Ct 2107 (2013).
204 Genetic Technologies Limited v Genelex Corporation (2012) 1:2012cv02190, Delaware District Court.
Technologies Limited has also launched patent litigation against the Bioscientia Institute for Medical Diagnostics, based in Ingelheim, Germany. A preliminary action has also been initiated against Hendrix Genetics BV, based in Boxmeer, The Netherlands.

The United States Patent and Trademark Office have increasingly subjected Genetic Technologies Limited’s patents to scrutiny — with US Patent No 5,612,179 on non-coding DNA undergoing repeated re-examination.\(^{208}\)

It is curious that, after a decade of controversy, the validity of GTG’s patents have not been fully tested in litigation, whether in Australia or internationally.

**Conclusion**

The dispute between Cancer Voices Australia, Yvonne D’Arcy and Myriad Genetics Inc in the Federal Court of Australia foreshadows future conflicts over the ownership of, and access to cancer research, diagnostics, and treatment. The dispute highlights the need to listen to the voices of cancer patients, researchers, and inventors in patent disputes. Angelina Jolie has highlighted the need to take into account the interests of women affected by breast cancer and ovarian cancer:

> Breast cancer alone kills some 458,000 people each year, according to the World Health Organization, mainly in low- and middle-income countries. It has got to be a priority to ensure that more women can access gene testing and lifesaving preventive treatment, whatever their means and background, wherever they live. The cost of testing for BRCA1 and BRCA2, at more than $3,000 in the United States, remains an obstacle for many women. I choose not to keep my story private because there are many women who do not know that they might be living under the shadow of cancer. It is my hope that they, too, will be able to get gene tested, and that if they have a high risk they, too, will know that they have strong options. Life comes with many challenges. The ones that should not scare us are the ones we can take on and take control of.\(^{209}\)

\(^{207}\) Genetic Technologies Limited v General Genetics Corporation (2013) 1:2013cv00055, Delaware District Court.


The actor and activist observed of the decision of the Supreme Court of the United States: ‘I hope that this ruling will lead to more women at risk of breast cancer being able to get access to gene testing and take control of their lives’. 210

In *The Emperor of Maladies*, Siddhartha Mukherjee forecasts the future of cancer research:

But with cancer, where no simple, universal, or definitive cure is in sight — and is never likely to be — the past is constantly conversing with the future. Old observations crystallize into new theories; time past is always contained in time future … History repeats, but science reverberates. The tools that we will use to battle cancer in the future will doubtless alter so dramatically in fifty years that the geography of cancer prevention and therapy might be unrecognizable. Future physicians may laugh at our mixing of primitive cocktails of poisons to kill the most elemental and magisterial disease known to our species. But much about this battle will remain the same: the relentlessness, the inventiveness, the resilience, the queasy pivoting between defeatism and hope, the hypnotic drive for universal solutions, the disappointment of defeat, the arrogance and the hubris. 211

In this context, there is a need to ensure that intellectual property law plays a constructive role in the battle against cancer and in larger public health endeavors.

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211 Mukherjee, above n 2, 466.