

PATENTLY A PROBLEM? RECENT DEVELOPMENTS IN HUMAN GENE PATENTING AND THEIR WIDER ETHICAL AND PRACTICAL IMPLICATIONS

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*The issue of gene patenting has become re-enlivened with the recent decisions of both the Supreme Court of the United States and the Federal Court of Australia in regards to the patentability of isolated genetic material. The latter case, *Cancer Voices Australia v Myriad Genetics Inc*,¹ upheld the validity of a patent over the isolated BRCA1 gene and has highlighted the wider implications of gene patenting in Australia. This article examines the legal issues arising from that judgment in respect of the ‘manner of manufacture’ requirement for patentability. It also analyses the ethical consequences of gene patenting and the impact of the monopolistic market control that is facilitated by patents upon the delivery of biogenetic healthcare, industry investment and the dissemination of research results. It will further consider community concerns regarding possible limitations in access to genetic testing and treatment and suggest means of redressing such concerns.*

I INTRODUCTION

The emergence of genetic medicine as well as advancements in biotechnology have been accompanied by a significant proliferation in the number of patents granted over biological materials. Recent debates in Australia regarding the patenting of such substances, in particular human genomic materials, have raised concerns about the ethical and practical implications of patenting in the biotechnology sector. This debate surrounding the patentability of genetic materials has been recently re-enlivened by the judgment of Nicholas J in *Cancer Voices Australia v Myriad Genetics Inc (Myriad Genetics)*,² which upheld the validity of a patent over isolated human genetic material.

This article will firstly provide an overview of the particular issues that *Myriad Genetics* raised in regards to the ‘manner of manufacture’ requirement for patentability and will also discuss the views that have been expressed about the case so far. The article will further provide a balanced view not only of the practical, but also ethical implications of gene patenting. In this respect, it will be examined whether the monopolistic market control provided by patents has an

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¹ [2013] FCA 65 (15 February 2013).

² [2013] FCA 65 (15 February 2013).

inhibitory effect on the provision of genetically derived healthcare services and the capacity to conduct unfettered biotechnological research. The wider bioethical implications of patenting human biological materials under the *Patents Act 1990* (Cth) ('*Patents Act*') will also be explored to ultimately determine whether the rationale behind patenting human genetic material is supported by compelling justifications.

II RECENT DEVELOPMENTS: THE *MYRIAD* CASE IN THE UNITED STATES

On 13 June 2013, the Supreme Court of the United States handed down its long-awaited decision in *Association for Molecular Pathology v Myriad Genetics*.³ The biotechnology firm Myriad Genetics discovered the precise location and sequence of the BRCA1 and BRCA2 genes, mutations of which are associated with a greater risk of breast and ovarian cancer. The company obtained several patents based upon these findings, which provided it with the exclusive right to isolate an individual's BRCA1 and BRCA2 genes and perform medical tests for detecting these mutations. However, the Supreme Court found Myriad's patents over isolated human DNA sequences to be invalid.

The case has had a long procedural history; it was originally heard in the Southern District Court of New York,⁴ where Judge Sweet noted that Myriad's mere isolation of the BRCA genetic sequences did not render them sufficiently distinct from this material as it exists within the human body. Accordingly, his Honour found that Myriad's patents essentially covered products of nature and were therefore invalid. Myriad's appeal to this decision was granted, and the case was subsequently heard in the United States Court of Appeals for the Federal Circuit, which partly overturned Judge Sweet's decision. Importantly, it reversed the finding that Myriad's isolated BRCA gene sequences were not eligible for patent protection.⁵ Judge Lourie, writing for the majority, emphasised the importance of the cleaving of isolated DNA from its chromosomal environment as evidence that the isolated material is fundamentally distinct from DNA as it exists within the body. His Honour concluded that the material's resulting distinctive chemical identity satisfied the requirement that patented material be markedly different from naturally occurring substances.

Subsequent to this decision, however, the Association for Molecular Pathology sought a petition to the Supreme Court for a writ of certiorari, which was granted. The Supreme Court vacated the decision,⁶ and remanded the case back to the Federal Circuit to be reconsidered in light of the important recent decision in *Mayo Collaborative Services v Prometheus*.⁷ On remand, the Federal Circuit once again found in favour of Myriad Genetics, holding the relevant isolated DNA to be patent eligible and essentially reiterating its previous judgment.⁸ In

³ 569 US 12-398 (2013).

⁴ *Association for Molecular Pathology v U.S. Patent & Trademark Office*, 702 F Supp 2 d 181 (SDNY 2010).

⁵ *Association for Molecular Pathology v United States Patent and Trademark Office*, 653 F 3d 1329 (Fed Cir, 2011).

⁶ *Association for Molecular Pathology v Myriad Genetics Inc*, 132 S Ct 1794 (2012).

⁷ 132 S Ct 1289 (2012).

⁸ *Association for Molecular Pathology v US Patent and Trademark Office US Patent and Trademark Office*, 689 F 3d 1303 (Fed Cir, 2012).

regards to the relevance of *Mayo*, Judge Lourie found that *Mayo* was directed to questions regarding the boundaries between patent-eligible methods and laws of nature and was therefore not an applicable precedent to the relevant principle claims in *Myriad*, which mainly related to isolated DNA molecules and product patents.

Following this ruling, the Supreme Court granted the plaintiffs' application for certiorari and heard an appeal from the Federal Circuit's decision in April 2013. The Supreme Court restricted the appeal to the central issues of whether isolated genes are products of nature that cannot be patented, or whether they constitute human-made inventions that are eligible for patent protection. In invalidating the BRCA patents held by Myriad, the court held that isolated naturally-occurring DNA sequences are indeed products of nature and are not patent eligible merely by virtue of having been separated from their environment. In reaching this conclusion, the court examined the essence of Myriad's scientific accomplishments and found that 'Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes,'⁹ but that Myriad did not create an invention.

As a consequence of this decision, broad biotechnology product claims to isolated DNA will likely no longer be considered patentable in the United States. However, the decision interestingly leaves open some opportunities for gene patenting by making a distinction between natural DNA and synthetic DNA, otherwise known as cDNA.¹⁰ In concluding that isolated natural DNA is not patentable, but cDNA is eligible for such protection, the Supreme Court appears to have been concerned to preserve the 'delicate balance between creating incentives that lead to creation, invention and discovery' and otherwise 'impeding the flow of information that might permit [or] spur invention.'¹¹ In other words, the Supreme Court sought to maintain investment and research incentives through the preservation of the patent eligible status of cDNA, but precluded the possibility of extensive monopolies over isolated naturally occurring genetic material. Ultimately, the Supreme Court's ruling addressed a significant point of legal contention in a series of contradictory court rulings spanning several years. It constitutes a shift in patent law jurisprudence and overturns three decades of the award of patents on human genes by the United States Patent and Trademark Office.

Most notably for an Australian context, the decision is at odds with the recent ruling of the Federal Court of Australia in February 2013 in *Myriad Genetics*.¹² In this case, Nicholas J held that isolated DNA falls under the ambit of patentability. The Supreme Court's decision does not have a direct legal impact on Australian gene patent jurisprudence, however, the findings of the United States court may be considered by the Full Court of the Federal Court when it hears an appeal to Nicholas J's decision later this year. However, until the Full Court provides judgment, Nicholas J's decision remains current authority on the patentability of isolated gene sequences in Australia.

⁹ 569 US 12-398 (2013), p12.

¹⁰ 569 US 12-398 (2013), p16.

¹¹ 569 US 12-398 (2013), p11.

¹² [2013] FCA 65 (15 February 2013).

III RECENT AUSTRALIAN DEVELOPMENTS: *MYRIAD GENETICS* AND THE MANNER OF MANUFACTURE REQUIREMENT

On 15 February 2013, Nicholas J handed down his judgment in *Myriad Genetics*, a case that has highlighted several legal and ethical issues surrounding human gene patenting. The suit was initiated by breast cancer survivor Yvonne D'Arcy and the patient advocacy group Cancer Voices Australia against Myriad Genetics & Laboratories and its exclusive Australian licensee, Genetic Technologies Ltd. The catalyst for the case was an attempt by Genetic Technologies to actively enforce its patent rights against other laboratories over the BRCA1 and BRCA2 genes,¹³ biological traits that are strongly associated with an increased susceptibility to breast and ovarian cancer.¹⁴ It was the first Australian court case to challenge the practice of granting patents over human genetic material and a patentee's exclusive right to exploit such material to the exclusion of others.¹⁵ The specific issue before the Federal Court was whether, under the *Patents Act*, a valid patent may be granted for a claim covering naturally occurring DNA or RNA that has been isolated.¹⁶ In holding that Myriad's patent could validly cover such biological materials, the case has wide-ranging implications, particularly for biotechnological research and the treatment of many conditions with genetic markers.

Under the *Patents Act*, the patentability of biological materials is dependent upon the satisfaction of several preconditions. Section 18 provides a statutory basis for patenting biological materials that are novel and involve an 'inventive step', in that their subject matter is new and has not previously been made available.¹⁷ A further requirement is that an invention possesses a degree of utility, which essentially requires that it have an actual, rather than a speculative future use.¹⁸ However, in *Myriad Genetics*, Nicholas J's judgment turned on the specific requirement that the subject of Myriad's patent, an isolated composition comprising of naturally occurring DNA and RNA, is 'a manner of manufacture' within the meaning of s 6 of the *Statute of Monopolies 1623* (UK), as required under s 18(1)(a) of the *Patents Act*.¹⁹ It is this statutory requirement that has perhaps been in most need of judicial clarification. However, in attempting to

¹³ University of Tasmania Faculty of Law, *BRCA Patent Law Suits* (11 September 2012) University of Tasmania <<http://www.utas.edu.au/law/brca-patent-law-suits>>; Genetic Technologies, *Genetic Technologies to Enforce Rights to BRCA Patents* (September 2009) <<http://www.gtglabs.com.au/announcements/genetic-technologies-to-enforce-rights-to-brca-patents>>.

¹⁴ Piri Welsh, *The Role of Genetics in Breast and Reproductive Cancers* (Springer, 2009) 108.

¹⁵ University of Tasmania Faculty of Law, above n 13.

¹⁶ *Myriad Genetics* [2013] FCA 65 (15 February 2013) [1].

¹⁷ *Patents Act (1990)* (Cth) s 18(1). See also *Rescare Ltd v Anaesthetics Supplies Pty Ltd* (1992) 25 IPR 119, 142.

¹⁸ *Patents Act (1990)* (Cth) s 18(1)(c); David Keays, 'Patenting DNA and Amino Acid Sequences' (1999) 7 *Health Law Journal* 69, 80.

¹⁹ Section 6 of the *Statute of Monopolies 1623* (UK) stipulates:

Provided also and be it declared and enacted that any declaration before mentioned shall not extend to any letters patent and grants of privilege, for the term of 14 years or under hereafter to be made of the sole working or making of any manner of new manufacture within this realm to the true and first inventor and inventors of such manufactures which others, at the time of making such letters or grant, shall not use, so as also they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home or hurt of trade or generally inconvenient.

provide this sense of clarity, Nicholas J's application of the manner of manufacture test has rendered this requirement a contentious issue.²⁰ This section provides an overview of the main issues that *Myriad Genetics* highlighted in regards to the manner of manufacture requirement and provides a review of what has been said so far of the case.

The term 'manner of manufacture' is not defined by the *Patents Act*, however, the basis of the current legal conception of this term was established by the High Court of Australia in *National Research Development Corporation v Commissioner of Patents* ('NRDC').²¹ In that case, the court endorsed an expansive definition of this term, holding that an invention can be so characterised 'if it is an artificially created state of affairs' that 'belongs to a useful art, as distinct from a fine art' and possesses value in a field of economic endeavour.²² In this respect, mere discoveries, natural phenomena, ideas, scientific theories and laws of nature fail to satisfy the criteria for patentability.²³

In declining to restrict the manner of manufacture concept to an exact verbal formula or definition, the High Court embraced the view that this requirement should be a flexible and dynamic concept,²⁴ the meaning of which continues to evolve over time with newly emerging technological advancements. Accordingly, no set definition of the term 'manner of manufacture' has emerged, and this requirement has become subject to a conceptual and open-textured inquiry.²⁵ In *Myriad Genetics*, this was the approach that was followed by Nicholas J, who opined that 'the concept of manner of manufacture has a 'broad sweep' intended to encourage developments that are by their nature often unpredictable.'²⁶ This inclusive nature of the manner of manufacture requirement has been furthered by the general judicial reluctance to invoke the restrictive proviso within s 6 of the *Statute of Monopolies*. Section 6 provides that patents should not be granted where they are 'contrary to the law or mischievous to the state by raising prices of commodities at home or hurt trade or [are] generally inconvenient.'²⁷ Arguably, this section enables the grant of a patent to be invalidated on public policy

²⁰ Amy Corderoy, 'This Judgment Simply Ignores the Common Sense Approach: Cancer Advocates Hit Out at BRCA1 Cancer Gene Ruling', *The Sydney Morning Herald* (online), 15 February 2013 <<http://www.smh.com.au/national/health/this-judgment-simply-ignores-the-common-sense-approach-cancer-advocates-hit-out-at-brca1-cancer-gene-ruling-20130215-2ehop.html>>; Isabel Hayes and Toby Mann, 'Calls for Law Change After Gene Ruling', *The Sydney Morning Herald* (online), 15 February 2013 <<http://news.smh.com.au/breaking-news-national/calls-for-law-change-after-gene-ruling-20130215-2egvc.html?skin=text-only>>.

²¹ (1959) 102 CLR 252.

²² *Ibid* 275 [22]. See also *Re Virginia-Carolina Chemical Corporation's Application* (1958) RPC 35, 36.

²³ *NRDC* (1959) 102 CLR 252, 264; *Milton Edgar Anderson* [2008] APO 19 (11 August 2008); *Diamond v Chakrabarty*, 447 US 303, 309 (1980). See also Mark Davidson, Ann Monotti and Leanne Wiseman, *Australian Intellectual Property Law* (Cambridge University Press, 2011) 450; Australian Law Reform Commission, *Genes and Ingenuity – Gene Patenting and Human Health* Report No 99 (2004) 121.

²⁴ *NRDC* (1959) 102 CLR 252, 271; *Grant v Commissioner of Patents* (2006) 154 FCR 62, 64.

²⁵ Justine Pila, 'Inherent Patentability in Anglo-Australian Law: A History' (2003) 14 *Australian Intellectual Property Journal* 109, 110; Clare Bradin, 'A Response to the Senate Inquiry into the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*' (2012) 23 *Australian Intellectual Property Journal* 49, 51.

²⁶ [2013] FCA 65 (15 February 2013) [86].

²⁷ *Statute of Monopolies* 1623 (UK), s 6.

grounds where such a grant would be injurious to society. Although this passage is often cited, and indeed is referred to in the recent judgment of Nicholas J, its potential to restrict patents that transgress public policy boundaries has been largely under-utilised. 'General inconvenience' has in fact been rejected by the Federal Court as a stand-alone ground of invalidity,²⁸ and so this potentially far-reaching constraint on the grant of patents found in the *Statute of Monopolies* manner of manufacture clause has essentially become blunted.

Apart from highlighting the generality of the manner of manufacture test, *Myriad Genetics* has more specifically brought attention to the failure of case law to provide sufficient guidance as to the threshold of inventiveness, namely the appropriate enquiry to be undertaken when determining if the requisite 'artificially created state of affairs' has been established under the manner of manufacture test.²⁹ Even though Nicholas J concluded that 'it is the element of human intervention that allows one to ... characterise the relevant state of affairs as being artificial,' his Honour nevertheless recognised that '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.'³⁰

The uncertain boundaries of this threshold have rendered the examination of patents within complex scientific fields, particularly human genetics, a challenging endeavour for the judiciary. The amorphous nature of this aspect of the manufacture requirement and the judicial reluctance to stipulate a requisite minimum degree of human intervention has led to a wide variety of subject matter with varying degrees of intervention being considered 'artificially created.'³¹ For instance, in the *Myriad Genetics* judgment, it was mere human intervention involved in extracting and purifying nucleic acid found in human cells from other cellular components that provided the requisite intellectual effort necessary to render the resulting isolated nucleic acid a 'manner of manufacture.'³² This was a particularly contentious aspect of Nicholas J's judgment, because even though the physical properties of the relevant biological material did not change, the mere removal of this substance from its natural environment gave rise to the requisite artificially created state of affairs. In fact, Professor Dianne Nicol has concluded regarding the *Myriad Genetics* decision that 'it [means] that this manner of manufacture requirement has very few teeth. 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.'³³ The judgment could therefore open the door for permitting the patenting of a wide range of other human genetic materials, even in circumstances where there has been minimal human intervention.

²⁸ *Welcome Real-Time SA v Catuity* [2001] FCA 445 (17 May 2001) [131]–[132].

²⁹ *NRDC* (1959) 102 CLR 252; Bradin, above n 25, 54; William van Caenegem, *Intellectual and Industrial Property in Australia* (Kluwer Law International, 2009) 168.

³⁰ [2013] FCA 65 (15 February 2013) [102].

³¹ Davison, Monotti and Wiseman, above n 23, 443.

³² [2013] FCA 65 (15 February 2013) [108].

³³ Sunanda Creagh and Will Mumford, 'Historic Ruling Allows Private Firms to Patent Human Genetic Material', *SBS World News* (online), 15 February 2013 <<http://www.sbs.com.au/news/article/1737464/Historic-ruling-allows-private-firms-to-patent-hum>>.

IV RECENT RESPONSES TO *MYRIAD GENETICS*

Those opposed to gene patenting have expressed concern with these possible implications of Nicholas J's reasoning. Following the decision, lawyers for the plaintiff as well as patent law experts expressed disagreement with the judgment, arguing that the content of Myriad's patent does not represent an invention, as the isolation of BRCA1 is no more than the scientific discovery of a naturally occurring phenomenon.³⁴ In other words, despite the energy and ingenuity expended in creating isolated genetic sequences that are homologous to those that occur naturally, the mere separation of these substances from the larger human genome should not necessarily be termed an 'invention' if the results are identical to the sequence of its native homologue. These sentiments effectively take issue with the current judicial view that only minimal human intervention is required to bring about an artificially created state of affairs under the manner of manufacture test.

Critical responses to the decision have also speculated as to its future legal implications, arguing that although Nicholas J's reasoning related to a specific isolated gene mutation, it could be applied to patents over any human gene, leading to a proliferation in the grant of gene patents.³⁵ While this may be true, such comments must be tempered against the fact that the decision only considered the manner of manufacture requirement, and not the remaining preconditions for patentability. For instance, there was no judicial consideration in *Myriad Genetics* of whether isolated human gene sequences would satisfy the requirement of an inventive step or whether these materials possess the requisite degree of utility. These requirements may in fact present further hurdles to the patentability of other types of genetic material,³⁶ and Nicholas J's judgment may therefore not necessarily have the wide implications that have been suggested.

On the other hand, the decision was welcomed by the biotechnology industry, a sector that relies largely on patents for the protection of investment and research in genetic technologies. Nicholas J's judgment arguably reflects elements of the industry's belief that skill and intellectual effort in the isolation of DNA sequences should be rewarded through patent protection. As will be discussed in Part VII of this article, the judgment in favour of Myriad Genetics removed concerns that innovation within the life sciences industry would be stifled and foreign and domestic investment in genetic research would decline if isolated genetic material were removed from patent eligibility. The decision essentially reassures the industry of its ability to protect and commercialise innovations through the intellectual property rights system.

In response to these commercial considerations, opponents of gene patenting have criticised the decision's failure to acknowledge the importance of human dignity and equity and have lamented its effective endorsement of the commodification of the human body.³⁷ However, these concerns, which have featured heavily in the

³⁴ See, eg, Luigi Palombi, 'Patent Law Must Recognise Human Genes are No Invention', *ABC Online* (online), 20 February 2013 <<http://www.abc.net.au/unleashed/4528914.html>>.

³⁵ Creagh and Mumford, above n 33.

³⁶ Lucy Hartland, 'Cancer Voices Australia v Myriad Genetics Inc' (2013) 25(9) *Australian Intellectual Property Law Bulletin* 191, 192.

³⁷ Palombi, above n 34.

popular media, are not necessarily of significant legal relevance. Responses to the decision that are arguably of greater legal cogency have centered upon the perceived unsatisfactory nature in which Nicholas J interpreted the degree of human intervention necessary to bring about the requisite artificially created state of affairs under the manner of manufacture test. This is a potentially significant criticism and is likely to constitute the key issue in the appeal against the Federal Court's decision. In this forthcoming case, the appellants are likely to argue that Nicholas J erred in finding that the isolation of DNA was considered a form of new manufacture. The argument's greatest merit may rest on the fact that Nicholas J stated in his judgment that the BRCA gene was not relevantly different inside or outside of the human body. This statement may assist the appellants in contenting that the mere isolation of DNA therefore cannot create a state of affairs that can be considered 'artificial.' Interestingly, as discussed in Part II, the Supreme Court of the United States recently upheld the essence of this proposition, holding that isolated human genes are not sufficiently distinct from genes that exist within the body and are hence not eligible for patent protection.

By highlighting the relatively low threshold of the manner of manufacture test, *Myriad Genetics* has also led to strong calls for the law in this area to be reformed. The primary criticism of the manner of manufacture test as applied in *Myriad Genetics* centred on its inability to effectively distinguish between 'discoveries' and 'inventions'. Following the judgment, commentators invoked this rhetoric, expressing the view that isolated human genes do not constitute 'inventions,' but rather the 'discovery' of a natural phenomenon; they are products of nature that have not been transformed into products of human effort and labour.³⁸ According to this view, any outcomes of such scientific procedures ultimately remain a product of human evolutionary and natural processes and should therefore be deemed unpatentable. Yet under current patent law, such products may constitute the subject of a valid patent.

One previous attempt to address these concerns was reflected in the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (Cth) ('*Patent Amendment Bill*'), which was introduced into the Senate in late 2010 as a Private Member's Bill, and aimed to reinforce the distinction between discoveries and inventions. The merit of this approach to amending gene patent law will be examined below to determine whether the calls for similar reforms could effectively ameliorate the above concerns that have been raised following *Myriad Genetics*.

Nicholas J's ruling in *Myriad Genetics* indicates that under s 18 and the *NRDC* jurisprudence, there is no legal basis to demand that the subject of a patent be markedly different to matter that already exists in nature. However, the *Patent Amendment Bill* attempted to preclude such results by expressly excluding from patentability 'biological materials, whether isolated or purified ... which are identical or substantially identical to such materials as they exist in nature.'³⁹ The reform Bill defined 'biological materials' to include DNA, RNA, proteins, cells

³⁸ ABC News, 'Biotech Industry Worries About Investment Uncertainty After US Supreme Court Patent Ruling', *The World Today*, 14 June 2013 (Luigi Palombi) <<http://www.abc.net.au/worldtoday/content/2013/s3781908.htm>>.

³⁹ Patent Amendment (Human Genes and Biological Materials) Bill 2010 (Cth), item 3(2)(b).

and fluids. Amending the *Patents Act* to include a similar qualification may assist in demonstrating a legislative intent to remove such biological materials from the ambit of patentability, an intent that was found by Nicholas J in *Myriad Genetics* to be noticeably absent from s 18 of the *Patents Act*. This requirement for patentable material to be distinct from naturally occurring substances may exclude genes from patentability that have merely been isolated, such as BRCA1, and thereby ameliorate concerns that the current law gives licence to biotechnology companies to effectively claim ownership of naturally occurring substances that they have merely discovered.⁴⁰

It has been argued that prohibiting the patenting of materials that are ‘substantially identical’ to such materials as they exist in nature would not present significant difficulties, as the term ‘substantially identical’ is a measure of differentiation that is not a foreign concept to intellectual property jurisprudence, being widely used in the law of trademarks.⁴¹ However, such arguments ignore the complexity of the environment in which patent law, as opposed to trademark law, can operate. Introducing into s 18 this legislative requirement to identify a sufficient distinction between patented biological materials and their naturally occurring states may ultimately be unsatisfactory. This is because it would be difficult to define the requisite degree of differentiation between purely biotechnological products and naturally occurring substances. In this regard, the National Health and Medical Research Council observed that the exclusion from patentability of materials that are ‘substantially identical’ to materials existing in nature would create uncertainty as to the patentability of a large number of biotechnologically-derived substances. For example, products of synthetic biology, while not themselves biological materials, replicate naturally occurring substances and would prima facie appear to be excluded from patentability under the above legislative reforms.⁴² The breadth of resulting exclusions would have significant implications for current and particularly future genetic research, as the delineation between synthetic and naturally occurring substances becomes increasingly blurred. For instance, under the Minimal Genome Project, researchers recently created a partially synthetic species by synthesising the genome of the *Mycoplasma mycoides* bacterium and transplanting the synthesised genome into the existing cell of a *Mycoplasma capricolum* bacterium that had its DNA removed.⁴³ The resulting synthetic bacterium is considered a viable organism capable of replicating itself. Synthetic forms of life such as this invention further obfuscate the delineation between natural and artificial entities, a distinction that is becoming increasingly difficult to define.

⁴⁰ See, eg, *Ruling on Gene Patents Highlights Need to Change Law* (15 February 2013) Cancer Council of Australia <<http://www.cancer.org.au/news/media-releases/ruling-on-gene-patents-highlights-need-to-change-law.html>>.

⁴¹ *Trade Marks Act 1995* (Cth) ss 23, 44, 60, 102, 120, 122, 124, 133, 146, 230. See also Luigi Palombi, Submission No 103 to the Senate Standing Committee on Legal and Constitutional Affairs, *Inquiry Into the Patent Amendment (Human Genes and Biological Materials) Bill 2010* (Cth), 24 February 2011, 2.

⁴² Senate Legal and Constitutional Affairs Committee, *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (2011) 23.

⁴³ Priya Venkatesan and Michael Peters, ‘Bioeconomy and Third Industrial Revolution in the Age of Synthetic Life’ (2011) 2 *Contemporary Readings in Law and Social Justice* 148.

Accordingly, drawing a distinction between naturally occurring biological materials and materials that have been sufficiently modified would involve protracted examination of a complex niche area of science, a task that the courts would not necessarily be able to readily undertake in navigating the patent landscape. Such an inquiry would necessitate judicial consideration of a rather nebulous and highly scientific concept, and as such, a greater element of uncertainty may be introduced into the law surrounding the patentability of biotechnological materials, which, as Nicholas J described in *Myriad Genetics*, already possesses ‘an almost metaphysical dimension.’⁴⁴

V IMPLICATIONS FOR THE MANNER OF MANUFACTURE REQUIREMENT

The recent calls for reform and criticisms of the manner of manufacture test that have been made in response to *Myriad Genetics* may need to be somewhat tempered. As discussed above, the boundaries of the manner of manufacture test have not necessarily been defined very strictly and they have admittedly been interpreted wider than some would prefer.⁴⁵ However, the flexibility that is inherent in the current test should not be undervalued. It is this element of malleability that facilitates the potential for the judiciary to respond to new technological developments in times of rapid scientific and technological innovation. Professors Ann Monotti and Sam Ricketson have observed that, as science and technology advance, what is considered to be patentable is becoming increasingly contentious at the margins, yet courts have been able to address this issue by a process of progressive interpretation within the current test.⁴⁶ Despite the early origins of the manner of manufacture test, the current requirements are framed with sufficient generality to enable the concept of patentability to keep pace with, and adapt to advances in technology. Despite the perceived lack of rigidity in the test, several reviews into Australian patent law have recommended that it be maintained in its current form as a threshold test for patentability.⁴⁷ The common reason for these recommendations centres upon the open-textured nature of the test.⁴⁸ The reviews concluded that the breadth of the current test imbues it with the capacity to respond to emerging inventive concepts and new developments in human ingenuity and technologies.⁴⁹

In this context, attempting to reformulate the current manner of manufacture test may introduce an element of rigidity that would detract from the test’s adaptability and versatility. Any attempts to re-write or codify aspects of the test would not necessarily bring greater clarity to the manner of manufacture requirement. This can be partly attributed to ‘a general understanding, by both courts and legislatures, that it is impossible to find a form of language that will

⁴⁴ *Myriad Genetics* [2013] FCA 65 (15 February 2013) [102].

⁴⁵ See, eg, Palombi, above n 34; Creagh and Mumford, above n 33.

⁴⁶ Ann Monotti and Sam Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (Oxford University Press, 2003) [3.22].

⁴⁷ See Senate Legal and Constitutional Affairs Committee, above n 42; Senate Community Affairs References Committee, *Gene Patents* (2010); Australian Law Reform Commission, above n 232; Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (September 2000).

⁴⁸ See, eg, Australian Law Reform Commission, above n 23, 127; Intellectual Property and Competition Review Committee, above n 47, 49.

⁴⁹ See, eg, Senate Community Affairs References Committee, above n 47, 11; Australian Law Reform Commission, above n 23, 127.

adequately cover, at any one time, the multifarious and diverse forms in which human inventiveness may manifest itself.’⁵⁰ More precise verbal formulae may instead place unnecessary fetters on the test’s ability to respond to relevant technological changes, or in fact have the unintended consequence of introducing interpretive difficulties and a degree of uncertainty to the test until it is brought to the consideration of a higher court.⁵¹

One particular criticism of the manner of manufacture test that should also be addressed relates to the apparently archaic statutory language within which it is encapsulated. It has been argued that the wording of s 6 of the *Statute of Monopolies* appears obscure in a modern context.⁵² However, this has not necessarily hindered the application of the test, as the courts have developed a body of principles surrounding this test that have been formulated in modern language. It must be noted that the *Patent Act*’s reference to s 6 of the *Statute of Monopolies* merely invokes its principles and does not require strict and literal adherence to its terms. The obscurity of the statute’s archaic language in regards to manner of manufacture therefore does not present overwhelmingly cogent grounds for criticising the test. Even in civil law systems, it is not considered feasible to be able to discern the true meaning of the law solely from the legislative text,⁵³ and it is recognised that ‘there is an overlying patina of judicial decisions that must be known if the law is to be comprehended.’⁵⁴ This ‘patina’ of case law in regards to the manner of manufacture requirement has been provided by the High Court in the *NRDC* case as well as the long line of subsequent decisions that have applied its reasoning. In fact, a further opportunity for the judiciary to solidify this body of knowledge will arise in the appeal that has been recently launched against *Myriad Genetics* in the Federal Court. This case will provide the opportunity for the court to provide further guidance on the test, and specifically the degree of human intervention necessary to render the subject of a patent an artificially created state of affairs, this being an aspect of the test that has arguably received the most criticism.

Considering the merits of the current formulation of the test that have been discussed above, criticisms of the law may need to be tempered, particularly in light of the forthcoming appeal in the Federal Court. In addition, to further answer the question raised by *Myriad Genetics* as to whether the law should be amended, apart from examining specific issues relating to statutory language, legal threshold requirements and judicial interpretation, what is also required is a fundamental re-exploration of the ethical considerations underlying gene patenting. As moral concerns have provided a significant basis for the recent criticisms of the current law, the ethical and moral implications of gene patenting therefore deserve greater emphasis in the current debate.

⁵⁰ Monotti and Ricketson, above n 46.

⁵¹ Intellectual Property and Competition Review Committee, above n 47, 148; Australian Law Reform Commission, above n 23, 121.

⁵² See, eg, Advisory Council on Intellectual Property, *Patentable Subject Matter* Final Report (2010) 57.

⁵³ *Ibid*, 43.

⁵⁴ Dennis Pearce and Robert Geddes, *Statutory Interpretation in Australia* (LexisNexis, 6th ed, 2006) 277.

VI ETHICAL CONSIDERATIONS

As the first Australian case to uphold the practice of granting patents over human genetic material, *Myriad Genetics* has raised not only legal, but also significant ethical issues regarding the suitability of human genetic material for patentability. Dr Luigi Palombi expressed the concern that as a result of the Federal Court's decision, 'effectively everything in the human body can be considered patentable, the human body is now a commodity. Its components are a commodity,'⁵⁵ sentiments that tend to portray human gene patenting as an unethical practice.

At the centre of the intersection between biotechnology and patent law inevitably lies the contentious role of ethics and morality. The debate over the patenting of human genes, more than any other biological material, is a focal point for several divergent moral concerns. The concept of what is considered ethical in the area of gene technology remains amorphous and continues to evolve over time – as technology and science progress, new moral issues inevitably arise. This multi-faceted nature of genetics, coupled with the lack of consensus regarding the delineation of the ethical from the unethical, inherently gives rise to complex conceptual and ethical considerations.⁵⁶

A *The commodification of human life undermines human dignity*

Several moral questions arise from the now judicially sanctioned practice of patenting certain human genetic materials. From one ethics perspective, patenting human biological materials may be seen to undermine human dignity by commodifying human life. Patents traditionally serve an economic function, which 'presupposes an ability to determine the economic value of the patentable entity.'⁵⁷ In this respect, patenting human materials facilitates the assignment of economic value to individuals. Modern bioethical and neo-Kantian thought endorses the principle that humans possess worth that cannot be quantified in economic terms.⁵⁸ The application of market rhetoric to patented human material under current patent law may therefore represent a commodification of individuals in violation of their intrinsic human dignity. In effect, this conception of humans as constituting vendible parts of commercial value may violate the essence of what it means to be human.

The Kantian notion that human beings possess dignity, moral worth and a rational sense of autonomy, opposes such commodification of human life. This view finds reflection in Kant's 'Formula of Humanity', a moral principle which posits that human beings possess intrinsic, rather than extrinsic value.⁵⁹ In other words, a

⁵⁵ Creagh and Mumford, above n 33.

⁵⁶ Elizabeth Ng, 'Interaction Between Ethics and Biotechnology Patent Law' (2010) 22 *Singapore Academy of Law Journal* 93, 93; Philip Grubb and Peter Thomsen, *Patents For Chemicals, Pharmaceuticals and Biotechnology* (Oxford University Press, 5th ed, 2010) 315.

⁵⁷ Suzanne Ratcliffe, 'The Ethics of Genetic Patenting and the Subsequent Implications on the Future of Health Care' (2011) 27(2) *Touro Law Review* 435, 442.

⁵⁸ Tom Beauchamp and James Childress, *Principles of Biomedical Ethics* (Oxford University Press, 4th ed, 1996); Thomas Hill, *Dignity and Practical Reason in Kant's Moral Theory* (Cornell University Press, 1992); David Resnik, 'DNA Patents and Human Dignity' (2001) 29 *Journal of Law, Medicine and Ethics* 152, 155.

⁵⁹ Ian Kerridge, Michael Lowe and Cameron Stewart, *Ethics and Law For the Health Professions* (Federation Press, 3rd ed, 2009) 12.

moral duty exists to treat all human beings as ends in themselves, and not solely as a means to other ends.⁶⁰ It can be argued that this fundamental principle should be considered in guiding the legally mandated uses of new biotechnological inventions, to eschew practices that undermine humans' inherent worth.

However, these ethical arguments may be criticised on the basis that assigning an economic value to individual human biological components does not necessarily equate to the commodification of an individual.⁶¹ In this respect, it is important to differentiate between complete and incomplete commodification. David Resnik observes that for several years, scientists have patented complex molecules that occur within the human body, such as proteins, hormones and lipids, without particularly strong moral opposition being voiced.⁶² This process merely represents an 'incomplete commodification' of human substances. The patenting of human genetic material, Resnik argues, similarly constitutes an 'incomplete commodification' that will not inexorably lead to the 'complete commodification' of humans as a whole.⁶³ In any event, human beings are already commonly defined by market rhetoric without significant objection. Putting a price on human life through insurance policies, negligence suits or even wages and salaries as compensation for human labour are examples of current practices that apply market rhetoric to human beings.⁶⁴

A common related argument that also criticises the relegation of humans to a quasi chattel-like status under the *Patents Act* asserts that because patents over human biological materials confer proprietary rights on patentees, gene patenting promotes a system of ownership over human beings.⁶⁵ However, this argument confuses intangible intellectual property rights with physical property rights. The intellectual property rights that patents grant over isolated genetic material under the *Patents Act* do not necessarily grant positive physical property rights over parts of each person's human body. Rather, they confer a right upon the patentee to exclude others from the manipulation and manufacture of certain genetic sequences for a specified period of time. In this respect, ethical arguments based on the notion that patents reduce human life to the property of patentees, which have been recently put forward by supporters of the applicants in *Myriad Genetics*, do not necessarily offer an entirely convincing argument against patenting.

As a consequence, the argument that patents reduce human life to a commodity may possess moral resonance in the context of patenting entire living organisms, however, this argument loses some force in respect of patenting only genes. On this view, it may be argued that s 18 of the *Patents Act*, which prohibits the

⁶⁰ Immanuel Kant, *Groundwork of the Metaphysics of Morals* (H Patton trans, Harper 1953) 428 [trans of: *Grundlegung zur Metaphysik der Sitten* (first published 1785)]. See also Resnik, above n 58, 155; Ratcliffe, above n 57, 441.

⁶¹ Australian Law Reform Commission, above n 23, 71.

⁶² Resnik, above n 58, 158.

⁶³ *Ibid* 160.

⁶⁴ *Ibid* 156.

⁶⁵ Ruth Macklin, 'The Ethics of Gene Patenting' in Alison Thompson and Ruth Chadwick (eds), *Genetic Information: Acquisition, Access and Control* (Springer, 1999) 129, 130; David Resnik, 'The Morality of Human Gene Patents' (1997) 7 *Kennedy Institute of Ethics Journal* 43; Ratcliffe, above n 57, 441.

patenting of ‘*human beings* and the biological processes for their generation’⁶⁶ [emphasis added] may be justified, however, excluding a wider range of biological substances, such as human genetic material, may not be as compelling.

B *Genes maketh the (wo)man?*

A further concern that arises is that permitting the patenting of human genetic material under current case law and legislation fails to recognise the uniqueness and *sui generis* nature of the human genome and its centrality in forming the essence of a human being.⁶⁷

Many divergent opinions exist regarding the meaning of personhood and its precise relationship with an individual’s genetic composition. What constitutes ‘humanness’ is essentially a metaphysical question. In the Cartesian tradition, a dichotomy between the material body and the immaterial human essence was traditionally assumed to exist. However, 21st century phenomenology presents a different image that places greater emphasis on the unity of body and mind ‘in which all structures and functions of the body are modes of the person and there is no sharp duality between the person and the body.’⁶⁸ This theory of genetic essentialism seeks to challenge the metaphysical separation of the human body and the human person by suggesting that genes intrinsically constitute the very essence of human existence.⁶⁹ Genetic material is accordingly not only closely linked to an individual’s physicality, emotional and intellectual composition, but also to his or her personhood and sense of self.⁷⁰ In this respect, Rogeer Hoedemaekers and Wim Dekkers suggest that the human genome has assumed the position of a cultural symbol, commenting that ‘the gene is not *just* another part of the body ... but rather is an entity with an unprecedented social power to completely change humans.’⁷¹ This view suggests that the human genome sequence codes the human essence and that no individual or corporation should retain control over human genetic material.⁷²

However, this genocentric approach essentially equates genetic identity with personal identity. Yet it may be contended that a human is more than the sum of his or her genealogical composition, an argument that renders the metaphysical conflation of the human genetic makeup and human essence somewhat tenuous. Under this view, genes are not inherently tied to the essence of an individual; it should be noted, for example, that fruit flies share 60 per cent of their DNA with humans,⁷³ bonobos 98.7 per cent,⁷⁴ and chimpanzees more than 99 per cent.⁷⁵

⁶⁶ Patents Act (1990) (Cth) s 18.

⁶⁷ Senate Legal and Constitutional Affairs Committee, above n 42.

⁶⁸ Rogeer Hoedemaekers and Wim Dekkers, ‘Is There A Unique Moral Status of The Human DNA that Prevents Patenting?’ (2001) 4(4) *Kennedy Institute of Ethics Journal* 359, 360.

⁶⁹ Peg Tittle, *Ethical Issues in Business: Inquiries, Cases and Readings* (Broadview Press, 2000); Resnik, above n 58.

⁷⁰ Hoedemaekers and Dekkers, above n 68, 376.

⁷¹ *Ibid.*

⁷² Melissa Sturges, ‘Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Mankind’ (1997) 13 *American University International Law Review* 219, 249; Ratcliffe, above n 57, 442.

⁷³ BBC News, *Fruit Fly Genes Success* (18 February 2000) <<http://news.bbc.co.uk/2/hi/science.stm>>.

From a purely chemical perspective, human genes may therefore be considered merely another arrangement of complex molecular structures that is shared by several other living organisms, and as such they are not necessarily solely responsible for creating the unique nature of humans.⁷⁶ In fact, suggesting that humans may be reduced to a piece of code may itself constitute a very affront to human dignity to which opponents of gene patenting claim to strongly object.

C Common heritage of humankind

Opponents of human gene patenting have also argued that the current patentable status of human genes is ethically unacceptable because the human genome constitutes the common heritage of humankind.⁷⁷ The United Nations has traditionally applied the common heritage doctrine to areas such as the deep seabed and the Antarctic, declaring under Article 37(2) of the *United Nations Convention on the Law of the Sea* that such areas cannot be subject to alienation by any one state.⁷⁸ In characterising the status of the human genome, an analogy may similarly be drawn to the concept of *res communis humanitatis*, which may provide the basis for an ethical argument against permitting solely private control over the manipulation of human genomic material. According to this reasoning, it may be argued that the 'privatisation' of genetic sequence information, which it can be contended is a product of human evolutionary processes, should not belong to a single patentee, but rather to all of humankind.⁷⁹

This argument finds support in Article 1 of the *Universal Declaration on the Human Genome and Human Rights*, which states that '[t]he human genome underlies the fundamental unity of all members of the human family ... in a symbolic sense, it is the heritage of humanity.'⁸⁰ In fact, one of the primary purposes of the Human Genome Project was to identify all human genes and render them freely available within the public domain to encourage research and development and to maximise their benefit to society.⁸¹ These sentiments find expression in the Bilbao Declaration, an international statement on the legal implications of the Human Genome Project, which proclaims that the human gene sequence does not belong to any specific individual, but rather to humankind of

⁷⁴ Seth Borenstein, *Chimp Genome May Shed Light on Our Dark Side* (13 June 2012) Science on NBC News <http://www.msnbc.msn.com/id/47800795/ns/technology_and_science-science/t/hippie-chimp-genome-may-shed-light-our-dark-side/#.UIPzKRzqbRF>.

⁷⁵ Ann Gibbons, 'Bonobos Join Chimps As Closest Human Relatives', *ScienceNow* (online), 13 June 2012 <<http://news.sciencemag.org/sciencenow/2012/06/bonobo-genome-sequenced.html>>.

⁷⁶ Resnik, above n 58, 158.

⁷⁷ Patricia Lacy, 'Gene Patenting: Universal Heritage vs Reward for Human Effort' (1998) 77 *Oregon Law Review* 783, 798, citing Hubert Curien, 'The Human Genome Project and Patents' (1991) 254 *Science* 1710, 1710.

⁷⁸ *United Nations Convention on the Law of the Sea*, opened for signature 10 December 1982, 1833 UNTS 3 (entered into force 16 November 1994) art 37(2).

⁷⁹ Senate Legal and Constitutional Affairs Committee, above n 42, 51.

⁸⁰ *Universal Declaration on the Human Genome and Human Rights*, GA Res, 53rd session, A/RES/53/152 (9 December 1998).

⁸¹ Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation, National Research Council, *Reaping the Benefit of Genomic and Proteomic Research: Intellectual Property Rights, Innovation and Public Health* (National Academies Press, 2006).

present and future generations.⁸² From this concept, it can be extrapolated that human genetic information constitutes a shared resource that exists for a common benefit and should not be monopolised for the advantage of one single entity. This is arguably a practice that may be permitted under current gene patent law.

VII PROHIBITING HUMAN GENE PATENTING: COMPATIBILITY WITH AUSTRALIA'S INTERNATIONAL OBLIGATIONS

Apart from purely ethical concerns regarding the suitability of human genetic material as a patentable subject matter, a further consideration that should be noted is Australia's international obligations in relation to standards of intellectual property protection. Excluding human biological materials such as genes from patent protection may conflict with Australia's international obligations, most notably those under the *Agreement on Trade Related Aspects of Intellectual Property Rights* ('TRIPS').⁸³ This agreement establishes a minimum standard of patent protection that each member of the World Trade Organisation (WTO) must provide under domestic law. In particular, article 27(1) notes that patent protection should be available 'for any inventions, whether products or processes, *in all fields of technology*'⁸⁴ [emphasis added] and should not discriminate with respect to specific areas of technology. The *Canada-Patent Protection* case provides extensive commentary on the parameters for assessing the TRIPS non-discrimination provision.⁸⁵ In that case, the WTO Panel held that the meaning of the term 'discriminate' encompasses 'the unjustified imposition of differentially disadvantageous treatment.'⁸⁶ Excluding human genetic material from patentability may appear to subject these biological materials to differential treatment by expressly excluding these substances from patent protection.

The precise degree of freedom that domestic policy makers are afforded in legislating with respect to the patentability of *particular* materials admittedly remains uncertain. However, such freedom appears to be quite limited, with several commentators observing that article 27(1) in practice currently allows very little scope for discriminatory treatment between various fields of technology.⁸⁷

Alternatively, it may be contended that the potential discrimination between human genetic and other materials under any reforms prohibiting gene patenting is justified under article 27(2) of TRIPS. This provision permits WTO member states to exclude inventions from patentability if they are 'immoral' or contrary to the public order, providing that:

⁸² International Workshop on Legal Aspects of the Human Genome Project, 'Bilbao Declaration' (1993) 44(2) *International Digest of Health Legislation* 234; Barbara Looney, 'Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical and Policy Foundations of an International Agreement' (1995) 26 *Law & Policy in International Business* 231, 239.

⁸³ Marrakesh Agreement Establishing the World Trade Organization (Agreement on Trade-Related Aspects of Intellectual Property Rights) opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995) annex 1C ('TRIPS').

⁸⁴ TRIPS art 27(1).

⁸⁵ Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States, WTO Doc WT/DS114/R (17 March 2000).

⁸⁶ *Ibid* 49.

⁸⁷ Alison Heath, 'Preparing for the Genetic Revolution – The Effect of Gene Patents on Healthcare and Research and the Need for Reform' (2005) 11 *Canterbury Law Review* 59, 78.

members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.⁸⁸

However, it may be contended that the exclusion of human genetic material from patentability may not be permitted under article 27(2), as this exclusion does not serve to protect *ordre public* or morality under the widely accepted definition of these terms. In *Plant Genetic Systems/Glutamine Synthetase Inhibitors*, the European Patent Office Technical Board of Appeal defined *ordre public* as encompassing the protection of the environment, public security and physical integrity of individuals.⁸⁹ This definition was endorsed in *Kingdom of the Netherlands v European Parliament and Council of the European Union*,⁹⁰ where Judge Jacobs similarly concluded that inventions which were primarily likely to seriously prejudice human, animal or plant life or threaten the social structure that ties society together are contrary to *ordre public* and should be excluded from patentability.

Indeed, the *ordre public* exception has only been successfully raised in two cases within the European jurisdiction. Commentators observe that article 27(2) has a particularly narrow practical application, and any exclusions to patentability under this provision are likely to be invoked only in rare and extreme cases.

Without significant evidence that the current practice of patenting human genetic material seriously prejudices human life or undermines the structure of public order, arguments in favour of removing such material from the scope of patentability may not be able to rely on the article 27(2) exception to the *TRIPS* prohibition on discrimination. The exclusion of such biological materials from patentability may consequently attract the disapproval of other *TRIPS* member states by transgressing significant international legal obligations that Australia has assumed.

VIII PRACTICAL CONSIDERATIONS ARISING FROM THE *MYRIAD GENETICS* CASE

The current status of isolated human genetic materials as patentable raises several considerations in areas of healthcare, research and development. In particular, several concerns relate to the overall effect of gene patenting upon access to genetically derived healthcare services, such as gene therapy and cancer testing, as well as the ability to conduct unfettered biotechnological research.

A Access to healthcare services

Because a patent holder possesses an exclusive right to prohibit other parties from utilising the subject matter of a patent, patentees may exercise monopolistic control over the utilisation and manipulation of certain biological materials. This problem arises most visibly in the field of diagnostic genetic testing, in which

⁸⁸ *TRIPS* art 27(2).

⁸⁹ (Unreported, Boards of Appeal, European Patent Office, T0356/93, 21 February 1995) [5].

⁹⁰ C-377/98 9 October 2001 [38]. See also Adrian White, 'The Ethics: Gene Patenting and Human Health' (2004) 15 *Australian Intellectual Property Journal* 6, 11.

patentees may restrain any other laboratory from offering testing for specified patented genetic sequences.⁹¹ Several studies indicate that in such circumstances, patenting may lead to restricted availability and prohibitive costs of genetic and pharmacogenetic testing.⁹² This is one of the primary concerns of patient advocacy groups following the recent *Myriad Genetics* decision.

The impacts of such monopolistic market control are exemplified by the much-publicised practices of Myriad Genetics, which holds 23 patents over mutations in the BRCA1 and BRCA2 genes, traits that are strongly associated with an increased susceptibility to breast and ovarian cancer.⁹³ This company actively enforced its patents against several laboratories in the United States by refusing to grant licenses to testing laboratories or imposing highly restrictive terms on any licenses issued.⁹⁴ As a consequence, Myriad was able to require all diagnostic testing to be performed by their own laboratory at a cost greater than \$3,000 per patient.⁹⁵ In neighbouring Canada, where Myriad has not been able to impose its patent rights, the same genetic test is available at a third of the cost.⁹⁶ The figure that Myriad charges in the United States is also more than four times the \$700 that French laboratories charge,⁹⁷ as a result of which many potentially at-risk individuals are unable to afford this test.⁹⁸ Under Myriad's monopolistic business model, patients are also unable to obtain a second opinion or utilise a laboratory with alternative testing methods, impediments that greatly compromise access to reliable testing outcomes, which is particularly concerning given the possibility of false-negative test results in this field of diagnostics.⁹⁹ Cases such as Myriad highlight the potential impacts that a patent-facilitated genetic testing monopoly may have on the delivery of equitable healthcare in Australia. In fact, in 2003 and 2008, Myriad's Australian licensee, Genetic Technologies Ltd, attempted to enforce its patents on testing for the BRCA1 and BRCA2 genes in Australia, an attempt that was only eventually thwarted by sustained public objection.

Following the recent decision in *Myriad Genetics*, commentators have expressed concerns that Myriad may attempt to monopolise the tests for BRCA1 and

⁹¹ Ratcliffe, above n 57, 446; Lori Andrews, 'The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs' (2002) 2 *Houston Journal of Health Law & Policy* 65, 86.

⁹² Mildred Cho et al, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3.

⁹³ John Candlish, *Genetics, Molecular Biology and The Law* (Wildy Simmons & Hill, 2010) 178.

⁹⁴ Dianne Nicol and Jane Nielsen, 'Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry' (Occasional Paper No 6, Centre for Law and Genetics, 2003) 9.

⁹⁵ Jonathan Stempel, 'Myriad Wins Gene Patent Ruling from US Appeals Court', *Reuters* (online), 16 August 2012 <<http://www.reuters.com/article/2012/08/16/us-myriad-patent-idUSBRE87F12K20120816>>; Lori Andrews and Jordan Paradise, 'Gene Patents: The Need for Bioethics Scrutiny and Legal Change' (2005) 5 *Yale Journal of Health, Policy, Law & Ethics* 403, 408.

⁹⁶ 'Gene Monopoly; Australian Court Rules in Favor of Genetic Patenting', *RT News* (online) 16 February 2013 <<http://rt.com/news/australia-genes-patent-law-368/>>.

⁹⁷ Candlish, above n 93, 178.

⁹⁸ Alexandra Ridley and Dianne Nicol, 'Is There Still a Place for Gene Patents in Australia?' (2011) 19 *Journal of Law and Medicine* 282, 288.

⁹⁹ *Ibid.*

BRCA2 genetic mutations,¹⁰⁰ which may include demands that public hospitals do not provide these tests.¹⁰¹ If this occurs, the resulting inequity in access to such testing would concentrate the benefits of gene testing technology within a narrow stratum of society. However, the benefits and burdens of scientific undertakings should arguably be equally distributed in a manner that does not disproportionately disadvantage any groups in a society.¹⁰² The ability to charge exploitative prices for genetic testing that is inherent in a patent-facilitated market monopoly would render the financially disadvantaged segments of the community unable to access diagnostic services. Although the government offers diagnostic services through its genetic familial cancer testing scheme as well as the Medicare Benefits Schedule,¹⁰³ which offer financially accessible testing for particular medical conditions, the range of testing that these services provide is currently very limited. In this respect, the market monopoly facilitated by the patentability of genetic testing under the *Patents Act 1990* (Cth) and current gene patent jurisprudence may have the potential to hinder access to genetic testing and treatment.

On the other hand, it may be argued that these concerns may not necessarily bear out in practice in the Australian jurisdiction. Although companies in foreign jurisdictions, particularly the United States, have actively attempted to enforce patents over genetic testing processes, studies conducted in Australia have provided little evidence that instances of attempted patent enforcement against laboratories are as prevalent in the Australian environment.¹⁰⁴ A study by Professor Dianne Nicol and Dr Jane Nielsen found that, while fears may exist regarding the enforcement of gene patents, in practice, very few companies have actively attempted to enforce their patent rights.¹⁰⁵

However, this situation may change in the near future, following the precedent set by *Myriad Genetics* as well as the growth of the Australian biotechnology sector, which may lead to increased levels of domestic patent enforcement. In 2012, 82 per cent of Australian biotechnology firms experienced significant growth.¹⁰⁶ In fact, the ten fastest-growing biotechnology companies in the Asia Pacific region in 2011 were all Australian companies, with the first-ranking firm Mesoblast Ltd experiencing 2802 per cent growth, Biotron 583 per cent and Prana Biotechnology 355 per cent.¹⁰⁷ The increased commercialisation of this sector may lead to patent rights being more strictly enforced to protect valuable market investments, an occurrence that could considerably change the landscape of patent

¹⁰⁰ 'Call for Change in Gene Patent Laws', *The Age* (online), 15 February 2013 <<http://news.theage.com.au/breaking-news-national/calls-for-law-change-after-gene-ruling-20130215-2egvc.html>>.

¹⁰¹ *Ruling on Gene Patents Highlights Need to Change Law* (15 February 2013) Cancer Council of Australia <<http://www.cancer.org.au/news/media-releases/ruling-on-gene-patents-highlights-need-to-change-law.html>>.

¹⁰² Beauchamp and Childress, above n 58, 258; Lacy, above n 77, 801.

¹⁰³ Australian Medical Association, *Genetic Testing 2012* (April 2012) <<http://ama.com.au/position-statement/genetic-testing-2012>>.

¹⁰⁴ Nicol and Nielsen, above n 94, xi.

¹⁰⁵ *Ibid* 42.

¹⁰⁶ AusBiotech, *Industry Position Survey: Biotechnology* (April 2012) <http://www.ausbiotech.org/data/downloads/Biotechnology%20survey%202012_Final.pdf>.

¹⁰⁷ 'Asia's Fastest 50 Companies', *BioSpectrum* (online), June 2012, 7.

enforcement in the field of biotechnology. Additionally, with advances in genetic sequencing, researchers will be able to make further scientific findings that investors may seek to commercially exploit through the use of patents. For example, in September 2012, through parallel sequencing of the exome, scientists at Melbourne's Peter MacCallum Cancer Centre identified two new risk-predisposing mutations in the FANCC and BLM genes, which are each believed to be another gene indicative of increased breast cancer susceptibility.¹⁰⁸ Developments such as these may provide the basis for the invention of new types of gene-based diagnostic testing, possibly creating more situations in which entities will attempt to protect their commercial interests by enforcing patent rights. In practice, this may lead to the establishment of gene monopolies in the area of healthcare provision to the possible detriment of patients who may need to pay increased costs to access such services.

*B Commercialising innovation:
the effects of patentability on research and investment*

1 Patents as incentives to invest

On the other hand, within the biotechnology industry, gene patents act as the currency that is used to encourage investment in research and development. Although the ultimate role of patents is to exclude competitors from exploiting a patentee's invention, the legalised monopolies that patents create also incentivise innovation by providing investors with greater security of investment returns.¹⁰⁹ The research and development of biologic medicines is a complex, expensive and protracted undertaking, with a new drug often necessitating more than a decade to develop and approximately \$1.2 billion to bring to market.¹¹⁰ Due to this high cost of conducting pre-commercialisation research and development, it is important for businesses, particularly small start-up research entities, to secure investment. Enterprise investors would have little incentive to incur the extremely high initial capital input necessary to develop biologic medical products, conduct trials and obtain marketing approval, without a relatively secured opportunity to recover their initial investment. Such an opportunity is presented through the legally defined period of market exclusivity that is provided for under the *Patents Act* for patented inventions.

This is particularly important in the development of diagnostics, with commentators observing that 'diagnostics are notoriously low-profit margin products ... if the right to develop a diagnostic were to be shared by more than one company, the economic incentive to develop it is likely to evaporate.'¹¹¹ In other words, the absence of an award of monopolistic control over

¹⁰⁸ Peter MacCallum Cancer Centre, 'Finding Pieces of The Breast Cancer Puzzle: Exome Analysis Reveals Two Potential Risk-Predisposing Genes' (Media Release, 28 September 2012) 1; Ella Thompson et al, 'Exome Sequencing Identifies Rare Deleterious Mutations in DNA Repair Genes FANCC and BLM as Potential Breast Cancer Susceptibility Alleles' (2012) 8 *PLOS Genetics* 1, 2.

¹⁰⁹ Centre for International Economics, *Economic Analysis of the Impact of Isolated Human Gene Patents* Final Report (2013) 33.

¹¹⁰ *Ibid.*, 89; Senate Legal and Constitutional Affairs Committee, above n 42, 45.

¹¹¹ Aparna Surendran, 'US NIH Draft Guidelines Threaten Diagnostics Sector' (2004) 22 *Nature Biotechnology* 496, 496; Brian Zadorozny, 'The Advent of Gene Patenting: Putting the Great Debate in Perspective' (2010) 13 *SMU Science and Technology Law Review* 89, 94.

biotechnological inventions may disincentivise investment in this area. Additionally, because biotechnological inventions are expensive to produce, yet comparatively inexpensive to re-produce, without patent protection, market competitors could relatively inexpensively reverse engineer non-patented inventions,¹¹² hampering the ability of investors to recover funds. The right of market exclusion that patents grant assists in mitigating such risks.¹¹³

Removing human genetic material from the ambit of patentability may therefore detract from the advantages provided by the current research investment paradigm. The effects of this would extend to many institutions, including universities, which file approximately 40 per cent of all applications on gene sequences and are increasingly reliant on external funding through partnerships with corporate and venture capital entities,¹¹⁴ particularly in light of the significant cuts to government research funding that were announced in October 2012.¹¹⁵ The ability of these research institutions to attract commercial partnerships is currently strengthened by relatively greater tangible investment security that patents offer. In fact, The University of Sydney has estimated that restrictions to current patent law would undermine the patentability of many inventions generated by their science and medicine faculties, and that over 25 per cent of its 221 active patent families would be adversely affected.¹¹⁶ Therefore, although opponents of gene patenting purport to promote unfettered research and development, restricting current patent law may ultimately have the potential to hamper such research endeavours.

In addition, restricting the patentability of human genetic material has the potential to not only undermine domestic, but also foreign investment. A prohibition on the patenting of such biological materials would be productive of a disparity between the legal intellectual property framework of Australia and foreign jurisdictions. As a corollary of the comparative restrictiveness that would be generated within the Australian intellectual property law environment, foreign investment flow into the domestic biotechnology industry may be deterred or technology transfer from overseas entities may be significantly reduced.¹¹⁷ Additionally, restrictive patenting laws may also disincentivise the release of overseas-produced drugs into the Australian market due to manufacturers' concerns of exposing their products to intellectual property free-riders. This would greatly limit the commercialisation and availability of new products within the domestic market. Considering that globally, there are currently over 400 biological drugs in development aimed at treating illnesses such as cancer, diabetes and Alzheimer's,¹¹⁸ the exclusion of human biological materials from the

¹¹² Senate Legal and Constitutional Affairs Committee, above n 42, 45.

¹¹³ Zadorozny, above n 111, 102; Centre for International Economics, above n 109, 95.

¹¹⁴ Australian Law Reform Commission, above n 23, 409.

¹¹⁵ Andrew Trounson, 'Research Cut Stirs University Divisions', *The Australian* (online), 24 October 2012 <<http://www.theaustralian.com.au/higher-education/research-cut-stirs-university-divisions/story-e6frgcjx-1226501828960>>; Bianca Hall, 'Research Cuts Anger Universities', *Sydney Morning Herald* (online), 22 October 2012 <<http://www.smh.com.au/opinion/political-news/research-cuts-anger-universities-20121022-280zv.html>>.

¹¹⁶ Senate Legal and Constitutional Affairs Committee, above n 42, 48.

¹¹⁷ *Ibid* 46.

¹¹⁸ Evidence to the Senate Legal and Constitutional Affairs Committee, *Patent Amendment (Human Genes and Biological Materials) Bill 2010*, Canberra, 28 April 2011, 36 (Brendan Shaw).

ambit of patentability may significantly limit Australian patients' access to such newly developed drugs.

Recent studies also indicate that if the patentability of human biological materials is prohibited, Australian biotechnology firms may face significant challenges, not only in attracting capital investment, but also in securing downstream partners, research collaborators and later-stage alliances with pharmaceutical companies.¹¹⁹ Professor Dianne Nicol emphasises the instrumentality of patents in attracting such partnerships, observing:

Patents are often used to get venture capital and to negotiate with downstream pharmaceutical companies and partners, and they are all looking for robust intellectual property protection. So if there is any uncertainty about the scope of protection, this could well deter investment [and] deter downstream partnering opportunities.¹²⁰

Removing patent protection for biological inventions may accordingly undermine many incentives for a wide range of entities to invest in biotechnological firms, which may ultimately stymie progress in research and development.

2 *Monopoly over the market, not over scientific knowledge?*

The unfettered dissemination of knowledge has traditionally been a central tenet of promoting scientific endeavour.¹²¹ Professor Robert Merton describes this flow of information as 'an integral element of the scientific ethos.'¹²² He observes that:

Substantive findings of science are a product of social collaboration and [should be] assigned to the community ... The institutional conception of science as part of the public domain is linked with the imperative for the communication of findings. Secrecy is the antithesis of this norm.¹²³

The rate of progress in realising medical advancements depends on the extent to which the results of investigations flow freely among researchers. Under this ethos of sharing, patents are theorised to incentivise disclosure and avoid the suppression of scientific information by providing protection for researchers' findings, which in turn enables them to disclose their knowledge.¹²⁴ Removing the ability to patent biological inventions may diminish this level of protection for research output, which may result in greater reluctance to disseminate results. Some open-access resource regimes do attempt to facilitate the dissemination of

¹¹⁹ Dianne Nicol, 'Implications of DNA Patenting: Reviewing the Evidence' (2011) 21 *Journal of Law and Information Science* 7, 33.

¹²⁰ Evidence to the Senate Legal and Constitutional Affairs Committee, *Patent Amendment (Human Genes and Biological Materials) Bill 2010*, Canberra, 28 April 2011, 60 (Dianne Nicol); Senate Legal and Constitutional Affairs Committee, above n 41, 45.

¹²¹ Frank Washko, 'Should Ethics Play a Special Role in Patent Law?' (2006) 19 *Georgetown Journal of Legal Ethics* 1027, 1028.

¹²² Robert K Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (University of Chicago Press, 1973) 273–4.

¹²³ *Ibid.*

¹²⁴ Matthew Rimmer and Alison McLennan, *Intellectual Property and Emerging Technologies: The New Biology* (Edward Elgar, 2012) 198; Looney, above n 82, 244; Ruth Macklin, above n 65, 134; Ratcliffe, above n 57, 445.

information outside the patent system, such as the BioBricks commons model, which promotes the proactive disclosure of scientific knowledge despite the non-assertion of intellectual property rights.¹²⁵ However, these programs remain in a nascent state and would not likely constitute a practical and widespread means of sharing information in the near future.

In this respect, removing the element of protection provided by patents may detract from researchers' willingness to publicise findings. If gene patenting is restricted, then logically one way for entities to protect their investments is to keep scientific advances confidential. This may create a risk that biotechnology and pharmaceutical companies may shift to a model of trade secrets, for which there are no time limits or statutory limitations after which an invention becomes open to exploitation by others.¹²⁶ Such a situation would detract from the scientific community's ability to compile an extensive shared knowledge base to facilitate the development of follow-on inventions. Without the free exchange of published scientific findings, researchers may also unknowingly build on knowledge that constitutes less than the total accumulation of current scientific understanding, or even duplicate research efforts.¹²⁷ Prohibiting the patenting of human genetic material could therefore undermine the current information-sharing paradigm that operates within the area of biotechnology under the *Patents Act*.

3 *Patents stifle research: the concept of the scientific anticommons*

On the other hand, it may be argued that patenting does not have a positive, but rather an inhibitory effect on biotechnological research and development.¹²⁸ Pursuant to this view, patenting biological materials has the potential to create a scientific 'anticommons'.¹²⁹ Professors Michael Heller and Rebecca Eisenberg crystallised this concern in their theory of the 'tragedy of the anticommons', which posits that when multiple patent holders actively enforce their exclusivity rights over a scarce resource, potentially valuable resources will be rendered prone to underuse.¹³⁰

Applying this theory, a large number of patents on biotechnological inventions creates a 'patent thicket,' in which an overlapping set of broad foundational patent rights requires researchers intending to commercialise new biotechnological inventions to enter into multiple license negotiations with several patentees to obtain highly expensive licenses.¹³¹ It has been noted that 'these obligations

¹²⁵ BioBricks Foundation, *Programs* (2012) <<http://biobricks.org/programs/>>.

¹²⁶ Senate Legal and Constitutional Affairs Committee, above n 42, 50.

¹²⁷ David Blumenthal et al, 'Data Withholding in Academic Genetics' (2002) 287 *Journal of the American Medical Association* 473, 473.

¹²⁸ Timothy Caulfield, 'Human Gene Patents: Proof of Problems' (2010) 84 *Chicago-Kent Law Review* 133, 136.

¹²⁹ Michael Heller and Rebecca Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698.

¹³⁰ *Ibid*; Rimmer and McLennan, above n 124, 272; Caulfield, above n 128, 136.

¹³¹ Carl Shapiro, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting' in Adam Jaffe, Josh Lerner and Scott Stern (eds), *Innovation, Policy and the Economy* (MIT Press, 2001) 119; Zadorozny, above n 88, 105.

significantly delay or even halt the pace of innovation.’¹³² This situation problematises in several ways the acquisition of information necessary for scientific progress; obtaining multiple licenses is not only a complex and time-consuming undertaking extraneous to research activities, but it also involves considerable financial resources. In this respect, patents particularly restrict the ability of downstream researchers to access upstream patented inventions in order to transform gene technology into commercial products. This is due to the cumulative nature of royalty stacking and reach-through royalty provisions, under which downstream firms carry a significant financial burden to pay royalty fees to licensors. Firms that operate in highly competitive fields, such as vaccine development and cancer therapy, must also navigate a complex patent landscape regarding genes, cell lines, vectors, antigens and other technologies, often requiring multiple in-line licenses to secure permission to develop their products.¹³³ For example, the Malaria Vaccine Initiative has been confronted with several complex patent claims relating to the Merozoite surface protein-1, a pathogen instrumental in developing a vaccine for this parasitic disease. Several different patent families were attached to this biological material, as well as to add-on technologies concerned with other specialised antigens and nucleic acid sequences that are of significant utility in constructing a vaccine.¹³⁴ The Malaria Vaccine Initiative is concerned that royalty stacking and excessive licence fees may severely hinder further research into the malaria vaccine. In such situations, commercial research organisations may often consider shifting to another area of research due to the complexity of patents on necessary research tools.¹³⁵ Interferences such as these may ultimately hinder the development of biological technologies that can provide valuable benefits to public healthcare.

4 *The anticommons theory in practice*

However, the detrimental effects predicated by the anticommons theory in the field of biotechnological research have not necessarily been supported by empirical studies.¹³⁶ Research findings support the theory that the ability to patent biological materials does not generally have an inhibitory effect on scientific research.¹³⁷ Most notably, a survey of 381 academic scientists indicated

¹³² Matthew Rimmer, *Patent Law and Biological Inventions* (Federation Press, 2006) 86. See also Heller and Eisenberg, above n 129; Rebecca Eisenberg, ‘Bargaining over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?’ in Rochelle Dreyfuss, Diane Zimmerman and Harry First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (Oxford University Press, 2001).

¹³³ Nicol, above n 119, 33.

¹³⁴ Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (Nuffield Council, 2002) 43.

¹³⁵ Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights* (2002) <http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf>.

¹³⁶ Stephen Schilling, ‘DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents’ (2012) 61 *Duke Law Journal* 731, 746; Timothy Caulfield, ‘Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies’ (2006) 24 *Nature Biotechnology* 1091, 1092; Christopher Holman, ‘The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation’ (2007) 76 *University of Missouri-Kansas City Law Review* 295; David Castle, ‘Intellectual Property and Nutrigenomics’ (2008) 16 *Health Law Review* 58, 62; Caulfield, above n 128, 138.

¹³⁷ Rimmer and McLennan, above n 124, 82.

that only one per cent reported experiencing delays or having to make modifications due to the existence of third-party patents,¹³⁸ with no researchers reporting that investigations were halted by such patents.¹³⁹ The survey found 'little empirical basis for claims that restricted access to intellectual property is currently impeding biomedical research.'¹⁴⁰ Highly similar results are reflected in a survey conducted by Professor Dianne Nicol and Dr Jane Nielsen.¹⁴¹ Their study concluded that very few researchers are in fact concerned about any possible restrictive effects on access to research inputs or hindrances to scientific investigations due to the existence of patent claims over substances that they are utilising in research activities. The study found that in most cases, research is able to proceed in a very similar fashion, despite the existence of such patents.¹⁴²

An examination of the effects of patenting human biological substances therefore suggests that the patentability of these materials may not necessarily be inhibitory to the effective provision of genetically derived healthcare services and the capacity to conduct unfettered biotechnological research.

IX WEIGHING UP THE COMPETING CONSIDERATIONS

As examined above, following the outcome in *Myriad Genetics*, one of the main concerns expressed by the community relates to the possibility of increased costs and a decline in the availability of genetic testing for conditions with genetic markers. While it is important to encourage innovation and research through the patent system, it is equally important to ensure that the public interest is met through the delivery of affordable genetic testing and treatment services. If gene patent law continues to allow the patenting of naturally occurring gene sequences, safeguards must be utilised to address concerns regarding the possibility of decreased access to healthcare services.

In such a situation, government agencies could be required to intervene to prevent companies with gene monopolies charging unaffordable fees for genetic tests and treatment. One option in this respect may involve the invocation of compulsory licenses,¹⁴³ which are authorisations provided by a national authority, without or against the consent of the patent holder, that permit the exploration of a patented product or process.¹⁴⁴ Under s 133(1) of the *Patents Act*, a court may grant a compulsory license if the 'reasonable requirements of the public' with respect to a patented invention have not been satisfied.¹⁴⁵ An application could be made, for example, in a situation where demand in Australia for a patented product is not being met and the patent holder refuses to supply the product on reasonable terms.¹⁴⁶ Such a licence, if granted, may enable a public sector health authority or

¹³⁸ John Walsh, Charlene Cho and Wesley Cohen, 'View from the Bench: Patents and Material Transfers' (2005) 309 *Science* 2002, 2002.

¹³⁹ Schilling, above n 136, 747.

¹⁴⁰ *Ibid.*

¹⁴¹ Nicol and Nielsen, above n 69, 172.

¹⁴² *Ibid.*

¹⁴³ Human Genetics Society of Australasia, *HGSA Urges Federal Government to be Prepared to Defend Human Genetic Testing* (18 February 2013) <<http://www.hgsa.org.au/2013/02/hgsa-urges-federal-government-to-be-prepared-to-defend-human-genetic-testing/>>.

¹⁴⁴ William van Caenegem, *Intellectual Property Law in Australia* (Wolters Kluwer, 2010) 112.

¹⁴⁵ *Patents Act 1990* (Cth) s 133(2)

¹⁴⁶ *Patents Act 1990* (Cth) s 135.

other organisation to provide a patented medical genetic test or healthcare service where patients' needs are not being adequately met. Although few compulsory licenses have so far been granted under Australian patent law, this option may provide an avenue for redressing community concerns about the affordability of genetic testing and biogenetic healthcare.

An alternative option may be for public healthcare providers to invoke the Crown use provisions under the *Patents Act*.¹⁴⁷ Under these provisions, state or federal government bodies are entitled to exploit a patented invention, without first obtaining permission from the patent holder to meet the healthcare needs of the Australian community. This may allow authorised entities to provide access to medical genetic testing that involves patented processes or products.¹⁴⁸ Although rarely invoked in the past, this option may provide another mechanism to address concerns that gene patents may adversely impact upon the provision of healthcare services to the public. However, whether these existing legal mechanisms will be able to effectively redress concerns regarding possible limitations in access to genetic testing and treatment is difficult to assess at this stage.

X CONCLUSION

Despite several recent calls for reforms to patent law following the case of *Myriad Genetics*, the issue of human gene patenting must be considered cautiously. This area inherently raises several complex legal, ethical and practical questions. Patenting in the field of biotechnology may provide an incentive mechanism for investment and the dissemination of research findings, which are central tenets of scientific endeavour. A closer examination of patenting from an ethics perspective also suggests that patenting biological materials will not necessarily precipitate the complete commodification of human beings, nor does it derogate from the intrinsic worth and uniqueness of individuals. However, in spite of this, concerns that the monopolistic market control that is facilitated by patents may derogate from achieving equitable access to genetic testing and biogenetic healthcare services are rightly justified and must therefore be addressed through government initiatives to ensure that the research and development benefits that patents provide will flow into the community. Indeed, given the growing importance and attention that gene patenting has recently gained, the gene patenting debate is likely to be re-ignited once more in the Australian Parliament and these issues will receive greater consideration, a welcome process in light of the rapid development of genetic technology and the increasing global significance that gene patenting has assumed both in Australia and overseas.

¹⁴⁷ *Patents Act 1990* (Cth) s 163(1).

¹⁴⁸ *Stack v Brisbane City Council* (1994) 131 ALR 333.