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# Medical law reporter

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## CANCER VOICES AUSTRALIA v MYRIAD GENETICS INC [2013] FCA 65: SHOULD GENE PATENT MONOPOLIES TRUMP PUBLIC HEALTH?

*At a time when the double mastectomy of Angelina Jolie has highlighted the importance of genetic testing for breast cancer, the Federal Court's decision in Cancer Voices Australia v Myriad Genetics Inc [2013] FCA 65 has clarified that, for now at least, isolated DNA and RNA can constitute a patentable invention under s 18(1)(a) of the Patents Act 1990 (Cth). This is a significant decision for companies seeking to secure patents over DNA and genetic material, whether isolated or not. This column critically examines this case in the context of parallel legal action currently underway in the United States. It also reviews it with regard to political and bureaucratic inaction in Australia (much of which relies upon an overly restrictive interpretation of the High Court decision in National Research Development Corp v Commissioner of Patents (1959) 102 CLR 252) that has compromised the setting of cost-effective public health limits on patentable subject matter concerning the human genome.*

### INTRODUCTION

Few debates at the borders of law and technology have resonated within individual and community conscience as much as that concerning the patenting of human DNA and other genetic materials (gene patents). For almost 20 years, the issue has received significant attention from academics, governments and the research community.<sup>1</sup> Repeated attempts by Members of the House of Representatives and Senators to amend Australia's *Patents Act 1990* (Cth) to ban gene patents have been defeated by the biotechnology corporate sector, related research organisations and risk-averse government policy-makers.<sup>2</sup>

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<sup>1</sup> For a small sample of the debate surrounding gene patents see Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health, Report 99* (Commonwealth of Australia, Sydney, 2004), <http://www.alrc.gov.au/publications/report-99> viewed 1 March 2013; Australian Parliament, Senate Community Affairs Reference Committee, *Gene Patents* (Senate, Canberra, 2010), [http://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate\\_Committees?url=clac\\_ctte/completed\\_inquiries/2008-10/gene\\_patents/report/index.htm](http://www.aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=clac_ctte/completed_inquiries/2008-10/gene_patents/report/index.htm) viewed 1 March 2013; Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), <http://www.nuffieldbioethics.org/patenting-dna/patenting-dna-chapter-downloads> viewed 1 March 2013; Walpole I, Dawkins HJS, Sinden PD et al, "Human Gene Patents: The Possible Impacts on Genetic Services Healthcare" (2003) 179 MJA 203; Nicol D, "Human Gene Patents: Under Whose Control?" (2003) 179(4) MJA 181; Lawson C, "Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition" (2002) 30 FL Rev 97; Nicol D, "On the Legality of Gene Patents" (2005) 29 MULR 809; Palombi L, *Gene Cartels: Biotech Patents in the Age of Free Trade* (Edward Elgar Publishing Ltd, USA, 2009).

<sup>2</sup> See the Australian Democrats' *Patent Amendment Bill 1996* (Cth); Senator Bill Heffernan's *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (Cth); and Melissa Parke MP's own, as yet untabled, Private Members' Bill: ABC, "Gene Research Should be An Open Playing Field", *Lateline* (14 May 2012), <http://www.abc.net.au/lateline/content/2012/s3502733.htm> viewed 14 March 2013. The threat of "unintended consequences" was recently used to successfully scuttle Senator Bill Heffernan's Private Members' Bill: Australian Parliament, *Patent Amendment (Human Genes and Biological Materials) Bill 2010 Final Report* (2011), [http://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate\\_Committees?url=legcon\\_ctte/completed\\_inquiries/2010-13/patent\\_amendment/report/index.htm](http://www.aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=legcon_ctte/completed_inquiries/2010-13/patent_amendment/report/index.htm) viewed 2 March 2013; see also Palombi L, "Who Owns the Rights to the Human Body? It's Patently Obvious", *The Conversation* (31 May 2011), <https://theconversation.edu.au/who-owns-the-rights-to-the-human-body-its-patently-obvious-835> viewed 1 March 2013, cf Hilton D and Clark J, "Patent Amendment Bill Could Kill Access to New Medicines", *The Conversation* (31 May 2011), <http://theconversation.edu.au/patent-amendment-bill-could-kill-access-to-new-medicines-637> viewed 1 March 2013.

This column does not propose to revisit the gene patents policy debate except to focus on a recent court decision with significant implications for the question of whether “isolated” or “purified” DNA constitutes a “patentable invention”. The decision in question is that of a single judge of the Australian Federal Court in *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65. It held that isolated or purified genomic DNA, as well as complementary DNA (cDNA), can be patented. The authors explore the extent to which this case supports the view that a doctrinaire approach to the High Court of Australia’s “celebrated”<sup>3</sup> decision on what constitutes a patentable invention in *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 (NRDC) has facilitated the subversion of important social and environmental limitations on patent monopolies.<sup>4</sup>

## BACKGROUND: THE BRCA CANCER GENES AND MYRIAD’S PATENT

Germline mutations in various genes, including *TP53*, *PTEN*, *STK11/LKB1*, *CDHI*, *CHEK2*, *ATM*, *MLH1* and *MSH2*, are associated with an increased risk of hereditary breast and ovarian cancer.<sup>5</sup> Two specific genes, the **Breast Cancer gene 1** (BRCA1) and **Breast Cancer gene 2** (BRCA2), are held responsible for the majority of inheritable breast and ovarian cancers,<sup>6</sup> and some 5 to 10% of breast cancers among women in the United States.<sup>7</sup> Women with a harmful mutation in either BRCA gene have a lifetime risk of breast cancer some five times higher than women without a mutation.<sup>8</sup> Advances in genetic screening and diagnostics, coupled with gene-specific therapeutics,<sup>9</sup> have improved survival times for women with advanced cancers and allow at-risk women to take measures to avoid hereditary breast and ovarian cancers, eg “prophylactic” or “preventative” mastectomy and/or abdominal hysterectomy with bilateral salpingo-oophorectomy.<sup>10</sup>

Such radical measures, even if described as preventative, can only be ethically suggested by health practitioners on the basis of adequate and accurate clinical data, preferably supported by more than one genetic test. Supporting this ethical norm are the Medical Board of Australia’s guidelines entitled *Good Medical Practice*, which require doctors to consider “the balance of benefit and harm in all clinical-management decisions” in their care of a patient, to provide “treatment options based on the best available information”, and to support their patient’s “right” to seek “a second opinion”.<sup>11</sup> The ability of doctors and their women patients to access accurate and affordable genetic testing has been

<sup>3</sup> *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 was referred to as a “celebrated” judgment in *Grain Pool (WA) v Commonwealth* (2000) 202 CLR 479 at [45] (Gleeson CJ, Gaudron, McHugh, Gummow, Hayne and Callinan JJ).

<sup>4</sup> *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46 at [138] (Lord Walker).

<sup>5</sup> National Cancer Institute, *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA> viewed 8 March 2013; Turnbull C and Rahman N, “Genetic Predisposition to Breast Cancer: Past, Present, and Future” (2008) 9(3) *Annual Review Genomics Human Genetics* 321; Campeau PM, Foulkes WD and Tischkowitz MD, “Hereditary Breast Cancer: New Genetic Developments, New Therapeutic Avenues” (2008) 124(1) *Human Genetics* 31.

<sup>6</sup> “According to the Patent, mutation of the BRCA1 gene is thought to account for approximately 45% of familial (hereditary) breast cancer, and at least 80% of familial cancer involving both breast and ovarian cancer”: *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 at [57]; National Cancer Institute, n 5.

<sup>7</sup> National Cancer Institute, n 5.

<sup>8</sup> Breast cancer is the second leading cause of cancer deaths for Australian women: Cancer Australia, *Report to the Nation – Breast Cancer 2012* (Cancer Australia, Sydney, 2012) p 11; National Cancer Institute, n 5.

<sup>9</sup> For example, Trastuzumab (brand name HERCEPTIN™).

<sup>10</sup> Bacha OM, Gregoire J, Grondin K et al, “Effectiveness of Risk-reducing Salpingo-oophorectomy in Preventing Ovarian Cancer in a High-risk French Canadian Population” (2012) 22(6) *International Journal of Gynaecological Cancer* 974; Berek JS, Chalas E, Edelson M et al, “Prophylactic and Risk-reducing Bilateral Salpingo-oophorectomy: Recommendations Based on Risk of Ovarian Cancer” (2010) 116(3) *Obstetrics and Gynecology* 733; National Cancer Institute, *Preventive Mastectomy*, <http://www.cancer.gov/cancertopics/factsheet/Therapy/preventive-mastectomy> viewed 8 March 2013.

<sup>11</sup> Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia* (AHPRA) at [2.2.4], [2.2.6], [2.2.8], <http://www.medicalboard.gov.au/Codes-Guidelines-Policies.aspx> viewed 10 March 2013; see also Australian Medical Association, *Code of Ethics* (2004, revised 2006), <https://ama.com.au/codeofethics> viewed 10 March 2013; World Medical Association, *International Code of Medical Ethics*, adopted by the 3rd General Assembly of the World Medical Association, London, England, October 1949 (as amended at the 57th WMA General Assembly, Pilanesberg, South Africa, October 2006),

hindered, however, by patent monopolies which have claimed broad rights over isolated genomic DNA and, in the *Myriad Genetics Inc* case, delayed affordable access to more accurate diagnostic tests.<sup>12</sup>

In 1995 Myriad Genetics Inc, a United States company based in Salt Lake City, Utah, filed a standard patent application with IP Australia.<sup>13</sup> The claimed invention was titled “in vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene” and related to “methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene (BRCA1), some mutant alleles of which cause susceptibility to cancer, in particular breast and ovarian cancer”.<sup>14</sup>

Myriad’s patent included 30 specific claims, including three “composition of matter” (or subject matter) claims (at [69]):

- (1) an isolated nucleic acid coding for a mutant or polymorphic BRCA1 polypeptide, said nucleic acid containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No:1 one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19 [of the patent];
- (2) an isolated nucleic acid as claimed in claim 1 which is a DNA coding for a mutant BRCA1 polypeptide, said DNA containing in comparison to BRCA1 polypeptide encoding sequence set forward in SEQ.ID No:1 one or more mutations set forth in Tables 12, 12A and 14 [of the patent]; and
- (3) an isolated nucleic acid as claimed in claim 1 which is a DNA coding for a polymorphic BRCA1 polypeptide, said DNA containing in comparison to the BRCA1 polypeptide encoding sequence set forward in SEQ.ID No:1 one or more polymorphisms set forth in Tables 18 and 19 [of the patent].

As outlined in the patent specification, “SEQ.ID No 1” is a “sequence listing” for the BRCA1 wild-type gene (at [64]). This sequence “consists of 5,914 base pairs and represents the coding sequence of a nucleic acid (cDNA) which encodes the BRCA1 polypeptide”. Federal Court judge Nicholas J argued that, because the listing is confined to the cDNA, it contains “only the exonic sequences including the non-coding sequences that appear at the beginning and end of the sequence” (at [64]). Myriad’s patent also included several “method” claims over various diagnostic techniques, the most broad one claiming a patent over

a method for diagnosing a predisposition for breast and ovarian cancer in a human subject which comprises determining whether there is a germline alteration in the sequence of the BRCA 1 gene in a tissue sample of said subject compared to the nucleotide sequence set forth in SEQ.ID No:1 or a wild-type allelic variant thereof, said alteration indicating a predisposition to said cancer being selected from the mutations as set forth in Tables 12, 12A and 14.<sup>15</sup>

## CANCER VOICES AUSTRALIA V MYRIAD GENETICS INC

After facing no opposition or requests for re-examination, Myriad’s patent was sealed by IP Australia in June 1998.<sup>16</sup> While Myriad provides its own “BRCA*Analysis*” [sic] testing services in the United States,<sup>17</sup> it entered into an exclusive licence arrangement with Gene Technology Ltd (GTL) in Australia to provide BRCA1 and BRCA2 testing for Australian women. GTL’s history of

<http://www.wma.net/en/30publications/10policies/c8> viewed 10 March 2013.

<sup>12</sup> See American Civil Liberties Union (ACLU), *BRCA: Plaintiffs’ Memo in Support of Motion for Summary Judgment* (2009), <http://www.aclu.org/free-speech-womens-rights/brca-plaintiffs-memo-support-motion-summary-judgement> viewed 10 March 2013; ACLU, *BRCA: Complaint* (2009) at [102], [103], <http://www.aclu.org/free-speech/brca-complaint> viewed 10 March 2013.

<sup>13</sup> Information on Patent No 686004 can be found on IP Australia’s Patent Database, <http://pericles.ipaustralia.gov.au/ols/auspat/applicationDetails.do?applicationNo=1995033212#> viewed 8 March 2013.

<sup>14</sup> Patent No 686004, <http://pericles.ipaustralia.gov.au/ols/auspat/applicationDetails.do?applicationNo=1995033212#> viewed 8 March 2013.

<sup>15</sup> Claim 17, Patent No 686004, <http://pericles.ipaustralia.gov.au/ols/auspat/applicationDetails.do?applicationNo=1995033212#> viewed 8 March 2013.

<sup>16</sup> The latest the patent will expire is 11 October 2015.

<sup>17</sup> Myriad Genetics, *BRCAAnalysis*, <http://www.myriad.com/products/bracanalysis> viewed 10 March 2013.

on-and-off-again enforcement and “gifting” of its BRCA licence rights has been well documented and led directly to the present legal challenge in the Federal Court,<sup>18</sup> as did Myriad’s own pro-monopolist behaviour in the United States judicial system.<sup>19</sup>

In June 2010 Ms Yvonne D’Arcy and cancer support organisation Cancer Voices Australia (Cancer Voices) (collectively, the applicants) commenced proceedings in the Sydney registry of the Federal Court of Australia to challenge the validity of Myriad’s BRCA1 gene patent.<sup>20</sup> Specifically, the applicants sought an order to “revoke claims 1, 2 and 3 of Australian Patent No 686004 on the ground that they do not disclose a ‘patentable invention’ for the purpose of s 18(1)(a) of the [*Patents Act 1990* (the Act)]”.<sup>21</sup> The applicants’ case was modelled on, and referred to, a similar action in the United States.<sup>22</sup>

In contrast to the United States challenge, however, the Australian case focused solely on the composition claims, not the diagnostic methods claims (eg, Claim 17). Furthermore, the applicants limited the grounds of their challenge to invalidity under s 18(1)(a) of the Act (no “patentable invention”) and did not argue any other ground of invalidity, such as “lack of novelty, lack of inventive step, [or] lack of utility” (at [8]).<sup>23</sup>

The United States plaintiffs in their challenge attacked numerous composition and method claims by Myriad as invalid under United States law relating to patentable inventions and the non-patentability of natural phenomena.<sup>24</sup> They also claimed that various claims by Myriad over “abstract ideas” were “unconstitutional” under the “Copyright Clause” of the United States *Constitution* and the First and Fourteenth Amendments, which concern free speech and “equal protection” rights respectively.<sup>25</sup> The United States plaintiffs were successful in their challenge before the District Court in New York.<sup>26</sup> They lost on the appeal to the Federal Court of Appeals (before a two: one split court), and then again on a subsequent appeal to the same Court of Appeals, following an order by the United States Supreme Court vacating the court’s earlier decision (again, the court split two: one). The case has again returned to the Supreme Court for a final decision, with oral arguments heard on 15 April 2013. The United States result is notable because Myriad lost in its

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<sup>18</sup> See a summary in Vines T, “You are Not a Drug”, *New Matilda* (5 July 2012), <http://newmatilda.com/2012/07/05/you-are-not-drug> viewed 1 March 2013; Australian Parliament, Senate Community Affairs Reference Committee, n 1; Maurice Blackburn Lawyers, “Biotech Company Monopoly on Cancer Genes is Unlawful: Australian Test Case Over Patents”, *Press Release* (8 June 2010).

<sup>19</sup> *Assoc for Molecular Pathology v PTO and Myriad Genetics* 702 F Supp 2d 181 (2010). The case remains under appeal before the Supreme Court, Docket No 2010-1406 (cert granted 30 November 2012), <http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/12-398.htm> viewed 10 March 2013. The most recent United States Federal Circuit Court of Appeals citation for the case is *Assoc for Molecular Pathology v Myriad Genetics, Inc* 689 F 3d 1303 (2012).

<sup>20</sup> *Cancer Voices Australia (ABN 93 322 703 427) v Myriad Genetics Inc*, Case No NSD643/2010, <https://www.comcourts.gov.au/file/Federal/P/NSD643/2010/actions> viewed 1 March 2013.

<sup>21</sup> Amended Application, filed by Maurice Blackburn Lawyers, 6 May 2011; Amended Statement of Claim, filed by Maurice Blackburn Lawyers, 6 May 2011, NSD643/2010, file details (no public documents), <https://www.comcourts.gov.au/file/Federal/P/NSD643/2010/actions> viewed 1 March 2013.

<sup>22</sup> *Assoc for Molecular Pathology v PTO and Myriad Genetics* 702 F Supp 2d 181 (2010).

<sup>23</sup> Interestingly, however, the applicants initially sought to rely on s 18(2) of the *Patents Act 1990* (Cth) – which holds that “Human beings, and the biological processes for their generation” are not patentable inventions – to challenge Myriad’s patent. This argument was abandoned at trial. See Nicholas J’s summary of the case: *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 at [6].

<sup>24</sup> Specifically on the ground that isolated DNA did not constitute a patentable invention for the purposes of Title 35 USC 101: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

<sup>25</sup> United States *Constitution*, Art 1, § 8(8): “[The Congress shall have Power ...] To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”. See ACLU, *BRCA: Plaintiffs’ Memo in Support of Motion for Summary Judgment* (2009), <http://www.aclu.org/free-speech-womens-rights/brca-plaintiffs-memo-support-motion-summary-judgement> viewed 10 March 2013; ACLU, *BRCA: Complaint* (2009) at [102], [103], <http://www.aclu.org/free-speech/brca-complaint> viewed 10 March 2013.

<sup>26</sup> The District Court, however, dismissed the constitutional aspects of the plaintiffs’ appeal.

attempt to reinstate its patent over its diagnostic methods. Only its composition claims over the isolated BRCA genes were reinstated by the Court of Appeals.<sup>27</sup>

Before the Australian Federal Court, Myriad relied on the principles outlined in the High Court of Australia's decision in the *NRDC* case, and countered that the challenged patents satisfied the manner of manufacture test in s 18(1)(a) of the Act because "it claims a product [isolated or purified genomic DNA] that consists of an artificial state of affairs, providing a new and useful effect that is of economic significance" (at [7]).

Each side called expert witnesses during the five-day hearing in February 2012,<sup>28</sup> with significant aspects of the scientific discussion in Nicholas J's final decision drawn from the affidavit of Professor Rasko, an expert witness called by the respondents (Myriad) but not cross-examined (at [9], [46]).<sup>29</sup>

## IMPACT OF THE HIGH COURT'S NRDC PRINCIPLES ON THE FEDERAL COURT DECISION

The applicants asked the Federal Court to determine a very specific question of general application: "whether under the *Patents Act 1990* (Cth) ..., a valid patent may be granted for a claim that covers naturally occurring nucleic acid ... [being DNA or RNA] from a *naturally occurring* sequence ... that has been 'isolated'" (at [1], emphasis added).

Ultimately, Nicholas J answered that question in the affirmative, holding (at [138]) that isolated DNA was a patentable invention for the purposes of s 18(1)(a) of the Act, and dismissed the applicants' challenge to Myriad's gene patent with costs. The applicants have appealed.<sup>30</sup>

To reach his decision Nicholas J addressed three principal considerations:

- What is the proper scope of "manner of manufacture" under s 18(1)(a) of the Act, especially in relation to "laws or products of nature"?
- Does the process of isolating DNA represent sufficient human intervention to make the final product an "artificial state of affairs"?
- Are there any other legitimate policy considerations that would militate against finding isolated DNA a patentable invention?

The first two considerations go to the crux of the gene patent debate: is isolated DNA an invention?

At the centre of the Western patent system is the requirement for a patentable invention.<sup>31</sup> Under s 18(1)(a) of the Act, a patentable invention is one that "is a manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*". This definition is further elaborated in Sch 1 of the Act to mean "any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the *Statute of Monopolies*".<sup>32</sup> This somewhat circular definition has left determining the scope of "patentable invention" with the courts.

<sup>27</sup> *Assoc for Molecular Pathology v Myriad Genetics, Inc* 689 F 3d 1303 (2012).

<sup>28</sup> Dr Suthers (called by the applicants) and Professor Brown (called by the respondents) were both cross-examined: *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 at [9].

<sup>29</sup> See eg *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 at [46]-[53]. Nicholas J devoted extensive time to outlining the basic science behind DNA and the isolation and purification process (at [10]-[54]).

<sup>30</sup> *D'Arcy v Myriad Genetics Inc*, Federal Court of Australia, Case NSD359/2013, <https://www.comcourts.gov.au/file/Federal/P/NSD359/2013/actions> viewed 12 March 2013.

<sup>31</sup> *Statute of Monopolies, Ch 3 21 Ja 1 (1623)* (UK), s 6; *Patents Act 1990* (Cth), s 18(1)(a); United States *Constitution*, Art 1, § 8, cl 8; *WTO Agreement – Agreement on Trade Related Aspects of Intellectual Property Rights* [1995] ATIS 8 (TRIPS Agreement), Art 27(1), Annex 1C.

<sup>32</sup> It is not necessary in this analysis to examine the detail of s 6 of the *Statute of Monopolies 1623*, nor its qualifications. But see recent attempts to reintroduce (or restore) the ability of courts to invalidate patents which are "generally inconvenient": *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (Cth); Palombi L, Submission 103 to the Senate Legal and Constitutional Affairs Committee Inquiry into the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*, [http://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate\\_Committees?url=legcon\\_ctte/completed\\_inquiries/2010-13/patent\\_amendment/submissions.htm](http://www.aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=legcon_ctte/completed_inquiries/2010-13/patent_amendment/submissions.htm) viewed 13 March 2013.

Nicholas J emphasised (at [81]) that the words “manner of [new] manufacture” are not to be read in a literal sense,<sup>33</sup> but “are expressions that bring into play principles and concepts which have been developed over many years to ensure that patent law keeps up with advances in industry and technology” (at [79]).

Starting thus, Nicholas J began his analysis (at [81]) with the “celebrated judgment” in *NRDC*, in particular the High Court’s statement that:

It is therefore a mistake ... to treat the question whether a given process or product is within the definition [of manner of manufacture] as if that question could be restated in the form: “Is this a manner (or kind) of manufacture?” ... The right question is: “Is this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the *Statute of Monopolies*?”<sup>34</sup>

The question so framed naturally leads to a “widening conception of the notion” of manufacture (and thus invention).<sup>35</sup> In Australia it has resulted in a settled judicial principle that any “product that consists of an artificially created state of affairs which has economic significance” can be considered patentable subject matter (at [88]).<sup>36</sup> As discussed below, this overly broad conception of “manner of manufacture”, including methods for treating humans, has not successfully been rebuffed by legislators: a result which has been taken by judges to indicate support for past decisions. This leads, inexorably, to an ever-shrinking intellectual commons. Critics have claimed that “shorthand” judicial reformulations have short-circuited the very principles-based approach to the interpretation of “manner of manufacture” in its appropriate legal and social context that the High Court imperfectly sought to encourage in the *NRDC* case.<sup>37</sup>

Nicholas J cited the *NRDC* principles as authority for the position that a court is not required “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” (at [103]). Seeking to avoid the rigid application of the *NRDC* principles, the applicants “argued that what the High Court said in *NRDC* should not be taken too literally” (at [110]). In support of this view they quoted Lord Walker’s statement in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46 at [138]:

There is always a danger that any judicial summary of principle may, precisely because it is concise, practical and repeatedly cited, take on a life of its own, as if it were a statutory text with its own problems of construction to be resolved.

While Nicholas J agreed with this statement “[a]t the most general level”, he appeared, in fact, to miss the interlocutor’s intent (at [110]):

[Here], however, I am not concerned with the construction of statutory text. The present case is to be resolved not by reference to statutory language in any conventional sense, but by the application of principles and concepts developed by the Courts as explained in *NRDC* and other relevant authorities.

The constricted approach the judge ended up applying to determining the bounds of “patentable invention” is at odds with the principles-based approach to statutory interpretation pursued by the plaintiffs in their United States challenge. There, the plaintiffs sought – and succeeded at first instance

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<sup>33</sup> *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 269; *Joos v Commissioner of Patents* (1972) 126 CLR 611. “Newness” was imported into the requirement of s 18(1)(a) in *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 183 CLR 655.

<sup>34</sup> *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 269, quoted with emphasis in *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 at [84].

<sup>35</sup> *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 269, 271.

<sup>36</sup> *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252. Section 18(1)(a) of the Act deals essentially with patent *eligibility*. A valid patent must meet other tests set out in the Act.

<sup>37</sup> Monotti AL, “The Scope of ‘Manner of Manufacture’ Under the Patents Act 1990 (Cth) after *Grant v Commissioner of Patents*” (2006) 34(3) FL Rev 461, referring to *CCom Pty Ltd v Jiejing Pty Ltd* (1994) 51 FCR 260. See also Australian Law Reform Commission, n 1 at [6.43].

– to draw on past judicial decisions that rejected patents over isolated pine needles, fibres, purified uranium and tungsten,<sup>38</sup> and patent claims over natural phenomena.<sup>39</sup>

Nicholas J, however, rejected attempts to link the applicants' arguments to the United States *Myriad* decision, stating (at [135]):

In any event, it seems to me that the [US District Court and Court of Appeals] *Myriad* decision does not provide any direct assistance to either side in the present case. I say this for two reasons. First, the law in Australia is different. I must apply the law as explained in *NRDC*. 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.

Clearly Australian patent law differs in some respects from the United States regime; however, both laws derived from a common English source and both have at their centre the requirement for an invention.<sup>40</sup> Nicholas J's reliance on the High Court's decision in *Grain Pool (WA) v Commonwealth* (2000) 202 CLR 479 for his view discounted that the legal controversy in that case was on the scope of s 51(xxiii) of the Australian *Constitution*, not s 18(1)(a) of the Act.<sup>41</sup> While the High Court in *Grain Pool* differentiated between the United States and Australian constitutional environments, it did not negate the relevance of United States cases concerning patentable subject matter, only perhaps suggesting that the United States *Constitution* imported an "express purposive element" into all United States intellectual property law that was absent in s 51(xxiii).<sup>42</sup>

Overall, Nicholas J's approach reduced any opportunity for the applicants to pursue a principles-based approach to the interpretation of s 18(1)(a). This suggests that, contrary to the intention of the High Court in *NRDC*, its statements have become either an "exact verbal formula" for s 18(1)(a) or a "dead-hand" on patent law, preventing any meaningful social or environmental limitations on the manner of manufacture test. Indeed, the judge's approach seems to bear out critics who have claimed that such "shorthand" judicial reformulations are short-circuiting the broad principles-based approach to the interpretation of "manner of manufacture" that the High Court should have encouraged more clearly in the *NRDC* case.<sup>43</sup>

## PARLIAMENT'S INACTION ON THE GROWTH OF GENE PATENTS

Absent legislative exclusion of specific subject matter,<sup>44</sup> or a judicial willingness to expand the law incrementally to a jurisprudentially rich appreciation of fundamental principles, a lower court deciding whether some composition or method is patent eligible is only to be guided by past precedent: precedent that supports the ever-widening of patentable subject matter.<sup>45</sup> Nicholas J went one step further in finding comfort from the absence of legislative action on gene patents (at [112]):

<sup>38</sup> ACLU, *BRCA Plaintiffs' Memo in Support of Motion for Summary Judgment* (2009), pp 22-26, <http://www.aclu.org/free-speech-womens-rights/brca-plaintiffs-memo-support-motion-summary-judgement> viewed 10 March 2013; ACLU, *BRCA Complaint* (2009) at [52], <http://www.aclu.org/free-speech/brca-complaint> viewed 10 March 2013.

<sup>39</sup> *Mayo Collaborative Services v Prometheus Laboratories, Inc* 132 S Ct 1289 (2012).

<sup>40</sup> *Patents Act 1990* (Cth), s 18(1)(a) and Title 35 USC 101 both go to patentable subject matter.

<sup>41</sup> And in the context of the *Plant Breeder's Rights Act 1994* (Cth).

<sup>42</sup> Namely, a limitation that United States intellectual laws are limited to the "promot[ion] and Progress of Science and useful Art" [sic]: *Grain Pool (WA) v Commonwealth* (2000) 202 CLR 479 at [28]-[32].

<sup>43</sup> Monotti, n 37, referring to *CCom Pty Ltd v Jiejing Pty Ltd* (1994) 51 FCR 260. See also Australian Law Reform Commission, n 1 at [6.43].

<sup>44</sup> For example, *Patents Act 1990* (Cth), s 18(2). Cf *Patents Act 1977* (UK), s 1(2), which excludes "discoveries", "scientific theories", "a scheme" or "rule or method for performing a mental act", and the *Patents Bill 2008* (NZ), s 1(2), currently under debate.

<sup>45</sup> And thereafter finds its way into the Patent Examiners Manual: IP Australia, *Patent Examiners Manual* at [2.9.1.1], [http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent\\_Examiners\\_Manual.htm](http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm) viewed 13 March 2013. See also the comment of Lockhart J in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 19: "There is no statutory provision in Australia prohibiting the grant of a patent for a process of medical treatment of a human ailment or disease in a human being. It is noteworthy that Parliament had the opportunity to exclude methods of treating the human body when it enacted the 1990

The inference to be drawn [from the failure of Parliament to enact the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*] is that it was not the intention of Parliament at the time the Act was passed to deal with the issue of “gene patenting” by way of express statutory exclusion along the lines of s 18(2), but to leave it to the Courts to apply the law as settled in the *NRDC* case and other relevant authorities.

With respect, this confidence is misplaced. While Senator Heffernan’s Bill died in committee, Parliament never formally voted on it.<sup>46</sup> Similarly, the numerous bipartisan efforts by legislators to introduce an exemption for genetic materials suggest a real disquiet within Parliament over gene patents.<sup>47</sup> Further, such a view fails to take into account how imperfectly Parliament represents democratic interests in these days of excessive privatisation of public utilities, incessant private sector lobbying of, and revolving-door consultancy arrangements with, government, as well as the impact of the multinational corporate sector on domestic regulation through trade agreements.

His Honour also raised the Australian Government’s response to the several reports into gene patenting and related matters,<sup>48</sup> stating that the government “*specifically accepted* the [Australian Law Reform Commission’s (ALRC)] recommendation that the [Patents] Act *not* be amended to exclude (inter alia) genetic materials” (at [119], emphasis in original). This is not accurate. The government’s acceptance was only “in principle”,<sup>49</sup> and the response as a whole indicated that the government was aware of the “complexities of providing incentives for creating innovations, enabling further innovation and cost effective access to innovations”.<sup>50</sup> Moreover, the government responses specifically noted the “strong public concern about affordable access to healthcare” and stated that any future amendments to s 18 of the Act would include “public exposure of the legislation drafting instructions”.<sup>51</sup>

These differences in interpretation are not trivial and should be seen through the lens of government decision-making processes. Common practice sees public servants from various departments (some briefly seconded from the private sector and/or assisted by private sector consultants) prepare responses for governments. As such, the soft approval of the ALRC’s recommendation must be seen in the context of the contemporaneous disagreement between the federal Department of Health and Ageing and IP Australia at the 2011 Senate Committee hearing into Senator Heffernan’s Bill to ban gene patents.<sup>52</sup> Seen this way, it is clear that there is no firm opinion yet in government on how to address the problems thrown up by gene patents and the broad scope of the *NRDC* principles.<sup>53</sup>

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Act, but the limit of the exclusion was s 18(2), namely: ‘human beings, and the biological processes for their generation, are not patentable inventions.’”

<sup>46</sup> The Committee report recommending the Senate not pass the Bill was tabled, along with a dissenting report: Commonwealth, Senate, *Parliamentary Debates* (21 September 2011) p 6748 (Senator Bill Heffernan).

<sup>47</sup> See the Australian Democrats’ *Patent Amendment Bill 1996* (Cth); Senator Bill Heffernan’s *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (Cth) sponsored in the Senate by Independent Senator Xenophon, Greens Senator Siewert and in the House of Representatives by Independent Rob Oakeshott, and fellow Liberals Malcolm Turnbull and Peter Dutton MP; and Melissa Parke MP’s own, as yet untabled, Private Members’ Bill which has the support of Senator Heffernan: ABC, n 2.

<sup>48</sup> Commonwealth of Australia, *Australian Government Response to Senate Community Affairs Reference Committee Gene Patents Report* (November 2011), [http://www.ipaustralia.gov.au/pdfs/Australian\\_Government\\_Response\\_to\\_Senate\\_Committee\\_Gene\\_Patents\\_Report.pdf](http://www.ipaustralia.gov.au/pdfs/Australian_Government_Response_to_Senate_Committee_Gene_Patents_Report.pdf) viewed 14 March 2013.

<sup>49</sup> The exact language of the response: “The Government accepts Recommendation 7-1 (a) *in principle* and (b) *in full* but not (c) of the ALRC 99 Report...” (emphasis added): Commonwealth of Australia, n 48, p 17.

<sup>50</sup> Commonwealth of Australia, n 48, p 17.

<sup>51</sup> Commonwealth of Australia, n 48, p 15.

<sup>52</sup> The Department of Health and Ageing agreed with the “intention” of the Bill to the extent that it sought to clarify the discovery/invention distinction, while the Department of Innovation, Industry, Science and Research opposed the Bill outright. See the comments of the Secretary of the Department of Health and Ageing and the Deputy Director-General of IP Australia: Commonwealth, Senate Legal and Constitutional Affairs Committee, *Committee Debates* (29 April 2011) pp 35-36 (Jane Halton and Fatima Beattie); Department of Health and Ageing, Submission 68 to the Senate Legal and Constitutional Affairs Committee Inquiry into the *Patent Amendment (Human Genes and Biological Material) Bill 2010*, [http://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate\\_Committees?url=legcon\\_ctte/completed\\_inquiries/2010-13/](http://www.aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=legcon_ctte/completed_inquiries/2010-13/)



Finally, while a court's reliance on Parliament's intention can only stretch so far,<sup>54</sup> it is important to note that the *Patents Act 1990* (Cth) was passed 10 years before the conclusion of the Human Genome Project,<sup>55</sup> and seven years before UNESCO's *Universal Declaration of Human Rights and the Human Genome* which considers the genome to be "in a symbolic sense, the heritage of humanity" and states that the genome "in its natural form shall not give rise to financial gains".<sup>56</sup> It should be open to a progressive court to consider the history of the relevant field of invention – in this case, human genetics and medical treatment – and import considerations from such relevant international statements of principle or use them to calibrate the appropriateness of domestic norms within the great normative conversation of humanity.

## ECONOMIC SIGNIFICANCE OF AN ARTIFICIAL STATE OF AFFAIRS

In both the Australian and United States cases significance was placed on the act of breaking covalent bonds as part of the process of isolating genomic DNA.<sup>57</sup> In the United States, Lourie J stated in *Assoc for Molecular Pathology v Myriad Genetics, Inc* 689 F 3d 1303 at 1329 (2012):

[I]n nature, the claimed isolated DNAs are covalently bonded to such other materials. Thus, when cleaved, an isolated DNA molecule is not a purified form of a natural material, but a distinct chemical entity that is obtained by human intervention.<sup>58</sup>

Likewise, Nicholas J drew attention to Myriad's reliance on the act of breaking covalent bonds (at [72], [73]-[74]); however, he appeared to go further than the United States Court of Appeals in holding (at [104]):

The physical properties of the naturally occurring material may have changed as a result of it having been isolated. But even if the physical properties of the material have not changed, the removal of the material from its natural environment and its separation from other cellular components may still give rise to what might reasonably be described as an artificial state of affairs.<sup>59</sup>

What was important to his Honour was simply that "in the absence of human intervention, naturally occurring nucleic acid does not exist outside the cell, and 'isolated' nucleic acid does not exist inside

[patent\\_amendment/submissions.htm](#) viewed 15 March 2013; cf Department of Innovation, Industry, Science and Research and IP Australia, Submission 94 to the Senate Legal and Constitutional Affairs Committee Inquiry into the *Patent Amendment (Human Genes and Biological Material) Bill 2010*, [http://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Committees?url=legcon\\_ctte/completed\\_inquiries/2010-13/patent\\_amendment/submissions.htm](http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Committees?url=legcon_ctte/completed_inquiries/2010-13/patent_amendment/submissions.htm) viewed 15 March 2013.

<sup>53</sup> Indeed, the current Productivity Commission review into compulsory licensing, and the review of "pharmaceutical patents", may be seen as another attempt to find consensus: Bradbury D and Dreyfus M, "Balancing Access to Technology and Innovation", *Media Release* (29 June 2012), <http://ministers.treasury.gov.au/DisplayDocs.aspx?doc=pressreleases/2012/059.htm&pageID=003&min=djba&Year=&DocType=0> viewed 25 August 2012; IP Australia, *Review of Pharmaceutical Patents in Australia* (IP Australia), <http://www.ipaustralia.gov.au/about-us/public-consultations/review-pharmaceutical-patents> viewed 15 March 2013.

<sup>54</sup> *Acts Interpretation Act 1901* (Cth), s 15AB.

<sup>55</sup> At the announcement of the completion of the first survey of the human genome by a publicly-funded scientific team, the then United Kingdom Prime Minister, Tony Blair, stated: "We, all of us, share a duty to ensure that the common property of the human genome is used freely for the common good of the whole human race." See Office of the White House Press Secretary, *Remarks by the President [and Others] on the Completion of the First Survey of the Entire Human Genome Project* (26 June 2000), [http://www.ornl.gov/sci/techresources/Human\\_Genome/project/clinton2.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/project/clinton2.shtml) viewed 14 March 2013.

<sup>56</sup> *The Universal Declaration on the Human Genome and Human Rights* was adopted unanimously and by acclamation at UNESCO's 29th General Conference on 11 November 1997, <http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genome-and-human-rights> viewed 14 March 2013.

<sup>57</sup> See the discussion in *Assoc for Molecular Pathology v Myriad Genetics, Inc* 689 F 3d 1303 at 1329 (2012) (Lourie J) and the expert evidence call in *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 at [73].

<sup>58</sup> The other majority judge was more strongly persuaded by arguments of continuity: "[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community" (at 1344), citing *Festo Corp v Shoketsu Kinzoku Kogyu Kabushiki Co* 535 US 722 at 739 (2002). Cf the dissent of Bryson J (at 1335).

<sup>59</sup> It does appear, however, that when Nicholas J referred to "isolated" DNA in quotes he was referring to DNA that had been isolated – by whatever measure – and purified: "It is only after both these steps are performed that the extracted and purified product may be properly described as 'isolated' in the sense that word is used in the disputed claims": *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 at [108]. But cf his general comments at [104], which suggest a more fluid understanding.

the cell” (at [108]). Consequently, “the patentability of the isolated nucleic acids referred to in the disputed claims does not turn upon what changes have been made to the chemical composition of such substances as a result of them having been isolated” (at [108]). It did not matter, nor was it even a relevant consideration, that the isolated DNA in question had “precisely the same chemical composition and structure as that found in the cells of some human beings” (at [106]).<sup>60</sup>

The capacity of such a reading of s 18(1)(a) to constrain vast tracts of creative human interaction with objective reality within patent monopolies has caused concern within the academic community. Nicol, eg, commented: “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.”<sup>61</sup> And while his Honour was at pains to note (at [76]) that “the disputed claims are not to genetic information per se” but to the tangible, isolated DNA, it is questionable how meaningful this assurance is, given the unique nature of DNA and its functional role.

It is important to remember that the court did not examine (and was not asked to determine) if the claimed isolated BRCA genes per se were “inventive” by the standards required of s 7 of the Act.<sup>62</sup> Likewise, while the NRDC asks examiners and judges to consider whether the patent claims a new process or composition of matter that consists of or produces “an artificial state of affairs providing a new and useful effect *that is of economic significance*”, Nicholas J was only required to assess the first part of that test. Prior to trial, the applicants had “accepted that the subject matter of the disputed claims was of ‘economic significance’” (at [8]).

The narrowness of the applicants’ case was perhaps an unwise tactical decision.<sup>63</sup> First, even if successful, the applicants would only succeed in overturning the composition of matter claims (Claims 1-3), not the method claims relating to Myriad’s BRCA*Analysis*. One of the applicants, Ms D’Arcy, did not appear aware of this reality,<sup>64</sup> a fact noted by some commentators.<sup>65</sup> Secondly, by confining the challenge to s 18(1)(a), they lost an opportunity to challenge the patent on other grounds, including inventiveness.

Finally, the concession on “economic significance” was possibly premature, given the patent was directed towards diagnosing and treating humans.<sup>66</sup> An exclusion for surgical and treatment methods for humans has long existed under various patent regimes and provided one final opportunity to import ethical and social considerations as a counterpoint to economic principles.<sup>67</sup> To some, it may seem obvious that the treatment of a human is of economic significance:<sup>68</sup> healthy workers contribute to the

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<sup>60</sup> “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”: *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 at [103]; cf *Diamond v Chakrabarty* 447 US 303 at 310 (1980).

<sup>61</sup> Nicol D, quoted in Slezak M, “Victory for Gene Patent Firm in Australian Court”, *New Scientist* (15 February 2013), <http://www.newscientist.com/article/dn23180-victory-for-gene-patent-firm-in-australian-court.html> viewed 16 March 2013.

<sup>62</sup> Indeed, Nicholas J stated that his “reasons have nothing to say about the possible invalidity of the disputed claims on any other ground”: *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 at [137].

<sup>63</sup> Noting, however, that Maurice Blackburn and counsel acted pro bono for Cancer Voices and Ms D’Arcy.

<sup>64</sup> Hall L, “Patient Advocates Test Law on Human Gene Patents”, *Sydney Morning Herald* (21 February 2012), <http://www.smh.com.au/technology/sci-tech/patient-advocates-test-law-on-human-gene-patents-20120220-1tjo7.html> viewed 15 March 2013.

<sup>65</sup> Summerfield M, “As Myriad Gene Trial Starts, Are Cancer Advocates Being Misled?”, *Patentology* (22 February 2012), <http://blog.patentology.com.au/2012/02/as-myriad-gene-trial-starts-are-cancer.html> viewed 15 March 2013.

<sup>66</sup> A party to a case before the High Court is currently arguing this point and seeking a ruling on whether methods of treatment of the human body are patentable inventions within the meaning of s 18(1)(a) of the *Patents Act 1900* (Cth): *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd*, Case No S1/2013, [http://www.hcourt.gov.au/cases/case\\_s1-2013](http://www.hcourt.gov.au/cases/case_s1-2013) viewed 12 March 2013.

<sup>67</sup> On the grounds that a patent over isolated human DNA, that had the effect of interfering with a doctor’s ability to treat, would be “generally inconvenient”: *Joos v Commissioner of Patents* (1972) 126 CLR 611 at 623 (Barwick CJ). A survey of jurisdictions was undertaken in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 7-13; *Patents Act 1977* (UK), s 4(2).

<sup>68</sup> See generally *Maeder v Busch* (1938) 59 CLR 684; *Joos v Commissioner of Patents* (1972) 126 CLR 611 at 618 (Barwick CJ).

economy, healthy children grow into workers and consumers and a high quality of life ensures people remain productive for longer.<sup>69</sup> But this ignores the different ethical norms underpinning medical treatment, eg the duty to render assistance in an emergency,<sup>70</sup> the special nature of the doctor-patient relationship,<sup>71</sup> and democratic measures supporting non-market-based health care pricing.<sup>72</sup>

## CONCLUSION

The dominance of autonomous consent and the virtue of respect in patient care suggest that the “economic significance” of treating a patient (eg one with inherited breast cancer) should be subsidiary,<sup>73</sup> if not largely irrelevant, to clinical decision-making in a society with a genuine commitment to foundational social virtues such as justice and equity.<sup>74</sup> Yet a patent over genetic information (potentially critical to the diagnosis and treatment of such a patient) forces “economic significance” to the front of her health practitioner’s mind and this cannot of itself be a foundational social virtue.

When the law, as here, pretends that “economic significance” is a foundational social virtue, then it restricts that physician’s ability to refer their patient for a second confirmatory test. It restricts the patient’s ability to make informed decisions about her welfare and treatment options. Where cost is an issue, as it has been in the United States, the inability to afford testing and the refusal of some health insurance providers to reimburse second tests deny access to lifesaving care in deference to the monopoly premium afforded a patented good.<sup>75</sup> For some women who, because of an uncommon or unstudied genetic heritage, receive incomplete information from a commercial genetic screening operator, restrictions on their ability to seek testing from other providers may constitute actionable discrimination.

This type of harm to vulnerable patients cannot be brushed aside by pleading the “immense research and intellectual effort” of isolating DNA (at [109]). Many intellectual efforts are not patent eligible, including the creative arts, scientific theorems and the teachings of philosophers. The first antibiotic and attenuated polio vaccine, as well as the internet, were either gifted to the public domain or – at the time – patent ineligible, notwithstanding the substantial money, time and hope invested in their development.<sup>76</sup> Strenuous efforts were made at the international level to ensure that the interests

<sup>69</sup> See the list outlined by Barwick CJ in *Joos v Commissioner of Patents* (1972) 126 CLR 611 at 618; cf *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 15 (Lockhart J). The subsuming of medical science into the service of the economy is perhaps an inevitable destination for capitalism: Drahos P, “Patents, Practical Ethics and Scientists” (2011) 29(3) *Prometheus: Critical Studies in Innovation* 345.

<sup>70</sup> *Lowns v Woods* (1996) Aust Torts Reps 81-376; Medical Board of Australia, n 11 at [2.5].

<sup>71</sup> Australian Medical Association, n 11 at [1.1.1], [1.1.3], [1.1.12], <https://ama.com.au/codeofethics> viewed 10 March 2013.

<sup>72</sup> For example, the *Health Insurance Act 1973* (Cth) establishing universal health care, and the Pharmaceutical and Medical Benefits Schemes established under the *National Health Act 1953* (Cth) and supported by s 51(xxiiiA) of the Australian Constitution.

<sup>73</sup> See the dissent of Sheppard J in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 41: “It is not going too far, I think, to say that the Court should not contemplate the grant of letters patent which would give to one medical practitioner, or perhaps a group of medical practitioners, a monopoly over, for example, a surgical procedure which might be greatly beneficial to mankind. Its denial might mean the death or unnecessary suffering of countless people. I cannot think that this is really what the medical profession as a whole would seek to achieve. Its whole history is a denial of the proposition.” Lockhart J was also aware of the necessary “balancing exercise” (at 16).

<sup>74</sup> National Health and Medical Research Council, *National Statement on Ethical Conduct in Human Research* (Commonwealth of Australia, Canberra, 2007) Ch 2.2; Government of the United States, *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No 10, Vol 2* (Government Printing Office, Washington, DC, 1949) pp 181-182, <http://history.nih.gov/research/downloads/nuremberg.pdf> viewed 14 March 2013.

<sup>75</sup> See generally ACLU, *BRCA: Plaintiffs’ Memo in Support of Motion for Summary Judgment* (2009), <http://www.aclu.org/free-speech-womens-rights/brca-plaintiffs-memo-support-motion-summary-judgement> viewed 10 March 2013; ACLU, *BRCA: Complaint* (2009) at [102], [103], <http://www.aclu.org/free-speech/brca-complaint> viewed 10 March 2013.

<sup>76</sup> Quora, “How Much Money Did Jonas Salk Potentially Forfeit By Not Patenting the Polio Vaccine?”, *Forbes.com* (9 October 2012), <http://www.forbes.com/sites/quora/2012/08/09/how-much-money-did-jonas-salk-potentially-forfeit-by-not-patenting-the-polio-vaccine> viewed 14 March 2013; cf Zwahlen R, “The Real Reason Why Salk Refused to Patent the Polio

of future generations in researching the human genome would not be unconscionably compromised by patents. Likewise, professional skills of diagnosis and treatment require years of dedication but remain outside the scope of patentable inventions.<sup>77</sup>

The dispute over how generally the High Court's *NRDC* "principles" should constrain patent exclusions in areas such as genetic testing for breast cancer is likely to intensify rather than abate.<sup>78</sup> Some of the reasons for this are embedded in that decision itself. First, the High Court decision concerned a method patent, involving a method of applying herbicide, whereas the present case concerned a composition of matter claim – isolated DNA. Secondly, while the court in *NRDC* left open the possibility for certain exclusions from patentability, including methods for the treatment of humans,<sup>79</sup> it did not go into detail about how such exclusions were in practice to be incorporated into the principles it was enunciating. Finally, although the High Court recognised various other policy considerations relevant to patent eligibility, including national development and the need for an "industrial or commercial or trading character",<sup>80</sup> the relevance of these values in subsequent applications of the *NRDC* principles has diminished, with other social values, eg, respect for human dignity (including integrity of the human genome) and environmental sustainability featuring more prominently in jurisprudential deliberations.

The judgment here discussed emphasised the need for a statement of objects to be included in the *Patents Act 1990* (Cth): a recommendation of the ALRC, the Senate and the Federal Government's own Australian Council on Intellectual Property.<sup>81</sup> This recommendation was accepted by the government in 2011 with a specific comment suggesting that the statement will "give effect to these recommendations and its intention that patents should not lead to patients being denied reasonable access to healthcare".<sup>82</sup> Yet, this work has not progressed.

The debate over gene patents in the community and through the courts in *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 and *Assoc for Molecular Pathology v Myriad Genetics Inc* 689 F 3d 1303 (2012) is not over. The publicity given to hereditary breast cancer by Angelina Jolie's double mastectomy no doubt will increase the demand for this genetic testing and the related patents will then impose higher private and public costs.<sup>83</sup> Both cases are set for appeal, and Parliament may still consider a Private Members' Bill to amend s 18(1)(a) of the *Patents Act*. For now, however, the rigid adherence of courts and patent examiners to the short-hand reformulations of the *NRDC* principles is blind to the damaging social and environmental implications of permitting intellectual monopoly privileges over too broad a conception of invention.

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*Declaration: Tim Vines worked at the Department of Health and Ageing in 2011. The views expressed here are his own.*

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Vaccine", *BIOTechNOW* (27 January 2012), <http://www.biotech-now.org/public-policy/patently-biotech/2012/01/the-real-reason-why-salk-refused-to-patent-the-polio-vaccine-a-myth-in-the-making#> viewed 14 March 2013.

<sup>77</sup> For a recent example, see *Mayo Collaborative Services v Prometheus Laboratories, Inc* 132 S Ct 1289 (2012).

<sup>78</sup> Indeed, a central part of the *NRDC* judgment was the court's rejection of the judicial creation of an "exact verbal formula" for manner of manufacture: *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 271; Monotti, n 37.

<sup>79</sup> *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 275.

<sup>80</sup> *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 271, 275.

<sup>81</sup> Commonwealth of Australia, n 48, p 13.

<sup>82</sup> Commonwealth of Australia, n 48, p 13.

<sup>83</sup> Lindeman G, "Angelina Jolie Has Had a Double Mastectomy, So What is BRCA1?". *The Conversation* (14 May 2013), <https://theconversation.com/angelina-jolie-has-had-a-double-mastectomy-so-what-is-brca1-14227> viewed 15 May 2013.