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# GENE PATENTS IN AUSTRALIA: A GAME THEORY APPROACH

Kate M. Mead<sup>†</sup>

*Abstract:* Gene patent validity is one of the most controversial issues in patent law. In Australia, the question of whether to eliminate human gene patents has reached both Parliament and the federal courts. Opponents of gene patents argue that gene patents increase the cost of healthcare and impede progress in genetic research. Proponents respond that gene patents are essential incentives for the biotech industry, and that Australia has an obligation to recognize them under the WTO-administered Treaty on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”). Because patents require inventors to publically disclose their discoveries, Australia’s rejection of the gene patent system would allow Australian companies to benefit from these disclosures without compensating the patent holder—implicating industries and legal regimes far beyond its borders. Australia has the power to decide whether gene patents are valuable to its citizens. This comment represents the controversy as a game between Australia and the rest of the developed world, where it “cooperates” if it continues to respect gene patent rights and it “defects” if it declares genes unpatentable. From Australia’s perspective, the immediate economic benefits of eliminating gene patents may outweigh its costs. However, the long-term costs of eliminating gene patents may be unacceptable to proponents of gene patents. In addition, impending advances in genetic sequencing technology will render gene patents economically insignificant, regardless of whether gene patents are a beneficial policy decision. An international solution, which incentivizes cooperation or punishes defection, is necessary for rational state actors to recognize gene patents. Ultimately, this paper proposes three potential solutions to this problem: A) starting a new intellectual property regime for human genes, B) creating a specialized patent regime for human genes, and C) incentivizing individual governments to fund research through public, non-commercial sources.

## I. INTRODUCTION

Gene patents represent one of the most controversial issues in modern patent law. The controversy concerns whether human genes should continue to be patent eligible. Criticisms of gene patents fall into three broad categories: legal,<sup>1</sup> moral,<sup>2</sup> and utilitarian.<sup>3</sup>

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<sup>†</sup> Juris Doctor expected in 2014, University of Washington School of Law. I would like to thank Professor Steve Calandrillo for his assistance with the project. I would also like to thank my peers at the Pacific Rim Law & Policy Journal, particularly Alec Paxton, Courtney Skiles, and Alyson Palmer for their thoughtful feedback. Finally, thanks to Dominic Forte for his emotional support through the writing process.

<sup>1</sup> See, e.g., Dianne Nichol, *On the Legality of Gene Patents*, 29 MELBOURNE U. L. REV. 809 (2006) (using legal interpretation to critique gene patents, but also acknowledging the practical effects of gene patents). But see David B. Resnik, *Discoveries, Inventions, and Gene Patents in WHO OWNS LIFE?* 135

The utilitarian arguments advanced by critics are particularly telling because they demonstrate that both proponents and opponents of gene patents have the same goal: to increase access to and understanding of genetic diseases as quickly as possible.<sup>4</sup>

Theoretically, patent systems increase the rate of technological innovation.<sup>5</sup> Neither side of the gene patent debate argues that genetic research is not important or should not be promoted. In fact, opponents of gene patents argue that patents inhibit the development of genetic research.<sup>6</sup>

As evidenced by the development of the World Trade Organization's Trade Related Aspects of Intellectual Property ("TRIPS") agreement, patent policy must be considered on an international scale. If TRIPS is ineffective, then countries can reap the majority of the potential benefits of gene patents without participating in its drawbacks and those countries are incentivized to eliminate gene patents entirely. This comment argues that nations which directly subsidize genetic tests, such as Australia, are incentivized to eliminate gene patents.

Additionally, given that the purpose of patents is to increase technological innovation, patent policy is inherently tied to advances in technology. Here, however, proponents of gene patents have a problem.

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(David Magnus, et. al., Prometheus Books 2002) [hereinafter WHO OWNS LIFE?] (arguing that the discovery versus invention distinction is "fundamentally misguided," and that it should not be a meaningful distinction as applied to genetic "discoveries").

<sup>2</sup> See, e.g., Barbara Looney, *Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement*, 26 L. & POL'Y INT'L BUS. 231, 236 (1994) (describing moral objections to patenting human genes). But see Mark J. Hanson, *Patenting Genes and Life, Improper Commodification?* in WHO OWNS LIFE? 161, 162 (arguing that that moral objections dealing with encroachment of "market thinking on subjective properties of persons and other living beings" is not a sufficient moral justification to ban gene patents). Note that in Europe, according to Article 53(a) of the European Patent Convention, technology can be precluded from legal patentability if the technology violates "public order and morality," creating an important overlap between moral and legal considerations in patent law. See Ari Berkowitz & Daniel H. Kevles, *Patenting Human Genes: The Advent of Ethics in the Political Economy of Patent Law*, in WHO OWNS LIFE? 75.

<sup>3</sup> For a concise summary of utilitarian arguments against gene patents, see the Australian Law Reform Commission ("ALRC") summary publication on gene patenting: ALRC, GENES AND INGENUITY: GENE PATENTING AND HUMAN HEALTH, ALRC REPORT 99 § 12 [hereinafter ALRC REPORT 99], available at <http://www.alrc.gov.au/publications/12-patents-and-human-genetic-research/impact-gene-patents-research>. Paradoxically, utilitarian opponents of gene patents argue that patents discourage innovation and investment in genetic research. See also Nuno Pires de Carvalho, *The Problem of Gene Patents*, 3 WASH. U. GLOBAL STUD. L. REV. 701 (2004); *infra* Part III.B.

<sup>4</sup> See, e.g., Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998).

<sup>5</sup> See *infra* Part III.A; see also Juan C. Ginarte & Walter G. Park, *Determinants of Patent Rights: A Cross-National Study*, 28 RES. POL'Y 283, 283-301 (1997).

<sup>6</sup> See *infra* Part III.B.

Developments in cost-effective methods of whole-genome sequencing will soon enable companies to test for genes without infringing on any gene patents.<sup>7</sup> This would allow companies and individuals to test for a patented gene without infringing on the patent, and in effect render a patent holder's exclusive license unenforceable. Ultimately, regardless of whether gene patents are formally eliminated, gene patent proponents will lose the battle by default.<sup>8</sup>

This comment examines both the policy supporting the recognition of human gene patents, and the impact of developing technology on the enforcement of gene patents. Part II establishes the background of human gene patents in Australia. Part III introduces utilitarian arguments for and against gene patents, while concluding that there is a strong policy argument for gene patents as applied to Australia. In Part IV, this comment establishes that, despite international agreements on intellectual property rights, countries like Australia are rationally motivated to eliminate gene patents. Part V introduces the effect of emerging whole-genome sequencing technology on currently recognized gene patents. Finally, Part VI introduces potential solutions for gene patent proponents, in order to maintain the benefits of gene patents beyond the advent of personalized medicine.

## II. BACKGROUND

Human gene patents are controversial, and the debate over gene patents is incredibly complex. In order to explain the arguments surrounding gene patents in Australia, this section introduces the basic background of Australian patent law and genome science. Section A introduces the history of the gene patent controversy in Australia. Section B explains the background of patent law in Australia. Section C describes the basic science of genetics and genomics, and introduces the scope of human gene patents as they currently exist.

### A. *History of the Gene Patent Controversy in Australia*

Last May, a federal member of Parliament, Melissa Parke, urged the Australian Parliament to ban all human gene patents.<sup>9</sup> On the Australian television program *Lateline*, she asserted that “genes . . . should be freely

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<sup>7</sup> See *infra* Part V.

<sup>8</sup> *Id.*

<sup>9</sup> Cth, Parliamentary Debates, Federation Chamber, 21 May 2012, 4977 (Melissa Parke, Member of the Australian Parliament for Fremantle) (Austl.)

available anywhere,” and should not be “locked up in the hands of private corporations.”<sup>10</sup>

Parke’s position was not novel or unusual. In 2002, the federal attorney general charged the Australian Law Reform Commission (“ALRC”) with “examin[ing] the laws and practices governing intellectual property rights over genetic materials and related technologies, with a particular focus on human health issues.”<sup>11</sup> After soliciting opinions from the public, the ALRC released its report, which asserted that gene patents were problematic,<sup>12</sup> but did not recommend explicitly excluding human genes from patent eligibility.<sup>13</sup> It also invited the government to respond to its findings.<sup>14</sup>

Before the government formulated a response, there was a flurry of analysis throughout the Australian government on the topic of gene patents. In 2010, the Senate released its own gene patents report, which recommended implementing a framework to reduce any adverse effects of gene patents on healthcare, medical research, and public health.<sup>15</sup> Later that year, the Australian Council on Intellectual Property<sup>16</sup> also issued a statement declining to recommend eliminating gene patents.<sup>17</sup> In response to the senate report, the government agreed to keep human genes patent eligible in 2011.<sup>18</sup>

The controversy within Parliament did not stop there. That same year, legislators in Parliament introduced the Patent Amendment (Human Genes and Biological Products) Bill 2010, which sought to amend the Patents Act 1990 to expressly forbid isolated deoxyribonucleic acid (“DNA”) from being

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<sup>10</sup> A transcript is available at <http://www.abc.net.au/lateline/content/2012/s3502733.htm>.

<sup>11</sup> ALRC REPORT 99, *supra* note 3.

<sup>12</sup> *See, e.g., id.* § 12.80 (noting that gene patents would become a problem if patent holders strictly enforced their rights).

<sup>13</sup> *Id.* Recommendation 7-1.

<sup>14</sup> *Id.*

<sup>15</sup> *Senate Community Affairs Committee Inquiry into Gene Patents*, PARLIAMENT OF AUSTRALIA, available at [http://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate\\_Committees?url=clac\\_ctte/completed\\_inquiries/2010-13/gene\\_patents\\_43/report/index.htm](http://www.aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=clac_ctte/completed_inquiries/2010-13/gene_patents_43/report/index.htm).

<sup>16</sup> The Australian Council on Intellectual Property is an independent council, appointed by the Australian government to advise it on novel legal issues. For more information, please see its website at <http://www.acip.gov.au/>.

<sup>17</sup> ADVISORY COUNCIL ON INTELLECTUAL PROPERTY, PATENTABLE SUBJECT MATTER, FINAL REPORT (December 2010), available at <http://www.acip.gov.au/library/ACIP%20PSM%20final%20report%204%20Feb%202011.pdf>.

<sup>18</sup> AUSTRALIAN GOVERNMENT RESPONSE TO SENATE COMMUNITY AFFAIRS REFERENCES COMMITTEE GENE PATENTS REPORT (Nov. 2011) [hereinafter GENE PATENTS REPORT 2011], available at [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).

patent eligible.<sup>19</sup> While the government finally released a new response to the senate report in 2011, recommending against eliminating gene patents,<sup>20</sup> the Patent Amendment (Human Genes and Biological Products) Bill is still actively being considered by Parliament.<sup>21</sup>

In addition to administrative and legislative action, the Australian judiciary became involved in the debate. On February 15, 2013, a federal court in Australia released an opinion confirming the patent eligibility of human genes under current law.<sup>22</sup> The case was filed to challenge Myriad Genetics' BRCA1 gene,<sup>23</sup> a gene discovered by Myriad which signals a high propensity for developing breast cancer in carriers.<sup>24</sup> Despite this initial ruling by the district court, it has been appealed by the challenging party.<sup>25</sup>

Beyond Australian jurisdiction, the U.S. Supreme Court has also accepted a challenge to Myriad's patents as a part of its 2013 term.<sup>26</sup> Given that Australian courts often use U.S. court opinions as persuasive authority for determining patent cases,<sup>27</sup> the U.S. case may affect future challenges to gene patents in the Australian federal court system.

While the gene patent debate has raged throughout the world for years, it is still an incredibly controversial issue. Because of parliamentary and judicial challenges to gene patents, they are still an open issue in Australia. Much of the legal debate regarding gene patents, however, has its

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<sup>19</sup> Patent Amendment (Human Genes and Biological Products) Bill 2010 (Cth.) (Austl.), available at <http://www.comlaw.gov.au/Details/C2011B00012>.

<sup>20</sup> Dr Martin O'Brien, *The Gene Patents Debate in Australia—An Update*, SPRUSON & FERGUSON, available at [http://www.spruson.com/au/epublications/newsalerts/GenePatentsDebate\\_Update.html](http://www.spruson.com/au/epublications/newsalerts/GenePatentsDebate_Update.html) (report is referenced in this source).

<sup>21</sup> See Patent Amendment (Human Genes and Biological Products) Bill 2010 (Cth.) (Austl.).

<sup>22</sup> *Cancer Voices Australia v Myriad Genetics Inc.* [2013] FCA 65 (Austl.).

<sup>23</sup> *Id.* at 2.

<sup>24</sup> *Id.* The BRCA1 and BRCA2 genes are some of the most successful discoveries in genetic research. An estimated ten percent of all cases of breast cancer are traceable to mutated BRCA1 and BRCA2 genes. *Genetics*, BREASTCANCER.ORG (Sept. 17, 2012), available at <http://www.breastcancer.org/risk/factors/genetics>. Women who have both mutated genes have up to an eighty percent chance of developing breast cancer in their lifetimes. *Id.* Thus, the discovery of which variations of the BRCA1 and BRCA2 genes are associated with breast cancer was a major breakthrough in cancer prevention. Patients who test positive for the mutations early in their lives are able to plan their healthcare management plans accordingly. See Mark D. Schwartz, *Impact of BRCA1/BRCA2 Counseling and Testing on Newly Diagnosed Breast Cancer Patients*, 22 J. CLINICAL ONCOLOGY 1823 (2004).

<sup>25</sup> Joe Schneider, *Myriad Genetics Win on Gene Patent Ownership is Appealed*, BLOOMBERG, Mar. 3, 2013, available at <http://www.bloomberg.com/news/2013-03-04/myriad-genetics-win-on-gene-patent-ownership-is-appealed.html>.

<sup>26</sup> *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012), cert. granted, 133 S.Ct. 694 (U.S. Nov. 30, 2012) (No. 12-398).

<sup>27</sup> *Aktiebolaget Hässle v. Alphapharm* (2002) 212 CLR 411 ("The reasoning in . . . United States authorities should be accepted in preference to the path apparently taken in the English decisions").

basis in the patent law regime in Australia. The following section summarizes general patent law in Australia.

*B. Patent Law in Australia*

Australia's patent obligations are set forth in both its domestic patent laws and international agreements. The origins of Australian patent law are traceable to English patent law.<sup>28</sup> In 1623, the English Parliament enacted the Statute of Monopolies, which authorized the Crown to issue a "letters patent" for "any manner of new manufactures within [the] realm" to "the true and first inventors of such manufacture."<sup>29</sup> Although the English Crown awarded monopolies to individuals prior to the Statute of Monopolies, the recipients of those monopolies did not have to be the inventors, nor did those inventions have to be new and useful.<sup>30</sup> The Statute of Monopolies changed the award of exclusive rights for inventions from merely awards of royal favor into awards for advancements in art and technology.<sup>31</sup>

As an English colony, and a member of the "realm,"<sup>32</sup> early Australian inventors applied for patents in England.<sup>33</sup> After the Australian colonies established independent legislatures, an inventor could also directly petition a given legislature to pass a private bill that effectively awarded a patent.<sup>34</sup> The first formal Australian patent system was established in 1852, when the New South Wales legislature passed its first patent act.<sup>35</sup> On June 1, 1904, the different patent systems of each colony were consolidated into a single Australian commonwealth agency to oversee all patents in Australia. This agency is known as IP Australia, and still administers the patent system today.<sup>36</sup>

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<sup>28</sup> It should be noted that the English system was not the first patent system in the world. The basic elements of patent law can be traced to a fifteenth century Venetian statute, which provided a ten-year monopoly to inventions that were novel and useful. See MARTIN J. ADELMAN, RANDALL R. RADER, & JOHN R. THOMAS, *CASES AND MATERIALS ON PATENT LAW* 8 (3d ed.).

<sup>29</sup> Statute of Monopolies, 1623, 21 Jac 1, c. 3, § 6 (Eng.).

<sup>30</sup> See Chris R. Kyle, "But a New Button to an Old Coat": *The Enactment of the Statute of Monopolies*, 19 J. LEGAL HIST. 203 (1998).

<sup>31</sup> *Id.*

<sup>32</sup> Statute of Monopolies, *supra* note 29.

<sup>33</sup> *Patents: History*, STATE LIBRARY OF VICTORIA (Dec. 12, 2012), available at <http://guides.slv.vic.gov.au/patents>.

<sup>34</sup> See e.g., *South Australian Private Act No. 1 of 1848* (Cth.) (Austl.) (recording a patent application for an "improved windlass").

<sup>35</sup> See Barton Hack, *A History of the Patent Profession in Colonial Australia* (1984) (presented at the Annual Conference of the Institute of Patent Attorneys of Australia).

<sup>36</sup> *Our History*, IP AUSTRALIA (2012), <http://www.ipaustralia.gov.au/about-us/what-we-do/our-history/> (Last visited May 1, 2013).

The last major overhaul to patent eligibility in Australia occurred with the Patents Act of 1990. In this act, any “article of manufacture” is patent eligible if it is novel, useful, and was not used secretly before the application date.<sup>37</sup> The Patents Act, unlike U.S. patent statutes, also specifically excludes human beings,<sup>38</sup> plants, and animals<sup>39</sup> from patent eligibility.<sup>40</sup> Given the vague language of the Patents Act, IP Australia guidelines are important for determining (on a practical level) which patent applications are likely to be granted.

Internationally, Australia is similarly situated to other developed countries such as the U.S. Australia entered into the Paris Convention in 1925, and is still a member of the World Intellectual Property Organization (“WIPO”).<sup>41</sup> In 1995, Australia became a member of the World Trade Organization (“WTO”), and is thus a signatory to the Trade-Related Aspects of Intellectual Property Rights agreement (“TRIPS”).<sup>42</sup>

Although Australia has an independent patent system, with an independent body of common law, Australian courts have borrowed from other jurisdictions. Notably, the High Court of Australia has acknowledged that it finds U.S. jurisprudence to be particularly helpful when resolving patent issues.<sup>43</sup> Because of the similarity of the systems, and the breadth of patent cases in the U.S., Australian courts look towards U.S. patent cases in emerging technological areas such as biotechnology.<sup>44</sup>

With respect to human genes, IP Australia officially states that “a DNA or gene sequence that has been isolated may be patentable.”<sup>45</sup> According to the agency, a given isolated DNA structure is patentable so

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<sup>37</sup> *Patents Act 1990* (Cth) ch. 1, s 18.1 (Austl.)

<sup>38</sup> *Id.* § 18.2.

<sup>39</sup> *Id.* § 18.3. One major difference between biotechnology patents in Australia and the U.S. is the validity of plant patents. Section 18 of Australia’s Patents Act 1990 explicitly states that plants are not patent eligible. In contrast, the U.S. Congress specifically created a separate patent regime for plants. See 35 U.S.C. 161 (2006).

<sup>40</sup> While the United States Code does not specifically state that human beings are not patent eligible, the other barriers of patent eligibility in 35 U.S.C. 101 (2006) and various common law rules effectively result in the same outcome as the Australian statute. See *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

<sup>41</sup> *Treaty Database, Paris Convention, Australia*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, [http://www.wipo.int/treaties/en/remarks.jsp?cnty\\_id=184C](http://www.wipo.int/treaties/en/remarks.jsp?cnty_id=184C) (last visited May 12, 2013).

<sup>42</sup> *Australia and the WTO*, WORLD TRADE ORGANIZATION, [http://www.wto.org/english/thewto\\_e/countries\\_e/australia\\_e.htm](http://www.wto.org/english/thewto_e/countries_e/australia_e.htm).

<sup>43</sup> *Aktiebolaget Hässle v. Alphapharm* (2002) 212 CLR 411.

<sup>44</sup> Brief for Cancer Council Australia et al. as Amici Curiae Supporting Petitioners at 5, *Ass’n for Molecular Pathology v. Myriad Genetics* (No. 12-298).

<sup>45</sup> *Patents for Biological Inventions*, IP AUSTRALIA, Dec. 6, 2012, <http://www.ipaustralia.gov.au/get-the-right-ip/patents/about-patents/what-can-be-patented/patents-for-biological-inventions/> (last visited May 1, 2013).



long as it follows the other statutory rules of patentability.<sup>46</sup> Thus, isolated DNA patents are currently issued and valid in Australia. Despite this seemingly expansive definition, so-called “gene” patents are actually quite narrow. The following section describes the legal scope of gene patents, and compares it to the scientific scope of genes and genetic testing.

### C. *Genes and Genetic Testing*

Patent law is concerned with defining technology at the forefront of science and engineering. Thus, it is necessary to discuss the relationship between the scientific definition of genes, and its relationship to the legal definition of genes in gene patents. Those definitions are not equivalent.

From a scientific perspective, genes represent the information contained in each individual that provide for the blueprints of physical traits.<sup>47</sup> Each human has a total of 46 chromosomes, which are particles made up of strands of DNA and packed with protein.<sup>48</sup> Twenty-three chromosomes are inherited from each parent—forming the basis of inheritability.<sup>49</sup>

While DNA encodes plans for an organism, it must be translated into usable proteins to be expressed in that organism.<sup>50</sup> DNA is “transcribed” into complementary strands of ribonucleic acid (“RNA”), which is then “translated” into amino acids. Amino acids are the biological building blocks of polypeptides, which include proteins.<sup>51</sup> Proteins are perhaps the most important molecules that comprise each human body—they can be hormones,<sup>52</sup> they can make up muscle,<sup>53</sup> they can be used to coagulate blood.<sup>54</sup> Proteins are so important that DNA—which exists for the sole purpose of encoding protein—can determine an individual’s appearance or propensity for disease.<sup>55</sup> In summary, DNA is used to create RNA, and RNA is used to create chains of amino acids, including proteins. DNA essentially acts as a blueprint for the physical and chemical structures that define individual human beings.

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<sup>46</sup> *Id.*

<sup>47</sup> GENETICS 50 (Richard Robinson ed., 2003).

<sup>48</sup> *Id.* at 133.

<sup>49</sup> *Id.* at 132.

<sup>50</sup> *Id.* at 50.

<sup>51</sup> *Id.* at 198.

<sup>52</sup> *Id.* at 160.

<sup>53</sup> BIOLOGY 109 (Richard Robinson ed., 2005).

<sup>54</sup> *Id.* at 86.

<sup>55</sup> GENETICS, *supra* note 47, at 213.

Despite the apparent simplicity of genetics, it is quite laborious to research in practice. It may seem as though genetic research is as simple as comparing DNA sequences between individuals. However, the process is complicated by the fact that not every DNA sequence contained in an individual's chromosomes is actually used to create proteins.<sup>56</sup> Some DNA sequences are never translated to RNA.<sup>57</sup> Some RNA sequences are never transcribed into amino acids.<sup>58</sup> Sometimes, certain cellular conditions change what DNA is translated into RNA, or what RNA is transcribed into amino acids.<sup>59</sup> Thus, genetic research is more than about determining the sequence of an individual's DNA; it concerns determining DNA sequences that are actually "expressed."<sup>60</sup> Those usable sequences of DNA are known as genes.<sup>61</sup>

Although they are known as "gene" patents, the term is a bit of a misnomer. In scientific terms, a gene is a sequence and location of an encoding chain of DNA within the human genome.<sup>62</sup> The subject matter of gene patents, in contrast, is merely isolated fragments of DNA.<sup>63</sup> In order to have utility as a diagnostic tool, those fragments share a sequence with human genes as they appear in the genome.<sup>64</sup> However, a gene patent does encompass a genetic sequence: it only protects an isolated segment of DNA that shares a sequence with a human gene.<sup>65</sup> The subject matter of an eligible gene patent is a distinct, artificial molecular entity.<sup>66</sup> Thus, a gene patent is not literally a patent on a gene—it is a patent on "isolated DNA."

In the U.S.,<sup>67</sup> Australia,<sup>68</sup> and other nations,<sup>69</sup> isolated DNA molecules that match the sequence of human genes are patent eligible. Australia and

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<sup>56</sup> *Id.* at 51.

<sup>57</sup> *Id.* at 62.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* at 66 (describing how different cellular conditions during early development can change gene expression). Gene expression refers to "the process through which information in a gene is used to produce the final gene product: an RNA molecule or a protein." *Id.* at 61.

<sup>61</sup> *Id.* at 61.

<sup>62</sup> *Id.* at 50.

<sup>63</sup> *See, e.g.,* Association for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303, 1313 (Fed. Cir. 2012), *cert. granted*, 133 S.Ct. 694 (U.S. Nov. 30, 2012) (No. 12-398) (opinion below, holding that isolated DNA is patent eligible subject matter).

<sup>64</sup> *Id.* at 1332.

<sup>65</sup> *Id.* at 1331.

<sup>66</sup> *Id.* at 1332.

<sup>67</sup> The U.S. Supreme Court has recently granted certiorari on a challenge to the patent eligibility of Myriad's human gene patents. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S.Ct. 694 (2012) (accepting certiorari).

<sup>68</sup> GENE PATENTS REPORT 2011, *supra* note 18.

the U.S. share similar patent eligibility requirements for isolated DNA molecules.<sup>70</sup> Since an isolated DNA sequence does not occur naturally,<sup>71</sup> the patentability of isolated DNA is assumed under the broader category of novel chemical structures.<sup>72</sup> Thus, when Myriad Genetics and its co-inventors received patents for the BRCA1 and BRCA2 “genes,” those patents were exclusive licenses for fragmented, isolated DNA molecules.<sup>73</sup>

It may seem that, because gene patents do not literally encompass human genes, they are not necessary to test for human genes as they appear in the cell. However, isolated DNA molecules (and portions of those molecules) are essential for our most popular, low-cost genetic testing method: polymerase chain reaction (“PCR”).<sup>74</sup>

PCR requires the use of small isolated DNA fragments that are complementary with a targeted gene.<sup>75</sup> These fragments are known as “primers.”<sup>76</sup> The process begins when primers are added to a sample of a patient’s DNA.<sup>77</sup> PCR occurs in three stages. During the denaturation stage, the solution is heated, causing the bonds between the patient’s double-stranded DNA to break, leaving complementary single-stranded DNA.<sup>78</sup> During an annealing stage, the solution is cooled, allowing the single-stranded DNA to reattach.<sup>79</sup> This sample is made to contain significantly more “primers” than the single stranded DNA fragments.<sup>80</sup> The primers are much more likely to attach to the patient’s single-stranded DNA, than the

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<sup>69</sup> Isabelle Huys et al., *The Fate and Future of Patents on Human Genes and Genetic Diagnostic Methods*, 13 NATURE REVIEWS GENETICS 441, 442 (2012).

<sup>70</sup> ALRC REPORT 99, *supra* note 3, § 8.

<sup>71</sup> Chemical structures that do not occur naturally theoretically meet the novelty requirements set forth in Australian patent law (Patents Act 1990, Section 7), and U.S. patent law (35 U.S.C. § 102). Neither the Australian challenge, nor the U.S. challenge to Myriad’s gene patents included a challenge based on novelty. See *Cancer Voices Australia v Myriad Genetics Inc.* [2013] FCA 65, 8 (Austl.); *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012), *cert. granted*, 133 S.Ct. 694 (U.S. Nov. 30, 2012) (No. 12-398).

<sup>72</sup> *Cancer Voices Australia v Myriad Genetics Inc.* [2013] FCA 65, 8 (Austl.); *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012), *cert. granted*, 133 S.Ct. 694 (U.S. Nov. 30, 2012) (No. 12-398).

<sup>73</sup> *Cancer Voices Australia v Myriad Genetics Inc.* [2013] FCA 77 (Austl.).

<sup>74</sup> The 1993 Nobel Prize in chemistry was awarded for the development of PCR. THE NOBEL PRIZE IN CHEMISTRY 1994, [http://www.nobelprize.org/nobel\\_prizes/chemistry/laureates/1993/](http://www.nobelprize.org/nobel_prizes/chemistry/laureates/1993/) (last visited May 8, 2013).

<sup>75</sup> Randall K. Saiki et al., *Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase*, 239 SCI. 487, 487 (1988).

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

single-stranded DNA to its original complement.<sup>81</sup> During the “elongation” stage, the attached primers guide a heat-stable DNA polymerase enzyme to replicate the targeted gene.<sup>82</sup> The denaturation, annealing, and elongation cycle is repeated many times, amplifying the replicated gene.<sup>83</sup> If the PCR test is positive, the solution contains many copies of the DNA fragment, making it relatively simple to test for the presence of that fragment.<sup>84</sup>

If the patient’s DNA had the gene that the primer was designed to target, the process produces numerous copies of the genetic sequence. A positive PCR test is designed to create lots of isolated DNA molecules with the same sequence as the targeted gene. Thus, while a “gene” patent does not encompass the patient’s DNA, it does encompass the molecular structure created by the PCR process.

The foregoing discussion demonstrates that a positive PCR test for a patented gene literally infringes on that patent, because it is designed to produce many copies of the matching isolated DNA molecule. As such, gene patents practically preclude all other companies and individuals from testing for that gene in a cost-effective way.<sup>85</sup> In both the U.S. and Australia, Myriad Genetics has the power to keep researchers, healthcare organizations, and other companies from using PCR to test for BRCA1 and BRCA2, thus excluding all of its currently viable commercial competitors.<sup>86</sup>

It is important to note that scope of gene patents does not cover “genetic information per se,”<sup>87</sup> nor does it cover “naturally occurring DNA and RNA as they exist in cell.”<sup>88</sup> Each gene patent literally covers an artificial strand of DNA with the same sequence as a naturally occurring DNA sequence. Myriad’s BRCA1 patent, for example, could not “be infringed by someone who merely reproduced a naturally occurring DNA sequence in written or digital form.”<sup>89</sup>

Australia and the U.S. issue patents for isolated DNA molecules. When a sequence matches a gene sequence, it is referred to as a “gene” patent, despite the fact that it is not actually a patent on a gene. However, using PCR, those isolated DNA sequences are produced in the process of

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<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> This is possible using gel electrophoresis and southern blot techniques. *Id.* at 488.

<sup>85</sup> However, arguably, this will change. *See infra* Part V.

<sup>86</sup> *See Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012), *cert. granted*, 133 S.Ct. 694 (U.S. Nov. 30, 2012) (No. 12-398).

<sup>87</sup> *Cancer Voices Australia v Myriad Genetics Inc.* [2013] FCA 65, 76 (Austl.).

<sup>88</sup> *Id.* at 77

<sup>89</sup> *Id.* at 87.

testing for the presence of a gene in a patient's genome. Although Myriad's patents only encompass the isolated DNA molecule which has a matching sequence to the BRCA gene, it is currently effective in preventing unauthorized BRCA testing.

### III. GENE PATENTS BENEFIT SOCIETY

This section establishes the proposition that gene patents provide a substantial benefit to society by promoting genetic research. Section A introduces the concept that patents promote innovation and technological advancement. Section B introduces various criticisms of using patent law to promote genetic research. Section C compares the genetic industry to the pharmaceutical industry, and concludes that patent protection is essential to the genetic industry as it is to the pharmaceutical industry. Finally, Section D explains Australia's Raising the Bar Act and its importance in ensuring that human gene patents do not deter innovation.

#### *A. Basic Patent Theory: Patents Increase the Rate of Innovation in a Given Technological Area, and Promote Technological Advancement*

Scientific research is supported by both commercial and non-commercial sources.<sup>90</sup> Commercial sources of research include for-profit companies such as Myriad Genetics.<sup>91</sup> Non-commercial sources include non-profit charitable organizations,<sup>92</sup> as well as publicly-funded laboratories (e.g., university laboratories).<sup>93</sup> Logically, the total advance of this field is dependent on the combined contributions of both sources of research.

Patent law encourages commercial sources of genetic research to publicly disclose their technological advances.<sup>94</sup> In exchange for the right to

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<sup>90</sup> Richard R. Nelson, *The Simple Economics of Basic Scientific Research*, 67 J. OF POL. ECON. 297, 302 (1959).

<sup>91</sup> A record of Myriad's Security and Exchange Commission filings can be found on its website: <http://www.myriad.com/>.

<sup>92</sup> See, e.g., PHG FOUNDATION, <http://www.phgfoundation.org/> (last visited Jan. 5, 2013) (supporting medical research as an independent charitable organization).

<sup>93</sup> The National Science Foundation's grants regarding "genes and genome systems" fund non-commercial research laboratories. See NATIONAL SCIENCE FOUNDATION, GENES AND GENOME SYSTEMS CLUSTER, [http://www.nsf.gov/funding/pgm\\_summ.jsp?pims\\_id=12780](http://www.nsf.gov/funding/pgm_summ.jsp?pims_id=12780) (last visited May 8, 2013).

<sup>94</sup> See *supra* Part II.A (patent law in Australia); see also Frederic M. Scherer, *The Economics of Human Gene Patents*, 77 ACAD. MED. 1348, 1363 ("Not allowing [gene] patents in the future would discourage some research supported by private-sector investment.").

exclude other parties from profiting from their invention for a limited time, an inventor discloses how to make and use that invention.<sup>95</sup>

Without the right to exclude, commercial genetic researchers may be either discouraged from investing in genetic research, or protect their discoveries under trade secret law.<sup>96</sup> If commercial firms do not invest in genetic research, it logically follows that less total research would be performed to discover gene-disease correlations. If they do invest in genetic research, but decide to protect human gene inventions through trade secret, several problems would occur.

A company that protects its gene discovery through trade secret law would still be able to exercise a monopoly over and charge a fee for the use of that gene, except, unlike patents, a company can protect its secret, potentially forever.<sup>97</sup> Proponents point out that as long as a company properly protects its trade secret, the public may never get a “generic” version of that genetic test, increasing costs to consumers.<sup>98</sup> In addition, under a trade secret regime, the public may never learn about a given genetic discovery.<sup>99</sup> At the very least, this may cause researchers to unnecessarily and inefficiently re-research gene/disease correlations—simply because they would have no way of knowing whether a given gene/disease correlation had already been discovered.

In addition to resorting to trade secret law, there is an additional drawback of rejecting human gene patents. Even assuming that genetic research is supported by both commercial and non-commercial sources, the results of commercial sources of genetic research provide more economic benefits than non-commercial sources.<sup>100</sup> The more links between genes and

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<sup>95</sup> *Patents Act 1990* (Cth.) s 40 (Austl.).

<sup>96</sup> Trade secret law is governed by tort in common law countries. Essentially, so long as a piece of intellectual property is kept secret from the rest of the world, the keeper retains exclusive use without having to publicly disclose the intellectual property through the patent system. For more information about trade secrets in Australia, see the IP Australia website at <http://www.ipaustralia.gov.au/get-the-right-ip/other-types-of-IP/confidentiality-trade-secrets/>.

<sup>97</sup> *Id.*

<sup>98</sup> See Robert G. Bone, *A New Look at Trade Secret Law: Doctrine in Search of Justification*, 86 CAL. L. REV. 241, 265 (1998) (noting that trade secret law offers inventors the chance to set a value for their inventions, higher than the one prescribed by patent law).

<sup>99</sup> *Id.* at 266 (citing Steven N. S. Cheung, *Property Rights in Trade Secrets*, 20 ECON. INQUIRY 40, 44 (1982)).

<sup>100</sup> See *Research Funding as an Investment: Can we Measure the Returns?*, U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, April 1986, available at <http://www.fas.org/ota/reports/8622.pdf> (showing that money spent in the private sector provides more of an economic benefit than money spent in the public sector). Although genetic research is a relatively new area of biotechnology, other more developed areas of technology have proven to be entirely dependent on private sector contributions. See, e.g., C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 18 N.Y.U.

diseases discovered, the greater the scientific benefit<sup>101</sup> derived from genetic research.<sup>102</sup> Theoretically, the rate of innovation is proportional to the amount of research funding invested in a given field. Commercial sources invest vastly more funding into genetic research than non-commercial sources,<sup>103</sup> thereby supporting the presumption that the commercial sector provides more development of genetic linkages than the public sector.

In addition, commercial sources are better suited to offer technologies to end-users.<sup>104</sup> While both commercial and non-commercial sources invest in researching technology, generally only commercial sources fund regulatory approval processes<sup>105</sup> and manufacturing.<sup>106</sup> Commercial inventors are absolutely vital sources of new medical diagnostics, because they are the only sources which actually prepare medical products for patient

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L. REV. 1553 n. 25 (2006) (indicating that the pharmaceutical industry is highly dependent on public- and private-sector contributions).

<sup>101</sup> For example, as more genes are characterized, the more physicians will be able to tailor effective pharmaceutical treatments for their patients. Geoffrey S. Ginsburg & Jeanette J. McCarthy, *Personalized Medicine: Revolutionizing Drug Discovery and Patient Care*, 19 TRENDS IN BIOTECHNOLOGY 491, 491 (2001).

<sup>102</sup> See Subha Madhavan et al., *Rembrandt: Helping Personalized Medicine Become a Reality Through Integrative Translational Research*, 7 MOLECULAR CANCER RES. 157, 157 (2009) (showing that an integrated database of genetic information is more useful to researchers and clinicians than independently-discovered genetic links).

<sup>103</sup> According to Ernst and Young, the U.S. biotechnology industry invested approximately 17.2 billion dollars in R&D. ERNST & YOUNG, BEYOND BORDERS: GLOBAL BIOTECHNOLOGY REPORT 2012, available at [http://www.ey.com/GL/en/Industries/Life-Sciences/Beyond-borders---global-biotechnology-report-2012\\_Financial-performance-heads-back-to-normal](http://www.ey.com/GL/en/Industries/Life-Sciences/Beyond-borders---global-biotechnology-report-2012_Financial-performance-heads-back-to-normal). In contrast, the amount of money invested in research grants by the U.S. National Institutes of Health (“NIH”) was approximately 21 billion dollars. U.S. NATIONAL INSTITUTES OF HEALTH, RESEARCH GRANTS: FUNDING BY INSTITUTE, available at <http://report.nih.gov/NIHDataBook/Charts/Default.aspx?showm=Y&chartId=206&catId=0>. The NIH’s investment represents research grants awarded to all areas of medical research—a vastly more expansive field than merely biotechnology. Only an estimated 5.6 billion dollars of the NIH budget was spent funding biotechnology research in 2011. U.S. NATIONAL INSTITUTES OF HEALTH, ESTIMATES OF FUNDING FOR VARIOUS RESEARCH, CONDITION, AND DISEASE CATEGORIES (2013), [http://report.nih.gov/categorical\\_spending.aspx](http://report.nih.gov/categorical_spending.aspx) (last visited Jan 5, 2013).

<sup>104</sup> Gregory D. Graff et al., *The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology*, 21 NATURE BIOTECH. 989, 989 (2003) (“The economics of R&D in agricultural biotechnology have been similar to those of R&D in agrochemicals or pharmaceuticals, with universities specializing in basic research but lacking the resources or expertise needed for commercialization of products resulting from the new technologies, something which requires substantial investments in product development and biosafety testing.”).

<sup>105</sup> The U.S. Food and Drug Administration (“FDA”) is responsible for approving new drugs for safety and efficacy. 25 U.S.C. § 355(a) (2006). Looking at the lists of new drug clearances on the FDA website shows that each drug is sponsored by a company, rather than an independent researcher or publicly-funded laboratory. See the pharmaceutical approval listing at DRUGS@FDA, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm> (last visited May 8, 2013).

<sup>106</sup> See Roy Widdus, *Public-Private Partnerships for Health: Their Main Targets, Their Diversity, and Their Future Directions*, 70 BULL. WORLD HEALTH ORG. 713, 718 (2001) (explaining that “the public sector lacks expertise and experience . . . in product development, production process development, manufacturing, marketing, and distribution”).

use. Every piece of medical technology available in a hospital or medical clinic was produced by a company.

Moreover, it may be impossible to truly separate commercial and non-commercial sources of genetic research. Many non-commercial sources of scientific advancement are quasi-commercial.<sup>107</sup> That is, patenting and licensing are incentives for traditionally non-commercial sources such as publicly-funded universities.<sup>108</sup> For example, in the United States, the Bayh-Dole Act enabled universities to patent their employees' inventions, even if those inventions were supported by public funding from the federal government.<sup>109</sup> This suggests that by removing commercial incentives for genetic research (*i.e.*, by eliminating patent eligibility of human gene patents), non-commercial sources of genetic research are not capable of filling the void left by commercial sources.

### B. *A Major Criticism of Gene Patents: The Anticommons Effect*

Patent law is not without its detractors. Critics of the assumption that patents increase the rate of innovation have postulated that biotechnology patents contribute to an "anticommons effect": an accumulation of patents in the biotechnology space contributes to royalty stacking, which causes decreased access to the technology.<sup>110</sup> When there are a large number of licenses necessary to use a patented technology, a patent "thicket" is

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<sup>107</sup> David C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL'Y 99, 101 (2001) (describing the historical overlap of U.S. university research and industry); David C. Mowery et al., *IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT 2* (2004) ("there is little doubt that U.S. universities now are more heavily and directly involved in patenting and licensing of research results than any other time in their history"); see Robert L. Hotz, *Falling From Grace, Science and the Pursuit of Profit*, in *WHO OWNS LIFE?* 175 (criticizing the overlap of industry and public research); Ian Cockburn & Rebecca Henderson, *Public-Private Interaction in Pharmaceutical Research*, 93 PNAS 12725, 12729 (1996).

<sup>108</sup> Pierre Azoulay, Waverly Ding, & Tobey Stuart, *The Impact of Academic Patenting on the Rate, Quality, and Direction of (Public) Research Output*, 57 J. OF INDUS. ECON. 637 (2009); see Lynne G. Zucker & Michael R. Darby, *Star Scientists and Institutional Transformation: Patterns of Invention and Innovation in the Formation of the Biotechnology Industry*, 93 PNAS 12709, 12711 (1996) ("In biotechnology, early major discoveries were made by star scientists in universities but commercialized in [new biotechnology companies]."); see generally Donald S. Siegal, David Waldman, & Albert Link, *Assessing the Impact of Organizational Practices on the Relative Productivity of University Technology Transfer Offices: an Exploratory Study*, 32 RES. POL'Y 27 (2003).

<sup>109</sup> 35 U.S.C. § 200-212 (1980) (Bayh-Dole Act).

<sup>110</sup> This phenomenon was originally applied to biotechnology in Heller *supra*, note 4. See also Jorge A. Goldstein, *Critical Analysis of Patent Pools*, in *GENE PATENTS AND COLLABORATIVE LICENSING MODELS* 50 (Geertrui Van Overwalle ed., 2009); Carmen E. Correa, *The SARS Case: IP Fragmentation and Patent Pools*, in *GENE PATENTS AND COLLABORATIVE LICENSING MODELS* 42 (Geertrui van Overwalle ed., 2009).



created.<sup>111</sup> Royalty stacking may cause researchers to under-use patented technology as well as generally inhibit access to genetic testing technology.<sup>112</sup> Critics postulate that numerous patents from different sources will prevent whole-genome analysis because the complexity of licensing and royalty payments will deter entrants into genetic research.<sup>113</sup>

Despite these concerns, the anticommons effect has not borne out in practice, regardless of the fact many gene patents have been issued.<sup>114</sup> Licensing of gene patents is widely available in the industry.<sup>115</sup> When genetic researchers do not acquire a license, they are still able to conduct research in a jurisdiction where the patent holder has not filed a patent, or research the gene without a license.<sup>116</sup> In practice, given the “secrecy of research programs, costs of lost goodwill among researchers, costs of litigation, the relatively small damages to be collected from blocking research use, and the interest in the patent owner in allowing research advances in most cases,” researchers<sup>117</sup> are generally not punished for using a patented gene without a license.<sup>118</sup>

Additionally, in other potential patent thickets, industry-motivated patent pools have dealt with the problem of royalty stacking. Patent pools are agreements between multiple patent owners which allow third parties to license all of those patents in a cohesive package.<sup>119</sup> In the past, patent pools have emerged in other technology markets with overlapping patent rights, including markets related to sewing machines,<sup>120</sup> aircraft,<sup>121</sup> and MPEG-2

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<sup>111</sup> Birgit Verbeure, *Patent Pooling for Gene-Based Diagnostic Testing*, in GENE PATENTS AND COLLABORATIVE LICENSING MODELS 3 (Geertrui Van Overwalle ed., 2009).

<sup>112</sup> *Id.* at 3.

<sup>113</sup> *Id.*; Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECH. 1091, 1093 (2006) (“The empirical research suggests that the fears of wide spread anti-commons that block the use of upstream discoveries have largely not materialized.”).

<sup>114</sup> Caulfield et al., *supra* note 113 at 1093 (“The empirical research suggests that the fears of wide spread anti-commons that block the use of upstream discoveries have largely not materialized.”); NATIONAL RESEARCH COUNCIL COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN RESEARCH AND INNOVATION, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH (Stephen A. Merrill & Anne-Marie Mazza eds., 2005); MICHAEL M. HOPKINS ET AL., THE PATENTING OF HUMAN DNA: GLOBAL TRENDS IN PUBLIC AND PRIVATE SECTOR ACTIVITY (THE PATGEN PROJECT) (2006), available at [http://www.wipo.int/patentscope/en/programs/patent\\_landscapes/documents/patgen\\_finalreport.pdf](http://www.wipo.int/patentscope/en/programs/patent_landscapes/documents/patgen_finalreport.pdf) (describing the effects of patent law on European biotechnology).

<sup>115</sup> Pressman et al., *Patenting and Licensing Practices for DNA-Based Patents at U.S. Academic Institutions*, 24 NATURE BIOTECH. 31 (2005).

<sup>116</sup> Caulfield *supra*, note 113 at 1093.

<sup>117</sup> This observation applies to non-commercial researchers. *See id.*

<sup>118</sup> *Id.*

<sup>119</sup> Birgit Verbeure, *Patent Pooling for Gene-Based Diagnostic Testing*, in GENE PATENTS AND COLLABORATIVE LICENSING MODELS 3 (Geertrui Van Overwalle ed., 2009).

<sup>120</sup> *Id.*

technology.<sup>122</sup> Scholars have suggested that patent pooling is a natural solution to concerns about the potential anti-innovation effects of gene patents.<sup>123</sup>

*C. The Commercial Genetic Testing Industry, Like the Pharmaceutical Industry, May be Particularly Dependent on the Patent System*

The needs of the commercial genetic research industry are not entirely known, but may be comparable to the pharmaceutical industry. Even critics of patent systems suggest that patent eligibility is more important in certain industries.<sup>124</sup> One of the industries most dependent on patent protection is the pharmaceutical industry.<sup>125</sup> This dependence is a product of the high cost it takes to bring a new pharmaceutical or biologic to market.<sup>126</sup>

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<sup>121</sup> Harry T. Dykman, *Patent Licensing Within the Manufacturer's Aircraft Association*, 46 J. PATENT OFFICE SOC'Y 646 (1964).

<sup>122</sup> Lawrence A. Horn, *Case 1. The MPEG LA® Licensing Model: What Problem Does It Solve in Biopharma and Genetics?* in GENE PATENTS AND COLLABORATIVE LICENSING MODELS 33 (Geertrui Van Overwalle ed., 2009); see Letter from Joel I. Klein, Assistant Attorney General, Department of Justice, Antitrust Division, to Gerrard R. Beeney, Esq. (June 26, 1997).

<sup>123</sup> See Ted J. Ebersole, Marvin C. Guthrie, & Jorje A. Goldstein, *Patent Pools as a Solution to Problems of Diagnostic Genetics*, 17 INTELL. PROP. & L.J. 6 (2005); see also JEANNE CLARK ET AL., U.S. PATENT AND TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? (2000), available at <http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf>; Verbeure *supra* note 119 (indicating that patent pooling may be a solution to gene patent thickets); Horn, *supra* note 122.

<sup>124</sup> See Steve P. Calandrillo, *An Economic Analysis of Property Rights in Information: Justifications and Problems of Exclusive Rights, Incentives to Generate Information, and the Alternative of a Government-Run Reward System*, 9 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 301, 324 (1998) (indicating that monetary awards are necessary to encourage innovation in the pharmaceutical industry, but that those awards currently only exist through the patent system).

<sup>125</sup> Adelman, *supra* note 28 at 905; Hemphill, *supra* note 100 at 1562 (“almost uniquely, in [the pharmaceutical industry] the patent is considered necessary to recoup financial investment”); see Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, MICROECONOMICS 1, 2 (1991). The biotechnology industry is also highly dependent on patent protection. Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 47 FORDHAM L. REV. 477, 480 (“across the board, this is a very patent-sensitive field of research”); Iain M. Cockburn, *Intellectual Property Rights and Pharmaceuticals: Challenges and Opportunities for Economic Research*, ECON. INTELL. PROP. 150, 152, [http://www.wipo.int/export/sites/www/ip-development/en/economics/pdf/wo\\_1012\\_e\\_ch\\_5.pdf](http://www.wipo.int/export/sites/www/ip-development/en/economics/pdf/wo_1012_e_ch_5.pdf) (last visited May 1, 2013) (“In this sector . . . patents are the most visible and perhaps most important form of intellectual property”). Patent protection is also generally acknowledged as important in the biotech industry. Rochelle K. Seide & Carmella L. Stephens, *Ethical Issues and Application of Patent Laws, in WHO OWNS LIFE?* 60 (“[In the biotech industry,] patent protection is essential as it reduces commercial risks and provides economic incentives to commitment of capital and human resources”).

<sup>126</sup> Stephen M. Paul et al., *How to Improve R&D Productivity: the Pharmaceutical Industry's Great Challenge*, 9 NATURE REVIEWS DRUG DISCOVERY 203, 203 (2010) (estimating that it takes an investment of approximately \$1.8 billion to take a drug to market in the U.S.).

The considerable cost of producing marketable drugs is a function of two factors: research and development costs,<sup>127</sup> and regulatory costs.<sup>128</sup> Research and development costs include the costs of developing drugs that ultimately fail to reach the market.<sup>129</sup> Like pharmaceutical research, genetic research is also incredibly expensive.<sup>130</sup> However, the two markets currently have different regulatory approval requirements.

Genetic discoveries are not subject to pre-market approval processes. However, this is likely to change. Given the potentially broad dependence of clinicians on genetic tests, numerous national<sup>131</sup> and international<sup>132</sup> organizations have called for mandatory regulatory approval for genetic tests. Not only do the significant research costs make gene researchers dependent on the patent system to protect their inventions so that they can recoup their investments, but coming regulatory costs will soon deepen that dependence.

Moreover, the genetic testing industry may be particularly dependent on IP protection because genetic tests are so easy to copy. Like pharmaceuticals or biologics,<sup>133</sup> gene-disease correlations can be easily

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<sup>127</sup> *Id.*

<sup>128</sup> Eisenberg *supra*, note 125, at 481 (“a big chunk [of the money it takes to bring a drug to market] comes from the costs of conducting clinical trials to win FDA approval”).

<sup>129</sup> Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?* 28 *MANAGERIAL & DECISION ECON.* 469, 471 (2007).

<sup>130</sup> See Isaac C. Kohane, *Using Electronic Health Records to Drive Discovery in Disease Genomics*, 12 *NATURE REVIEWS GENETICS* 417, 417 (2011).

<sup>131</sup> In the United States, representatives from the National Institutes of Health and the Food and Drug Administration have suggested that pre-market approval for genetic tests is warranted. Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 *NEW ENG. J. MED.* 301 (2010) (expressing that the U.S. Food and Drug Administration and the National Institutes of Health are planning to regulate the genetic testing industry as genetic tests become a more standard diagnostic tool in medicine). In 1998, Australia and New Zealand entered into the Trans Tasman Mutual Recognition Agreement, which explicitly established regulatory approval processes for genetic testing services. *Trans-Tasman Mutual Recognition Act 1997* (Cth.) (Austl.). In addition, given that the Australian Pharmaceutical Benefits Scheme independently evaluates genetic tests for efficacy, there is currently a measure of regulatory costs for firms that own genetic tests and who want those tests covered under Medicare. See *infra* Part IV.C; see also *Case Study: Australia*, WORLD HEALTH ORGANIZATION GENOMIC RESOURCE CENTRE, available at <http://www.who.int/genomics/policy/australia/en/index.html> (last visited May 8, 2013).

<sup>132</sup> See, e.g., *Quality & Safety in Genetic Testing: An Emerging Concern*, WORLD HEALTH ORGANIZATION, [http://www.who.int/genomics/policy/quality\\_safety/en/index.html](http://www.who.int/genomics/policy/quality_safety/en/index.html) (last visited May 8, 2013) (describing the World Health Organization’s activities promoting quality assurance in genetic testing).

<sup>133</sup> Hemphill *supra* note 100 (indicating that pharmaceutical patents are also an “information good” because it is “relatively straightforward and cheap for others to manufacture” pharmaceuticals after they have been publicly disclosed).

applied to new patients after they are discovered.<sup>134</sup> Unlike pharmaceutical or biologic inventions, which require significant investment to copy,<sup>135</sup> a gene-disease correlation could be applied to new patients easily after the sequence and location is publicly disclosed.<sup>136</sup>

As a result of high development and impending regulatory costs, as well as the fact that genetic discoveries are easy to copy, the commercial genetic research industry is only possible with some form of IP protection for its inventions. Since patents establish exclusive licenses in the hands of the inventors, patent law enables inventors to exclude copiers and thus profit from the patented technology without competing with unscrupulous copiers. Currently, patent and trade secret protection offer the only viable sources of IP protection for genetic research firms.<sup>137</sup> Thus, many scholars believe that human gene patents are important to the commercial genetic research industry.<sup>138</sup>

*D. Australia's "Raising the Bar" Act Attenuates the Fear of Royalty Stacking and Contributes to a Particularly Effective Patent System*

Both the ALRC<sup>139</sup> and the ACIP<sup>140</sup> recommended that an experimental use defense to patent infringement would promote scientific research in Australia.<sup>141</sup> In 2011, Parliament passed the Raising the Bar Act,<sup>142</sup> which generally exempts non-commercial researchers from patent infringement.<sup>143</sup>

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<sup>134</sup> See *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1315 (Fed. Cir. 2012), *cert. granted*, 133 S.Ct. 694 (U.S. Nov. 30, 2012) (No. 12-398) (explaining that three of the plaintiffs in the case could "immediately" begin BRCA testing in their medical laboratories).

<sup>135</sup> Biologic products are considered more difficult to copy than pharmaceutical products. See Val Brickates Kennedy, *Amgen CEO Assesses Generic Threat*, MARKETWATCH, Mar. 1, 2006, [http://articles.marketwatch.com/2006-03-01/news/30800936\\_1\\_aranesp-amgen-ceo-biotechnology-drugs](http://articles.marketwatch.com/2006-03-01/news/30800936_1_aranesp-amgen-ceo-biotechnology-drugs) (last visited May 1, 2013).

<sup>136</sup> See *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1315 (Fed. Cir. 2012), *cert. granted*, 133 S.Ct. 694 (U.S. Nov. 30, 2012) (No. 12-398).

<sup>137</sup> Trade secret protection is essentially available over any information that can be kept a secret. Patent protection is, of course, already available for isolated DNA sequences. See *supra*, Part II.A.

<sup>138</sup> See, e.g., Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L.R. 295, 356 (2007) ("the use of these [gene patents] to incentivize the development of this increasingly important class of drugs would likely support an argument in favor of allowing gene patents"); Glen McGee, *Gene Patents Can be Ethical*, 7 CAMBRIDGE Q. OF HEALTHCARE ETHICS 417, 419 (2000);

<sup>139</sup> Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 Explanatory Memorandum, para. 24.

<sup>140</sup> *Id.* at para. 23.

<sup>141</sup> For a more thorough discussion of these recommendations, see Part II (A).

<sup>142</sup> Raising the Bar Act 2012 (Cth.) (Austl.).

<sup>143</sup> Raising the Bar Act 2012, (Cth.) s 119C (Austl.).

This Act allows unauthorized use of patented technology, so long as it is for non-commercial research purposes.<sup>144</sup> The Act's explanatory memorandum noted that, while the patent system "exists to encourage innovation and promote the dissemination of technical knowledge,"<sup>145</sup> the "benefits of this system are diminished where there is uncertainty about the extent to which patent rights impinge on freedom to do research."<sup>146</sup> Thus, it created a statutory experimental use exception, which exempts researchers from patent infringement if the research is conducted "as part of discovering new information or testing a principle or supposition."<sup>147</sup>

In order to preserve the commercial value of patents, the experimental use exception does not apply to research activities with a "predominantly commercial purpose."<sup>148</sup> Patents on research tools are also not subject to the experimental use exception, because those tools are developed for the purpose of commercially exploiting basic research.<sup>149</sup>

In effect, this law creates an exemption that prevents gene patent thickets from developing in non-commercial research settings by allowing non-commercial researchers to use patented technology without the threat of a patent infringement suit. Given that one of the major concerns of human gene patents is that patent eligibility stalls non-commercial genetic research,<sup>150</sup> Australia has effectively circumvented a major utilitarian argument against gene patents. As a result, Australia's patent system is uniquely situated to promote innovation in genetic research. If there is a patent system where gene patents can incentivize genetic research, Australia is it.<sup>151</sup>

#### IV. COUNTRIES LIKE AUSTRALIA ARE NOT CURRENTLY INCENTIVIZED TO PROTECT HUMAN GENES IN THEIR RESPECTIVE PATENT SYSTEMS

Given ongoing discussion over gene patents in Parliament and the courts, Australia is still in a position to evaluate whether gene patents are good for its citizens. This section proposes that, while gene patents throughout the world may be a good thing, it would be rational for Australia

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<sup>144</sup> Raising the Bar Act 2012 (Cth.) (Austl.).

<sup>145</sup> Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 Explanatory Memorandum, Acts for Experimental Purposes, s 119C.

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

<sup>149</sup> *Id.*

<sup>150</sup> *See supra*, Part III.B.

<sup>151</sup> Scherer, *supra* note 94 (indicating that a research exemption can boost technological innovation in genetic research).

to eliminate gene patents. Section A frames the international benefits of patent law. Section B explains why TRIPS is unlikely to interfere with a potential decision to eliminate gene patents. Section C introduces Australia's universal healthcare system, which may shoulder the costs of patented genetic tests. Section D proposes a game theory model which shows that Australia is currently in a position where it would be more rational to eliminate gene patents than keep them.

*A. Benefits of Each Patent System Are Felt by the Entire World, Whereas Costs of Each Patent System Are Felt Only by the Administering State*

Patent laws are determined in individual countries. Despite the immense amount of import-export transactions, and the rapid information sharing enabled by the Internet, patents are only enforceable in the country where they are filed and granted.

Previously, this comment argued patent law aims to incentivize innovation<sup>152</sup> and encourage inventors to disclose their inventions to the public. Disclosure, in turn, brings the rest of the industry up to speed on novel advancements in a particular technological area. This encourages innovation by both educating the industry and preventing wasteful research investments on technologies that have already been invented.

Disclosure is the key to the benefits of patent law. However, disclosing an invention in one country also discloses that invention in other countries. For example, records of U.S. patents are widely available on the USPTO website,<sup>153</sup> whether accessed from within the United States or from Australia. Thus, researchers in Australia also benefit from the U.S. patent system. Similarly, Australian patents are accessible online from the United States.<sup>154</sup>

However, the costs of each country's patent system are only directly felt by commercial actors in that jurisdiction. For example, patents in the U.S. are not enforceable in Australia.<sup>155</sup> If a company fully disclosed a gene-disease discovery and acquired a U.S. patent as a result of that disclosure, and Australia did not grant a patent on that disclosure, Australian businesses would be free to profit from tests for that gene without compensating the

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<sup>152</sup> See *supra* Part III.A.

<sup>153</sup> To search U.S. patents or patent applications, see <http://www.uspto.gov/patents/process/search/>.

<sup>154</sup> Australian patents can be accessed via AusPat: <http://www.ipaustralia.gov.au/auspat/index.htm>.

<sup>155</sup> See 35 U.S.C. § 271(a) (2006); see also *Patents Act 1990* (Cth.) s 13(3) (Austl.).

U.S. patent holder.<sup>156</sup> The American company would also be without recourse in Australian courts.

Ultimately, patent laws are established by individual countries. However, the benefits of establishing patent laws extend beyond the borders of those countries. Therefore, utilitarian models concerning patent laws of any sort should be designed with an international perspective. In fact, international agreements which seek to unify patent law to some extent do exist: most importantly, through the World Trade Organization (“WTO”).

*B. TRIPS Does not Necessarily Compel WTO Members to Protect Human Genes Through Patents*

A major condition for WTO membership is acceptance and ratification of the TRIPS agreement.<sup>157</sup> TRIPS is a multilateral agreement that partially unifies patent law across WTO members.<sup>158</sup>

Opponents of gene patents are constrained by Article 33 of TRIPS, which prevents any member from discriminating against any area of technology. This prevents nations from specifically excluding areas of technology from patent eligibility. Thus, if Australia sought to specifically exclude isolated DNA inventions from patent eligibility, it would potentially be subject to WTO sanctions.<sup>159</sup>

However, there are several exceptions to TRIPS Article 33. Article 27 of TRIPS allows member states to exclude certain inventions from patentability if it is “necessary to protect *ordre public* or morality.”<sup>160</sup> Given the profound controversy surrounding gene patents throughout the world, Australia might be justified in eliminating gene patents via legislation under Article 27 of TRIPS by arguing that ownership of human genes is contrary to public morality. TRIPS also allows member states to block patentability of diagnostic techniques.<sup>161</sup> Commercial firms like Myriad Genetics use

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<sup>156</sup> See 35 U.S.C. § 271(a) (2006); see also *Patents Act 1990* (Cth.) s 13(3) (Austl.).

<sup>157</sup> Overview: The TRIPS Agreement, World Trade Organization, [http://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm) (last visited May 8, 2013).

<sup>158</sup> *Id.*; see J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement*, 29 INT'L L. 345 (1995).

<sup>159</sup> TRIPS Article 44 empowers judges to order injunctions for violations of the agreement. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 44, Apr. 5 1994, 33 I.L.M. 1197, 1215. Article 45 empowers judges to order payment of monetary damages in certain cases. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 45, Apr. 5 1994, 33 I.L.M. 1197, 1215.

<sup>160</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27.2, Apr. 5 1994, 33 I.L.M. 1197, 1208.

<sup>161</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27.3(a), Apr. 5 1994, 33 I.L.M. 1197, 1208.

gene patents primarily for diagnostic purposes.<sup>162</sup> If Parliament blocked the use of gene patents for diagnostic tests, it would fall squarely into the language of the diagnostic test exception.<sup>163</sup>

These exceptions to TRIPS render Article 33 moot in the gene patent debate. Despite the aim of encouraging uniform patent protection across the developed world, TRIPS is unlikely to bar countries like Australia from eliminating gene patents.

A successful judicial challenge to the validity of human gene patents would also not violate TRIPS. The challenges to gene patent validity in the United States and Australia assert that isolated DNA inventions are not patent eligible under the existing patent law regimes of those jurisdictions.<sup>164</sup> Thus, the WTO could find that isolated DNA inventions are not patent eligible, so long as the theory is based on a non-discriminatory, existing general law of patent eligibility.

Ultimately, the language of TRIPS does not appear to apply to a judicial or parliamentary decision to eliminate gene patents. Despite the fact that TRIPS was created to establish uniform patent laws, due to its extensive exceptions, it does not compel uniformity in the gene patents arena.

### C. *Australia's Expansive Healthcare Coverage for Its Citizens Provides a Direct Cost to Recognizing Healthcare-Related Patents*

The Australian government provides universal healthcare to its citizens through a system called Medicare.<sup>165</sup> Medicare was established (in

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<sup>162</sup> *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1314 (Fed. Cir. 2012), cert. granted, 133 S.Ct. 694 (U.S. Nov. 30, 2012) (No. 12-398).

<sup>163</sup> Under Article 27.3(a) of TRIPS, member states may exclude "from patentability . . . diagnostic, therapeutic and surgical methods for the treatment of humans or animals." Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27.3(a), Apr. 5 1994, 33 I.L.M. 1197, 1208. Additionally, Article 8 (which allows public health considerations while designing patent laws) combined with Article 31 (which allows the granting of compulsory licenses in certain healthcare related patents) suggests that WTO member states could essentially ignore gene patents that they find particularly problematic. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 8, Apr. 5 1994, 33 I.L.M. 1197, 1201; Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 5 1994, 33 I.L.M. 1197, 1209. For a more thorough discussion of the potential gene patent-related exceptions to the general bar against technology discrimination under TRIPS, see Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NATURE REVIEWS GENETICS 803, 807 (2002). See also, Alan O. Sykes, *TRIPs, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* JOHN M. OLIN LAW & ECONOMICS WORKING PAPER no. 140, 7 (discussing the methods that developing countries use to relax pharmaceutical patent rights under TRIPS if the patents are deemed injurious to public health).

<sup>164</sup> *Petition for Writ of Certiorari, Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1313 (Fed. Cir. 2012), cert. granted, 133 S.Ct. 694 (U.S. Nov. 30, 2012) (No. 12-398).

<sup>165</sup> *Medicare*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HUMAN SERVICES, <http://www.human.services.gov.au/customer/information/welcome-medicare-customers-website>. (last visited May 1, 2013).



its modern form) in 1983 with the passage of the Health Legislation Amendment Act 1983.

Medicare administers the Pharmaceutical Benefits Scheme (“PBS”),<sup>166</sup> which is responsible for subsidizing individual treatments and diagnostics. If the administrators of Medicare determine that a particular diagnostic test is essential to the distribution of healthcare to Australian citizens, it directly subsidizes that test through PBS.<sup>167</sup>

Since patents create limited monopolies, on-patent technologies are almost universally more expensive than off-patent technologies. That is, since patents put exclusive licenses in the hands of the inventor, the inventor is free to charge whatever she chooses for use of the patented technology. In many cases, the premium for patented technology is passed down directly to the consumer. However, the “consumer” in the medical industry is effectively the government in countries which heavily subsidize medical diagnostics for patients.

In this case, the Australian government sets patent policy,<sup>168</sup> and subsidizes medical tests through PBS. In effect, by allowing patents on medical technologies, the government directly pays more. Patents on human genes represent a direct cost to any government which subsidizes healthcare costs for its citizens.<sup>169</sup>

*D. Under a Game Theory Model, Countries like Australia Are Incentivized to Eliminate Healthcare-Related Patents like Human Gene Patents*

Game theory is a popular way to evaluate the rationality of different possible decisions.<sup>170</sup> Game theory enables policy-makers, among others, to weigh the benefits of an actor’s potential decisions under different circumstances, and design policies that promote rational decision-makers to perform the actions that the policy-makers prefer.

Under a game theory model, the overall payoff to Australia for recognizing gene patents is the difference of the benefit of doing so, minus

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<sup>166</sup> *National Health Act 1953* (Cth) (Austl.); *National Health (Pharmaceutical Benefits) Regulations 1960* (Cth) (Austl.).

<sup>167</sup> For an explanation of the process required to get a medical product listed on PBS, see the PBS website at <http://www.pbs.gov.au/info/industry/listing/listing-steps>.

<sup>168</sup> For example, this can happen through Parliament. See *supra* Part II.A.

<sup>169</sup> In fact, similar pressure incentivized the Canadian province of Ontario to offer its own genetic test for the BRCA genes, in violation of Myriad’s valid Canadian patent. See Laura Eggerston, *Ontario Defies US Firm’s Genetic Patent, Continues Cancer Screening*, 166 CMAJ 494 (2002).

<sup>170</sup> For an introduction to game theory as applied to legal issues, see Douglas G. Baird et al., *GAME THEORY AND THE LAW* (1994).

the costs. The benefits are comprised of the acceleration<sup>171</sup> in research due to the rest of the world’s protection of gene patents (“A(w)”) as well as the acceleration in domestic research accrued by Australia because of its enforcement for gene patents (“A(a)”). The direct cost of Australia’s recognition of gene patents is equal to the increase in healthcare spending through Medicare and the PBS (“C”). Assuming that the rest of the world recognizes gene patents, Australia’s most rational decision depends on weighing the benefit produced by Australia’s relatively small contribution to the global genetic testing market against the costs accrued by the Australia government for paying for expensive, on-patent genetic tests.

Table 1 represents a payoff matrix for both Australia and the world. The decisions of the world are represented by the vertical axis. The decisions of Australia are represented by the horizontal axis. The first quantity in each box represents the payoff to Australia, and the second quantity represents the payoff to the rest of the world.

TABLE 1

	Patentable	Unpatentable
Patentable	$A(a) + A(w) - C(a)$ <sup>172</sup>	$A(w)$
Unpatentable	$A(a) - C(a)$	0

Variable A(a) represents the acceleration of innovation due to Australia’s market contribution, and A(w) represents the acceleration of innovation due to the rest of the world’s market contribution, where A(w) is much greater than A(a). Variable C(a) represents the direct costs to the Australian government as a result of paying for more expensive, on-patent genetic tests.<sup>173</sup>

Given the variety of different payouts for Australia, it is necessary to consider its decision to cooperate or defect in the context of the other “player’s” decision. In this case, the other player is the world. If the rest of

<sup>171</sup> See *supra* Part III.A.

<sup>172</sup> In this model, it would be rational to declare gene patents invalid in Australia if  $C(a) < A(a) + A(w)$ . However, if the United States eliminates gene patents altogether, it is more likely that gene patents would be irrational in Australia, because the inequality would change to  $C(a) < A(a)$ .

<sup>173</sup> This author assumes that the cost of on-patent genetic tests are much more protracted in the United States. The two primary regimes where the U.S. government pays for healthcare costs are Medicaid and Medicare. As far as this author knows, Medicaid does not yet cover non-emergency genetic tests such as BRCA1 and BRCA2. Medicare patients are primarily middle-aged and older, which is a population where genetic tests like BRCA1 and BRCA2 are no longer nearly as relevant; if members of that population are carriers, they will be beyond an age where prophylactic treatment will have an effect. While it is true that heightened costs are detrimental to the U.S. government in less direct ways (for example possible loss in tax revenue), those costs are not addressed here.

the world eliminates gene patents, then Australia can choose the payouts in the right column. Either Australia can decide to boost the worldwide innovation and incur more costly healthcare services (by recognizing gene patents, top-right choice), or it can follow along with the rest of the world and defect (by not recognizing gene patents, bottom-right choice). Given that Australia's healthcare market is small compared to the rest of the world,<sup>174</sup> it seems unlikely that a robust biotech industry could be sustained by only Australian consumers. Incurring the costs of paying for more expensive genetic tests would also put Australia at a disadvantage as compared to other countries—which would still reap the benefits of Australian protection<sup>175</sup> without incurring the increased costs of healthcare services that patent protection would cause. In this sense, it seems perfectly reasonable to assume that if all other countries defect, Australia would rationally decide to also defect and not recognize gene patents.<sup>176</sup>

If the rest of the world decides to recognize gene patents, then Australia's choice falls between the two payouts in the left column. In this case, Australia receives the benefit of the boost to innovation that is provided by the worldwide genetic diagnosis market regardless of if it recognizes gene patents itself. Acting rationally, Australia should not recognize gene patents in the event that the world recognizes gene patents.

Both situations favor defection. In decision theory terms, Australia's dominant strategy is defection.<sup>177</sup> Of more concern, Australia's decision is not unlike that of other developed nations with significant healthcare markets. This suggests that it is rational for these countries to defect—despite the fact that worldwide recognition of gene patents may be a common good.

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<sup>174</sup> See Gerard F. Anderson et al., *Health Care Spending and use of Information Technology in OECD Countries*, 25 HEALTH AFF. 819, 820 (2006) (describing the per capita spending on health care by country, including Australia and the U.S.). See also *Australia*, WORLD BANK, <http://data.worldbank.org/country/australia> (last visited Feb. 5, 2013) (listing the population of Australia as 22.62 million. *But cf. United States*, WORLD BANK, <http://data.worldbank.org/country/united-states> (last accessed Feb. 5, 2013) (listing the population of the U.S. as 311.6 million). Not only does the United States spend more per capita on health care, but it also has a substantially higher population than Australia. Thus, Australia's health care market is much smaller than the United States', which means that Australia's health care market is small compared to the worldwide market (which includes many other countries in addition to the U.S.) relating to health care services.

<sup>175</sup> Mainly, the benefits of patenting a technology focus on disclosure. See *supra* Part III.

<sup>176</sup> Mathematically, this conclusion is represented by the following inequality:  $A(a) - C(a) < 0$ ; or  $A(a) < C(a)$ .

<sup>177</sup> While the model in this section assumes that the game is only played once, dominant strategies do not change with game iterations.

Thus, despite the mutual benefit of cooperation, countries are incentivized to defect.<sup>178</sup>

V. WHOLE-GENOME SEQUENCING WILL EFFECTIVELY ELIMINATE HUMAN GENE PATENTS REGARDLESS OF WHETHER CURRENT LEGAL CHALLENGES TO THE PATENT ELIGIBILITY OF GENE PATENTS SUCCEED

Growing success in genetic sequencing technology threaten the viability of gene patents. Gene patents are only valuable so long as it is necessary to use the physical isolated DNA molecule<sup>179</sup> to perform a process such as a genetic test. However, recent changes threaten to replace the need to isolate DNA molecules in order to test for individual genes. This section explores the likely outcome of such developments and concludes that the gene patent debate will ultimately be mooted by developing technology. Regardless of the success of challenging patents on isolated DNA, researchers will soon be able to test for patented genes without directly infringing on those patents. Section A outlines the ongoing development and viability of whole-genome sequencing. Section B explains why whole-genome sequencing is problematic to gene patent proponents.

A. *The Development of Genome Sequencing and the Limits of Gene Patent Infringement*

Gene patents are currently useful in controlling access to corresponding genetic tests. However, this control may be limited as genetic testing moves away from PCR. This section explores developing alternatives to PCR—methods which do not require the production of isolated DNA. The value of isolated DNA patents that represent human genes is the ability of the patent holder to exclude other parties from testing for that gene. To reiterate, “gene” patents as they currently stand are not patents on the genes within genomes, but rather, they are on “distinct molecular entities” that enable genetic testing services to test for a given gene within an individual’s genome.<sup>180</sup>

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<sup>178</sup> Note that despite the fact that the model predicts that countries like Australia are not incentivized to recognize gene patents, they certainly do at the moment. It appears that this is the result of historical accident. Existing Australian patent laws allowed the patent eligibility of isolated DNA. *See supra* Part II.A and Part II.B. Gene patent opponents then were faced with arguing that the government has to take affirmative steps to eliminate isolated DNA from patent eligibility. The results of this argument are pending, given the judicial appeal and parliamentary advocacy. *See supra* Part II.A.

<sup>179</sup> This analysis also extends to isolated DNA equivalents under the doctrine of equivalents.

<sup>180</sup> *See supra* Part II.A.

However, many developing methods of genomic sequencing do not require the use of isolated DNA fragments. The Archon X-Prize,<sup>181</sup> established in 2006, is a competition that has agreed to award \$10 million to the first group of researchers who can sequence 100 human genomes in a given time,<sup>182</sup> with a certain level of accuracy,<sup>183</sup> and under a given budget.<sup>184</sup> Unlike traditional genetic tests, whole-genome sequencing refers to a process that reduces a person's entire genome into its ordered sequence of DNA monomers.<sup>185</sup> Whole-genome sequencing does not require independent gene testing via PCR.<sup>186</sup> As of 2013, two teams have signed up to compete for the prize, which signals incredible development in whole-genome sequencing technology.<sup>187</sup>

Team Ion Torrent will compete using ion semiconductor sequencing. Ion semiconductor sequencing is an emerging whole-genome sequencing method.<sup>188</sup> Unlike PCR, the process does not produce isolated DNA sequences. It takes naturally-occurring patient DNA and sequences it

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<sup>181</sup> The Archon X-Prize website is available at <http://genomics.xprize.org/>.

<sup>182</sup> The prize will be awarded to the first team to sequence 100 genomes in less than thirty days. Larry Kedes & Grant Company, *The New Date, New Format, New Goals and New Sponsor of the Archon Genomics XPRIZE Competition*, 43 NATURE GENETICS 1055, 1055 (2011).

<sup>183</sup> *Id.* ("no more than 1 error per 1,000,000 bases").

<sup>184</sup> *Id.* (\$1,000 per genome or less").

<sup>185</sup> *Frequently Asked Questions*, ARCHON X-PRIZE, <http://genomics.xprize.org/competition-details/frequently-asked-questions>.

<sup>186</sup> Theoretically, under Australian patent law, defendants may "infringe in substance," even if they do not infringe directly. This theory is similar, but less expansive, than the United States theory of infringement under the doctrine of equivalents. In *PhotoCure ASA v Queen's University at Kingston* [2005] FCA 344, the Federal Court of Australia adopted the U.K.'s version of infringement in substance. See *Improver Corporation v Remington Consumer Products Limited* [1990] FSR 181 at 189. If the variant "has a material effect on the way the invention works," then it is outside of the scope of the claim. *Photocure* at 195. If the variant is nonobvious at the time of the claim, then it is outside of the scope of the claim. *Id.* If a "reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention," then uses beyond the primary meaning are outside of the claim. *Id.* Given that gene patents in Australia specifically recite limitations of isolated DNA, (*see supra* Part II.C) and the Federal Court of Australia recently confirmed that isolated DNA limitations are necessary for their patent eligibility (*see supra* Part II.C), it is unlikely that a genetic test that does not physically use the patented molecule would infringe on the gene patent.

<sup>187</sup> *Teams*, ARCHON GENOMICS X-PRIZE, <http://genomics.xprize.org/teams>.

<sup>188</sup> The technological basis for the sequencer that will be used by Ion Torrent in the Archon X-Prize competition this year was published in *Nature* in 2011: Jonathan M. Rothberg, *An Integrated Semiconductor Device Enabling Non-Optical Genome Sequencing*, 475 NATURE 348 (2011). This sequence method requires a patient's native DNA to be suspended in a solution with deoxyribonucleotide triphosphate ("dNTP") molecules. The process induces DNA replication, which causes each DNA strand to separate. Four types of dNTP molecules are used—which match the four types of DNA nucleotides. During the induced replication process, the dNTP molecule that complements the template strand attaches to the template, releasing a hydrogen ion. The hydrogen ion is sensed using an ion-sensitive field-effect transistor ion sensor. The process is incredibly rapid, and performed on a microfluidic platform.

directly. Since gene patents are not on the sequence, but rather on isolated DNA with a matching sequence, researchers can sequence whole genomes using ion semiconductor sequencing without infringing on any gene patents.

The Wyss Institute at Harvard University, led by the renowned geneticist Dr. George Church, has also agreed to compete in the X-Prize competition this year.<sup>189</sup> Although the Wyss Institute has not shared what sort of sequencing method it will use in the competition, Dr. Church's research group is known for developing polony sequencing.<sup>190</sup> This method divides up patient DNA into random segments, and sequences each segment using an imaging method.<sup>191</sup> It uses two types of DNA fragments: existing proprietary primers, and chopped-up genomic DNA samples to be sequenced. Neither of those fragments, however, necessarily must match genes at all. Consequently, polony sequencing is another method in which gene patents do not necessarily inhibit genetic analysis.

Neither technology is common in clinical practice. However, if either technology is advanced enough to win the Archon X-Prize, medical practice would be one step nearer to utilizing widespread whole-genome sequencing. While no one can say with certainty that the teams can meet the technical standards of the prize, the teams are optimistic.<sup>192</sup>

*B. Widespread Whole-Genome Sequencing Will Render Human Gene Patents Effectively Valueless*

Whole-genome sequencing methods have the potential to make gene patents valueless because they do not require the use of patented isolated DNA sequences. Even if Australia and other countries continue to recognize gene patents as they currently stand, the gene patent regime will not incentivize genetic research at all when whole-genome sequencing becomes common practice—because gene patents will be incredibly easy to design around.

Cheap and fast genetic sequencing is inevitable.<sup>193</sup> When it comes into popular use, companies will no longer be able to use patents on isolated

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<sup>189</sup> *Wyss Institute Team at Harvard University*, ARCHON GENOMICS X-PRIZE, <http://genomics.xprize.org/teams/wyss-institute-team>.

<sup>190</sup> See Jay Shendure et al., *Accurate Multiplex Polony Sequencing of an Evolved Bacterial Genome*, 309 SCI. 1728 (2005).

<sup>191</sup> *Id.* at 1729.

<sup>192</sup> *Life Technologies to Compete in \$10 Million Archon Genomics X PRIZE*, ARCHON GENOMICS X-PRIZE (2013), <http://genomics.xprize.org/media/press-releases/life-technologies-compete-10-million-archon-genomics-x-prize>.

<sup>193</sup> The X-Prize foundation, which seeks to encourage the development of a cheap and fast genetic sequencing technology, seems to be approaching a level of success. See the foundation's website at

DNA to exclude others from testing for the human genes.<sup>194</sup> This is due to a fundamental difference in technology, rather than law; PCR tests require the use of isolated DNA that matches the targeted gene,<sup>195</sup> while genetic sequencing does not.

Whether nations decide that gene patents are important to genetic research or not, advances in genetic sequencing technology will make that choice for them. If human gene patents cannot be used to control testing for patented genes, then they will effectively lose value. Proponents of gene patents, who may believe that the incentives contained within gene patents are necessary to incentivize and pay for genetic research,<sup>196</sup> should be concerned with the developments of whole genome sequencing. Without a viable method of both encouraging disclosure of genetic discoveries, and ensuring the return on investment for regulatory approval processes, it is difficult to see how a commercial enterprise would continue to invest in genetic research.<sup>197</sup>

Moreover, proponents of gene patents will be forced to switch from defense to advocacy. Present patent laws in Australia and the United States are not equipped to protect genetic research investments from whole-genome sequencing. Proponents will be forced to convince independent nations to take affirmative steps to expand protection over human genes. By doing nothing, the impending success of viable whole-genome sequencing will render gene patents ineffective for encouraging commercial genetic research. However, proponents are facing an uphill battle: given the fact that countries like Australia are encouraged to eliminate gene patents altogether,<sup>198</sup> it may be extraordinarily difficult to convince countries like Australia to go out of their way to protect human genes under the patent system. Opponents, on the other hand, are advantaged by these developments. Rather than suing over the validity of isolated DNA patents, opponents may serve their cause more effectively by supporting the development of whole-genome sequencing.

Proponents have a problem. Even if the gene patent challenges in the United States and Australia fail, gene patents will be in effect defeated with

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xprize.org. For the 2013 competition, multiple teams with allegedly qualifying inventions have entered the X-Prize competition. Quite generally, the X-Prize competition is viewed as the gateway into personalized medicine: if an invention is capable of meeting the foundation's specifications, then it would be cost-effective for major health insurance providers to sequence patient genomes as a method of routine care.

<sup>194</sup> See *supra* Part V.A.

<sup>195</sup> See *supra* Part I.C.

<sup>196</sup> See *supra* Part III.

<sup>197</sup> See *supra* Part III.A and Part.C.

<sup>198</sup> See *supra* Part IV (D).

the development of fast and inexpensive whole-genome sequencing. Proponents should focus on asking individual jurisdictions to broaden intellectual property protection on human genes.

VI. IN ORDER TO INCENTIVIZE COMMERCIAL INVESTMENT IN GENETIC RESEARCH, AN INTERNATIONAL AGREEMENT PROVIDING FOR THE IP PROTECTION OF HUMAN GENES IS NECESSARY

Given that disclosure in a single given jurisdiction means that anyone in the world can access that information, it is appropriate for patent law policy to be considered on a global scale.<sup>199</sup> As discussed in Part IV, TRIPS does little to prevent countries such as Australia from “defecting” by refusing to acknowledge gene patents.

According to scholars, the goal of any law—domestic or international—is to prevent games with an equilibrium point of mutual defection.<sup>200</sup> Unfortunately, TRIPS fails to motivate countries like Australia to maintain patent protection for human genes.<sup>201</sup>

Proponents of gene patents must advocate for a new protective regime for human genes. Given that the industrialized world has something to gain from gene patents, and yet if countries like Australia behave rationally they would not recognize gene patents,<sup>202</sup> a new international regime is appropriate in this case. Several alternatives have been discussed, including the possibility: A) that human genes should be protected in a new, non-patent intellectual property regime, B) that human genes should be protected in a reformed international patent regime, or C) that nations should come together to consolidate regulatory approval, and facilitate paying for regulatory approval through public funding. Each possible solution is discussed in brief below.

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<sup>199</sup> See *supra* Part IV.A.

<sup>200</sup> See Bartosz Brozek, *The Normativity of Law*, in *STUDIES IN THE PHILOSOPHY OF LAW, VOLUME 7: GAME THEORY AND THE LAW* (Jerzy Stelmach & Wojciech Zaluski eds., 2011).

<sup>201</sup> See *supra* Part IV.D.

<sup>202</sup> See *supra* Part IV.



A. *Protecting Human Genes Through an Alternative Intellectual Property Regime*

First, countries may decide to create a new intellectual property regime for human genes.<sup>203</sup> Proponents argue that an international agreement that protects genetic discoveries from being freely used is the most appropriate solution.<sup>204</sup> Some proponents describe putting genetic discoveries in an international “trust,” administered by an international organization that could assist licensing agreements.<sup>205</sup>

In terms of the game theory model, it would still increase the rate of innovation, because it would directly reward researchers who discover new genes. However, it would not eliminate the drawbacks of gene patents, such as the problem of increased healthcare expenditures. The balance between those two variables depends on how the policy values this new form of intellectual property.

The agreements would have to be lucrative enough to encourage commercial investment in genetic research, in order to incentivize investments by commercial sources. However, ultimately the costs of genetic tests protected under an alternative intellectual property regime would be paid by medical insurance providers, including (particularly in Australia’s case) governments because of healthcare subsidies. In addition, creating a new intellectual property regime may introduce unnecessary complexity into international intellectual property policy. It begs the question of whether the same goal could be served by simply using the patent system—which individual nations and industries know and understand.

B. *Protecting Genetic Discoveries Through the Patent System*

Another alternative is to reform TRIPS or WIPO agreements to cover genetic sequence information through the patent system. Present domestic patent systems do not protect genetic sequences.<sup>206</sup>

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<sup>203</sup> See Looney, *supra* note 2. See also, Janet Hope, *Open Source Genetics: Conceptual Framework*, in *GENE PATENTS AND COLLABORATIVE LICENSING MODELS* 171 (Geertrui van Overwalle ed., 2009) (describing an open source model for genetic research).

<sup>204</sup> See Looney, *supra* note 2.

<sup>205</sup> *Id.* at 268.

<sup>206</sup> For example, in Australia, the Patents Act of 1990 only allows “articles of manufacture” to be patented. Gene-disease correlations are more akin to discoveries or ideas, rather than physical “articles of manufacture.” Thus, Australian patent law is not equipped to protect genes once genome sequencing becomes the standard of practice. *Patents Act 1990* (Cth) (Austl.). Even in the United States, the current Myriad Genetics case controversy revolves around the patentability of isolated DNA, rather than the human genes themselves. *Petition for Writ of Certiorari, Ass’n for Molecular Pathology v. U.S. Patent and*

This is not the first time that there is a developing area of technology that apparently will not be protected by common patent systems. In the 1930s, the U.S. Congress recognized that life forms were not patentable, but research into life forms should be encouraged through the patent system.<sup>207</sup> As a result, it created a separate patent regime for plants.<sup>208</sup> The plant patent regime is still in effect today, and is attributable for dramatic improvements in U.S. agricultural yields since the 1930s.<sup>209</sup>

Using U.S. plant patents as an example, WIPO or the WTO could establish a separate patent regime for genetic discoveries. With this new regime, WIPO or WTO could manipulate the duration of gene patents, or impose compulsory licensing schemes. A new patent regime could give organizations and nations more flexibility to increase or reduce the scope of patent protection for human genes. Given that genetic research is a particularly young field of biotechnology, flexibility is particularly important.

One major limitation is getting member states to agree to a novel and untested system.<sup>210</sup> The other potential problem is that patent law traditionally does not have a fair use exception—which can create inadvertent infringement.<sup>211</sup> However, a new gene patent regime could be created in a way to address this concern.

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Trademark Office, 689 F.3d 1303, 1313 (Fed. Cir. 2012), *cert. granted*, 133 S.Ct. 694 (U.S. Nov. 30, 2012) (No. 12-398).

<sup>207</sup> See also former Chief Justice Burger's analysis of how the plant patent system was meant to protect naturally-derived plants under patent law, because natural plants were not otherwise patent eligible, *Diamond v. Chakrabarty*, 447 U.S. 303, 131 (1980).

<sup>208</sup> Plant Patent Act of 1930, ch. 497, 46 Stat. 703 (1930) (later developed into 35 U.S.C. § 161).

<sup>209</sup> JACK RALPH KLOPPENBURG, *FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY*, 1492-2000 5 (2005) ("Since 1935, yields of all major crops in the United States have at least doubled, and at least half of these gains are directly attributable to genetic improvements").

<sup>210</sup> Given that the impetus of TRIPS was apparently through powerful industry voices, and no such powerful voices exist in the budding field of genetic research, negotiations for a new gene patent agreement are unlikely. See Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069 (1996). However, this also means that nations could negotiate on the basis of governmental—rather than industry—needs. See generally *id.*

<sup>211</sup> See Rebecca Eisenberg, *How Can You Patent Genes?* in *WHO OWNS LIFE?* 126 (Geertrui van Overwalle ed., 2009) (criticizing patent law as a method to encourage genetic research). But see Arti K. Rai et al., *Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery*, in *GENE PATENTS AND COLLABORATIVE LICENSING MODELS* 247 (Geertrui van Overwalle ed., 2009) (describing contractual models for encouraging public-private sector IP agreements in the pharmaceutical industry). See also *supra* note 53.

C. *Funding the Regulatory Approval Process Through Public Investment*

Even if we assume that publicly funded genetic research can manage the substantial burden of being the only source of new genetic links, the regulatory process will still be a hurdle to get a genetic test to the market.<sup>212</sup> Like other diagnostic technology, consumers expect that an alleged gene-disease link is reasonably certain. This certainty may be established through a regulatory approval process, which would generally be funded by the company seeking to bring the product to market.<sup>213</sup> Without intellectual property protections over genes, there would not necessarily be a market to encourage companies to invest in the regulatory process. At the very least, it is appropriate to find a solution to pay for the regulatory hurdles of gene-disease correlations.

One possible way to do so is to use public funds to pay for the regulatory process. If a government pays for a gene-disease clinical trial, then genetic testing services could freely provide genetic link information to physicians. Moreover, for the sake of efficiency, it would be appropriate for different regulatory authorities from different nations to come together, share data, and test the gene-disease correlations in a cohesive international regulatory panel. There is no reason why scientific conclusions cannot be accepted across borders.

While this is the least invasive method of addressing the regulatory hurdle problem, it inherently suffers from losing commercial investments into genetic research. Currently, in all areas of medical technology, commercial investment far surpasses public investment.<sup>214</sup> The drawbacks of solutions A and B may not be so bad as to surpass the drawbacks of making commercial investment into research impossible. In terms of the game theory model introduced in Section IV.D, the “A” terms would be less than those in a system which protected genes more thoroughly, however, the “C” term would be nearly eliminated.

VII. CONCLUSION

The genetic research industry currently stands on a precipice. Cheaper genome sequencing technology will enable a new age of widespread genetic sequencing and personalized medicine. Before this

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<sup>212</sup> See *supra* Part III.C.

<sup>213</sup> See *supra* Part III.C.

<sup>214</sup> See *supra* Part III.A.

occurs, governments should consider what sort of patent policy will allow genetic science to develop at the fastest rate, and the lowest cost.

Patents are a proven method of accelerating research and development investment in the commercial world. Patents are particularly important in highly regulated areas of technology like pharmaceuticals, due to time-consuming and expensive regulatory trials. It is likely that genetic tests will soon face similar regulations. Thus, gene patents are a viable method of accelerating genetic research in the future.

However, for a country that pays for the genetic tests of its citizens, it acutely feels the financial costs of each gene patent. Despite the utilitarian benefits of gene patents, countries like Australia may believe that the costs outweigh the benefits.

Because the costs related to a single developed country's elimination of gene patents are felt by all countries, a more robust international agreement guaranteeing gene patents is necessary. Such an agreement is possible through existing intellectual property regulating bodies such as the WTO.

Developments in genetic sequencing technology create another dilemma. Present gene patent regimes only protect isolated DNA, which are valuable in controlling inexpensive PCR tests—the standard gene testing process in industry. However, when whole-genome sequencing becomes standard practice, the patents on primers that represent genes will be functionally useless.

Proponents of gene patents should take action, if they hope to maintain the benefits of gene patents in the future. They should promote change at an international level, to encourage individual countries from reaping the benefits of other patent systems, without accruing the costs. Commentators have suggested several possible international solutions to this problem. Nations could agree to create a new intellectual property regime entirely, or make a special exception to the international patent system. At the very least, an international organization should find a way to facilitate regulatory approval processes for genetic tests in individual nations.

Regardless of your belief that gene patents represent a boon or burden to society, the gene patent debate will shift with impending developments in technology.