

Analyzing Recent Trends in the
Debate Over Gene Patents:
United States and Australia

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I. INTRODUCTION

The scope of patentable subject matter for genome modifications is a hotly contested and ever-evolving area of intellectual property law both domestically and internationally.¹ In particular, many debate the moral, economic, and scientific implications of granting patents to isolated genetic material of humans.² Many countries, such as Canada, Japan, and European Union member states maintain an expansive view of patentable subject matter, arguing that isolated genes are patent-eligible.³ The United States (“U.S.”) and Australia, on the other hand, have recently scaled back the scope of patentable subject matter by excluding isolated genes, turning back their own decades-long jurisprudence.⁴

This article is a reaction to the High Court of Australia’s decision in *D’Arcy v. Myriad Genetics, Inc.* (“*D’Arcy*”) and argues that the High Court’s holding should be broadly interpreted – narrowing the scope of patentable subject matter.⁵

Section II of this article provides a brief overview of modern biotechnology giving particular attention to the underlying gene patent

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1. See generally Adam Mosoff, *Why History Matters in the Patentable Subject Matter Debate*, 64 FLA. L. REV. FORUM 23 (2012) (cautioning against the assumption that the American patent system was born fully formed and complete); Cynthia M. Ho, *Global Access to Medicine: The Influence of Competing Perspectives*, 35 FORDHAM INT’L L. J. 1 (2011) (discussing the competing perspectives inherent in patent law within a social science framework).

2. See generally Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1628-29 (2001) (providing a comprehensive survey of the gene patent debate, both domestically and abroad).

3. Emma Barraclough, *What Myriad Means for Biotech*, WIPO MAGAZINE, Aug. 2013, at 21, available at http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2013/wipo_pub_121_2013_04.pdf.

4. Molly Jamison, *Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate*, 15 CHI. J. INT’L L. 688, 696 (2015).

5. *D’Arcy v. Myriad Genetics Inc.* [2015] HCA 35 (Austl.).

controversy.⁶ Section III (A) provides historical context for gene patent jurisprudence beginning with the Supreme Court’s landmark decision in *Diamond v. Chakrabarty* (“*Chakrabarty*”).⁷ Section III (B) highlights the recent shift toward a narrowed interpretation of patentable subject matter as seen in *Association for Molecular Pathology v. Myriad Genetics* (“*Myriad*”), while Section III (C) concludes with a discussion of the fallout from *Myriad* and its influence abroad.⁸ Section IV discusses the Australian High Court’s decision in *D’Arcy* by providing a brief historical overview of Australian gene patent jurisprudence and then contemplating the early consequences of *D’Arcy*.⁹ Finally, Section V argues for a broad interpretation of the High Court’s decision to make isolated genetic material patent-ineligible using the U.S. Supreme Court’s decision in *Myriad* and Australia’s international treaty obligations as backdrop.¹⁰

II. BIOTECHNOLOGY AND THE DEBATE OVER GENE PATENTS

The word “biotechnology” is an amalgam of “biology” and “technology”; aptly, biotechnology is technology based on biology.¹¹ Humans have used biotechnology in one form or another for over 6,000 years.¹² Today, it is a source of breakthrough products that “combat debilitating and rare diseases, reduce our environmental footprint, feed the hungry, use less and cleaner energy, and have safer, cleaner, and more efficient industrial manufacturing processes.”¹³ More concretely, there are over 250 biotechnology healthcare products and vaccines available, which have reduced the rates of previously untreatable diseases.¹⁴ Through advancements in biotechnology, researchers are now able to create tailor-made medicines based on proteins, enzymes, and ribonucleic acid (“RNA”) molecules that are associated with specific genes and diseases.¹⁵ These advancements, although immeasurably valuable, are not free from controversy, especially with regard to gene patents.¹⁶

Gene patents are patents on particular sections of deoxyribonucleic acid

6. See *infra* pp. 2-4.

7. See *infra* pp. 5-6.

8. See Section III (B) *infra* pp. 6-8; Section III(C) *infra* pp. 8-10.

9. See Section IV *infra* pp. 10-12.

10. See Section V *infra* pp. 12-15.

11. *What is Biotechnology?*, BIOTECHNOLOGY INDUS. ORG., <https://www.bio.org/articles/what-biotechnology> (last visited Sept. 28, 2015).

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.*

16. *Why Are Gene Patents Controversial?*, ECONOMIST (Apr. 18, 2013, 11:50 PM), <http://www.economist.com/blogs/economist-explains/2013/04/economist-explains-why-gene-patents-controversial>.

(“DNA”) rather than the entire sequence (the human genome).¹⁷ Since biotechnology can be costly to develop,¹⁸ a substantial investment of money and time is needed before a safe and effective product can be made available to the general public.¹⁹ As such, biotech companies protect their investments through patents and other intellectual property rights.²⁰ After a biotech company isolates genetic material or a mutation, such as the material that detects the risk of breast and ovarian cancers, the company then seeks to recoup its research and development costs by patenting the material or mutation.²¹

However, because patents are government-sanctioned monopolies, the importance of carefully and clearly crafting the scope of patentable subject matter is of great importance.²² On the one hand, a patent gives its owner, such as a biotech company, the right to exclude others from making, using, selling, offering to sell, or importing what is patented.²³ In theory, this gives companies the ability to recoup their investment and perhaps incentivize further research.²⁴ On the other hand, a government-sanctioned monopoly allows patent holders to price its patented technology well above what the fair market would dictate.²⁵ As a result, a biotech company can take

17. Gitter, *supra* note 2, at 1628-29.

18. See Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really \$802 Million?*, 25 HEALTH AFF. 420, 420 (2006) (estimating \$868 million, and varying between \$500 million and \$2 billion by drug type and company).

19. *Id.* at 427.

20. Richard A. Epstein & F. Scott Kieff, *Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents*, 78 U. CHI. L. REV. 71, 72 (2011) (“Patents are praised as a spur to innovation, which is only made possible with the predictable enforcement of rights of Exclusion for the patented technology.”).

21. Kristen L. Burge, *Personalized Medicine, Genetic Exceptionalism, and the Rule of Law*, 8 WASH. J.L. TECH. & ARTS 501, 513 (2013). There are four categories of gene patents. *Id.* First, there are patents on the gene itself, either in whole or in part, which includes claims to isolated nucleotide sequences. *Id.* The second category includes patents on proteins (and their function within the organism) encoded by the genes. *Id.* Third, patents may issue to vectors, which are DNA molecules used to artificially transfer foreign genetic material from one organism to another where it can be replicated and/or expressed. *Id.* Finally, patents may be issued to genetically modified cells or organisms, the processes used for the making of genetically modified products, and the uses of genetic sequences or proteins for genetic testing. *Id.*

22. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730-31 (2002) (“The patent laws ‘promote the Progress of Science and useful Arts’ by rewarding innovation with a temporary monopoly.” (quoting U.S. CONST. art. I, § 8, cl. 8.)).

23. 35 U.S.C. § 271 (2010).

24. See Jamison, *supra* note 4, at 709 (arguing that uneven patent enforcement and legal uncertainty about the patentability of isolated genetic material could “dampen innovation because of uncertainty about recouping the high costs of [research and development]”).

25. See Cydney A. Fowler, Comment, *Ending Genetic Monopolies: How the TRIPS Agreement’s Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide*, 25 AM. U. INT’L L. REV. 1073, 1093 (2010) (arguing that allowing gene patenting closes access to the market and forecloses competition, which, in turn, allows genetic

advantage of patent rights to price a potentially life-saving product out of the reach of people in need.²⁶ For over thirty years, courts around the world have wrestled with deciding where to draw the line; to date, the international community remains in disaccord about what should be patentable.²⁷

III. *CHAKRABARTY* TO *MYRIAD*: THE GENESIS OF THE SCOPE OF PATENTABLE SUBJECT MATTER AND GENES IN THE UNITED STATES

In the U.S., Congress established a framework for the scope of patentable subject matter.²⁸ The U.S. Patent Act of 1952 § 101 (“§ 101”) provided that “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent . . .”²⁹ For most technology this is an easy test to apply.³⁰ However, for genetic material, courts have struggled to clearly craft the scope of patentable subject matter, which has created a controversy since gene patents were first issued in the United States in the 1980s.³¹

A. *Chakrabarty: The Explosion of Gene Patents*

U.S. courts have traditionally interpreted § 101 quite broadly.³² Patent offices and courts in developed nations typically grant patents liberally to encourage investment in biotechnology.³³ This was especially true in the U.S. when the Supreme Court decided *Chakrabarty* in 1980.³⁴ *Chakrabarty* involved a patent application for a genetically modified bacterium capable of breaking down multiple components of crude oil.³⁵ The United States Patent and Trademark Office (“USPTO”) rejected the patent claims, reasoning that Congress did not intend § 101 to cover living things such as laboratory

monopolies negatively impacting both consumers and researchers).

26. *Id.*

27. Gitter, *supra* note 2, at 1624-25.

28. U.S. CONST. art. I, § 8, cl. 8.

29. 35 U.S.C. § 101 (1952).

30. See INTELLECTUAL PROPERTY LAW: CASES & MATERIALS 148 (Lydia P. Loren & Joseph S. Miller eds., 4th ed. 2015) (“From fluoxetine hydrochloride, the active ingredient in Prozac (U.S. Patent No. 4,314,081) to bubble wrap (U.S. Patent No. 3,142,599) to the airplane (U.S. Patent No. 821,393), practical solutions to concrete problems fall comfortably within the scope of § 101.”).

31. See Stephen H. Schilling, *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents*, 61 Duke L.J. 731, 732 (2011) (discussing the unique issues presented by gene patents and arguing that concerns regarding gene patents, such as the concern that gene patents will restrict patient access to genetic diagnostic tests and impede research, have “engendered overreactions” by U.S. courts).

32. Jamison, *supra* note 4, at 694.

33. *Id.*

34. *Id.* at 695.

35. *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

created microorganisms.³⁶ However, the Supreme Court overruled the USPTO decision, concluding that the language of § 101 is broad and that Congress intended the scope of patentable subject matter to include “anything under the sun that is made by man.”³⁷ This sweeping approach resolved the case in favor of *Chakrabarty*, the named inventor.³⁸

Chakrabarty immediately opened the door to the patenting of isolated gene sequences in the U.S.³⁹ As a result, the number of biotechnology patents issued annually increased rapidly.⁴⁰ Further, *Chakrabarty* influenced other countries to adopt an expansive view of patentable subject matter that allows for gene patents.⁴¹ In Australia, the decisions in the lower courts in *D’Arcy* evidence the wide influence *Chakrabarty* had abroad.⁴²

However, a marked shift in policy began after the year 2000: the number of gene patents issued decreased and challenges to the validity of such patents increased.⁴³ One such challenge, brought by the Association for Molecular Pathology and the University of Pennsylvania (“Plaintiffs”), alleged abusive enforcement of patent rights against Myriad Genetics, Inc. (“Myriad Genetics”), an American molecular diagnostic company.⁴⁴

36. *Id.* at 306.

37. *Id.* at 309-10.

38. *Id.* at 321-22.

39. See Jamison, *supra* note 4, at 695 (“In the 1980s and 1990s, the standards governing patentable subject matter expanded [as a result of the *Chakrabarty* decision], particularly in the field of biotechnology, and the issuance of biotech patents, including gene patents, increased.”).

40. See *id.* (explaining that by 1998, annual biotech patents issued by the USPTO peaked at 5,977). From the years following *Chakrabarty* in the mid-1980s to the late 1990s, patent intensity, which is “the measure of patents obtained per research and development dollar,” approximately doubled. Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 5 (2005).

41. See Jamison, *supra* note 4, at 696.

42. See Sections IV and V *infra* pp. 10-15.

43. See Jamison, *supra* note 4, at 695 (noting multiple explanations for the leveling off of biotech patents and suggesting “the shift in policy seems to have been ‘largely stimulated by a convergence of a general social unease, the emergence of preliminary data and literature on the possible adverse practical ramifications of gene patents, and several high-profile patent protection controversies.’” (quoting Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1091 (2006))).

44. See E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Public Policy Storm*, 12 GENETICS MED. 39, 61 (Supp. 2010) (noting how many in the scientific and clinical communities believed that Myriad tried to “impede basic research” and that it entered the U.S. market in an aggressive manner when, with a family of U.S. patents over the breast cancer genes and control over the diagnostics tests, it sent cease-and-desist letters to university researchers). The Plaintiffs to the suit included: the Association for Molecular Pathology, a not-for-profit scientific society; American College of Medicine Genetics, a private, non-profit voluntary organization of clinical and laboratory geneticists; the American Society for Clinical Pathology, which represents the medical specialty of pathology and laboratory medicine; the College of American Pathologists, a national medical society; and various individual plaintiffs

B. Myriad: Changing Trends in U.S. Gene Patent Law

In *Myriad*, the question before the Supreme Court was whether isolated, purified DNA molecules were patentable subject matter under the statutory language of § 101.⁴⁵ Myriad Genetics had “discovered the precise location and sequence of two human genes (BRCA1 and BRCA2 genes), mutations of which can substantially increase the risks of breast and ovarian cancer.”⁴⁶ Myriad Genetics sought, and was issued, a family of patents, which the Plaintiffs felt were overly broad.⁴⁷ In fact, the patents on the BRCA1 and BRCA2 genes permitted Myriad Genetics to prevent doctors and researchers from conducting further research.⁴⁸ Neither party disputed that Myriad Genetics had not created or altered any of the genetic information encoded in the two genes or the genetic structure of DNA itself since the location and order of the nucleotides existed in nature before Myriad Genetics discovered them.⁴⁹ As such, the Supreme Court unanimously held that Myriad Genetics’ claims to isolated natural DNA fell outside the scope of § 101, making them patent-ineligible.⁵⁰ The Supreme Court relied on the so-called “significantly different” standard, which in natural product cases requires that the patent-seeker add new or useful improvements to the original gene sequence.⁵¹ The Supreme Court held that Myriad Genetics did not meet the significantly different standard.⁵²

Nevertheless, the *Myriad* decision surprised the biotech industry, as well as some scholars, who believed the decision was a departure from thirty years of gene patent jurisprudence since *Chakrabarty*.⁵³ After all, as some scholars argued, “anything under the sun that is made by man” would seem to include genetic material that was isolated by researchers.⁵⁴ Those in the biotechnology industry, specifically research and development companies

representing researchers from various American universities such as the University of Pennsylvania, Yale, and Columbia. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 702 F. Supp. 2d 181, 186 (S.D.N.Y. 2010).

45. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

46. *Id.* at 2110-11.

47. Jamison, *supra* note 4, at 690.

48. Sarah E. Hagan, *DNA Real Estate: The Myriad Genetics Case and the Implications of Granting Patent Eligibility to Complimentary DNA*, 35 N. ILL. U. L. REV. 205, 221 (2014).

49. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013).

50. *Id.* at 2120.

51. *Id.* at 2117.

52. *Id.*

53. Jamison, *supra* note 4, at 696; *see also* Arti K. Rai, *Diagnostic Patents at the Supreme Court*, 18 MARQ. INTELL. PROP. L. REV. 1, 2 (2014) (discussing the Supreme Court’s treatment of gene patents in light of the recent “heated public controversy over whether such patents pose an impediment to patient access and control of medical decision making”).

54. Gitter, *supra* note 2, at 1641.

that rely heavily on investors, feared the market for genetic testing would suffer because investment in such research would decrease stifling innovation.⁵⁵ Alternatively, those who supported the decision hailed it as a victory for increased patient access to diagnostic testing and medicines and for patient and physician autonomy in the diagnostic process.⁵⁶ In the end, *Myriad* effectively invalidated thousands of gene patents in the U.S., leaving many to question the long-term implications of the decision.⁵⁷

C. *Myriad*: Narrow Scope, Broad Implications

As noted above, the Supreme Court relied heavily on the “significantly different” test for natural product cases in rejecting the BRCA claims against Myriad Genetics.⁵⁸ However, Myriad Genetics was successful in defending against attacks on the validity of several of its other patents.⁵⁹ For example, Myriad Genetics also held patents to exclusively synthesize a strand of nucleotides referred to as complimentary DNA (cDNA).⁶⁰ Before reaching the Supreme Court, the lower court found that cDNA are naturally occurring products because they are the result of a natural splicing process.⁶¹ Notwithstanding the decision of the lower court, the Supreme Court held that cDNA is not naturally occurring and is therefore patent-eligible, in contrast to DNA.⁶² The Supreme Court reasoned that the synthesized strand does not occur as a natural phenomenon and is only producible in a lab setting, thus validating Myriad Genetics’ cDNA patents.⁶³ While the decision left the door open to other questions such as the patentability of proteins, antibodies, or other pharmaceutical products such as new chemical entities isolated from natural resources, subsequent cases have declined to explore such questions.⁶⁴

However, comparing the Supreme Court’s decisions in *Chakrabarty* and *Myriad*, along with its interpretation of § 101 will help answer some of these

55. Hagan, *supra* note 48, at 221.

56. Arti K. Rai, *Biomedical Patents at the Supreme Court: A Path Forward*, 66 STAN. L. REV. ONLINE 111, 111 (2013), available at <http://www.stanfordlawreview.org/sites/default/files/online/articles/RaiSLR.pdf>.

57. Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 221 (S.D.N.Y. 2011).

58. *Molecular Pathology*, 133 S. Ct. at 2117.

59. *Id.* at 2119.

60. *Id.*

61. Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 186-90 (S.D.N.Y. 2010).

62. *Molecular Pathology*, 133 S. Ct. at 2119.

63. *Id.*

64. Alex Boguniewicz, *Discovering the Undiscoverable: Patent Eligibility of DNA and the Future of Biotechnical Patent Claims Post-Myriad*, 10 WASH. J.L. TECH. & ARTS 35, 42 (2014).

questions — at least until the Supreme Court conclusively defines the “substantially different” standard.⁶⁵ The *Myriad* Court rejected the BRCA claims because Myriad Genetics had not made “new or useful” improvements to the original gene sequence, reasoning they were structurally the same as the genes in their natural state.⁶⁶ On the other hand, the Supreme Court held that cDNA easily met the threshold for § 101 despite the fact that the basic structure of cDNA is “dictated by nature, not by the lab technician.”⁶⁷ Similarly, the *Chakrabarty* Court held that adding plasmids to the bacterium pushed the resulting product into the realm of patentability since it was the result of “human ingenuity.”⁶⁸ Thus, *Myriad* seems to be a rather narrow holding.⁶⁹ After *Myriad*, determining whether a natural product meets the “substantially different” standard under § 101 could come down to the slightest variation — as long as the variation does not occur as a natural process.⁷⁰ In effect, biotech companies will likely protect the discovery of naturally occurring products by arguing the validity of the resulting product instead of the discovery itself.⁷¹ Although *Myriad* has been construed narrowly, it is a step toward a narrowed scope of patentability; many in the scientific community argue that this will prevent biotech companies from pricing diagnostic tests and tailor-made medicines far above normal market conditions and out of the reach of patients.⁷²

It remains unclear how *Myriad* will be applied to other areas of biotechnology such as proteins and antibodies or to other pharmaceutical products such as new chemical entities isolated from natural resources.⁷³ Nonetheless, the decision reflects a shift in Supreme Court jurisprudence toward a narrower interpretation of § 101 that excludes isolated genetic material from the scope of patentable subject matter.⁷⁴ The significance of the *Myriad* decision is evidenced by its influence abroad.⁷⁵

65. *Id.* at 44.

66. *Molecular Pathology*, 133 S. Ct. at 2117.

67. *Id.* at 2119.

68. *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980).

69. Boguniewicz, *supra* note 64, at 46-47.

70. *Id.*

71. *Id.* at 47.

72. David B. Agus, Op-Ed., *The Outrageous Cost of a Gene Test*, N.Y. TIMES, May 21, 2013, at A25.

73. Boguniewicz, *supra* note 64, at 46-47.

74. Ashley Winkler, *Association of Molecular Pathology v. Myriad Genetics, Inc.: Determining the Scope of the Supreme Court's Holding for Patentable Subject Matter*, 103 KY. L. J. 147, 147-148 (2015).

75. *D'Arcy v. Myriad Genetics Inc.* [2015] HCA 35, 19 (Austl.).

IV. THE AUSTRALIAN APPROACH: *D'ARCY V. MYRIAD GENETICS*

Australian patent law is largely rooted in English law.⁷⁶ In 1852, the first formal Australian patent system was established, and by 1904 a consolidated Australian commonwealth agency called IP Australia was formed to oversee all patents.⁷⁷ IP Australia continues to administer the patent system in Australia today.⁷⁸ IP Australia's role is similar to that of the USPTO: absent clear statutory language, both IP Australia and the USPTO interpret their respective patent laws to determine the scope of patentable subject matter.⁷⁹

The Australian counterpart to § 101, the Patents Act of 1990 ("Patent Act"), dictates that any article of manufacture is patent eligible if it is novel, useful, and not secretly used before the application date.⁸⁰ Section 101 and the Patent Act are substantially similar and traditionally have been interpreted in substantially the same way by their respective patent offices and judicial systems.⁸¹ Not coincidentally, these similarities have led the High Court of Australia to look to U.S. patent jurisprudence.⁸² In one case, the High Court noted that "United States authorities should be accepted in preference to the path apparently taken in the English decisions."⁸³ In biotechnology specifically, Australian courts look to U.S. patent cases as persuasive authority "because of the similarity of the systems, and the breadth of patent cases in the U.S."⁸⁴ In fact, until recently the Australian approach largely resembled the U.S. approach pre-*Myriad*; that is, Australia did not exclude isolated DNA structures from patentability.⁸⁵ However, just as in the U.S., the validity of such patents has been increasingly called into question in Australia.⁸⁶ Interestingly, a *Myriad Genetics* patent was also at the center of

76. Kate M. Mead, *Gene Patents in Australia: A Game Theory Approach*, 22 PAC. RIM. L. & POL'Y J. 751, 756 (2013).

77. *Id.*

78. *Id.*

79. *Id.* at 757.

80. *Patents Act 1990* (Cth) ch 1 § 18.1 (Austl.).

81. See Mead, *supra* note 76, at 757-58 (noting that the only difference between § 101 and the Patent Act is that the Patent Act also specifically excludes human beings, plants, and animals from the scope of patentable subject matter).

82. *Aktiebolaget Hässle v. Alphapharm* [2002] 212 CLR 411 (Austl.).

83. *Id.*

84. Mead, *supra* note 76, at 757.

85. *Patents for Biological Inventions*, IP AUSTRALIA (Mar. 4, 2014), <http://www.ipaustralia.gov.au/get-the-right-ip/patents/about-patents/what-can-be-patented/patents-for-biological-inventions/>.

86. Melissa Parke, a federal member of Parliament, urged the Australian Parliament to ban all human gene patents. See Commonwealth, *Parliamentary Debates*, Federation Chamber, 21 May 2012, 4977 (Melissa Parke, Member of the Australian Parliament for Fremantle (Austl.)). The Australian Law Reform Commission asserted in its report to the federal attorney general that gene patents were problematic. See ALRC, *Genes and Ingenuity: Gene Patenting and Human Health*, ALRC Report 99 s 12, <http://www.alrc.gov.au/>

a controversy that pushed the Australian judicial system toward a narrower scope more reflective of the U.S. approach.⁸⁷ With the Australian High Court's 2015 decision in *D'Arcy*, Australian patentable subject matter shifted, mirroring and perhaps directly following the U.S. approach of excluding isolated genetic material from the scope of patentability.⁸⁸

In *D'Arcy*, the Australian High Court ruled on the validity of Myriad Genetics' BRCA1 gene claim – the same gene at issue in *Myriad*.⁸⁹ The lower court – the Federal Court of Australia – unanimously ruled in favor of Myriad Genetics in 2013 and again in 2014.⁹⁰ The lower court's opinion largely mirrored the reasoning of *Chakrabarty* and affirmed the validity of patents on naturally occurring DNA sequences.⁹¹ The lower court made clear that the manufacture test for patent-eligibility under Australian law is different from the test that applies under § 101 after *Myriad*.⁹² However, in a ninety-three-page opinion, the High Court of Australia overruled the lower court's decision and revoked the BRCA1 claims of the Australian patent.⁹³ The High Court's opinion is laden with references to *Myriad* as persuasive authority and seems to rely heavily on the Supreme Court's reasoning in revoking the BRCA1 claims.⁹⁴ The next Section explores the scope of the holding and argues for a broad interpretation.

V. AN ECHO EFFECT: THE SCOPE OF *D'ARCY* AND THE *MYRIAD* INFLUENCE

While the full reach of *Myriad* and *D'Arcy* is not completely understood, one thing is clear: the exclusion of isolated DNA structures from the scope of patentability sets the U.S. and Australia apart from their economic rivals – namely, the European Union, Canada, and Japan.⁹⁵ Because the U.S. is a global leader on biotechnology patents, the *Myriad* holding was the impetus for change in Australia.⁹⁶ With the tide now turning against gene patents,

publications/12-patents-and-human-genetic-research/impact-gene-patents-research. Legislators in Parliament also introduced the Patent Amendment (Human Genes and Biological Products) Bill 2010, which sought to expressly forbid human DNA from being patent-eligible. See Patent Amendment (Human Genes and Biological Products) Bill 2010 (Cth.) (Austl.), <http://www.comlaw.gov.au/Details/C2011B00012>.

87. *D'Arcy v. Myriad Genetics Inc.* [2015] HCA 35, 1 (Austl.).

88. *Id.* at 88.

89. *Id.* at 1.

90. *D'Arcy v. Myriad Genetics Inc.* [2014] FCAFC 115 (Austl.).

91. *Id.* at 18.

92. *Id.* at 18.

93. *D'Arcy v. Myriad Genetics Inc.* [2015] HCA 35, 44 (Austl.).

94. *Id.* at 22, 33-34, 37-38, 61, 64, 66, 69.

95. See Barraclough, *supra* note 3 (arguing that jurisdictional differences will lead biotech companies to protect their investments through trade secret laws instead of patents, which in turn prevents disclosure, and thus hinders the advancement of the arts and sciences).

96. See *D'Arcy v. Myriad Genetics Inc.* [2015] HCA 35.

other countries may soon exclude isolated genetic material from the scope of patentable subject matter.

The *D'Arcy* decision came down in October 2015 and is the latest push toward a narrowed scope of patentability.⁹⁷ The *D'Arcy* Court began its determination of patentability by noting that “Parliament has left it to the courts to carry out a case-by-case development of a broad statutory concept according to the common law method in a representative democracy.”⁹⁸ The High Court pointed out that the function of the Patent Act, much like § 101, serves the larger purpose of encouraging innovation.⁹⁹ However, the High Court said that the means to encourage such innovation should not in fact “imped[e] advances and improvements by skilled, non-inventive persons.”¹⁰⁰ Nonetheless, the High Court relied on similar language used by the Supreme Court.¹⁰¹ Specifically, the High Court held that for a claimed invention to qualify for patent protection as a “manner of manufacture,” it must be something more than a mere discovery, which depends on the extent to which the product “individualizes” nature.¹⁰² The High Court held that the BRCA claims were not sufficiently individualized from the naturally existing genes because they were “the inevitable result of that which is inherent in the DNA.”¹⁰³ However, the High Court was hesitant to go further, limiting its holding to the facts of the case.¹⁰⁴

Although *D'Arcy* will likely be interpreted narrowly, it nonetheless propelled the gene patent debate to the forefront once again.¹⁰⁵ Interestingly, the High Court went only as far as the Supreme Court, leaving in question whether patents of proteins, antibodies, and new chemical entities isolated from natural resources are permissible.¹⁰⁶ Despite the narrow holdings, Australian and American courts should push for a broad interpretation of the cases and for a narrowed scope of patentability. A narrowed scope of patentability will ensure that researchers, doctors, and patients will have access to affordable medicines and diagnostic testing.¹⁰⁷ Moreover, by setting themselves apart from their economic rivals, one may question whether the U.S. and Australia are in violation of international treaty obligations.

97. *Id.*

98. *Id.* at 17.

99. *Id.* at 19.

100. *Id.* at 19-20.

101. *Id.* at 53.

102. *Id.*

103. *Id.* at 56.

104. *Id.*

105. Mead, *supra* note 76, at 757.

106. Winkler, *supra* note 74, at 147-149.

107. See Rai, *supra* note 56, at 111.

A. *Other Considerations: The Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”)*

Patent law is inherently diverse.¹⁰⁸ Variations in cultural attitudes, biases, and perspectives have led to differences in how nations define patentable subject matter.¹⁰⁹ Each patent system is a function of its nation’s territoriality, its government’s use of patent law to spur economic growth, and the cultural perspectives of its people.¹¹⁰ Not coincidentally, these variations have led to differences in how nations delineate the scope of patentable subject matter.¹¹¹

Notwithstanding these factors, patent regimes have become increasingly harmonized.¹¹² Due in large part to the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”), previously isolated and independent economies and cultures are becoming globalized.¹¹³ Yet, while Article 27 of TRIPS “recogniz[es] the underlying public policy objectives of national systems for the protection of intellectual property,” TRIPS still allows member countries flexibility.¹¹⁴ Specifically, TRIPS allows member countries to “adopt measures necessary to protect public health and nutrition” or “to promote the public interest in sectors of vital importance to their socio-economic and technological development.”¹¹⁵ This flexibility permits countries such as the U.S. to craft the scope of patentable subject matter thereby excluding isolated DNA.¹¹⁶

Despite the flexibility inherent in TRIPS, the threat of sanctions through TRIPS has contributed to a culture of over-compliance that discourages countries from experimenting with the protected flexibility.¹¹⁷ Due to the fact that the U.S. is a leader on the issue of patents, the country sits in a unique

108. See Jamison, *supra* note 4, at 705 (noting that differences in how countries define patentable subject matter stems from “territoriality, government use of patent law as a tool for economic growth, and cultural factors”).

109. *Id.*; see also Ho, *supra* note 1, at 19-29 (discussing the existence and operation of schemas, confirmation bias, and naïve realism in the context of two competing patent perspectives).

110. Jamison, *supra* note 4, at 705.

111. *Id.* at 700.

112. *Id.*

113. *Id.* TRIPS is the most comprehensive multilateral agreement on intellectual property. *Overview: The TRIPS Agreement*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm. (last visited Nov. 30, 2015). It sets out the minimum standards of protection to be provided by each member country, the procedures and remedies for the enforcement of intellectual property rights, and establishes dispute settlement procedures among member countries and the World Trade Organization. *Id.*

114. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197.

115. *Id.*

116. Molly Land, *Rebalancing TRIPS*, 33 MICH. J. INT’L L. 433, 439 (2012).

117. *Id.* at 434.

position – it is rarely sanctioned – tending instead to threaten and levy sanctions.¹¹⁸ In this regard, the U.S. may have the most flexibility of any country.¹¹⁹ After the *Myriad* and *D’Arcy* decisions, other countries may feel freer to change policy and exclude genes from the scope of patentability.¹²⁰

VI. CONCLUDING THOUGHTS:

MYRIAD, D’ARCY, AND THE GENE PATENT DEBATE

Without a doubt, the *Myriad*, and *D’Arcy* decisions have steered gene patent jurisprudence on a different course than the previous thirty years. In balancing the core principles underlying their respective patent law systems, the U.S. Supreme Court and Australian High Court have determined isolated DNA to be patent-ineligible. Although those in the biotech industry lambaste the *Myriad* and *D’Arcy* decisions, researchers, scientists, and doctors may now advance life-saving medicines and therapeutic treatments without the worry of patent litigation. *Myriad* and *D’Arcy* may be the impetus to change the ever-evolving patent regimes around the world, with Australia now joining the U.S. in excluding patents to isolated genetic material.

118. See Sarah R. Wasserman Rajec, *Evaluating Flexibility in International Patent Law*, 65 HASTINGS L.J. 154, 167 (2013) (“[T]he United States has been criticized for using coercive negotiating techniques to gain the consensus of developing countries. In particular, the Office of the United States Trade Representative threatened countries with trade retaliations under Special 301 Report if they chose to object to the negotiating positions of the United States on intellectual property rights in the TRIPS agreement.”).

119. *Id.*

120. Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013); *D’Arcy v. Myriad Genetics Inc.* [2015] HCA 35 (Austl.).