

**A “MYRIAD” OF CONTROVERSY OVER THE
QUESTION OF HUMAN GENE PATENT
ELIGIBILITY: A COMPARISON OF THE
DIFFERING APPROACHES IN THE UNITED
STATES AND AUSTRALIA**

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I.	INTRODUCTION	914
II.	BACKGROUND	916
	<i>A. United States</i>	916
	<i>B. Australia</i>	919
III.	REASONING OF THE COURTS	922
	<i>A. Supreme Court of the United States</i>	922
	<i>B. The Federal Court of Australia</i>	923
IV.	IMPLICATIONS OF PATENT ELIGIBILITY OR INELIGIBILITY OF HUMAN GENE SEQUENCES.....	924
	<i>A. Proponents to Gene Sequence Patenting</i>	925
	<i>B. Opponents to Gene Sequence Patenting</i>	929
V.	HUMAN GENE PATENT ELIGIBILITY DEBATE AS APPROACHED FROM OTHER COUNTRIES	932
	<i>A. The European Union</i>	933
	<i>B. Canada</i>	935

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914 *HOUSTON JOURNAL OF INTERNATIONAL LAW* [Vol. 38:3

C. Harmonization.....937

VI. CONCLUSION.....939

I. INTRODUCTION

Next came the patent laws. These began in England in 1624, and in this country with the adoption of our Constitution. Before then any man [might] instantly use what another man had invented, so that the inventor had no special advantage from his own invention. The patent system changed this, secured to the inventor for a limited time exclusive use of his inventions, and thereby added the fuel of interest to the fire of genius in the discovery and production of new and useful things.¹

Lincoln’s metaphor of patent law’s exclusive rights “add[ing] the fuel of interest to the fire of genius,” can be applied to the area of patents in another way besides to the “discovery and production of new and useful things.” The incentive of exclusive rights has also fueled a wealth of debate over the proper subject matter for patent protection.

The debate over whether human genes are eligible for patent protection has been prevalent for many years² and has come to the forefront once again. Currently, this issue is focused in the United States and Australia. In both countries, recent major decisions have shaken modern patent law.

In the United States, the U. S. Patent and Trademark Office (USPTO) has granted patent claims relating to newly identified

1. Abraham Lincoln, *Lecture: Discoveries, Inventions and Improvements*, in V COMPLETE WORKS OF ABRAHAM LINCOLN 113 (John G. Nicolay and John Hay eds., 1905).

2. Brief of Amicus Curiae Cancer Council Australia et al. in Support of Petitioner at 3, *Ass’n for Molecular Pathology v. Myriad Genetics*, 113 S. Ct. 2107 (No. 12-398) (Oct. 30, 2012).

human genes that are linked to the predisposition for diseases.³ Although the area of human genetics research is relatively new and evolving, patents on human gene sequences⁴ have been issued in Australia without much judicial intervention.⁵

The validity of gene patents held by the company Myriad Genetics has recently been challenged in both the United States and Australia.⁶ The Supreme Court of the United States' decision to invalidate human gene sequence patents and the Federal Court of Australia's decision confirming their validity have ignited continued debate on the issue.⁷

These decisions have far-reaching effects on medical research, patients seeking genetic therapies or testing, and the international character of patents as a whole. The impact of these decisions has sparked much debate from critics and proponents in the scientific, legal, public interest communities.⁸ The major scientific and public interest arguments focus on incentivizing

3. See Miri Yoon, *Gene Patenting Debate: The Meaning of Myriad*, 9 J. MARSHALL REV. INTELL. PROP. L. 953, 953-55 (2010) (stating that patents on human gene sequences have been granted by the USPTO).

4. A human gene sequence is the arrangement of the chemical building blocks in a given stretch of DNA, a gene, which tells scientists the kind of genetic information that is carried by the gene and allows them to analyze the gene for changes, mutations, which may cause disease. See *DNA Sequencing*, NAT'L INST. OF HEALTH, <http://www.genome.gov/10001177> (last visited Apr. 16, 2015) (describing DNA sequencing).

5. See THE CTR. FOR INT'L ECON., *ECONOMIC ANALYSIS OF THE IMPACT OF ISOLATED HUMAN GENE PATENTS* 12 (2013); see also *D'Arcy v. Myriad Genetics Inc.* [2014] FCAFC 115, 1-50 (Austl.) (upholding a patent claim granted in Australia for the sequence of the human BRCA1 gene).

6. See *Ass'n for Molecular Pathology*, 133 S. Ct. at 2111 (stating that the validity of patents for isolated DNA sequences held by Myriad Genetics were being challenged in the United States); see also *D'Arcy v. Myriad Genetics Inc.* [2014] FCAFC 115 ¶ 1 (Austl.) (stating that the validity of patents for human gene sequences owned by Myriad Genetics were being challenged in Australia).

7. See Chester S. Chuang & Denys T. Lau, *The Pros and Cons of Gene Patents*, THE RECORDER (Dec. 17, 2010, 11:40 am), <http://www.law.com/jsp/ca/PubArticleFriendlyCA.jsp?id=1202476378193> (describing how debate was sparked after the decision to invalidate human gene patents was made by a New York federal judge); see also *Australian Federal Court Rules Isolated Genetic Material Can be Patented*, THE GUARDIAN (Sept. 4, 2014, 11:39 PM), <http://www.theguardian.com/world/2014/sep/05/court-rules-breast-cancer-gene-brca1-patented-australia> [hereinafter *Australian*] (discussing criticism of the Australian federal court decision that isolated DNA sequences are patent eligible).

8. Yoon, *supra* note 3, at 953-55.

research and patient access.⁹ Specifically, arguments critical of gene patents center around restraining genetic research and making genetic testing excessively expensive for the public.¹⁰

This Comment examines the reasoning and policy implications of the two decisions, and suggests which decision yields the most favorable result. It then seeks to compare the approaches of the U.S. and Australian courts with other countries. It concludes by suggesting which approach produces the best outcome and proposes how and why gene patents should be regulated with international consistency.

II. BACKGROUND

In order to explain the arguments for and against the eligibility of human gene sequences for patenting, it is necessary to provide some background of the pertinent patent laws in the United States and Australia and the cases applying those laws in both jurisdictions. This section introduces a basic background of select United States and Australian patent law and the two major cases in the current controversy. Section A presents the law in controversy in the United States and a description of the case *Association of Molecular Pathology v. Myriad Genetics, Inc.*¹¹ Section B presents the law in controversy in Australia and a description of the case *D'Arcy v. Myriad Genetics, Inc.*¹²

A. United States

1. Pertinent Law

Congressional power to make laws about patents stems from Article I, Section 8, Clause 8 of the United States Constitution,

9. See Molly Sharlach, *Australian Court Upholds Patents on Human Genes*, THE SCIENTIST (Sept. 8, 2014), <http://www.the-scientist.com/?articles.view/articleNo/40951/title/Australian-Court-Upholds-Patents-on-Human-Genes/> (describing public health issues, such as the cost of genetic testing and increased competition, as part of the debate over the eligibility of gene sequences for patenting).

10. See Joanne van Harmelen & Odwa Mjezu, *Australia: The BRCA1 Case: A Myriad of Possibilities*, MONDAQ, <http://www.mondaq.com/australia/x/345240/Patent/The+BRCA1+Case+A+Myriad+Of+Possibilities> (last updated Oct. 9, 2014) (describing views of opponents to human gene sequence patenting).

11. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2107-2120.

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

which gives Congress the power “[t]o promote the Progress of Science and useful Arts, be securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹³ This grant of authority allowed Congress to enact the U.S. Patent Act, Title 35 of the United States Code.

Section 101, Inventions patentable, of Title 35 describes what inventions and discoveries are eligible for patent protection.¹⁴ Section 101 states, “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 therefore, subject to the conditions and requirements of this title.”¹⁵ The U.S. Supreme Court “has long held that this provision contains an important implicit exception. ‘[L]aws of nature, natural phenomena, and abstract ideas’ are not patentable.”¹⁶ This exception for products of nature is central to the debate over the patent eligibility of isolated human gene sequences in the recent U.S. case *Association of Molecular Pathology*.¹⁷

2. *Association of Molecular Pathology v. Myriad Genetics, Inc.*

This case concerned the validity of patents held by Myriad Genetics on genes that correlate with an increased risk of breast and ovarian cancer.¹⁸ This challenge was brought against Myriad by medical organizations, researchers, genetic counselors, and patients.¹⁹

Myriad obtained several patents after discovering the precise location and DNA sequence of the BRCA1 and BRCA2 genes,²⁰

13. U.S. CONST. art. I, § 8, cl. 8.

14. 35 U.S.C. § 101 (2012).

15. *Id.*

16. *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1293 (2012) (alteration in original) (citations omitted).

17. *See Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2107-20 (2013) (discussing the central issue of whether isolated human gene sequences are products of nature, making them ineligible for patent protection in the United States).

18. *Id.* at 2109; Adam Liptak, *Justices, 9-0, Bar Patenting Human Genes*, N.Y. TIMES, June 13, 2013, at A1.

19. *Ass’n for Molecular Pathology*, 133 S. Ct. at 2107.

20. BRCA1 and BRCA2 are two genes associated with inherited forms of breast cancer and ovarian cancer. *See BRCA1 and BRCA2: Cancer Risk and Genetic Testing*,

mutations of which can drastically increase the risk of breast and ovarian cancers.²¹ The claims under attack in these patents are those covering isolated DNA coding sequences for each of the two genes and claims covering common mutations in the BRCA1 and BRCA2 sequences.²²

After Myriad's discovery, other organizations were isolating the BRCA genes for use in genetic testing.²³ Myriad wrote letters to some organizations asserting the genetic testing activity infringed Myriad's patents and filed patent infringement claims against others. All of the target organizations agreed to cease the allegedly infringing activity of isolating the BRCA1 and BRCA2 genes.²⁴ This solidified Myriad's position as the only entity providing genetic testing on the BRCA1 and BRCA2 genes.²⁵

The present case arose when Oster, along with medical patients, advocacy groups, and other doctors, filed suit seeking a declaration that Myriad's patents were invalid under Section 101 of Title 35 of the U. S. Code.²⁶ The District Court granted summary judgment based on its conclusion that Myriad's sequence claims were invalid for covering "products of nature."²⁷ The U.S. Court of Appeals for the Federal Circuit reversed,²⁸ and the Supreme Court of the United States granted certiorari.

NAT'L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA> (last visited Jan. 8, 2015). Women with mutations in either of these genes have a higher risk of developing breast cancer than women without mutations. *Id.* Both normally regulate cell division, but mutations in the genes render them inactive causing uncontrolled cell growth, resulting in tumors. *See BRCA1*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/gene/BRCA1> (last visited Feb. 4, 2016) (discussing the role of BRCA1 in regulating cell division and how mutations can lead to tumors); *BRCA2*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/gene/BRCA2> (last visited Feb. 4, 2016).

21. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2109.

22. *Id.* at 2113.

23. *See id.* at 2114 (discussing several organizations that were performing genetic testing for BRCA mutations contemporaneously with Myriad).

24. *Id.*

25. *Id.*

26. *Id.*

27. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2114.

28. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1333 (Fed. Cir. 2011), *aff'd in part, rev'd in part sub nom.* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

The Supreme Court held that isolated DNA involves a “naturally occurring segment of DNA, precluding patent eligibility”; however, the Court found that synthetically created DNA, known as complementary DNA (cDNA), is not naturally occurring and is, therefore, patent eligible.²⁹ The central dispute was whether the act of isolating the DNA sequences was an inventive act that entitles the individual who first isolates it to a patent on the sequence.³⁰ The reasoning behind the Supreme Court’s decision will be discussed in Part III.

B. Australia

1. Pertinent Law

Section 18 of the Patents Act 1990 describes which inventions are eligible for patent protection in Australia.³¹ Contrary to the United States, there is no jurisprudential or statutory limitation to patent eligibility to exclude products of nature.³²

Section 18(1) of the Patents Act of 1990 sets out the eligibility requirements for obtaining a standard patent under Australian law.³³ This section states that an invention is patentable for the purposes of a standard patent if it is a “manner of manufacture,” is “novel and involves an inventive step,” and is “useful.”³⁴ Furthermore, the patent can only be granted if the manner of manufacture “was not secretly used in the patent area before the priority date of that claim.”³⁵

IP Australia, the Australian Government agency that administers rights and legislation related to intellectual property,³⁶ specifically lists in its guidelines for biological inventions that are patent eligible, “isolated DNA, RNA,

29. *Ass’n for Molecular Pathology*, 133 S. Ct. at 2107.

30. *Id.* at 2114.

31. *Patents Act 1990* (Cth) s 18 (Austl.).

32. *D’Arcy v. Myriad Genetics Inc.* [2014] FCAFC 115 (Jan. 5, 2014) 48 (Austl.).

33. *Patents Act 1990* (Cth) s 18 (Austl.).

34. *Id.*

35. *Id.*

36. *About Us*, IP AUSTRALIA, <http://www.ipaustralia.gov.au/about-us/> (last updated Apr. 4, 2015).

chromosomes and genes (including human DNA and genes).³⁷ It also lists an isolated DNA coding sequence for a gene as an example of a patentable invention.³⁸

While Australia has its own patent laws, policies, and jurisprudence, the Australian courts have borrowed common law and reasoning from other jurisdictions.³⁹ Particularly, the Australian High Court, the highest court in the federal court hierarchy, has looked towards U.S. patent cases for guidance.⁴⁰ However concerning the patentability of human gene sequences, the Federal Court of Australia chose not to follow the lead of the United States, as evidenced in the decision in *D'Arcy v. Myriad Genetics Inc.*⁴¹

2. *D'Arcy v. Myriad Genetics Inc.*

This case also concerns the validity of a patent held by Myriad in Australia for the BRCA1 gene, for its claims covering sequence and mutation sequences.⁴² Here, the Federal Court of Australia affirmed the February 2013 decision in favor of Myriad Genetics and the eligibility of human genes for patenting in Australia.⁴³

The case was brought by the patient advocacy group Cancer Voices Australia and Yvonne D'Arcy, a breast cancer survivor,

37. *Patents for Biological Inventions*, IP AUSTRALIA, <http://www.ipaustralia.gov.au/get-the-right-ip/patents/about-patents/what-can-be-patented/patents-for-biological-inventions/> (last updated Apr. 3, 2014).

38. *Id.*

39. See Kate M. Mead, *Gene Patents in Australia: A Game Theory Approach*, 22 PAC. RIM L. & POL'Y J. 751, 757 (2013) (describing the patent system in Australia).

40. See Brief of Amici Curiae Cancer Council Australia et al. in Support of Petitioner at 5, *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 12-398) (discussing Australian court's use of U.S. jurisprudence for guidance in patent law decisions).

41. Compare *D'Arcy v. Myriad Genetics Inc.* [2014] FCAFC 115 (Jan. 5, 2014) 50 (Austl.) (deciding that human gene sequences are eligible for patent protection based on manner of manufacture reasoning), with *Ass'n for Molecular Pathology v. Myriad Genetics Inc.*, 133 S. Ct. 2107, 2111 (2013) (holding that human gene sequences are not eligible for patent protection based on product of nature reasoning).

42. *D'Arcy*, [2014] FCAFC 115, 1 (Austl.).

43. See Sharlach, *supra* note 9 (discussing the Federal Court of Australia's decision concerning the patent eligibility of isolated human gene sequences).

against the U.S.-based Myriad Genetics.⁴⁴ Myriad holds the exclusive right to conduct tests for mutations in the BRCA1 gene in Australia as a result of owning the patent.⁴⁵

Cancer Voices Australia began legal action over patents associated with the BRCA1 gene in 2010, as they believed that patenting of the genetic sequence places limits on genetic testing, genetic research, and the development of treatments for genetically associated forms of breast cancer.⁴⁶ The action was brought on the grounds that Myriad lacked a manner of manufacture, as required by Section 18(1)(a) of the Patents Act 1990.⁴⁷

In February 2013, the Australian court ruled that genetic material associated with mutated versions of the BRCA1 gene, once isolated from the human body, are eligible for patent protection.⁴⁸ Cancer Voices of Australia and Mrs. D'Arcy appealed that decision, but the Federal Court of Australia unanimously upheld the previous decision that isolated gene sequences are patent eligible.⁴⁹ The Federal Court's reasoning will be discussed in further detail in Part III.

44. *See id.* (describing the original action brought by Cancer Voices Australia and Yvonne D'Arcy against Myriad); *Australian, supra* note 7 (discussing the original action brought against Myriad in Australia).

45. *See Australian, supra* note 7 (describing the original action and why it was brought against Myriad for the Australian patent it owns for the sequence and mutation sequences of the BRCA1 gene).

46. *See id.* (describing the original action and why it was brought against Myriad for the Australian patent it owns for the sequence and mutation sequences of the BRCA1 gene).

47. *See Australia – Full Court Confirms Isolated DNA is Patentable*, CONVENTUS LAW (Sept. 8, 2014), <http://www.conventuslaw.com/archive/australia-full-court-confirms-isolated-dna-is-patentable/> (discussing the original action brought against Myriad in Australia); *Patents Act 1990* (Cth) s 18(1)(a) (Austl.) (stating the manner of manufacture requirement for patentable inventions).

48. *See Australian, supra* note 7 (discussing the Federal Court's original decision in Feb. 2013).

49. *See Harmelen & Mjezu, supra* note 10 (detailing the unanimous decision of the Federal Court of Australia to uphold its previous decision concerning the patent eligibility of isolated human gene sequences).

III. REASONING OF THE COURTS

The Supreme Court of the United States and the Federal Court of Australia take diverging paths in deciding whether human gene sequences are eligible for patent protection in their respective countries. Part A will discuss the reasoning used by the Supreme Court of the United States in determining that human gene sequences are not patent eligible under the patent laws of the United States. Part B will examine the reasoning adopted by the Federal Court of Australia in concluding that human gene sequences are patent eligible under Australian patent law.

A. *Supreme Court of the United States*

The Supreme Court recognized that an implicit exception to patent eligibility exists for products of nature.⁵⁰ Therefore, the issue the Court had to determine was whether the process of isolation modified the gene sequence in a way that allows it to fall outside a product of nature.⁵¹ The U.S. Supreme Court decided that isolated segments of DNA are naturally occurring.⁵²

The Court further recognized that its previous decision in *Diamond v. Chakrabarty* was central to the inquiry in this case.⁵³ In *Chakrabarty*, scientists added plasmids to a bacterium, which enabled it to break down crude oil.⁵⁴ The Court held that the modified bacterium was patent eligible as a “nonnaturally occurring manufacture or composition of matter – a product of human ingenuity having a distinctive name, character [and] use.”⁵⁵ Whereas the original bacterium was a product of nature and not eligible for patent protection, the new bacterium had

50. *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1293 (2012); *Ass’n for Molecular Pathology v. Myriad Genetics Inc.*, 133 S. Ct. 2107, 2116 (2013).

51. *Ass’n for Molecular Pathology*, 133 S. Ct. at 2116.

52. *Id.* at 2111.

53. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); see *Ass’n for Molecular Pathology*, 133 S. Ct. at 2116 (discussing the *Chakrabarty* case and decision).

54. *Chakrabarty*, 447 U.S. at 305.

55. *Id.* at 309; *Ass’n for Molecular Pathology*, 133 S. Ct. at 2117.

markedly different characteristics from any found in nature due to the addition of the plasmids, rendering it patent eligible.⁵⁶

Justice Thomas stated that, by contrast, “Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.”⁵⁷ The Court concluded that Myriad found the location of a gene associated with breast cancer and identified mutations that increase the risk, but that discovery by itself does not render the BRCA gene sequences new compositions of matter that are patent eligible.⁵⁸

B. *The Federal Court of Australia*

In contrast to the U.S. Supreme Court’s focus on the similarity between “isolated” and “naturally occurring” nucleic acid sequences, the Federal Court of Australia stated that the focus of analysis should be the “differences in structure and function effected by the invention of man and not on the similarities.”⁵⁹ Therefore, the Court framed the issue as whether claims covering an isolated nucleic acid are for a “manner of manufacture”, as required by section 18(1)(a) of the Patents Act of 1990.⁶⁰

The Federal Court of Australia centered its reasoning on the meaning of “manner of manufacture” as described in *National Research Development Corporation v. Commissioner of Patents* (NRDC case).⁶¹ There, the Court upheld a patent for an herbicide as a manner of manufacture.⁶² The Court decided that it was

56. See *Chakrabarty*, 447 U.S. at 310; *Ass’n for Molecular Pathology*, 133 S. Ct. at 2117 (discussing the decision and reasoning of the Court in the *Chakrabarty* case).

57. *Ass’n for Molecular Pathology*, 133 S. Ct. at 2117.

58. *Id.* at 2117.

59. *Australia – Full Court Confirms Isolated DNA is Patentable*, *supra* note 47; *D’Arcy v. Myriad Genetics Inc.* [2014] FCAFC 115, 36 (Austl.).

60. See *D’Arcy*, [2014] FCAFC 22 (discussing the issue identified by the Federal Court of Australia); *Patents Act 1990* (Cth) s 18(1)(a) (Austl.) (stating the manner of manufacture requirement for patent eligibility in Australia).

61. See *D’Arcy*, [2014] FCAFC 115, 24 (discussing the Federal Court of Australia’s decision in the NRDC case); *Nat’l Research Dev. Corp. v. Comm’r of Patents* [1959] 102 CLR 252, 269 (discussing the Federal Court of Australia’s decision in the NRDC case).

62. See *Nat’l Research Dev. Corp. v. Comm’r of Patents* [1959] 102 CLR 252, 253 (Austl.) (discussing the decision made in the NRDC case).

sufficient for a product to result in “an artificially created state of affairs,” leading to an economically useful result.⁶³ The Federal Court of Australia noted that the process of isolating a gene produces an “artificial state of affairs” that may be eligible for patent protection.⁶⁴ It reasoned “the chemical and physical makeup of the isolated nucleic acid renders it not only artificial but also different from its natural counterpart.”⁶⁵

The Court pointed out that what is being claimed is not the gene sequence as it exists in the human body but, rather, when it is isolated from a cell.⁶⁶ Therefore, the claimed product is not the same as the naturally occurring product on account of the structural and functional differences caused by isolating the gene.⁶⁷ This chemical change combined with the different and beneficial utility of the isolated gene, led the Federal Court of Australia to conclude that isolated gene sequences are patentable subject matter under Australian law and the understanding of the meaning of “manner of manufacture” devised in the *NRDC* case.⁶⁸

The implications of the U.S. Supreme Court’s and the Australian Federal Court’s decisions reach beyond just their consequences for Myriad Genetics.

IV. IMPLICATIONS OF PATENT ELIGIBILITY OR INELIGIBILITY OF HUMAN GENE SEQUENCES

Critics and proponents of gene patents base their arguments on scientific and public interest perspectives.⁶⁹ The major scientific and public interest arguments focus on scientific

63. *Id.* at 277.

64. *See D’Arcy*, [2014] FCAFC 115, 50 (stating why the claimed product is properly subject to patent); *Nat’l Research Dev. Corp.*, 102 CLR 252, 277 (discussing the High Court of Australia’s decision holding that it is sufficient for a product to result in “an artificially created state of affairs” leading to an economically useful result).

65. *D’Arcy*, [2014] FCAFC 115, 49.

66. *Id.*

67. *Id.*

68. *Id.*

69. *See* Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 *UMKC L. REV.* 295-96 (2007) (considering the effects of human gene patents on scientific innovation and patient access).

research and patient access.⁷⁰ Gene patenting opponents believe that patenting human gene sequences inhibits scientific research, which is ultimately detrimental to society and patients.⁷¹ Conversely, proponents argue that allowing human gene sequence patents invigorates scientific research, in turn leading to a host of societal benefits.⁷²

Part A in this section will explore the views of the proponents human gene patenting. Part B will discuss the views of the opponents to human gene sequence patents.

A. *Proponents to Gene Sequence Patenting*

Proponents of gene sequence patenting argue that allowing “patenting of human DNA sequences is . . . likely to lead to medical innovations that promote the greatest happiness for the greatest number.”⁷³ They perceive patents as necessary to counteract the high cost of developing such technologies and to encourage continued innovation.⁷⁴ Because gene therapies hold the promise of discovering cures and advanced therapies for genetic diseases, biotechnology companies are investing heavily in genetic research.⁷⁵

Patent law encourages public disclosure of scientific research and technological advances.⁷⁶ In exchange for the right to exclude others from utilizing and profiting from their inventions for some time, an inventor must disclose how to make and use that

70. See Liptak, *supra* note 18 (examining effects of the United States decision that human gene sequences patent claims are ineligible for protection on scientific research and genetic testing availability to patients).

71. Jacob D. Moore, *The Forgotten Victim in the Human Gene Patenting Debate: Pharmaceutical Companies*, 63 FLA. L. REV. 1277, 1289 (2011) (explaining the effects of gene patenting on scientific research).

72. *Id.*

73. Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union*, 76 N.Y.U. L. Rev. 1623, 1659 (2001).

74. See Harmelen & Mjezu, *supra* note 10 (detailing the effects of gene patents on genetic research and innovation).

75. See Moore, *supra* note 71, at 1291.

76. See Harmelen & Mjezu, *supra* note 10 (describing how patents increase the rate of innovation and promote technological advancement).

invention to receive patent protection.⁷⁷ Without the benefit of exclusivity, researchers may be discouraged from investing in genetic research or inclined to protect their discoveries in ways that do not require disclosure, such as trade secret law.⁷⁸ Either of these results comes with consequences.

Protecting gene discoveries through trade secret law could still allow for a monopoly over the utilization of that gene, which is a major concern for opponents of gene patenting.⁷⁹ Under trade secret law, the research company could still charge a fee for the use of the gene, or the genetic discovery may never be revealed and may be protected potentially forever.⁸⁰ On the other hand, while patent protection provides the patentee with an exclusionary right, the right to exclude others from making, using, or selling your patented invention has a limited duration.⁸¹ From this, it is arguable that “reliance on trade secret law for protection of such inventions may in fact stifle innovation more than patenting such inventions, “in that such information may be kept out of the public domain as long as the company desires to maintain the confidentiality of the information.”⁸² At the very

77. See 35 U.S.C. § 101 (2012) (describing disclosure requirements in the application for patent protection in the United States); *Patents Act 1990* (Cth) s 40 (Austl.) (describing disclosure requirements in the application for patent protection in Australia).

78. See Mead, *supra* note 39, at 763 (describing the possibility of trade secret protection as an alternative to patent protection if gene sequences are not patent eligible).

79. See *id.* (examining the possibility of trade secret protection as an alternative to patent protection if gene sequences are not patent eligible).

80. See *id.* (discussing the consequences of trade secret protection on corporations and the public, including decreased innovation and research).

81. See ROGER E. SCHECHTER, *BLACK LETTER OUTLINES: INTELLECTUAL PROPERTY* 294 (3d ed. 2006) (describing the exclusive right conferred through patent protection); Patent Act, 35 U.S.C. §271a (2012) (“Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent”).

82. See Harmelen & Mjezu, *supra* note 10 (discussing trade secret protection as a consequence of the ineligibility of human gene sequences for patent protection). The “public domain” constitutes information that is free for all to use, and includes the fundamental building blocks for future progress and all intellectual property on which legal protection has expired. See SCHECHTER, *supra* note 81, at 75 (explaining the connection between intellectual property law and the public domain). A trade secret is any confidential information that is valuable to a company because it provides that company with a competitive advantage. *Id.* at 312. Trade secret protection is indefinite in duration,

least, this may cause unnecessary and inefficient re-research of gene-to-disease correlations, simply because there would be no way to know whether a given gene or correlation had already been discovered.⁸³ Furthermore, trade secret law does not protect the holder against reverse engineering or independent development of the technology by others, while patent protection does.⁸⁴

Limited protection duration and disclosure requirements, coupled with the experimental use exemption⁸⁵ from patent infringement, found in both the United States and Australia, and various licensing options may in fact facilitate innovation rather than stifle it.⁸⁶ Once a patent expires, the technology involved that made it new and useful becomes part of the public domain.⁸⁷ Even while patented, the new advances that warranted protection are disclosed to the public.⁸⁸ The effect is that researchers can build upon previous innovation.⁸⁹ If protected by trade secret law, new advances may never be disclosed and

lasting as long as the owner keeps the secret. *See id.* at 324 (describing the duration of protection provided by trade secret law).

83. *See* Mead, *supra* note 39, at 763 (examining the consequences of trade secret protection for gene sequences as opposed to patent protection).

84. *See* SCHECHTER, *supra* note 81, at 324 (reviewing the advantages of patent protection compared to trade secret protection).

85. Most countries, including Australia, provide for experimental use exemptions to patented subject matter, so the impact basic research and development is likely to be limited. *See* Harmelen & Mjezu, *supra* note 10 (discussing the experimental use exception to patent recognized in the United States and Australia). Experimental use exemptions allow for otherwise infringing activity to take place in certain situations, for example for experimentation required for FDA approval. *See Experimental Use Exception to Patent Infringement*, SYRACUSE U. C. L. (Mar. 31, 2014) <http://nysstlc.syr.edu/experimental-use-exception-to-patent-infringement/>.

86. *See* Mead, *supra* note 39, at 764-65 (discussing the possibility of trade secret protection as an alternative to patent protection if gene sequences are not patent eligible and its consequences).

87. *See* SCHECHTER, *supra* note 81, at 75 (detailing the entrance of intellectual property into the public domain). The term of a patent is 20 years from the date of the patent application, and patents are not renewable. *Id.* at 295.

88. *See* 35 U.S.C. § 101 (2012) (describing disclosure requirements in the application for patent protection in the United States); *Patents Act of 1990*, *supra* note 36, at s 40 (discussing disclosure requirements in the application for patent protection in Australia).

89. *See* SCHECHTER, *supra* note 81, at 75 (discussing how inventors and researchers build on the work of others and by having information disclosed and in the public domain with that materials free for all to use, this ensures the continuing stream of innovation).

therefore never built upon, stifling the progress of science, in this case, genetic research.⁹⁰ Furthermore, licensing and the experimental use exception allow use of currently patented inventions to be used for research and genetic testing during the life of the patent.⁹¹

Another way in which allowing patents on human genes encourages continued genetic research and development is through generating a return on investment.⁹² Billions of dollars are spent annually on biotechnology, pharmaceutical, and genetic research, many of which never come to fruition.⁹³ Allowing the patenting of successful developments in genetic research serves this purpose and ensures that companies will continue to invest in socially beneficial biomedical research.⁹⁴ Not providing patent protection for human genes may slow down the next big genetic breakthrough.⁹⁵ The owners of the human gene patents, Myriad for example, have not only discovered important information about certain human genes, but have built successful products that have benefited many.⁹⁶ These products and tests may never have been developed without the recoupment of research and development investments.⁹⁷

Additionally, critics of gene patents argue that patents of specific gene sequences creates high costs and limited access for

90. See *id.* at 324 (stating the possible indefinite duration of trade secret protection, inferring that information could never be revealed or released into the public domain and therefore never built upon by other researchers in the field).

91. See *Experimental Use Exception to Patent Infringement*, *supra* note 85 (describing the experimental use exception to patent infringement).

92. See Paula Burkes, *The Arguments Given For and Against Patenting Human Genes*, NEWS OK (Apr. 17, 2013), <http://newsok.com/the-arguments-given-for-and-against-patenting-human-genes/article/3786827> (arguing that allowing exclusive patent protection for gene sequences enables researchers to recoup funds put into the research process originally and in turn encourages continued innovation).

93. *Id.*

94. See *id.* (explaining how ensuring return on investment encourages continued investment in research).

95. See *id.* (describing a possible consequence if researchers and investors do not continue investing in genetic research for fear of not being able to significantly recoup from their investment).

96. See *id.* (describing how genetic research has been used to benefit many).

97. See Burkes, *supra* note 92 (discussing the potential impact if researchers and investors in genetic research are deincientized from further investment).

patients for whom that genetic test is medically necessary.⁹⁸ While such restrictions could increase a patient's burdens and costs, this is not unique to human gene patents.⁹⁹ Any patents covering health care products "can cause such deleterious effects and criticizing the high cost of patented therapies is a critique of the patent system as a whole and not specifically of gene patents."¹⁰⁰

Opponents of gene patenting proclaim negative implications on research and patient access to genetic testing employing surprisingly similar, yet mirror-imaged, arguments.

B. *Opponents to Gene Sequence Patenting*

Challengers believe that gene patents will limit research and development of genetic testing and treatments for genetic diseases.¹⁰¹ Furthermore, gene sequence patenting will make diagnostic testing for genetic diseases prohibitively expensive for patients.¹⁰²

From a scientific research standpoint, critics of gene patenting claim that human gene patents may hinder scientific progress because researchers hoping to work with patented genes need to ask the various patent owners for their permission and obtain a license to use the patented gene, thereby increasing costs and lowering efficiency.¹⁰³ This could become so prohibitive that researchers may stop working with patented genes altogether.¹⁰⁴ According to one report, a majority of genetic lab directors have disclosed that they have given up research in several areas due to

98. See Chester S. Chuang & Denys T. Lau, *The Pros and Cons of Gene Patents*, THE RECORDER (Dec. 17, 2010, 11:40 am), <http://digitalcommons.law.ggu.edu/cgi/viewcontent.cgi?article=1171&context=pubs> (explaining the argument that gene patents create higher costs for patients needing access to a genetic test).

99. See *id.* (suggesting that increased patient costs is not unique to gene patents).

100. *Id.*

101. See Harmelen & Mjezu, *supra* note 10 (describing views of opponents to human gene sequence patenting).

102. *Id.*

103. See Chuang & Lau, *supra* note 98 (discussing the need for researchers to obtain licenses to work with patented genes before being able to use it in further research).

104. *Id.*

concerns about gene patents.¹⁰⁵ Similarly, in one survey, around half of the members of the American Society of Human Genetics have disclosed that some research was limited due to concerns about gene-related patents.¹⁰⁶ Opponents point to such results as support for the view that gene sequence patents suppress research into genetic diseases.¹⁰⁷

This criticism relates to the “tragedy of the anticommons” phenomenon.¹⁰⁸ Francis Collins, National Institutes of Health Director wrote that, “The information contained in our shared [genome] is so fundamental, and requires so much further research to understand its utility, that patenting it at the earliest stage is like putting up a whole lot of unnecessary toll booths on the road to discovery.”¹⁰⁹ There are a multitude of functional genes in the human body, making it is possible that a single strand of DNA could be patented and owned by thousands of different researchers.¹¹⁰ A scientist would be unable to engage in basic genetic research without obtaining a license from each of the separate patents owners.¹¹¹ Accumulating the licenses to work with multiple genes could prove prohibitively costly, in terms of both time and money.¹¹² Ultimately, this could lead researchers to focus their efforts in an area that has fewer obstacles.¹¹³ Forcing scientists to continuously navigate the patent landscape is unproductive and negatively affects the way researchers work with and study gene sequences.¹¹⁴

105. Burkes, *supra* note 92.

106. *Id.*

107. *See id.* (describing stifling of research as a reason given by opponents for not allowing patents on human gene sequences).

108. *See* Moore, *supra* note 71, at 1289 (discussing the phenomenon termed the “tragedy of the anticommons” as related to the human gene patenting debate).

109. Eric Hoffman, *Why Gene Patents Are Bad Patients and Science*, AM. INTEREST (Aug. 9, 2011), <http://www.the-american-interest.com/?s=Why+Gene+Patents+Are+Bad+for+Patients+and+Science>.

110. Moore, *supra* note 71, at 1289.

111. *Id.* at 1289-90 (explaining how a researcher would be unable to work with a strand of DNA without first obtaining licenses from every gene patent holder who holds a patent on that particular strand).

112. *Id.* at 1290.

113. *Id.*

114. *Id.*

Professor Alan Ashworth, head of the Institute of Cancer Research and part of the team who discovered the BRCA2 gene stated that, “The argument that innovation will be stifled if there are no rewards for “invention” is particularly pernicious. Commercial organizations can be exceptionally innovative and it is only right that this is rewarded. But patenting is not the only way to ensure innovation.”¹¹⁵ Trade secret law and patent law are closely connected, and, to a large degree, they are alternative modes of protecting the same types of intangible assets.¹¹⁶ Protecting gene sequences through trade secret law, rather than patent law, has several advantages for researchers. Trade secret protection is less expensive to obtain than patent protection, which requires an expensive and extensive application process and renewal fees.¹¹⁷ Furthermore, from a patient access standpoint, trade secret protection allows for independent development by different researchers.¹¹⁸ This could provide greater access to genetic testing for patients as many different tests could be developed simultaneously.¹¹⁹ Patent law prevents independent development, as the first person to register and is granted a patent receives full exclusion power against anyone in that country.¹²⁰

The U.S. Supreme Court’s decision that human gene sequences are not patent eligible could lower the cost of genetic testing by increasing competition between providers, which is a potential benefit to public health.¹²¹ Actually, almost immediately after the Court ruled that human gene sequences are not eligible for patent protection, several laboratories announced that they would now be offering genetic testing for breast cancer risk,

115. Alan Ashworth et al., *Supreme Court BCRA Patenting Decision: Experts Respond*, THE CONVERSATION (June 14, 2013, 10:36 AM), <http://theconversation.com/supreme-court-brca-patenting-decision-expert>.

116. SCHECHTER, *supra* note 81, at 324.

117. *Id.*

118. See Chris Katopis, *Patients v. Patients?: Policy Implications of Recent Patent Legislation*, 71 ST. JOHN’S L. REV. 329, 346 (1997) (describing the difference between patent protection and trade secret protection).

119. See Hoffman, *supra* note 109 (arguing that the decrease in the quantity of medical researchers due to widespread gene patenting has diminished innovation).

120. Katopis, *supra* note 118, at 340.

121. Sharlach, *supra* note 9.

making it likely that the BRCA test may become more affordable and more readily available in the United States.¹²²

Gene patents also push research efforts towards gene-to-disease correlations and away from other possible environmental factors that may cause disease, such as exposure to toxic chemicals.¹²³ Most genetic tests only offer an estimate of the chances for developing a particular disease, but cannot account for the influence of other factors that contribute to the development of a disease.¹²⁴ The predictive power of the test for BRCA breast cancer mutations is high for persons with family histories of particular kinds of breast or ovarian cancer, but very low for women without a family history of breast cancer.¹²⁵ Gene patents focus our knowledge of these gene sequences to only their potential connection to a disease while preventing other researchers from looking at how that gene may interact with other genes or the outside environment.¹²⁶

V. HUMAN GENE PATENT ELIGIBILITY DEBATE AS APPROACHED FROM OTHER COUNTRIES

In determining whether allowing patents on human genes or not is the correct approach, it is important to look outside the United States and Australia at the approaches of other countries who have or are currently considering the issue. This section will discuss the approaches taken in the European Union and in Canada. In addition, it will examine the significance of consistency in patent laws internationally.

122. See Andrew Pollack, *After Patent Ruling, Availability of Gene Tests Could Broaden*, N.Y. TIMES, June 13, 2013, at A16 (discussing the potential increase in availability of breast cancer genetic testing after the United States ruled that human gene sequence claims are ineligible for patent protection); Libby Deshaies, *Recent Developments in Patient Medical Biotechnology: Myriad Genetics and the Affordable Care Act as Steps Towards Greater Patient Access*, 14 U. ILL. J.L. TECH. & POL'Y 307, 312 (2014) (discussing the response to the Supreme Court's decision in *Myriad*).

123. Hoffman, *supra* note 109.

124. *Id.*

125. *Id.*

126. *Id.*

*A. The European Union*¹²⁷

The European Patent Office examines European patent applications and considers whether to grant or refuse the patent based on European patent law and judicial interpretation thereof.¹²⁸ The Biotech Directive was passed in 1998 by European Parliament with the objective of clarifying the distinction between what is the proper subject of patent protection and what is not.¹²⁹ The Biotech Directive states that “biological material which is isolated from its natural environment or produced by means of a technical process” may be patentable “even if it previously occurred in nature.”¹³⁰

In order to be patentable, biotechnological “inventions” have to meet the same criteria as inventions in any other field.¹³¹ Patents are granted only for “inventions that are new, involve an inventive step, and are susceptible of industrial application.”¹³² Courts have defined “new” to mean something which is “made available to the public.”¹³³ Therefore, a human gene, which existed before, but had not been discovered and was not made

127. The 28 Member States of the European Union are as follows: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and United Kingdom. *Member States of the EU*, EUR. UNION, http://europa.eu/about-eu/countries/index_en.htm (last visited Feb. 12, 2015).

128. See *Patents on Biotechnology*, EUR. PATENT OFFICE, <http://www.epo.org/news-issues/issues/biotechnology.html> (last updated Nov. 25, 2013) (discussing patent process in the European Union).

129. See *Summaries of EU Legislation: Legal Protection of Biotechnological Inventions*, EUR. UNION, http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/pharmaceutical_and_cosmetic_products/126026_en.htm (last visited Feb. 12, 2015) (explaining the objective of the Directive of the European Parliament on the legal protection of biotechnological inventions).

130. Directive 1998/44, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, art. 3, 1998 O.J. (L 213) 18(EC); *US Case Highlights Problems for Human Gene Patents on Both Sides of the Atlantic, Says Expert*, OUT-LAW (Apr. 19, 2013), <http://www.out-law.com/articles/2013/april/us-case-highlights-problems-for-human-gene-patents-on-both-sides-of-the-atlantic-says-expert/>.

131. *Patents on Biotechnology*, *supra* note 128.

132. *Id.*

133. *Id.*

available to the public, could be patented when it is isolated, as long as it has industrial application.¹³⁴

However, companies or researchers seeking patent protection on gene sequences in the European Union are continually met with the challenge of proving that the process of isolating genes is a step inventive enough to warrant patent protection.¹³⁵ They must show that the subject matter for which patent protection is sought is inventive and not just a trivial or obvious further development of existing knowledge.¹³⁶

When speaking about the difficulties faced in European Union patent law concerning human gene patents, patent law expert Adrian Murray stated that

The application of the law on inventive step has been applied by the European Patent Office in an increasingly stringent manner over the last 20 years . . . This is principally because the techniques used to identify, isolate and reproduce sequences of interest from DNA have become increasingly mechanized during that time, making it considerably more difficult for patent applicants to establish that isolation of the sequences they are looking to protect required the expense of inventive effort, rather than simple routine experimentation.¹³⁷

He claims that the typical method of persuading the European Patent Office that a gene sequence meets the inventive step requirement is to establish that the gene exhibits unanticipated and distinctive effects specific to that particular gene.¹³⁸

After the Supreme Court's decision in *Association for Molecular Pathology*, the patent policy of the United States concerning gene patenting and that of the European Union are now in opposition. This discordance could have great

134. *Id.*

135. *See US Case Highlights Problems for Human Gene Patents on Both Sides of the Atlantic, Says Expert, supra* note 130 (discussing challenges that researchers face when trying to obtain a gene sequence patent in the European Union).

136. *See id.* (detailing the inventive step requirement for patent protection in the European Union).

137. *Id.*

138. *See id.* (outlining the best way for researchers to meet the inventive step requirement in the European Union to be able to obtain a patent on a gene sequence).

international policy implications, as the United States Patent and Trademark Office and the European Patent Office are two of the largest patent offices.¹³⁹

While the European Union and the United States have made firm decisions concerning whether gene sequences are the proper subject for patent protection, Canada is presently deciding their view on this issue.

B. Canada

The Canadian courts are currently dealing with the issue of patentability of human gene sequences.¹⁴⁰ The University of Utah holds Canadian patents on the gene associated with Long QT Syndrome, a genetic heart condition.¹⁴¹ The Children's Hospital of Eastern Ontario is working on developing a process to replace the current expensive genetic test used to diagnose the disease.¹⁴² The University of Utah has threatened to sue the hospital for infringement, and now the hospital is seeking to have the Supreme Court of Canada revoke or invalidate the patents held on the gene by the University in light of the recent ruling by the U.S. Supreme Court that human genes are not a patentable subject matter in the United States.¹⁴³

139. See Chaung & Lau, *supra* note 98 (predicting how the patent policies in the United States and the European Union could be in opposition leaving the potential for conflict in international patent policy).

140. See Riley Sparks, *5 Things to Know About the Canadian Gene Patent Case*, TORONTO STAR (Nov. 3, 2014), http://www.thestar.com/news/canada/2014/11/03/5_things_to_know_about_the_canadian_gene_patent_case.html (detailing the current controversy in Canada concerning the patentability of human gene sequences, specifically the gene associated with Long QT Syndrome). Long QT Syndrome is a disorder associated with heart rhythm that can cause fast and chaotic heartbeats, which may trigger sudden fainting or seizure. See *Diseases and Conditions: Long QT Syndrome*, MAYO CLINIC, <http://www.mayoclinic.org/diseases-conditions/long-qt-syndrome/basics/definition/con-20025388> (last visited Feb. 6, 2016) (explaining the genetic disease Long QT Syndrome and its effects on the heart of those afflicted).

141. *Id.*

142. See *id.* (summarizing how the Children's Hospital of Eastern Ontario has been using the gene on which The University of Utah holds a patent to try to develop a cheaper genetic test for discovering if patients have the particular mutation that is associated with Long CT Syndrome).

143. See *id.* (discussing that the Children's Hospital of Eastern Ontario is seeking to have the gene patent held by The University of Utah invalidated).

The closest the Supreme Court of Canada has previously come to addressing this issue was in the *Harvard Mouse* case.¹⁴⁴ The Court held that an oncogenic mouse was not the proper subject for patentability.¹⁴⁵ In this decision, the Supreme Court of Canada disagreed with its U.S. counterpart, despite the Canadian definition of patentable subject matter being derived from the definition found in the patent laws of the United States.¹⁴⁶ The Court based its reasoning on a distinction between lower and higher life forms, which it read into the terms “manufacture” and “composition of matter,” preventing the terms from encompassing higher life forms.¹⁴⁷ This distinction is not one that is drawn in Canada’s Patent Act.¹⁴⁸

In the current gene patenting debate in Canada, it seems like the scope of these same terms will reappear.¹⁴⁹ It remains to be seen whether Canada will follow the lead of the United States in disallowing gene patents.¹⁵⁰ Unlike the *Harvard Mouse* case, the current dispute in Canada impacts public access to necessary diagnostic testing, bringing new and more ominous societal considerations into the debate, similar to the considerations brought forth in the *Myriad* cases.¹⁵¹

144. Nathaniel Lipkus, *Gene Patents in Canada: A Myriad of Possibilities*, JUST BIOTECH, <http://www.justbiotech.ca/gene-patents-in-canada-a-myriad-of-possibilities> (last visited Feb. 8, 2015). The *Harvard Mouse* case refers to *Harvard College v. Canada*, in which Harvard applied for a patent on an oncogenic mouse and the process in which it was produced by. [2002] 4 S.C.R. 46. The process involves injecting a cancer-promoting gene, an oncogene, into fertilized mouse eggs. *Id.* Next the eggs are implanted into a female host mouse and developed to term. *Id.* Fifty percent of the offspring will have all of their cells affected by the oncogene, making them suitable for animal carcinogenic studies. *Id.* The process claims were allowed by the Patent Examiner, while the product claims were rejected. *Id.* The Commissioner of Patents confirmed the refusal of the product claims, which is why the case was taken to the court. *Id.*

145. *Harvard College*, 4 S.C.R. at 122-30 (holding that a higher life form is not patentable because it is not a “manufacture” or “composition of matter” within the meaning of “invention” in the section of the Patent Act of Canada that defines patentable subject matter).

146. Lipkus, *supra* note 144.

147. *Id.*

148. *Id.*

149. *Id.*

150. *Id.*

151. See Sparks, *supra* note 140 (discussing how the debate in Canada is about a gene associated with a heart condition and how The University of Utah holds a patent and

Arguably the outcome of the Canadian case should be consistent with the U.S. case, as the pertinent patent laws are almost identical and fitting genes into the category of “higher life forms” is a tough argument to press.¹⁵² Depending on where Canada falls on the issue of gene sequence patentability, the split in views between countries could increase, or this could be a step closer to international consistency within the intellectual property community on this issue.

C. Harmonization

In looking at the bigger picture, the goal is international consistency and harmonization in patent law around the world. Harmonization is the alignment of laws and procedures to ensure consistency and clarity of rights for the world’s inventors.¹⁵³ Harmonization is a prerequisite to maximizing the development and dissemination of innovation and thereby improving the quality of life for all people around the world.¹⁵⁴

The recently passed America Invents Act proclaims to “pave the way for greater patent harmonization.”¹⁵⁵ It states that “it is imperative that the international patent system provide consistent, cost-effective avenues to obtain reliable patent rights in multiple jurisdictions.”¹⁵⁶ The United States Patent and Trademark Office further claims that the passage of the America Invents Act enables it to lead in “creating an intellectual property world in which national and regional patent systems are harmonized in pursuit of creating an optimal environment for

threatened to sue if the Children’s Hospital of Eastern Ontario continues to develop a process to replace the expensive diagnostic testing currently in place).

152. See Jani Ihalainen, *Genetic Patents Saga Continues – Next Stop, Canada*, IP IUSTITIA (Dec. 1, 2014, 9:24 AM), <http://www.ipiustitia.com/2014/12/genetic-patents-saga-continues-next.html> (discussing the current patent debate in Canada and how the Court could possibly come out on the issue of gene sequence patent eligibility).

153. David J. Kappos, *Patent Law Harmonization – The Time Is Now*, LANDSLIDE, July/Aug. 2011, at 16.

154. *Id.* at 16–17.

155. *Harmonization: The Time is Now*, U.S. PATENT & TRADEMARK OFFICE, <http://www.uspto.gov/learning-and-resources/ip-policy/harmonization> (last visited Feb. 8, 2015).

156. *Id.*

technological innovation and diffusion.”¹⁵⁷ While this act may have made substantial strides toward the goal of international consistency, it has missed the mark in the currently prominent area of gene sequence patenting.

The United States Congress has previously promoted the ultimate goal of international harmonization in the intellectual property community through legislation.¹⁵⁸ One prominent example is the passage of the Sonny Bono Copyright Term Extension Act (CTEA) in 1998.¹⁵⁹ A big push for the passage of the CTEA came from the passage of an E.U. directive in 1993 instructing E.U. Member States, many of them major consumers of U.S. copyrighted works, to establish a copyright term life plus 70 years.¹⁶⁰ This longer term, however, would be denied to works of any non-Member State whose copyright laws did not secure the same extended term for its copyright owners, as directed consistent to the Berne Convention.¹⁶¹ By extending copyright term in the United States by 20 years (to life plus 70 years),

157. *Id.*

158. *See* CRAIG JOYCE ET AL., *COPYRIGHT LAW* 328, 332 (9th ed. 2013) (describing why Congress felt that it was necessary to reform the copyright laws).

159. *See id.* at 327-29 (explaining harmonization as a motivation for the passage to of the Sonny Bono Copyright Extension Act). The Copyright Term Extension Act, passed in 1998, provided for an extra 20 years of protection for U.S. owners of copyrighted works. *Id.* at 328. Before the CTEA, the Copyright Act of 1976 set the copyright term in the United States at life of the author plus 50 years. *Id.* at 327. The CTEA then extended this to life of the author plus 70 years. *Id.* at 328. For works created on or after January 1, 1978, copyright protection now extends for the life of the author plus 70 years. *Id.* For works created but not published or registered before January 1, 1978, the same terms apply. *Id.* For works created before 1978, and still in their original or renewal term of copyright when the CTEA came into effect, the renewal term is extended to 67 years, for a total maximum term of 95 years. *Id.* For works already in the public domain, and previous copyright protection had expired, there was no restoration of protection. *Id.* at 329.

160. *See id.* at 328 (examining the 1993 directive of the European Union to its member states to “harmonize” their terms of copyright protection using a basic term of life of the author plus 70 years).

161. *Id.* The Berne Convention is an international agreement that lays down a common framework with respect to intellectual property rights. THE UK COPYRIGHT SERVICE, FACT SHEET P-08: THE BERNE CONVENTION (last amended Dec. 6, 2011). The current text of the convention, to which the United States entered in 1989, is the Paris Act of 1971. *Id.*; JOYCE, *supra* note 158, at 37. An author from any country that adheres to the Berne Convention is awarded the same rights in all other countries that adhere as they allow their own national copyright owners, as well as any rights granted by the Convention. FACT SHEET P-08: THE BERNE CONVENTION.

Congress sought to ensure that U.S. copyright holders would receive the same protection in Europe as copyright owners in Member States.¹⁶² Also, by harmonizing the term of copyright with the European Union, Congress sought to further incentivize American authors and artists, as well as those from other countries, to create and distribute their works in the United States.¹⁶³ Supporters of extending copyright term in the United States with passage of the CTEA based their case, and Congress based its decision to pass the CTEA, on the benefits of international harmonization.¹⁶⁴

International harmonization in intellectual property law is an important objective to be considered when determining whether specific subject matters can be patented in a particular country, specifically gene sequences.

VI. CONCLUSION

The legal debate concerning gene patent eligibility has focused on technical aspects of patent law doctrine and not on the significant policy arguments surrounding the issue.¹⁶⁵ Therefore, taking into account health care access and research concerns when evaluating the issue is important.¹⁶⁶ The potential implications of allowing or not allowing researchers to patent human gene sequences may outweigh the direct technical decision of whether gene patents fit nicely into the patent law as it has been interpreted by the courts.

While it seems correct that simple gene sequences do not fit into the patent scheme of the United States as “products of nature,” it is possible that they fit in when isolated and chemically altered to make them useful in a laboratory.¹⁶⁷ However, even if isolated genes do not fall within the precise bounds of patent law

162. JOYCE, *supra* note 158, at 332.

163. *Id.*

164. *Id.* at 328.

165. Chuang & Lau, *supra* note 98.

166. *Id.*

167. See T.C., *Why Are Gene Patents Controversial?*, THE ECONOMIST (Apr. 18, 2013, 11:50 PM), <http://www.economist.com/node/21576354> (discussing Myriad’s claim that its patents are not on the genes as they exist in the body, but on the chemically altered and modified versions usable in a laboratory).

as previously decided in the United States, the consequences to genetic research and patient access greatly overshadow the need to stick with old law. Patents on gene sequences benefit both science and society. Research and medicine are global; there are international research collaborations and people traveling all over the world to receive medical care.¹⁶⁸ Country-specific patents do not really seem to capture reality in this way. Patients could order genetic tests on the internet and send them back for testing in another country. There is a strong need for harmonization in the area of gene patenting.

The United States should follow the lead of Australia and the European Union, which could in turn lead the way for Canada to decide human gene sequences are patentable. In the United States, this implicates the need for Congress to step in and change the current interpretation of the patent law by the courts. This could be a first step on the road to international harmonization of patent law.

168. See generally *A Global Perspective on Medicine*, YALE SCH. MED., <http://medicine.yale.edu/news/cedar/global.aspx> (last visited Mar. 6, 2015) (examining the idea of health, medicine, and research as a global effort and collaboration).