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The Forgotten Victim in the Human Gene Patenting Debate: Pharmaceutical Companies

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NOTE

THE FORGOTTEN VICTIM IN THE HUMAN GENE PATENTING
DEBATE: PHARMACEUTICAL COMPANIES

*Jacob D. Moore**

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INTRODUCTION

Scientific innovation is crucial to the prosperity, security, and health of a nation.¹ During the founding years of the United States, political leaders

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1. See President Barack Obama, Remarks at the National Medal of Science and National Medal of Technology and Innovation Ceremony (Oct. 7, 2009), *available at* http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-at-the-National-Medal-of-Science-and-National-Medal-of-Technology-and-Innovation-Ceremony/ (“Science is more essential

realized the need for such innovation and created the patent law system² as a means of protecting American citizens.³ The major goals of the United States patent law system are to provide the public with cutting-edge scientific discoveries and to enlighten the public as to how these discoveries can benefit society.⁴

In modern America, a substantial amount of patent protection is sought for inventions relating to the pharmaceutical industry. In recent decades, the pharmaceutical industry has expanded rapidly as researchers invent new and more effective drugs and products.⁵ The average life expectancy and quality of life of United States citizens has drastically increased in the past century, largely due to pharmaceutical innovation.⁶ Nonetheless, nearly sixty million people die each year, with many of these deaths caused by problems that pharmaceutical companies are striving to cure.⁷

In the late 1970s, scientific researchers began to view genetic material as a means of developing treatment options for a variety of human diseases.⁸ Today, approximately two-thirds of the new drugs that hit the market have been influenced by genetic research,⁹ and genetic material has

for our prosperity, our security, and our health, and our way of life than it has ever been.”); *see also* *Rockwell Graphic Sys., Inc. v. DEV Indus., Inc.*, 925 F.2d 174, 180 (7th Cir. 1991) (“The future of the nation depends in no small part on the efficiency of industry, and the efficiency of industry depends in no small part on the protection of intellectual property.”).

2. *See* U.S. CONST. art. I, § 8, cl. 8 (authorizing Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries”). *See generally* Act of Apr. 10, 1790, ch. 7, § 1, 1 Stat. 109, 110 (allowing federal protection for scientific inventions).

3. *See* George Washington, First Annual Address to Congress (Jan. 8, 1790), in 30 THE WRITINGS OF GEORGE WASHINGTON FROM THE ORIGINAL MANUSCRIPT SOURCES, 1745–1799, at 491, 491–92 (John C. Fitzpatrick ed., 1939) (stating that the general public’s “safety and interest require[] that they should promote such manufactories[] as tend to render them independent on others for essential, particularly military supplies”).

4. *See* *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989) (discussing the purpose of the United States patent system).

5. *See* Gregory J. Higby, *From Compounding to Caring: An Abridged History of American Pharmacy*, in PHARMACEUTICAL CARE 19, 36–37 (Calvin H. Knowlton & Richard P. Penna eds., 2d ed. 2003) (discussing the increase of pharmaceutical inventions in the 1950s).

6. *See* LAURA B. SHRESTHA, CONG. RESEARCH SERV., RL 32792, LIFE EXPECTANCY IN THE UNITED STATES 2–5 (2006) (showing that the average American life expectancy has increased by nearly thirty years in the past century and citing medical advances as a reason for these decreased mortality rates); *see also* The Henry J. Kaiser Family Found., *Kaiser Public Opinion Spotlight: Views on Prescription Drugs and the Pharmaceutical Industry*, 1 (Apr. 2008), available at http://www.kff.org/spotlight/rxdrugs/upload/Rx_Drugs.pdf [hereinafter Kaiser] (indicating that most American adults take prescription drugs and that a vast majority of Americans believe that prescription drugs improve quality of life).

7. *See* DEP’T OF HEALTH STATISTICS & INFORMATICS IN THE INFO., WORLD HEALTH ORG., THE GLOBAL BURDEN OF DISEASE: 2004 UPDATE 8, 22 (2008), available at http://www.who.int/healthinfo/global_burden_disease/GBD_report2004update_full.pdf (indicating that rates of mortality due to noncommunicable diseases are expected to increase in the coming decades).

8. MARTIN J. ADELMAN, RANDALL R. RADER & JOHN R. THOMAS, CASES AND MATERIALS ON PATENT LAW 59 (3d ed. 2009).

9. *See* Andrew Pollack, *The Genome at 10: Awaiting the Genome Payoff*, N.Y. TIMES, June 15, 2010, at B1, available at <http://www.nytimes.com/2010/06/15/business/15genome.html>

been linked to more than 850 human diseases.¹⁰ Additionally, biotechnology investors have indicated—with their pocketbooks—that they believe that the future of disease prevention and treatment is tied to genetic research.¹¹ Despite the fact that pharmaceutical companies have invested billions of dollars for development of gene-related cures and treatments for human illnesses,¹² the general public and the United States District Court for the Southern District of New York wish to rein in the intellectual property rights afforded to these companies.¹³ Furthermore, the United States Court of Appeals for the Federal Circuit (C.A.F.C.) is divided in regard to DNA patentability¹⁴ and has indicated that any change to DNA-patenting policy would be most effectively propagated legislatively.¹⁵

In our society, there is a large disconnect between the supposed interests of the public and the pharmaceutical industry. In general, the public desires medical innovation but prefers to benefit from these medical advances at minimal cost.¹⁶ Meanwhile, the pharmaceutical industry is merely a business, and businesses are built on profit maximization.¹⁷ Because the pharmaceutical business is premised on seemingly altruistic purposes, the industry is an easy target for individuals who cannot afford its services.¹⁸ Due to the nature of the pharmaceutical industry, profit

(indicating that the Research and Development President at Bristol-Myers Squibb and the Research Executive Vice President at Roche have both proclaimed that two-thirds of newly developed drugs have been influenced by genetic research).

10. See Nicholas Wade, *A Decade Later, Gene Map Yields Few New Cures*, N.Y. TIMES, June 13, 2010, at A1, available at <http://www.nytimes.com/2010/06/13/health/research/13genome.html?pagewanted=1&ref=business>.

11. See Pollack, *supra* note 9 (stating that Merck recently purchased a small gene research pharmaceutical company for \$1.1 billion).

12. *Id.*

13. See *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad I)*, 702 F. Supp. 2d 181, 232 (S.D.N.Y. 2010) (holding that isolated human DNA is not patentable).

14. See *infra* Section I.B.

15. See *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad II)*, No. 2010-1406, 2011 U.S. App. LEXIS 15649, at *66 (Fed. Cir. July 29, 2011) (stating that if DNA-related inventions are to be excluded from patentability, “the decision must come not from the courts, but from Congress”); *id.* at *98 (Moore, J., concurring) (basing his opinion partly on the “belief that we should defer to Congress, [he believes] . . . settled expectations tip the scale in favor of [DNA] patentability”).

16. See Kaiser, *supra* note 6, at 1 (explaining that most Americans attribute improved quality of life to advances in drug development, yet nearly half of surveyed Americans are displeased with pharmaceutical companies because they are “too focused on profits”).

17. See generally Steven G. Calabresi & Nicholas Terrell, *The Number of States and the Economics of American Federalism*, 63 FLA. L. REV. 1, 35–36 (2011) (discussing businesses manipulating output and pricing structures in order to maximize profit).

18. See Gina Kolata & Andrew Pollack, *In Costly Cancer Drug, Hope and a Dilemma*, N.Y. TIMES, July 6, 2008, at A1, available at <http://www.nytimes.com/2008/07/06/health/06avastin.html> (reporting that “patient advocates are . . . troubled by very expensive treatments”); see also Malcolm Gladwell, *High Prices: How to Think About Prescription Drugs*, THE NEW YORKER, Oct. 25, 2004, at 86, available at http://www.newyorker.com/archive/2004/10/25/041025crat_atlarge (discussing the commonly held viewpoint that “drug companies are troubled and corrupt”).

maximization benefits the general public. Therefore, decreasing pharmaceutical company profits necessarily has the unintended side effect of decreasing public health benefits.¹⁹ This complicated equilibrium has been convoluted further by the district court ruling, and the subsequent divided C.A.F.C. ruling, in the recent *Myriad* case.²⁰

This Note will explore the seemingly contradictory interests of the general public, the pharmaceutical industry, and the research community regarding human gene patents. Part I will look at the recent *Myriad* decisions in light of previous beliefs about the patentability of genetic material. Part II will examine the effect of gene patenting on scientific research and innovation. Parts III and IV will explore the effect of gene patents on both the general public and the pharmaceutical industry, and will seek to understand the belief dissonance between these two factions. Part V will consider how Congress has handled similar problems in the past through legislation, specifically in regards to plant patents and biological drugs. Part VI will discuss the possibility of finding a solution to the gene patent problem that satisfies the research community, the general public, and the pharmaceutical industry. Ultimately, this Note will analyze the success of prior legislation in order to propose a course of action that will appease all parties involved in the human gene patenting debate.

I. THE MYRIAD CASE

Congress has statutorily provided that anyone who “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.”²¹ In *Diamond v. Chakrabarty*,²² the first Supreme Court case involving patentability of genetic material, the Court ruled that genetically engineered bacteria were patentable subject matter.²³ The *Chakrabarty* Court focused on the Congressional intent of 35 U.S.C. § 101 in trying to decide whether genetically engineered bacteria were included within the statutory meaning of “‘manufacture’ or ‘composition of matter.’”²⁴ Because the patent law system was created with the idea that “‘ingenuity should receive a liberal encouragement,’”²⁵ the Court concluded

19. See Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT’L ECON. L. 849, 849–50 (2002) (citing David M. Cutler & Mark McClellan, *Is Technological Change in Medicine Worth It?*, 20 HEALTH AFF. 11, 23 (2001)) (implying that technological innovation is slowed by public backlash against the pharmaceutical industry).

20. *Myriad II*, No. 2010-1406, 2011 U.S. App. LEXIS 15649 (Fed. Cir. July 29, 2011); *Myriad I*, 702 F. Supp. 2d at 181.

21. 35 U.S.C. § 101 (2006).

22. 447 U.S. 303 (1980).

23. *Id.* at 318 (holding that Congress intended for 35 U.S.C. § 101 to be interpreted such that genetically modified bacteria are patentable subject matter).

24. *Id.* at 307 (quoting 35 U.S.C. § 101).

25. *Chakrabarty*, 447 U.S. at 308 (quoting 5 THE WRITINGS OF THOMAS JEFFERSON 75–76 (H.A. Washington ed., 1853)) (internal quotation marks omitted); see also *Graham v. John Deere*

that patentable subject matter includes “anything under the sun that is made by man.”²⁶ Including genetically engineered bacteria within the definition of “manufacture” or “composition of matter” was therefore deemed consistent with the purpose of the patent law system.²⁷ The Court concluded by urging Congress to legislatively address the patentability of genetic advances if the Court had misinterpreted the patentability statute.²⁸

While Congress has failed to address the issue of human gene patentability, the United States Patent and Trademark Office (USPTO) directly addressed the issue in the 2001 version of its Utility Examination Guidelines. Based on the updated guidelines, the mere discovery of a genetic sequence is not sufficient to obtain a patent.²⁹ However, if the gene sequence has a defined utility, then genetic material that has been isolated and purified is patentable, because it does not appear in nature in an isolated and purified form.³⁰ Even with this limitation in place, thousands of patents relating to genetic material have been granted by the USPTO.³¹ When the validity of genetic material patents has been questioned, courts have generally held that “pharmacological activity of any compound is obviously beneficial to the public,”³² and therefore upheld patents on functional genetic material.³³ Prior to the *Myriad* rulings, it was generally accepted by scholars that full-length genes were patentable subject matter if the gene had a known function and use.³⁴ It is within this context that the *Myriad* case began making its way through the United States judicial system.

Co., 383 U.S. 1, 7–10 (1966) (describing Thomas Jefferson as the “first administrator of our patent system” and discussing Jefferson’s philosophy on the purpose of patent law (quoting P.J. Federico, Operation of the Patent Act of 1790, 18 J. Pat. Off. Soc. 237, 238 (1936)) (internal quotation marks omitted)).

26. *Chakrabarty*, 447 U.S. at 309 (quoting S. REP. NO. 82-1979, at 5 (1952) and H.R. REP. NO. 82-1923, at 6 (1952)) (internal quotation marks omitted). The Court also noted that “laws of nature, physical phenomena, and abstract ideas [are] not patentable.” *Id.*

27. *Id.* at 309–10.

28. *Id.* at 317–18.

29. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

30. *Id.*

31. Brief of Amicus Curiae Genetic Alliance in Opposition to Certain Positions of the Plaintiffs at 9, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515).

32. *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980) (finding that research tests indicating the presence of pharmacological activity is evidence of an invention’s utility).

33. *Compare In re Fisher*, 421 F.3d 1365, 1377 (Fed. Cir. 2005) (indicating that absence of pharmacological activity reduces the likelihood that an invention has “utility”), with *Ex parte Bhat*, No. 2008-003946, 2009 WL 1742172, at *4 (B.P.A.I. June 16, 2009) (holding that genetic material with a known function satisfies the utility standard).

34. See, e.g., Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735, 766 (2000) (discussing the patentability of genetic material).

A. Myriad I: *United States District Court for the Southern District of New York*

The human genome contains between 20,000 and 25,000 functional³⁵ genes.³⁶ In the mid-1990s, researchers discovered a pair of genes, *BRCA1* and *BRCA2*, that are responsible for proper maintenance of breast and ovarian cells within the female human body.³⁷ Mutations to these genes result in a significantly increased likelihood that a woman will develop breast or ovarian cancer.³⁸ Armed with the knowledge of the presence of these genetic mutations, a patient can develop a proactive approach to the prevention and treatment of breast or ovarian cancer. Following identification of the *BRCA1* and *BRCA2* genes, Myriad Genetics, in collaboration with the University of Utah Research Foundation, was able to isolate these genes from the human body and develop a means of testing patients for the presence of mutations to these genes.³⁹ Myriad Genetics subsequently obtained U.S. and foreign patent protection on the isolated *BRCA1* and *BRCA2* genes⁴⁰ and diagnostic methods of testing for mutations to these genes.⁴¹

In 2009, the Association for Molecular Pathology filed a complaint in the U.S. District Court for the Southern District of New York, asserting that Myriad Genetics' patents were unenforceable because isolated human genes are unpatentable subject matter under 35 U.S.C. § 101.⁴² In analyzing the patentability of the claims, the court divided the claims into two subsets: "composition claims"⁴³ and "method claims."⁴⁴ Under 35 U.S.C. § 101, a claimed invention is patentable if it "possesses utility" and

35. Generally, genes function by producing proteins that direct physiological activities in the body. "Functional" genes are therefore defined as genes that ultimately lead to the production of proteins.

36. Int'l Human Genome Sequencing Consortium, *Finishing the Euchromatic Sequence of the Human Genome*, 431 NATURE 931, 943 (2004).

37. See Yoshio Miki et al., *A Strong Candidate for the Breast and Ovarian Cancer Susceptibility Gene BRCA1*, 266 SCI. 66 (1994) (discussing the identification of the *BRCA1* gene and linking the gene to breast and ovarian tissue); Richard Wooster et al., *Identification of the Breast Cancer Susceptibility Gene BRCA2*, 378 NATURE 789 (1995) (discussing the identification of the *BRCA2* gene and linking the gene to breast tissue).

38. See *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad I)*, 702 F. Supp. 2d 181, 203 (S.D.N.Y. 2010) (indicating that women with mutations to both the *BRCA1* and *BRCA2* genes face an 85% increase in the likelihood of developing breast cancer and a 50% increase in the likelihood of developing ovarian cancer).

39. *Id.* at 184, 202–03.

40. See U.S. Patent No. 5,747,282 (filed June 7, 1995) (patenting the isolated *BRCA1* gene); U.S. Patent No. 6,124,104 (filed Mar. 20, 1998) (patenting the isolated *BRCA2* gene).

41. See U.S. Patent No. 5,709,999 (filed June 7, 1995) (patenting a method of testing for mutations in the *BRCA1* gene); U.S. Patent No. US 6,895,337 B1 (filed Oct. 15, 2002) (patenting a method of testing for mutations in the *BRCA1* and *BRCA2* genes).

42. *Myriad I*, 702 F. Supp. 2d at 186.

43. *Id.* at 220.

44. *Id.* at 232.

“constitutes statutory subject matter.”⁴⁵ On all claims at issue, “it [was] undisputed that [the inventions] possess[ed] utility.”⁴⁶ Therefore, the sole question facing the court was whether the claimed inventions were a “product[] of nature,” and therefore excluded from patentability.⁴⁷

Myriad Genetics’ composition claims were directed to isolated DNA molecules coding for the *BRCA1* and *BRCA2* proteins. The *Myriad I* court defined isolated DNA as “a segment of DNA nucleotides existing separate from other cellular components normally associated with native DNA,” and recognized that such isolated DNA is not typically found in nature.⁴⁸ However, in analyzing the patentability of Myriad’s composition claims, the court created a new test, a Markedly Different Test, to determine if the claims fell within the products of nature exception to patentability.⁴⁹ Despite recognizing that chemical bonds must be broken and reformed in the creation of isolated DNA,⁵⁰ the court ruled that Myriad’s composition claims “merely constitute[] a difference in purity that cannot serve to establish subject matter patentability.”⁵¹ Because the court viewed Myriad’s composition claims as merely higher purity versions of native DNA, the “isolated DNA [was] not markedly different from native DNA” and was therefore “unpatentable subject matter.”⁵² In essence, Myriad’s

45. *Id.* at 220 (citing 35 U.S.C. § 101 (2006)).

46. *Id.*

47. *Id.* In general, courts have deemed inventions to be patentable unless they relate to a “law[] of nature, physical phenomena, [or] abstract idea[.]” Dana Remus Irwin, *Paradise Lost in the Patent Law? Changing Visions of Technology in the Subject Matter Inquiry*, 60 FLA. L. REV. 775, 778 (2008) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)) (internal quotation marks omitted).

48. *Myriad I*, 702 F. Supp. 2d at 217.

49. *Id.* at 227–28 (stating that the composition claims are patentable if the isolated DNA has “markedly different characteristics” from DNA found in nature (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)) (internal quotation marks omitted)).

50. *Id.* at 230 (stating that the claims at issue only involve *BRCA1* and *BRCA2* exon regions of gene sequences). For a discussion of why chemical bonds must be broken and reformed in order to isolate only exons, see *id.* at 197–98. Because chemical bonds are broken and reformed in the process of isolating exons, the process is more aptly described as a chemical reaction, not a chemical purification. See MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/reaction> (last visited July 8, 2011) (defining “reaction” as “a process involving change in atomic nuclei”).

51. *Myriad I*, 702 F. Supp. 2d at 229–30. The court implied that removing DNA from other cellular components is “purification” because of the type of chemical bonds that exist between DNA and cellular components. See *id.* at 195–96 & n.11 (stating that the “disassociation of histone proteins from DNA by [a] high salt solution[] indicat[es] lack of covalent bond[s] between DNA and histones”) (citing BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 208 fig. 4–24 (4th ed. 2002)). Furthermore, the Court acknowledged that “covalent chemical bonds . . . hold DNA itself together,” yet failed to acknowledge that isolating only a portion of native DNA necessarily involves breaking chemical covalent bonds. *Id.* Because covalent chemical bonds are being broken, the process of isolating DNA should be categorized as a “chemical reaction” rather than a chemical purification. It is well-established in the scientific community that a chemical reaction results in the formation of a different substance than the one present prior to the reaction.

52. *Id.* at 232. See *supra* notes 50–51 for a discussion of why isolated DNA is not merely a purified version of native DNA.

claims were nothing more than a “product of nature.” This holding was contrary to prior case law indicating that naturally occurring chemicals, if isolated and purified, represent patentable subject matter.⁵³ The court distinguished DNA from other chemical compounds, largely based on the “biological realit[y]” that DNA has a more important function than other chemical compounds.⁵⁴

Myriad Genetics’ method claims were directed toward a process of analyzing DNA sequence data to determine if a patient is predisposed to breast or ovarian cancer.⁵⁵ The United States Court of Appeals for the Federal Circuit had previously created the “machine-or-transformation” test, which states that “an application of a law of nature or mathematical formula to a known structure or process”⁵⁶ is patentable only if the process “(1) . . . is tied to a particular machine or apparatus, or (2) . . . transforms a particular article into a different state or thing.”⁵⁷ The *Myriad I* court applied the machine-or-transformation test to the claims at issue and held the claims were unpatentable subject matter under 35 U.S.C. § 101. The court held that, even if the claims “were construed to include [a] physical transformation,”⁵⁸ they would have been unpatentable nevertheless, because the transformation was not “[t]he essence of what [was] claimed.”⁵⁹ Notably, following the *Myriad I* ruling, the Supreme Court harshly criticized the exclusive application of the machine-or-transformation test to method claims⁶⁰ and indicated that constraining method claim patentability to only those claims that can pass the machine-or-transformation test “violates [patent law] statutory interpretation principles.”⁶¹

In holding that most of Myriad Genetics’ claims⁶² were invalid,⁶³ the United States District Court for the Southern District of New York departed from the commonly held view on the patentability of genetic

53. See *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911) (finding that isolated and purified adrenaline is patentable subject matter), *rev’d in part*, 196 F. 596 (2d Cir. 1912).

54. *Myriad I*, 702 F. Supp. 2d at 228.

55. *Id.* at 213–14.

56. *In re Bilski*, 545 F.3d 943, 953 (Fed. Cir. 2008) (emphasis omitted) (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)) (internal quotation marks omitted).

57. *Id.* at 954.

58. *Myriad I*, 702 F. Supp. 2d at 236–37.

59. *Id.* at 236.

60. *Bilski v. Kappos*, 130 S. Ct. 3218, 3226–27 (2010) (stating that “[t]he Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-transformation test as the exclusive test” for determining whether a claimed method is patentable under 35 U.S.C. § 101).

61. *Id.* at 3226. In light of the recent Supreme Court *Bilski* ruling, the *Myriad I* court erred in adopting a strict application of the machine-or-transformation test to Myriad Genetics’ method claims.

62. Judge Sweet ruled on the patentability of fifteen claims spread across seven different Myriad Genetics patents. *Myriad I*, 702 F. Supp. 2d at 211.

63. *Myriad I*, 702 F. Supp. 2d at 238.

material.⁶⁴ Prior to the ruling, isolated genetic material with a known function was deemed patentable subject matter.⁶⁵ The *Myriad I* decision was not only contrary to previous ideas regarding the patentability of genetic material, but was viewed by some as being “contrary to 200 years of natural products patenting.”⁶⁶

B. *Myriad II: United States Court of Appeals for the Federal Circuit*

On October 22, 2010, Myriad Genetics appealed the *Myriad I* ruling to the U.S. Court of Appeals for the Federal Circuit.⁶⁷ On appeal, the Department of Justice filed an amicus brief on behalf of the U.S. government supporting a policy change regarding the patentability of human genes.⁶⁸ The government stated that, “contrary to the longstanding practice of the [USPTO], . . . isolated genomic DNA . . . is not patent-eligible subject matter under 35 U.S.C. § 101.”⁶⁹ Despite acknowledging that isolated DNA does not exist in nature,⁷⁰ the government largely agreed with the final holding in *Myriad I*. While the government disagreed with the breadth of the court’s reasoning,⁷¹ it suggested that other patent law statutes, such as 35 U.S.C. § 103, might be better served to invalidate claims related to genetic material.⁷²

On July 29, 2011, despite the U.S. government’s position on the patentability of genetic material, the C.A.F.C. ruled that isolated DNA is patentable subject matter under 35 U.S.C. § 101.⁷³ While the court

64. Prior to the court’s ruling, some viewed the lawsuit as frivolous in light of Supreme Court precedent. See, e.g., Gene Quinn, *ACLU Files Frivolous Lawsuit Challenging Patents*, IPWATCHDOG.COM (May 14, 2009), <http://ipwatchdog.com/2009/05/14/aclu-files-frivolous-lawsuit-challenging-patents/id=3417>.

65. See Utility Examination Guidelines, *supra* note 29, at 1093 (stating that genetic material does not appear in nature in the isolated or purified form and that it may be patentable if it has a defined utility).

66. *Remarks on Science Friday: Gene Patenting by Kevin Noonan* (National Public Radio broadcast Dec. 11, 2009), available at <http://www.sciencefriday.com/program/archives/200912112> (discussing the pros and cons of gene patenting in general). For an example of a “natural products” patent issued in 1873, see U.S. Patent No. 141072 (filed May 9, 1873).

67. Brief for Appellants, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 2010-1406, 2010 WL 4600106 (Fed. Cir. Oct. 22, 2010).

68. Brief for the United States as Amicus Curiae in Support of Neither Party, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 2010-1406, 2010 WL 4853320 (Fed. Cir. Oct. 29, 2010).

69. *Id.* at *18.

70. *Id.* at *21.

71. See *id.* at *9–10 (stating that cDNAs, vectors, recombinant plasmids, chimeric proteins, vaccines, and genetically modified crops are patentable subject matter).

72. *Id.* at *17 (stating that claims to genetic material could be rejected for being obvious). According to 35 U.S.C. § 103, an invention is not patentable “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.” William A. Drennan, *The Patented Loophole: How Should Congress Respond to This Judicial Invention?*, 59 FLA. L. REV. 229, 237 (2007) (quoting 35 U.S.C. § 103(a) (2006)) (internal quotation marks omitted).

73. Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad II*), No. 2010-

determined that isolated DNA is patentable, a divided three-judge panel released a “majority” opinion,⁷⁴ a concurring opinion, and a dissenting opinion. In the majority opinion, Judge Lourie, based on a well-reasoned understanding of the underlying chemistry of isolated DNA, discussed at length the structural distinctions between isolated and native DNA. Even though isolated DNA may function similarly to native DNA, it is “a distinct chemical entity” that does not exist in nature and therefore is eligible for patent protection.⁷⁵ Furthermore, because of the distinct structural nature of isolated DNA, it should always be patentable under 35 U.S.C. § 101.

In contrast with the structural differences highlighted by Judge Lourie, Judge Moore believes that the functional differences between isolated and native DNA, in some circumstances, can enable isolated DNA to be patent eligible.⁷⁶ According to Judge Moore, the structural differences at issue “do not . . . necessarily make[] isolated DNA [patentable].”⁷⁷ Rather, the important question is “whether these differences impart a new utility” to the claimed DNA sequence.⁷⁸ Judge Moore’s restrictive view of patentable DNA, which is consistent with the USPTO view, imposes a significant limitation upon the scope of patentable material as defined by the majority opinion.

Lastly, Judge Bryson’s dissenting opinion largely aligns with the opinion of the Department of Justice. Judge Bryson agrees with the holding and reasoning of the District Court opinion, but limits the breadth of Judge Sweet’s definition of unpatentable DNA.⁷⁹ In essence, Judge Bryson believes that isolated DNA is the same as “that which appear[s] in . . . living human beings” and is therefore unpatentable.⁸⁰

While each member of the three-judge panel disagrees about the patentability, or reasoning therefore, of isolated DNA, all three judges agree regarding the patentability of Myriad’s medical diagnostic claims. The C.A.F.C. panel ruled that the majority of Myriad’s method claims were directed to unpatentable subject matter.⁸¹ Despite the Supreme Court’s *Bilski* decision,⁸² the C.A.F.C., like the District Court, applied the

1406, 2011 U.S. App. LEXIS 15649, at *63 (Fed. Cir. July 29, 2011).

74. What the judges refer to as the “majority” opinion is actually the controlling opinion of a single judge.

75. *Myriad II*, 2011 U.S. App. LEXIS 15649, at *57, *60, *63.

76. *Id.* at *92 (Moore, J., concurring).

77. *Id.* at *91.

78. *Id.* at *92.

79. Judge Bryson, like the other two judges on the panel, believes that cDNA is patentable subject matter. *Id.* at *61 (Lourie, J., majority opinion), *75-76 (Moore, J., concurring), *117 (Bryson, J., dissenting).

80. *See id.* at *117-42.

81. *Id.* at *67-68 (Lourie, J., majority opinion)

82. *See supra* Section I.A.

machine-or-transformation test to the claims at issue.⁸³ In recent years, the appropriate test used to assess the patentability of method claims has been a source of contention between the C.A.F.C. and the Supreme Court. Prior to the Supreme Court's *Bilski* decision, the C.A.F.C., in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*,⁸⁴ applied the machine-or-transformation test to medical diagnostic method claims similar to those in the *Myriad* patents.⁸⁵ In light of *Bilski v. Kappos*, the Supreme Court granted certiorari in the *Prometheus* case, vacated the judgment, and remanded the case back to the C.A.F.C.⁸⁶ On remand, the Federal Circuit reiterated its initial reasoning and reached the same result.⁸⁷ In light of the C.A.F.C.'s refusal to adopt the underlying principles articulated in *Bilski*, on June 20, 2011, the Supreme Court again granted a writ of certiorari in *Prometheus*.⁸⁸

Until the Supreme Court rules on *Prometheus*, the state of the law concerning medical diagnostic claims, such as those in *Myriad II*, will remain unclear. Based on the Supreme Court's continued involvement with *Prometheus*, it is unlikely that the machine-or-transformation test used in *Myriad II* was the appropriate test for determining patentability of medical diagnostic method claims. Regardless of the C.A.F.C.'s current opinion regarding the unpatentability of *Myriad*'s method claims, until the Supreme Court issues an opinion in *Prometheus*, the viability of *Myriad*'s method claims as *Myriad II* moves forward will be unresolved.

In light of the recent stance taken by the United States government in the *Myriad II* case and the divergent opinions of the three C.A.F.C. judges, it is evident that the patent law system as it relates to human genes is in a state of uncertainty. Based on the non-consensus of the C.A.F.C. in regard to the scope of DNA patentability and the dynamic state of the law in regard to medical diagnostic claims, it is likely that the *Myriad II* opinion will be appealed.⁸⁹ Even if *Myriad II* is appealed, the historical reluctance of the courts and the USPTO to effectuate a change in gene patent policy⁹⁰

83. *Myriad II*, 2011 U.S. App. LEXIS 15649, at *66 (Lourie, J., majority opinion) (“[W]e conclude that all but one of *Myriad*'s method claims . . . fail the machine-or-transformation test.”)

84. 581 F.3d 1336 (Fed. Cir. 2009). The claim at issue is directed to “determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder[.]” *Id.* at 1340.

85. *Id.* at 1342.

86. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 130 S. Ct. 3543 (2010).

87. *Id.* at 1355 (“We do not think that either the Supreme Court's *GVR Order* or the Court's *Bilski* decision dictates a wholly different analysis or a different result on remand.”).

88. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347 (Fed. Cir. 2010), *cert. granted*, 79 U.S.L.W. 3710 (June 20, 2011) (No. 10-1150).

89. See Courtenay Brinckerhoff, *Federal Circuit Issues Mixed Decision on Myriad Claims*, PHARMAPATENTS (June 30, 2011), <http://www.pharmapatentsblog.com/federal-circuit-decisions/federal-circuit-decides-myriad-oks-isolated-dna-claims/> (“It is likely that . . . Plaintiffs-Appellees will . . . petition for certiorari to the Supreme Court.”).

90. See *supra* notes 21–34 and accompanying text (discussing the willingness of the USPTO to grant patents related to genetic material, and the Supreme Court's position that genetic material patents are valid).

means that any change to the current system can be most effectively accomplished through legislation.⁹¹

The blanket ban on patentability of isolated human genes suggested by the United States is a dangerous proposition. The history of patent law teaches us that the inability to obtain market exclusivity disincentivizes innovation.⁹² “The economic philosophy behind the clause empowering Congress to grant patents . . . is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of . . . inventors in ‘Science and useful Arts.’”⁹³ If pharmaceutical companies cannot make a personal financial gain from human genetic research, then the eventual result will be a decrease in health benefits to the public. Ultimately, any successful gene patent legislation will take into account the interest of all involved parties: scientific researchers, the general public, and the pharmaceutical industry.

Myriad Genetics’ patents, and gene patents generally, have been a source of controversy in the research community,⁹⁴ among academic scholars,⁹⁵ and throughout the general public.⁹⁶ Scientific researchers worry that their research objectives will be constrained by the inability to incorporate patented genes into their research projects.⁹⁷ The result of impairing scientific research is a decrease in the pace of scientific innovation.⁹⁸ Academic scholars argue that the disconnect between the legislative branch of government, the judicial branch of government, and the patent law system creates a field that lacks clarity and breeds uncertainty.⁹⁹ Because of this, many believe that the patent law system

91. Up to this point, one of the problems relating to genetic material is that the “dramatic advances in genetics research have far outpaced lawmakers’ ability to address its social, ethical, and legal implications.” Patricia Alten, *GINA: A Genetic Information Nondiscrimination Solution in Search of a Problem*, 61 FLA. L. REV. 379, 381 (2009).

92. See *infra* Part V.

93. *Mazer v. Stein*, 347 U.S. 201, 219 (1954).

94. See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998) (arguing that gene patents simultaneously spur innovation and inhibit scientific research).

95. See James Boyle, *Enclosing the Genome: What Squabbles over Genetic Patents Could Teach Us*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 97, 105–06 (F. Scott Kieff ed., 2003) (discussing the pros and cons of patenting genes); E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS MED. S39, S44–48 (2010) (discussing the impact of the *BRCA1* and *BRCA2* patents on scientific research and the general public).

96. See *BRCA: Genes and Patents*, ACLU (May 27, 2009), <http://www.aclu.org/free-speech/brca-genes-and-patents#09> (arguing that the *BRCA1* and *BRCA2* gene patents undermine “bodily integrity[] and women’s health”).

97. See Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 8 (2003) (reporting that scientific researchers feel that gene patents increase the costs of research).

98. See Heller & Eisenberg, *supra* note 94, at 699.

99. Holman & Munzer, *supra* note 34, at 765 (“[T]here is no straightforward legal reason to deny patent protection to all ESTs.”)

should be altered either legislatively,¹⁰⁰ judicially,¹⁰¹ or departmentally.¹⁰² The general public is concerned that Myriad Genetics' monopoly over the *BRCA1* and *BRCA2* genes will result in decreased quality of testing procedures¹⁰³ and an inability to obtain testing due to prohibitively high costs to the patient.¹⁰⁴ Parts II through III explore these concerns in more detail.

II. THE EFFECT OF GENE PATENTING ON SCIENTIFIC RESEARCH

The effect of gene patenting on scientific research is a hotly debated issue. Gene patenting opponents believe that patenting human genes inhibits scientific research, which is ultimately detrimental to society. Conversely, gene patenting proponents believe that patenting human genes stimulates scientific research, leading to a multitude of societal benefits. The remainder of this Part explores the arguments put forth by both sides in the gene patenting debate relating to the affect of gene patenting on scientific research.

A. Opponents of Gene Patenting

The main argument put forth by researchers who oppose the idea of human gene patenting is that gene patenting inhibits scientific research. This problem relates primarily to what has been termed the "tragedy of the anticommons."¹⁰⁵ It is widely accepted among the scientific community that genes rarely function independently, but rather work in concert with other genes.¹⁰⁶ Because there are a multitude of functional genes in the human body, it is possible that a single strand of DNA could be "owned" by several thousand different researchers. In this situation, a researcher would be unable to engage in basic genetic research without first obtaining

100. See generally DEP'T OF HEALTH & HUM. SERVS., REPORT OF THE SECRETARY'S ADVISORY COMMISSION ON GENETICS, HEALTH, AND SOCIETY: GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 4-6 (2010) [hereinafter SACGHS] (recommending to Congress six different ways to alleviate the gene patent problem).

101. See DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 5 (2009) (arguing that the courts are best equipped for handling pharmaceutical patent-related problems).

102. See Katherine Drabiak-Syed, *Revisiting the USPTO's Examination Guidelines for Gene Patents: Congressional Inaction, USPTO Restraint, and Judicial Remedy*, 6 J. INT'L BIOTECHNOLOGY L. 204, 207, 209 (2009) (arguing that the USPTO should consider policy implications prior to the granting of a patent).

103. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad I*), 702 F. Supp. 2d 181, 206 (S.D.N.Y. 2010).

104. *Id.* at 203-04 (stating that some insurance providers do not cover *BRCA1* and *BRCA2* testing procedures and that costs to an uninsured patient surpass \$3000 per test).

105. See Heller & Eisenberg, *supra* note 94, at 698.

106. See Denise Caruso, *A Challenge to Gene Theory, a Tougher Look at Biotech*, N.Y. TIMES, July 1, 2007, at 33, available at http://www.nytimes.com/2007/07/01/business/yourmoney/01frame.html?pagewanted=1&_r=2 (discussing the complexities of the human genome).

a license from each of the separate “owners” of that strand.¹⁰⁷ For researchers engaging in such study, accumulating the licenses to work with multiple genes could prove prohibitively costly, both in terms of time and money.¹⁰⁸ Ultimately, this will lead researchers to engage in a less inventive course of study with fewer obstacles.

Choosing courses of research based on patent avoidance has several adverse effects. First, opting not to engage in cutting-edge research hinders scientific innovation.¹⁰⁹ If fewer scientists are trying to cure a disease, then fewer novel discoveries relating to that disease will be made. Additionally, some believe that gene patents prevent the improvement of already existing medical tests.¹¹⁰ Because gene patents inhibit competition for a period of time, the monopoly owner has no incentive to improve already existing tests.¹¹¹ It has also been argued that gene patents negatively impact “the culture of science.”¹¹² Forcing scientists to continuously navigate the patent landscape is unproductive and negatively “alter[s] the way in which researchers study and work with gene sequences.”¹¹³

B. Proponents of Gene Patenting

On the contrary, proponents of human gene patenting argue that it does not inhibit innovation,¹¹⁴ but rather, stimulates novel discoveries.¹¹⁵

107. See Heller & Eisenberg, *supra* note 94, at 699.

108. *Id.*

109. See Isabelle Huys et al., *Legal Uncertainty in the Area of Genetic Diagnostic Testing*, 27 NATURE BIOTECHNOLOGY 903, 903 (2009) (mentioning that gene patent opponents believe that “patent thickets” on genetic material will hinder scientific innovation).

110. See Michael Crichton, Op-Ed, *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, http://www.nytimes.com/2007/02/13/opinion/13crichton.html?_r=1&n=Top%2fReference%2fTime%20Topics%2fPeople%2fC%2fCrichton%2c%20Michael&oref=slogin (arguing that inventors should not be able to obtain patents on genetic material).

111. Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad I*), 702 F. Supp. 2d 181, 206 (S.D.N.Y. 2010) (arguing that Myriad’s *BRCA1* and *BRCA2* patents have “hindered the ability of patients to receive the highest-quality breast cancer genetic testing and [have] impeded the development of improvements to *BRCA1/2* genetic testing”).

112. Donald Zuhn, *Gene Patenting Debate Continues*, PATENT DOCS (June 9, 2009, 11:59 PM), <http://www.patentdocs.org/2009/06/gene-patenting-debate-continues.html> (quoting the statement of Shobita Parthasarathy, Co-Director of the Science, Technology, and Public Policy Program at the Ford School of Public Policy at the University of Michigan) (internal quotation marks omitted) (discussing the effects of gene patenting on genetic research).

113. *Id.*

114. See Christopher M. Holman, *Trends in Human Gene Patent Litigation*, 322 SCI. 198, 198 (2008) (“[A]ny chilling effect [as a result of gene patents] arises primarily from a perception of risk that may not comport with reality.”); Donald Zuhn, *Gene Patenting Debate Continues—Round Two*, PATENT DOCS (Aug. 4, 2009, 6:35 AM), <http://www.patentdocs.org/2009/08/by-donald-zuhn--gene-patenting-its-a-topic-that-public-radio-just-cant-seem-to-get-enough-of-this-summer-in-june-dr-han.html> (“The view that patent law somehow inhibits research is not well founded by attempts to look at [the] question in a non-anecdotal way.”).

115. See *Myriad I*, 702 F. Supp. 2d at 211 (arguing that gene patents stimulate biotechnological breakthroughs); Jim Greenwood, *Patents Promote Innovation*, USA TODAY, June 16, 2009, at 8A, available at http://www.usatoday.com/printedition/news/20090616/editorial16_st1.art.htm (arguing that a prohibition of gene patents would freeze biomedical

Because gene therapies hold the promise of finding cures for many problematic diseases, biotechnology companies are investing heavily in genetic research.¹¹⁶ This investment has ultimately led to scientific innovation that has “improved medical treatments, reduced suffering, and saved the lives of millions of Americans.”¹¹⁷ Furthermore, gene patent proponents argue that gene patenting does not adversely affect scientific research. Regarding the issue of gene patent inhibition of scientific advancement, research indicates that academic scientists are rarely affected by gene patents.¹¹⁸ Patenting genetic information places it in the public domain, thereby providing researchers with information from which they can make future discoveries.¹¹⁹ As evidence that gene patents do not inhibit scientific research, supporters point to the fact that over 8,000 research articles have been published relating to the *BRCA1* and *BRCA2* genes associated with Myriad Genetics’ patents.¹²⁰ It is difficult to argue that the *BRCA1* and *BRCA2* gene patents have inhibited scientific research relating to these genes when over 8,000 studies of the genes have been performed and published by academic researchers.

III. HOW GENE PATENTS AFFECT THE GENERAL PUBLIC

One of the primary concerns of the general public, relating to human gene patents, is the notion that patents are inhibiting citizens from obtaining adequate medical treatment.¹²¹ Myriad Genetics’ *BRCA1* and *BRCA2* patents give the company a monopoly over the ability to test for mutations to these genes. Because of this, “one lab dictates the standards

innovation).

116. See Joseph Fuller & Brock Reeve, Editorial, *Will We Lose in the Stem Cell Race?*, WASH. POST, Feb. 3, 2007, at A15, available at <http://www.washingtonpost.com/wp-dyn/content/article/2007/02/02/AR2007020201525.html> (discussing the billions of dollars that are invested in the biotechnology industry).

117. FED. TRADE COMM’N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION 3 (2009) (discussing how the lure of patent protection incentivizes biotechnological innovation).

118. See ORG. FOR ECON. CO-OPERATION & DEV., GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES 79 (2002) (finding that the number of gene patents that pose problems to scientific researchers is substantially smaller than the total number of gene patents that have been awarded); JOHN P. WALSH, CHARLENE CHO & WESLEY M. COHEN, PATENTS, MATERIAL TRANSFERS AND ACCESS TO RESEARCH INPUTS IN BIOMEDICAL RESEARCH: FINAL REPORT TO THE NATIONAL ACADEMY OF SCIENCES’ COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN-RELATED INVENTIONS 37 (2005) (indicating that only 1% of academic researchers are adversely affected by patents); John P. Walsh, Ashish Arora & Wesley M. Cohen, *Working Through the Patent Problem*, 299 SCI. 1021, 1021 (2003) (finding that a more complex patent landscape has not precluded research scientists from pursuing worthwhile research projects).

119. See F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691, 701 (2001) (stating that the patent process allows researchers to have access to information that would otherwise remain a secret).

120. See *Myriad I*, 702 F. Supp. 2d at 210.

121. *Id.*

for patient care in testing for [breast and ovarian cancer.]”¹²² The lack of competition created by the patents may allow Myriad Genetics to conduct lower quality tests and deemphasize the importance of testing accuracy and efficiency.¹²³ Furthermore, this monopoly creates a situation in which some patients are unable to obtain the genetic testing offered by Myriad Genetics. If a patient’s health insurance does not cover the testing, then the patient must pay over \$3,000 to have Myriad Genetics perform the test.¹²⁴ For many people, this price tag is prohibitively high.¹²⁵ By comparison, *BRCA1* and *BRCA2* testing is substantially more affordable in countries that refuse to recognize Myriad Genetics’ patents.¹²⁶ Additionally, countries that facilitate competition in *BRCA1* and *BRCA2* testing have been able to produce a test that is not only cheaper, but also more accurate.¹²⁷

The general public is also concerned about the ethical dilemma caused by human gene patenting.¹²⁸ Gene patenting opponents claim that pharmaceutical companies are “patenting life” and that “[you], or someone you love, may die because of a gene patent that should never have been granted in the first place.”¹²⁹ Opponents argue that corporations now “own” more than twenty percent of all human genes,¹³⁰ and that these genes, though located within every human body, are now the private property of patent owners.¹³¹ Because of private gene ownership, every time two individuals procreate, they are reproducing privately owned genes and therefore infringing upon the “invention” of another.¹³² The ability to patent genes affords owners the ability to “influence what technologies cost, whose cultural and ethical values they represent, and what aspects of the research and development process will be transparent—and to whom.”¹³³

Gene patent proponents argue that the general public’s opinion of gene

122. *Id.*

123. *Id.* at 206, 210.

124. *Id.* at 203.

125. *Id.* at 204.

126. *Ontario to Offer New Genetic Test for Breast, Ovarian Cancer*, CBC NEWS (Jan. 8, 2003), http://www.cbc.ca/health/story/2003/01/06/test_genetic030106.html (stating that the cost of genetic testing for breast and ovarian cancer in Canada is approximately one-third of the cost of testing in the United States).

127. *Id.* (stating that Canadian companies have created a genetic test for breast and ovarian cancer that is 10% more accurate than Myriad Genetics’ test).

128. See Kathryn Garforth, *Life as Chemistry or Life as Biology? An Ethic of Patents on Genetically Modified Organisms*, in *PATENTING LIVES: LIFE PATENTS, CULTURE AND DEVELOPMENT* 27, 52 (Johanna Gibson ed., 2008) (arguing that a human gene patent is “unethical because it denies the true nature of life and life forms, namely their autonomy, uniqueness and sanctity”).

129. Crichton, *supra* note 110 (arguing that gene patents should be prohibited).

130. Denise Caruso, *Someone (Other than You) May Own Your Genes*, N.Y. TIMES, Jan. 28, 2007, at 3, available at <http://www.nytimes.com/2007/01/28/business/yourmoney/28reframe.html>.

131. Crichton, *supra* note 110.

132. See DAVID KOEPSSELL, *WHO OWNS YOU?: THE CORPORATE GOLD-RUSH TO PATENT YOUR GENES* 156 (2009) (arguing that gene patents should be prohibited).

133. Caruso, *supra* note 130.

patenting has been swayed by emotional, anecdotal, and inaccurate pleas made by gene patent opponents.¹³⁴ In fact, entire articles have been written in an effort to dispel the “[f]alsehoods, [d]istortions and [o]utright [l]ies” promulgated by gene patent opponents.¹³⁵ The sensationalization of incorrect information—that human beings are now owned by pharmaceutical companies—has led the public to erroneously believe that pharmaceutical companies are “going to knock on [their] door . . . and give [them] a bill for using [the patent owner’s] gene.”¹³⁶ By accepting the emotional appeal of the opponents, the general public has come to desire a result that will ultimately be detrimental to American society.

IV. PHARMACEUTICAL COMPANIES AND GENE PATENTING

Because pharmaceutical companies are business ventures, they are primarily concerned with maximizing profits.¹³⁷ These companies invest more than \$50 billion annually in research and development efforts.¹³⁸ For many biotechnology companies, patents are the only means of convincing investors to fund lifesaving genetic research. Private investment in biotechnology is necessary because of the costly nature, both in terms of time and money, of bringing a pharmaceutical product to market.¹³⁹ It is estimated that the process of research, development, and marketing of a drug takes an average of nearly ten years¹⁴⁰ and between \$500 million and

134. Gene Quinn, *Emotion and Anecdotes Should Not Drive Patent Policy Debate*, IPWATCHDOG.COM (June 16, 2010), <http://ipwatchdog.com/2010/06/16/emotion-and-anecdotes-should-not-drive-patent-policy-debate/id=11260> (stating that gene patent opponents use emotional appeal to sway the general public).

135. See Kevin E. Noonan, *Falsehoods, Distortions and Outright Lies in the Gene Patenting Debate*, PATENT DOCS (June 15, 2009), <http://www.patentdocs.org/2009/06/falsehoods-distortions-and-outright-lies-in-the-gene-patenting-debate.html> (arguing that gene patent opponents’ propaganda “inhibits reasoned discussion, and . . . suggests . . . that gene patenting is just wrong somehow”).

136. See Noonan, *supra* note 66, at 00:21:35.

137. See Marlene Cimon & Paul Jacobs, *Biotech Battlefield: Profits vs. Public*, L.A. TIMES, Feb. 21, 1999, at A1, available at <http://articles.latimes.com/1999/feb/21/news/mn-10290> (stating that pharmaceutical companies’ first responsibility is to satisfy their shareholders as opposed to satisfying the public). *But see* Lisa M. Fairfax, *Easier Said than Done? A Corporate Law Theory for Actualizing Social Responsibility Rhetoric*, 59 FLA. L. REV. 771, 774 (2007) (discussing the possibility of large corporations’ profit maximization being second in importance to their commitment to nonshareholders).

138. *Stifling or Stimulating—The Role of Gene Patents in Research and Genetic Testing: Hearing Before the Subcomm. on Courts, the Internet and Intellectual Property of the H. Comm. on the Judiciary*, 110th Cong. 4 (2007).

139. Letter from Carl B. Feldbaum, President, Biotechnology Indus. Org., to Howard Coble, Chairman, House Judiciary Subcomm. on Courts, the Internet and Intellectual Prop. (Mar. 21, 2002), available at <http://bio.org/ip/action/Coble.pdf> (discussing the importance of patents to the pharmaceutical industry).

140. See Henry Grabowski, *Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition*, 7 NATURE REVIEWS DRUG DISCOVERY 479, 482 & fig.2 (2008) (discussing the time and financial costs of getting both chemical and biological therapies to the marketplace).

\$2 billion to complete.¹⁴¹ Furthermore, because of the difficulty of assessing which research projects will be successful, less than one percent of biotechnology research ventures ever make it to the marketplace.¹⁴² This low success rate means that the average biotechnology company will not be profitable until their successful products have been on the market for over twelve years.¹⁴³ Indeed, only about five percent of biotechnology companies are even profitable at all.¹⁴⁴ Because of the high risk and reward associated with investing in pharmaceutical companies, the industry would not be sustainable without the promise of patent protection for biotechnological discoveries.¹⁴⁵ Furthermore, disallowing patent protection would promote “free-riding” by competitors, which would likely further increase the costs of research and development relative to the profit gained.¹⁴⁶

To the extent that pharmaceutical companies would continue to develop novel therapeutics in the absence of patent protection, these companies would likely maintain their profit levels through acquisition of trade secrets.¹⁴⁷ Withholding scientific information from the public domain would detrimentally affect both the pace of scientific innovation and public well-being. When drug companies have opted to maintain genetic research secrecy as opposed to applying for patents in the past, these situations have been met with public outrage.¹⁴⁸ Academic researchers have accused these companies of costing taxpayers millions of dollars and “critically stalling the pace of scientific progress.”¹⁴⁹ Critics charged that previous decisions to keep genetic research advancement a secret “slowed research by four or five years.”¹⁵⁰ If all pharmaceutical companies protected their investments through trade secrets, the pace of innovation would slow, resulting in

141. See Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is it Really \$802 Million?*, 25 HEALTH AFF. 420, 427 (2006) (discussing the financial costs of getting a new drug to the marketplace).

142. See Grabowski, *supra* note 19, at 851.

143. See *id.* at 486 & fig.6.

144. Letter from Carl B. Feldbaum, *supra* note 120.

145. See Grabowski, *supra* note 19, at 851–52 (stating that patent protection is essential for continued investment in the pharmaceutical industry).

146. See generally Peter K. Yu, *The Graduated Response*, 62 FLA. L. REV. 1373 (2010) (discussing the “free-riding” problem as it relates to copyrights).

147. See SACGHS, *supra* note 100, at 26 (explaining that if patents were not available, inventors would seek trade secrets to protect their inventions). For a discussion of the pros and cons of trade secrets, see generally David S. Levine, *Secrecy and Unaccountability: Trade Secrets in Our Public Infrastructure*, 59 FLA. L. REV. 135 (2007).

148. From 1996 to 1998, a life-threatening strain of *Staphylococcus aureus* killed several people around the world, and public health officials became concerned about the possibility of an epidemic. Multiple private biotechnology companies had previously spent large amounts of time and money to decode the genome for this deadly bacterium, but those companies refused to freely share this information with government officials or other scientific researchers. See Cmons & Jacobs, *supra* note 137.

149. *Id.*

150. *Id.* (quoting the statement of Dr. Olaf Schneewind) (internal quotation marks omitted).

increased public expense, in terms of both financial costs and personal well-being.

In general, the U.S. economy has come to rely heavily on scientific innovation.¹⁵¹ Commercialized invention is good for the “long term growth and economy” of a country.¹⁵² Publicly traded biotechnology companies are estimated to be worth around \$360 billion,¹⁵³ a significant portion of which is infused into the American economy each year.¹⁵⁴ Additionally, the biotechnology industry is responsible for the creation of over seven million U.S. jobs.¹⁵⁵ Thus, the American economy, quality of life,¹⁵⁶ and national security¹⁵⁷ all depend heavily on the success of the biotechnology industry.

V. LEARNING FROM HISTORY: WHAT PLANTS AND DRUGS CAN TEACH US ABOUT GENES

A shift in human gene patenting policy seems inevitable.¹⁵⁸ Because of the importance of the pharmaceutical industry to the American economy, health, and way of life, any legislation curtailing the intellectual property rights of the industry should simultaneously promote industrial innovation. In determining the likely real-world effects of legislation on the pharmaceutical industry, it is helpful to look at the effects of previous legislation on both innovation and public benefit.

A. *The History of Agricultural Innovation*

The current controversy regarding the patentability of human genes is not the first time that gene patentability has been the subject of national debate.¹⁵⁹ The plant patentability debate preceded the human gene

151. See Lee Bendekgey & Diana Hamlet-Cox, *Gene Patents and Innovation*, 77 ACAD. MED. 1373, 1375 (2002).

152. Dianne Nicol & Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* 85 (Ctr. for Law and Genetics Occasional Paper No. 6, 2003) (internal quotation marks omitted), available at <http://www.lawgenecentre.org/Publication%20PDF/OccPap%206%20contents.pdf>; see also *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974) (recognizing that patent law has “a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens”).

153. BIOTECHNOLOGY INDUS. ORG., GUIDE TO BIOTECHNOLOGY 2008 at 2 (Roxanna Guilford-Blake & Debbie Strickland eds., 2008), available at <http://bio.org/speeches/pubs/er/BiotechGuide2008.pdf>.

154. *Id.* at 72.

155. K. John Morrow, Jr., *Is Building Biotech an Economic Magic Potion?*, 20 BIOPHARM. INT’L 82, 82 (2007).

156. See TASK FORCE ON THE FUTURE OF AM. INNOVATION, THE KNOWLEDGE ECONOMY: IS THE UNITED STATES LOSING ITS COMPETITIVE EDGE? 1–2 (2005) (discussing the fact that European and Asian countries are competing with the United States to be world leaders in scientific innovation).

157. *Id.* at 2 (discussing the relationship between American innovation and America’s status as a world power).

158. See *supra* Part I.

159. See Jim Chen, *The Parable of the Seeds: Interpreting the Plant Variety Protection Act in Furtherance of Innovation Policy*, 81 NOTRE DAME L. REV. 105, 108 (2005) (“[D]isputes over the

patentability debate by almost eighty years.¹⁶⁰ Because of the similarities between plant patents and human gene patents, it is informative to analyze the effects of governmental involvement in plant patentability.

Beginning in the late 1800s,¹⁶¹ the difficulty involved in obtaining patent protection for new varieties of plants “derail[ed] innovation in this field.”¹⁶² A major source of this difficulty was the inability of inventors to satisfy the written description requirement for utility patents under 35 U.S.C. § 112.¹⁶³ In order to more effectively benefit the public through production of a stable food supply, Congress enacted the Townsend–Purnell Plant Patent Act of 1930 (PPA).¹⁶⁴ The PPA effectively abolished the written description requirement for asexually reproduced plants, requiring instead that inventors deposit a plant specimen at the USPTO.¹⁶⁵ By providing inventors with patent rights, Congress financially incentivized the invention of novel plant breeds. As intended, the promise of plant patent protection resulted in an increase in scientific research related to asexually reproduced plant varieties.¹⁶⁶

While the PPA spurred scientific research on asexually reproduced plants, it did nothing to incentivize research on sexually reproduced plant varieties.¹⁶⁷ Because the seed and agriculture industries depend mostly on sexually reproduced plants, the PPA did not effectively promote development in these fields.¹⁶⁸ In order to stimulate the development of novel, sexually reproduced plant varieties, Congress enacted the Plant

ownership of plant genetic material have yielded some of the most emotionally explosive battles over intellectual property . . .”).

160. For a discussion of the plant patentability debate, see Nicholas J. Seay, *Protecting the Seeds of Innovation: Patenting Plants*, 16 AIPLA Q. J. 418 (1989).

161. *See id.* at 419–20.

162. *See* David G. Scalise & Daniel Nugent, *International Intellectual Property Protection for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT’L L. 83, 91 (1995) (discussing the difficulties associated with obtaining a plant patent prior to Congress’ passage of the Townsend–Purnell Plant Patent Act of 1930).

163. In order to obtain a patent, the inventor must satisfy a written description requirement. 35 U.S.C. § 112 (2006). In the patent application, the inventor must adequately describe his invention. The purpose of the written description requirement is to ensure that the inventor has actually invented and is in possession of what is claimed in the patent application. *See* Alison E. Cantor, *Using the Written Description and Enablement Requirements to Limit Biotechnology Patents*, 14 HARV. J.L. & TECH. 267, 296–97 (2000); Mark Alan Thurmon, *The Rise and Fall of Trademark Law’s Functionality Doctrine*, 56 FLA. L. REV. 243, 335 (2004) (stating that “a patent’s claims must be interpreted in light of the patent’s written description of the invention”); *see also* Elisa Rives, Comment, *Mother Nature and the Courts: Are Sexually Reproducing Plants and Their Progeny Patentable Under the Utility Patent Act of 1952?*, 32 CUMB. L. REV. 187, 198 (2001) (discussing the difficulties that inventors faced when attempting to patent novel plant varieties).

164. Pub. L. No. 71-245, 46 Stat. 376 (1930) (codified as amended at 35 U.S.C. §§ 161–64 (2006)).

165. *See* Rives, *supra* note 163, at 197–99.

166. *See* Scalise & Nugent, *supra* note 143, at 93 (discussing the increase in plant patents issued in the decades following the enactment of the PPA).

167. *See* Rives, *supra* note 163, at 199.

168. *Id.* at 199–200.

Variety Protection Act of 1970 (PVPA).¹⁶⁹ Based on the PVPA, the United States Secretary of Agriculture may issue a certificate to a plant breeder who creates a novel, sexually reproduced plant.¹⁷⁰ Similar to the PPA, the PVPA allows patent-like protection to an inventor who deposits a seed specimen at the Department of Agriculture.¹⁷¹ Congress included two exemptions to the PVPA certificate holder's property rights in order to balance the interests of the consumer and the seed industry: the Farmers' Privilege and the Research Exemption.¹⁷²

The Farmers' Privilege,¹⁷³ which allowed farmers to save and sell seeds from their crops, was a point of contention between farmers and seed growers. The Privilege allowed farmers to maximize profits at the expense of the seed companies' intellectual property interests. In 1994, under pressure from the seed industry, Congress amended the PVPA to significantly narrow the Farmer's Privilege such that farmers are now only able to save seeds for replanting, rather than sell them.¹⁷⁴

According to the Research Exemption, "[t]he use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under [the PVPA]."¹⁷⁵ The Research Exemption allows researchers to perform studies on PVPA-certified seeds, thereby promoting the advancement of agricultural biotechnology. This Exemption does not allow researchers to profit from "hybrid or different variet[ies]" of the certified seed, but allows them to use certified seeds as a "stepping stone[] to develop new varieties."¹⁷⁶

As intended, the passage of the PVPA promoted innovation in sexually reproduced agriculture. Protection of seed companies' intellectual property rights enabled the companies to financially benefit from the creation of new plant varieties, which led to increased investment in the field.¹⁷⁷ Within ten years of the enactment of the PVPA, "three times as many wheat and soybean and six times as many cotton varieties were developed than in the decade prior to the Act's passage."¹⁷⁸

As previously discussed, one of the driving forces behind Congress' passage of plant patent or certificate legislation was the inability of plant

169. See 7 U.S.C. § 2581 (2006).

170. See *id.* § 2483.

171. See *id.* § 2422(2).

172. See Rives, *supra* note 163, at 201–04 (discussing both exemptions).

173. 7 U.S.C. § 2543.

174. Rives, *supra* note 163, at 201–03.

175. Peter J. Goss, *Guiding the Hand that Feeds: Toward Socially Optimal Appropriability in Agricultural Biotechnology Innovation*, 84 CAL. L. REV. 1395, 1409 (1996) (quoting 7 U.S.C. § 2544).

176. See Rives, *supra* note 163, at 204.

177. See Edmund J. Sease & Robert A. Hodgson, *Plants are Properly Patentable Under Prevailing U.S. Law and This is Good Public Policy*, 11 DRAKE J. AGRIC. L. 327, 330 (2006) (discussing the effect of the PPA and the PVPA on "new plant innovations and varieties").

178. *Id.*

breeders to satisfy the written description requirement necessary to obtain a utility patent. As genetic engineering and identification techniques advanced, researchers became more able to adequately describe various plant breeds based on the plants' genetic sequences.¹⁷⁹ This development, combined with the judicial attitude regarding the patentability of genetic material,¹⁸⁰ allowed plant breeders to adequately satisfy the written description requirement of 35 U.S.C. § 112 and obtain plant utility patents. Recently, the Supreme Court reinforced the idea that genetically modified plants are intellectual property, protectable via utility patents.¹⁸¹ The ability of breeders to acquire a wider scope of protection through utility patents has "stimulated investment in the development and marketing of commercial [seed] varieties, such as genetically modified corn, soybeans, and cotton"¹⁸² In the last several decades, plant biotechnology innovation has advanced at a faster pace than the rate of advancement of all other technologies combined.¹⁸³

In many respects, the plant patenting debate mirrors the human gene patenting debate. Agricultural innovation can increase crop yields, maximize food nutritional value, preserve the environment, and stabilize farmers' outputs. Additionally, agricultural biotechnology can solve many global issues, such as food shortages and decreased biodiversity.¹⁸⁴ Nonetheless, scholars and researchers are concerned that the "tragedy of the anticommons" is affecting the agriculture industry.¹⁸⁵ Because utility patents do not contain a research exemption, scientists are concerned that the growing number of plant-related utility patents will inhibit their research.¹⁸⁶ Furthermore, an increase in plant patent protection has resulted

179. See Debra L. Blair, *Intellectual Property Protection and Its Impact on the U.S. Seed Industry*, 4 DRAKE J. AGRIC. L. 297, 315 (1999) (discussing the impact that advances in genetic engineering had on the ability of plant breeders to obtain plant utility patents).

180. See generally *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (holding that genetically modified bacteria are patentable); *Ex parte Hibbard*, 227 U.S.P.Q. (BNA) 443 (B.P.A.I. 1985) (holding that plants are patentable subject matter under 35 U.S.C. § 101).

181. See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 144 (2001) (holding that "[t]he plain meaning of § 101, as interpreted by this Court in *Chakrabarty*, clearly includes plants within its subject matter").

182. Michael R. Taylor & Jerry Cayford, *American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change*, 17 HARV. J.L. & TECH. 321, 346 (2004) (discussing the impact of plant utility patents on agricultural innovation).

183. Since 1981, the number of patents issued to plant biotechnology per year has increased almost nine-fold. In the same timeframe, "overall utility patents per year slightly more than doubled." *Id.* at 347.

184. See Mary Lynne Kupchella, Note, *Agricultural Biotechnology: Why It Can Save the Environment and Developing Nations, but May Never Get a Chance*, 25 WM. & MARY ENVTL. L. & POL'Y REV. 721, 721 (2001) (citing Gordon Conway, *Biotech Can Feed the World, or Divide It*, PLAIN DEALER, Oct. 19, 1999, at 9B).

185. See Taylor & Cayford, *supra* note 182, at 349–50 (discussing how "patent thickets" inhibit innovation).

186. *Id.* (noting that the largest research barriers "are simple refusals by [patent] owners to license [the patented technology]"); see also Elizabeth A. Rowe, *Patents, Genetically Modified Foods, and IP Overreaching*, 64 SMU L. REV. (forthcoming 2011) (discussing the propensity of

in a decrease in farmers' planting rights.¹⁸⁷ Farmers are outraged by the fact that patent laws prevent them from "saving seed,"¹⁸⁸ the high prices they are forced to pay to obtain seeds of superior plant varieties,¹⁸⁹ and the ways in which genetic engineering has altered the farming culture.¹⁹⁰

The last century of agricultural development teaches several lessons that can be applied to the human gene patenting debate: increased intellectual property protection results in increased innovation;¹⁹¹ innovation can be manipulated by legislation;¹⁹² and the process of finding a legislative balance that appeases both consumers and industries can be lengthy. Interestingly, the plant patent debate began in a time when breeders were afforded zero protection for their inventions, and legislation was used to promote innovation and protection of breeders' intellectual property. The opposite is true in the human gene patenting debate: the starting point is one in which intellectual property is afforded maximum protection, and the general public wishes to rein in this protection.

B. *The Hatch–Waxman Act: Legislation Regulating Pharmaceutical Drugs*

In the late 1970s and early 1980s, Congress had seemingly contradictory concerns: that the patent law system inadequately promoted pharmaceutical innovation and that the price of pharmaceuticals was skyrocketing.¹⁹³ The Federal Food, Drug, and Cosmetic Act of 1938

seed licenses to prohibit crop research).

187. See Kelly T. Crosby, *The United States and Iraq: Plant Patent Protection and Saving Seed*, 9 WASH. U. GLOB. STUD. L. REV. 511, 511 (2010) (discussing the fact that patent law favors large businesses).

188. *Id.* (quoting Elizabeth I. Winston, *Why Sell What You Can License? Contracting Around Statutory Protection of Intellectual Property*, 14 GEO. MASON L. REV. 93, 96 n.10 (2006)) (internal quotation marks omitted); see also Adam Liptak, *Saving Seeds Subjects Farmers to Suits over Patent*, N.Y. TIMES, Nov. 2, 2003, <http://www.nytimes.com/2003/11/02/us/saving-seeds-subjects-farmers-to-suits-over-patent.html?scp=45&sq=monsanto+%26+farmer&st=nyt> (discussing patent infringement suits between farmers and seed companies).

189. See William Neuman, *Rapid Rise in Seed Prices Draws U.S. Scrutiny*, N.Y. TIMES, Mar. 11, 2010, <http://www.nytimes.com/2010/03/12/business/12seed.html?pagewanted=1&sq=monsanto+%20&st=nyt+%20farmer&scp=19> (discussing the effect of seed company monopolies on seed prices).

190. See Verlyn Klinkenborg, *Editorial Observer: Biotechnology and the Future of Agriculture*, N.Y. TIMES, Dec. 8, 1997, at A24, available at <http://www.nytimes.com/1997/12/08/opinion/editorial-observer-biotechnology-and-the-future-of-agriculture.html?scp=48&sq=monsanto+%26+farmer&st=nyt> (arguing that farmers, not biotechnology companies, should be responsible for improving crops).

191. See Scalise & Nugent, *supra* note 162, at 93; Sease & Hodgson, *supra* note 177, at 330.

192. See, e.g., 35 U.S.C. § 112 (2006); Plant Variety Protection Act, 7 U.S.C. §§ 2321–2583 (2006).

193. Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch–Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 590 (2003); see also Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 188 (1999) (providing an overview of the Hatch–Waxman Act's legislative genesis).

(FDCA)¹⁹⁴ created the Food and Drug Administration (FDA) and gave it the authority to ensure the safety of any “new drug” before the drug was used in commerce.¹⁹⁵ In 1962, the FDCA was amended¹⁹⁶ to require a drug manufacturer to illustrate the effectiveness of its drug prior to FDA approval.¹⁹⁷ This new “effectiveness requirement” required a manufacturer to submit “substantial evidence” of the drug’s effectiveness through administration of the drug in multiple clinical studies.¹⁹⁸ Because manufacturers typically obtained patents as early in the research process as possible, the “effectiveness requirement” drastically shortened the period of time that the innovator could benefit from patent exclusivity.¹⁹⁹ In effect, “the 1962 Amendments . . . increase[d] the research costs of innovator firms and . . . reduce[d] the time they stood to benefit from the investment.”²⁰⁰ This increased cost was ultimately passed on to the consumer, resulting in price increases for many prescription drugs.²⁰¹

By the early 1980s, the nation struggled to find its place in the trilemma created by consumer health,²⁰² consumer budget,²⁰³ and promotion of prescription drug innovation.²⁰⁴ With the goal of reconciling these competing interests, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch–Waxman Act).²⁰⁵ In order to incentivize innovation, the Hatch–Waxman Act allows drug manufacturers to recoup patent term exclusivity for a period of time “equal to the ‘regulatory review period for the approved product.’”²⁰⁶ The Hatch–Waxman Act also provides inventors with additional periods of market exclusivity for certain types of drug innovations.²⁰⁷ Simultaneously, the

194. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399 (2006)).

195. Weiswasser & Danzis, *supra* note 193, at 587.

196. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as scattered sections of 21 U.S.C. (2006)).

197. Weiswasser & Danzis, *supra* note 193, at 587–88.

198. *Id.* (quoting § 102(c), 76 Stat. at 781) (internal quotation marks omitted).

199. Following the 1962 Amendments, “the FDA require[d] 10 to 15 years of preapproval [research and development] after a patent application [was] filed.” Sherry M. Knowles, *Fixing the Legal Framework for Pharmaceutical Research*, 327 Sci. 1083, 1083 (2010).

200. Weiswasser & Danzis, *supra* note 193, at 588.

201. *Id.* at 590.

202. The “effectiveness requirement” ensured that every commercial pharmaceutical drug benefited the health of the consumer. *Id.* at 588.

203. Consumer budget relates to the escalating costs of prescription medications. *Id.* at 590.

204. For a discussion of how to balance these competing interests, see James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable Aids Drugs to Low-End Consumers*, 53 FLA. L. REV. 727 (2001).

205. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2006)).

206. Weiswasser & Danzis, *supra* note 193, at 590–91 (quoting 35 U.S.C. § 156(c) (2000)) (explaining that the Hatch-Waxman Act allows manufacturers to extend patent exclusivity to a maximum of five years).

207. *Id.* at 591–93 (discussing extended periods of market exclusivity that are provided for discovery of new chemical entities and new clinical investigations).

Act promotes consumers' interests by increasing their access to generic pharmaceutical drugs.²⁰⁸ If a generic drug is the "same" or "bioequivalent" to an FDA-approved brand name drug, then the generic drug manufacturer will be allowed to undergo expedited FDA approval.²⁰⁹ Under expedited approval, the generic manufacturer is not required to go through clinical testing for the product.²¹⁰ Furthermore, the Hatch–Waxman Act provides a research exemption for generic manufacturers, allowing them to "experiment with patented brand-name drugs in order to establish the bioequivalency of generic drug substitutes and thereby obtain FDA approval of the generic drugs prior to the expiration of the brand-name patents."²¹¹ This exemption allows generic drugs to hit the marketplace the day after the brand-name drug patent expires.²¹² Patients therefore have access to generic-drug prices earlier than they would have previously. Because of this, "the Hatch-Waxman Act effectively establish[ed] a robust generic drug industry in the United States."²¹³

By adequately balancing the competing concerns of the consumer, the generic drug manufacturer, and the pharmaceutical company, the Hatch–Waxman Act²¹⁴ has successfully achieved Congress' goals.²¹⁵ The generic drug market has escalated since the passage of the Act,²¹⁶ yet market incentives continue to spur pharmaceutical innovation.²¹⁷ Since the Act's

208. *See id.* at 593–95 (describing the abbreviated approval process for generic drugs).

209. *Id.* at 594; *see also* Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1013–14 (2010) (discussing the Act's goal of promoting competition).

210. *See* Knowles, *supra* note 199, at 1083.

211. Ted Hagelin, *The Experimental Use Exemption to Patent Infringement: Information on Ice, Competition on Hold*, 58 FLA. L. REV. 483, 504 (2006). More recently, the effectiveness of the Hatch-Waxman Act is further increased by the Supreme Court's interpretation of 35 U.S.C. § 271's safe harbor provision, which the Court has extended to "all uses of patented inventions that are reasonably related to the development and submission of any information [to the FDA]." Rowe, *supra* note 186, at 127 n.246 (quoting *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005)) (internal quotation marks omitted). The Court's interpretation of this provision allows experimentation on patented drugs as long as the experimentation is related to "submission to the FDA." *Id.* Because of this expansive interpretation, patent holders "must tolerate the infringing activities of competitors who conduct FDA approval tests prior to the expiration of the patent terms." Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921, 933 (2006).

212. *See* Mossinghoff, *supra* note 193, at 190.

213. ADELMAN ET AL., *supra* note 8, at 906.

214. Only select provisions of the Hatch–Waxman Act have been discussed in this Note. As a whole, the Hatch–Waxman Act is "one of the most complex disciplines in the entirety of legal practice." *Id.*

215. *See* Weiswasser & Danzis, *supra* note 193, at 586.

216. *See* Laura W. Musselwhite & Jane Andrews, *Protect Pharmaceutical Innovation*, 328 SCI. 1354, 1354 (2010) (stating that in 2010, generic pharmaceuticals comprised 70% of the pharmaceutical market); *see also* Weiswasser & Danzis, *supra* note 193, at 607 (stating that the generic drug market has increased "from 19 percent of the total pharmaceutical market in 1984 to more than 47 percent [in 2003]").

217. Weiswasser & Danzis, *supra* note 193, at 607 (explaining that over \$32 billion was spent on research and development in 2003).

inception, the increased presence of generic pharmaceuticals on the market has saved the American healthcare system over \$730 billion.²¹⁸ Simultaneously, “the enactment of Hatch-Waxman . . . has helped unleash unprecedented investment in new drug research and development, which in turn has led to a period of unparalleled pharmaceutical innovation.”²¹⁹

Regardless of the success of the Act, it continues to be a matter of intense debate.²²⁰ Generic manufacturers believe that the Act impedes generic entry into the marketplace.²²¹ Pharmaceutical companies believe that the Act does not adequately compensate innovators for the time lost to the FDA approval process.²²² Since its inception, the Hatch–Waxman Act has been amended multiple times,²²³ and is still considered to be a work in progress.²²⁴

VI. SOLVING THE HUMAN GENE PATENTING PROBLEM

Much can be learned from the successful implementation of both the PVPA and the Hatch–Waxman Act, specifically in regards to research exemptions of patented technologies. Despite these exemptions, both plant research under the PVPA and prescription drug research under the Hatch–Waxman Act have thrived at unprecedented levels.²²⁵ Regarding the human gene patenting debate, the Advisory Committee of the Secretary of Health and Human Services has suggested that infringement liability exemptions should be implemented with respect to both medical professionals and researchers.²²⁶ Allowing medical professionals to perform genetic testing without infringement would undercut the financial incentive of human gene research and ultimately result in decreased investment in the pharmaceutical industry. However, the adverse effects of a research exemption on a patent holder’s financial gain would be far less threatening to the pharmaceutical industry. History has shown that

218. Musselwhite & Andrews, *supra* note 116, at 1354.

219. Pillman, *India Needs Its Hatch-Waxman Act for Healthcare*, DAILY NEWS & ANALYSIS, May 15, 2009, http://www.dnaindia.com/money/column_india-needs-its-hatch-waxman-act-for-healthcare_1256132 (statement of Kathleen Jaeger, President and CEO of Generic Pharmaceutical Association) (internal quotation marks omitted).

220. See, e.g., Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 750–51 (2002) (discussing an increased number of lawsuits resulting from the Hatch–Waxman Act).

221. See Weiswasser & Danzis, *supra* note 193, at 607.

222. See Knowles, *supra* note 199, at 1083–84.

223. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended at 21 U.S.C. § 355 (2006)); see also Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified as amended at 21 U.S.C. § 355 (2006)); Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988) (codified as amended at 21 U.S.C. § 355 (2006)).

224. See Weiswasser & Danzis, *supra* note 193, at 607–08 (discussing what types of reform efforts to Hatch-Waxman might be successful).

225. See *supra* Part V.

226. See SACGHS, *supra* note 100, at 94–95.

pharmaceutical economics can coexist with research exemptions on patented technologies.²²⁷ Legislation that allows research on patented human genes yet still allows infringement suits for any commercialization based on this research, would simultaneously promote the interests of both the consumer and the industry.

Many other ideas for how to fix the human gene patenting problem have been suggested, such as: compulsory licensing of patented genetic material,²²⁸ promotion of increased transparency in licensing standards,²²⁹ and restriction of the scope of patent protection.²³⁰ While these suggestions adequately protect the interests of consumers and researchers discussed in Parts II and III of this Note, they fail to effectively protect the interests of patent holders. In many of these academic proposals, the interests of the pharmaceutical industry have been largely ignored. Legislation that reduces patent holder rights will deter innovation, so provisions benefitting patent holders must be included. Furthermore, unless proposed legislation provides tangible benefits to the pharmaceutical industry, it is unlikely to be voted into law.²³¹ Similar to the Hatch–Waxman Act, the ideal human gene patent legislation would provide benefits to both the consumer and the industry.

Several legislative courses of action would compensate the pharmaceutical industry for allowing researchers to be exempted from

227. See *supra* Part V.

228. See Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18413, 18413–15 (proposed Apr. 11, 2005) (suggesting that compulsory nonexclusive or exclusive licensing procedures would benefit public welfare); see also ORG. FOR ECON. CO-OPERATION AND DEV., GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS 9 (2006), available at <http://www.oecd.org/dataoecd/39/38/36198812.pdf> (discussing implementing broad licensing requirements for research and investigation purposes). Generally, compulsory licensing would allow use of a patented invention if the use serves some beneficial public policy. See Jacqueline Lipton, *Information Property: Rights and Responsibilities*, 56 FLA. L. REV. 135, 163–64 (2004).

229. See SACGHS, *supra* note 100, at 99 (discussing how transparency in licensing requirements provides a degree of certainty to the research community).

230. See Marisa Noelle Pins, Note, *Impeding Access to Quality Patient Care and Patient Rights: How Myriad Genetics' Gene Patents Are Unknowingly Killing Cancer Patients and How to Calm the Ripple Effect*, 17 J. INTELL. PROP. L. 377, 412–13 (2010) (discussing the possibility of limiting the scope of patents associated with certain genetic conditions).

231. See Dan Eggen, *The Health Sector Has Donated Millions to Lawmakers*, WASH. POST, Mar. 8, 2009, at A09 (discussing campaign contributions made by the pharmaceutical industry and expressing “concern . . . that money is buying influence and policy changes” (citing Jerry Flanagan, Consumer Watchdog healthcare advocate) (internal quotation marks omitted)); see also AMS. FOR CAMPAIGN REFORM, FACT SHEET: MONEY IN POLITICS & PRESCRIPTION DRUGS (2010), available at <http://www.accreform.org/wp-content/uploads/2010/12/Fact-Sheet-Pharmaceutical-Money-in-Politics1.pdf> (stating that the pharmaceutical industry has invested nearly \$2 billion in lobbying and contributions to Congressional campaigns). See generally Filipe R. Campante, *Redistribution in a Model of Voting and Campaign Contributions* 32–33 (Kennedy Sch. of Gov't, Working Paper No. RWP07-045, 2007), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1019020 (finding a link between voting and campaign contributions); Rui J.P. de Figueiredo, Jr. & Geoff Edwards, *Does Private Money Buy Public Policy? Campaign Contributions and Regulatory Outcomes in Telecommunications*, 16 J. ECON. & MGMT. STRATEGY 547, 569 (2007) (finding that “private money in the form of campaign contributions can influence public policy outcomes”).

infringement liability. The most drastic measure would be a patent term extension for human gene patents. Research exemptions, medical professional exemptions, compulsory licensing, or any of the other proposed courses of action would result in decreased profits for patent holders. In order to effectively promote innovation despite this decrease in patent holder rights, the ideal pro-pharmaceutical legislation would extend the period of patent exclusivity. This could be done either by adjusting the start date of the patent term²³² or by adding years to the end of the term in a manner similar to the Hatch–Waxman legislation. Extending the patent term by several years could adequately compensate the patent holder for these lost profits.

Another option is to provide the pharmaceutical industry with increased tax credit incentives. On December 17, 2010, the Tax Relief, Unemployment Insurance Reauthorization, and Job Creation Act of 2010 went into effect.²³³ This Act extends, through the end of 2011, the active period of an earlier tax credit designed to refund businesses for their research and development spending.²³⁴ This tax credit was initially implemented in 1981 and has been extended fourteen times since its initial enactment.²³⁵ For years, the pharmaceutical industry has been lobbying for Congress to make this tax credit permanent,²³⁶ arguing that it would promote job growth and provide a level of certainty for investors.²³⁷ In providing the pharmaceutical industry with a permanent or increased financial incentive, the tax credit may counterbalance the concessions that the general public is demanding of the pharmaceutical industry.

A third option is to increase government funding of private research. In 1988, Congress passed the Advanced Technology Program (ATP)²³⁸ “to foster cooperation among government, industry, and academia to facilitate the generation of new technologies and techniques for the commercial

232. A patent is valid for twenty years from the time of filing. 35 U.S.C. § 154(a)(2) (2006). For human gene patents, beginning the patent term at the time of issuance (as opposed to the time of filing) would extend the term of patent exclusivity in a manner that would adequately compensate inventors for decreased patent holder rights associated with compulsory licensing or research exemptions.

233. Tax Relief, Unemployment Insurance Reauthorization, and Job Creation Act of 2010, Pub. L. No. 111-312, 124 Stat. 3296 (2010) (to be codified as amended at I.R.C. § 41).

234. *Id.*

235. See Karen Axelson, *Will the R&D Tax Credit Be Extended Again?*, NETWORK SOLUTIONS SMALL BUS. BLOG (Apr. 21, 2011, 6:00 AM), <http://www.networksolutions.com/smallbusiness/2011/04/will-the-rd-tax-credit-be-extended-again/>.

236. See Erik Greb, *Is PhRMA Credible About the R&D Tax Credit?*, PHARMA TECH TALK (Oct. 4, 2010, 9:49 AM), <http://blog.pharmatech.com/2010/10/04/is-phrma-credible-about-the-rd-tax-credit> (discussing “the pharmaceutical industry’s legislative priorities”).

237. See Grant Gross, *Obama Calls for Permanent R&D Tax Credit*, NETWORK WORLD (Sept. 8, 2010, 4:23 PM), <http://www.networkworld.com/news/2010/090810-obama-calls-for-permanent-rd.html> (discussing the benefits to the pharmaceutical industry of a permanent R&D tax credit).

238. Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107, 1115, *repealed by* America Competes Act of 2007, Pub. L. No. 110-69, 121 Stat. 572, 593.

market.”²³⁹ Through ATP, large pharmaceutical companies were able to secure federal funds to offset research and development costs. At its height, ATP was funded at \$431 million per year.²⁴⁰ Despite the overwhelming success of the program,²⁴¹ by 2006, Congress had decreased funding to ATP by over 40%.²⁴² In 2007, Congress replaced ATP with the Technology Innovation Program (TIP),²⁴³ which federally funds innovative research in “small and medium-sized businesses.”²⁴⁴ In 2009, TIP was funded at \$65 million,²⁴⁵ far less than federal funding of private research during the peak ATP years. While TIP may not discourage innovation, it does nothing to incentivize innovation at large pharmaceutical companies. Allowing large companies to reap the benefits of public funding would help offset the innovation deterrence caused by the passage of pro-consumer legislation.

CONCLUSION

The recent *Myriad I* and *Myriad II* decisions have brought the human gene patenting debate to center stage. By ruling in a manner that is inconsistent with both case law and USPTO policy, the *Myriad I* court took the first step toward effectuating change in the human gene patenting field. By failing to reach a consensus on the reasoning behind, or scope of, human gene patenting, the *Myriad II* court has intensified the need for certainty in the gene patenting field. Furthermore, the United States government’s participation in the appeals procedure indicates the necessity of a change to human gene patenting policy. The debate among researchers, consumers, and pharmaceutical companies is exacerbated by the moral and ethical implications of the field. In this context in particular, spurring innovation is essential, not just because of the intimate relationship between innovation and national prosperity, but also because of the direct impact of innovation on consumer health. Legislation curtailing patent holder rights should therefore simultaneously stimulate innovation.

The Hatch–Waxman Act provides the best example of patent-related legislation that simultaneously benefits seemingly competing interests.²⁴⁶ While pro-consumer regulation of human gene patents has been

239. WENDY H. SCHACHT, CONG. RESEARCH SERV., 95-36 SPR, THE ADVANCED TECHNOLOGY PROGRAM 1 (2007) [hereinafter ATP].

240. *Id.* at 3.

241. WENDY H. SCHACHT, CONG. RESEARCH SERV., RS 22815, THE TECHNOLOGY INNOVATION PROGRAM 3 (2008) [hereinafter TIP] (finding that “ATP shortened R&D cycles by half and accelerated technological progress . . . and increased private sector investment”).

242. *See* ATP, *supra* note 239, at 3.

243. America Competes Act of 2007, Pub. L. No. 110-69, 121 Stat. 572, 593 (codified as amended at 15 U.S.C. § 278n (2006)).

244. *See* TIP, *supra* note 241, at 5.

245. *Id.* at 1.

246. *See supra* Section V.B.

extensively discussed, pro-pharmaceutical provisions to any proposed legislation have been largely overlooked.²⁴⁷ Fortunately, there are many ways to continue to incentivize innovation while simultaneously reducing patent holder rights, including extending patent terms, increasing or stabilizing tax incentives, and increasing the scope of federal funding of private research. Ideally, increased concessions on the part of the pharmaceutical industry should be paired with a correlated increase in benefits afforded to the industry. Large concessions, such as compulsory nonexclusive licensing, should be paired with large incentives, such as extended patent terms. Minor concessions, such as a narrow research exemption, should be paired with minor incentives, such as a slight increase to federal funding of private research.

If the histories of plant and pharmaceutical drug patents teach us anything, it is this: there is no magic bullet. Finding an adequate solution to the problem is a lengthy process: both plant and drug patent legislation have been through multiple amendments to get where they are today. Congressional human gene patent legislation that is simultaneously pro-consumer and pro-pharmaceutical is the best way to start down the path to a compromise that consumers, researchers, and the pharmaceutical industry will all find acceptable.

247. *See supra* Part VI.