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Ending Genetic Monopolies: How the TRIPS Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide

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COMMENT

**ENDING GENETIC MONOPOLIES: HOW THE
TRIPS AGREEMENT’S FAILURE TO
EXCLUDE GENE PATENTS THWARTS
INNOVATION AND HURTS CONSUMERS
WORLDWIDE**

CYDNEY A. FOWLER*

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INTRODUCTION

Intellectual property has been protected globally for over 100 years.¹ In 1994, the World Trade Organization (“WTO”)

1. See Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, *as last revised at* Paris, July 24, 1971, 25 U.S.T. 1341, 1161 U.N.T.S. 30 (establishing the first international intellectual property protections for copyrighted material, which is currently in force in 164 Member States); Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, *as last revised at* Stockholm, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 (creating the first international intellectual property protections for patents, trademarks, trade names, and industrial designs, which are currently in force in 173 Member States). *But see* World Trade Organization [WTO], Understanding the WTO: Intellectual Property: Protection and Enforcement, http://www.wto.org/english/thewto_e/whatis_e/

promulgated the Agreement on Trade-Related Aspects of Intellectual Property (“TRIPS”),² which created stronger protections in an attempt to cover the intellectual property universe.³ While the purpose of these protections is to reward researchers and developers for their innovations and creative materials,⁴ it is evident that the TRIPS Agreement does not appropriately address the technological advancements of the past century.⁵

The current battleground in the war over gene patents is the United States.⁶ Opponents of gene patents just had their first victory in the United States District Court for the Southern District of New York which rejected the patentability of genetic material.⁷ This decision is the most recent headline showcasing the growing debate over the adequacy of limitations on patentable subject matter.⁸

tif_e/agrm7_e.htm (last visited Apr. 23, 2010) [hereinafter Understanding the WTO] (identifying areas not protected by the Berne and Paris Conventions, including computer programs and databases).

2. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 869 *U.N.T.S.* 299 [hereinafter TRIPS Agreement] (identifying the objectives of the TRIPS Agreement as to “promot[e] technological innovation and to . . . transfer and disseminat[e] . . . technology”).

3. See DUNCAN MATTHEWS, *GLOBALISING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT* 46 (2002) (explaining that TRIPS “built upon the legal base provided by earlier WIPO [World Intellectual Property Organization] Conventions”); Understanding the WTO, *supra* note 1 (emphasizing that TRIPS instituted new minimum standards of protection of intellectual property).

4. See MICHAEL NOVAK, *THE FIRE OF INVENTION, THE FUEL OF INTEREST: ON INTELLECTUAL PROPERTY* 27 (1996) (“[H]ow can anything be consumed if it has yet to be produced, and how can it be produced if there is no incentive for inventing it and bringing it to market?”).

5. Cf. MATTHEWS, *supra* note 3, at 46–47 (observing that the TRIPS Agreement leaves it up to Member States to enact more extensive protections, so long as they do not contravene the minimum standards in the Agreement).

6. E.g., Matthew Herper, *How Gene Patents Harm Innovation*, FORBES, April 1, 2010, <http://forbes.com/2010/03/31/gene-patent-myriad-business-healthcare-dna-biotech.html> (detailing the recent decision in the Myriad litigation and its likely appeal). “[T]he case brought a coalition of patients, scientists, and the American Civil Liberties Union [and] represents a significant turning point[;] . . . [a] battle in which the future of medicine confronted the past—and the future won.” *Id.*

7. See *Ass’n for Molecular Pathology v. United States Patent and Trademark Office*, No. 09-4515, 2010 U.S. Dist. LEXIS 30629 (S.D.N.Y. Mar. 29, 2010) (invalidating seven of twenty-three patents held by Myriad genetics on the basis that they are unpatentable subject matter under 35 U.S.C. § 101).

8. See, e.g., John M. Conley & Roberte Markowski, *Back to the Future:*

The controversy surrounding the patentability of genetic material is exemplified by the patents held by Myriad Genetics (“Myriad”). Myriad’s patents have caused global concerns, affecting communities in the European Union,⁹ Canada,¹⁰ and most recently, the United States.¹¹ The mutations of the “*BR*east *C*ancer” or BRCA genes patented by Myriad¹² may increase a person’s lifetime risk of developing breast cancer by up to eighty-seven percent and ovarian cancer up to forty-four percent.¹³ Myriad’s patents have raised

Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents, 85 J. PAT. & TRADEMARK OFF. SOC’Y 301, 305-06 (2003) (describing how the theory that genetic material belongs in the “public domain” has not been recognized by the law and has instead been treated as an afterthought where “things are in the public domain simply because there is no legal basis for owning them”).

9. See James Etheridge, *Europeans Claim Victory in BRCA1 Gene Patent Battle*, BIO WORLD INT’L, Feb. 9, 2005, at 3 (reporting that the European Patent Office modified Myriad’s BRCA patents); see also Press Release, European Patent Office, Technical Board of Appeal Maintains Further European Patent Relating to Breast and Ovarian Cancer Susceptibility Gene in Amended Form (Nov. 19, 2008), available at <http://www.epo.org/aboutus/press/releases/archive/2008/20081119.html> [hereinafter EPO Decision] (announcing that Myriad’s patent was reinstated in its amended form).

10. See Donald J. Willison & Stuart M. MacLeod, *Patenting of Genetic Material: Are the Benefits to Society Being Realized?*, 167 CAN. MED. ASS’N J. 259, 260 (2002) (considering the rationale behind the government of Ontario’s refusal to honor Myriad’s patent claim on genetic material).

11. See generally *Ass’n for Molecular Pathology*, 2010 U.S. Dist. LEXIS 30629 (contesting the validity of gene patents held by Myriad Genetics and granted by the U.S. Patent and Trademark Office); Andrew Pollack, *After Patent On Genes Is Invalidated, Taking Stock*, N.Y. TIMES, Mar. 31, 2010, at B1 (reporting that Myriad Genetics plans to appeal the U.S. District Court decision); John Schwartz & Andrew Pollack, *Judge Invalidates Human Gene Patent*, N.Y. TIMES, Mar. 30, 2010, at B1 (reporting decision of U.S. District Court finding human gene patents invalid); John Schwartz, *Cancer Patients Sue Testing Company and Government Over Gene Patents*, N.Y. TIMES, May 13, 2009, at A16 (reporting on the challenge to Myriad’s patents).

12. See Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics’ BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 136 nn.33-38 (2004) (identifying Myriad’s nineteen BRCA gene patents worldwide; United States (8), Europe (4), Canada (4), Australia (2), and New Zealand (1)).

13. Myriad Genetics, *Frequently Asked Questions: If My Test Result is Positive, What Are the Risks?*, <http://www.bracnow.com/faqs/#50> (last visited Apr. 23, 2010).

significant controversy on a global scale¹⁴ because the patents held by Myriad not only cover the BRCA gene mutations themselves, but include diagnostic tests and the use of the genes for advances in predictive medicine.¹⁵

Myriad's exclusive patent has been troublesome for patients. Women who have had or would like to have Myriad's diagnostic test may face significant roadblocks to their future health.¹⁶ Similarly, women seeking second opinions of Myriad's test results have been unable to obtain them because, until recently, Myriad held exclusive rights to both the genes and the screening tests.¹⁷ Consequently, women interested in taking serious prophylactic actions have been forced to use Myriad, which charges higher prices than other would-be competitors.¹⁸ Furthermore, subsequent researchers wishing to

14. See Paradise, *supra* note 12, at 136 (indicating that Myriad has obtained nineteen patents in four countries and the European Union related to the BRCA1 and BRCA2 genes).

15. See, e.g., Press Release, Myriad Genetics, Inc., Myriad Genetics Awarded U.S. Patent on BRCA1 Gene Mutations (Dec. 2, 1997), available at <http://www.highbeam.com/doc/1G1-20026567.html>. The press release explains that Myriad's BRCA1 patents and pending patents include:

- (i) an isolated BRCA1 gene and its primers, (ii) the use of a BRCA1 gene or its protein as a breast and ovarian cancer diagnostic; (iii) the use of a BRCA1 gene or its protein for predictive medicine to identify women who do not have cancer but have an increased risk of developing breast and/or ovarian cancer in the future; and (iv) a predisposition diagnostic test for specific deleterious mutations in a BRCA1 gene.

Id.

16. See Paradise, *supra* note 12, at 137–38 (noting that Myriad's patented test fails to identify up to 20% of the expected mutations).

17. See generally Rebecca Skoot, *Enough with Patenting the Breast Cancer Gene*, DOUBLE X, May 15, 2009, <http://www.doublex.com/section/health-science/enough-patenting-breast-cancer-gene> (last visited Apr. 23, 2010) (reporting that ovarian cancer patient Genae Girard could not obtain a second opinion on a test because Myriad refuses to allow other doctors or companies to conduct testing for its patented genes); see also Herper, *supra* note 6 (explaining that because the Myriad decision only invalidated seven of the company's twenty-seven patents related to its diagnostic test, it will likely be able to maintain its testing exclusivity). *But see* WILLIAM B. COLEMAN & GREGORY J. TSONGALIS, *MOLECULAR DIAGNOSTICS: FOR THE CLINICAL LABORATORIAN* 551 (Humana Press, Inc. 2006) (1997) (asserting that Myriad negotiated a use agreement with the National Cancer Institute, including "favorable terms" for testing services).

18. See Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 347 (2007) (identifying Myriad's lawsuit against the University of Pennsylvania for providing commercial BRCA1 genetic testing for a \$1900, and

study the company's gene sequences have been faced with a company almost completely unwilling to license its patent.¹⁹

This comment explores the current and past opposition to the patentability of genetic material in jurisdictions around the world and examines the need for an amendment to the TRIPS Agreement in order to encourage innovation and protect consumers worldwide. Part II provides background on intellectual property rights requirements under the TRIPS Agreement.²⁰ It also discusses the evolution of intellectual property rights and the issues arising from the debate on the patentability of genetic material.²¹ Part III argues that the language of Section Five of the TRIPS Agreement should specifically exclude genetic material from patentability in order to spur innovation and protect consumers.²² In addition, Part III also explores the problems inherent in requiring Member States to address intellectual property issues on an individual basis, a situation

noting that Myriad dropped the case soon after); Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 142 (2002) (noting that Myriad sent laboratories in Canada cease and desist letters demanding that they stop BRCA screening and refer BRCA testing directly to Myriad or MDS Laboratory Services of Toronto, a Myriad licensee); see also *In the Family* (PBS television broadcast Oct. 1, 2008) (documenting one woman's decision to get tested for the breast cancer gene, in light of financial distress, in order to make an educated decision regarding prophylactic health measures); Nick Mulcahy, *Lawsuit Challenges Patents on Breast Cancer Genes*, MEDSCAPE MEDICAL NEWS, May 14, 2009, <http://www.medscape.com/viewarticle/702892> (last visited Feb. 10, 2010) (noting that the cost for BRCA screening at the University of Pennsylvania would be half the \$3,000 Myriad charges).

19. See Holman, *supra* note 18, at 347 (noting how the University of Pennsylvania was pushed out of the diagnostic testing market by Myriad's threat of patent litigation); but see COLEMAN & TSONGALIS, *supra* note 17, at 551 (indicating that Myriad has negotiated a use agreement with "a reduced price" and "other favorable terms" for research done by the National Cancer Institute); Tom Reynolds, *NCI-Myriad Agreement Offers BRCA Testing at Reduced Cost*, 92 J. NAT'L CANCER INST. 596, 596 (2000) (presenting the NCI-Myriad Agreement as a model for how gene patents can support research within the scientific community).

20. See discussion *infra* Part I (introducing the relevant sections of the TRIPS Agreement).

21. See *id.* (providing an overview of how intellectual property rights evolved and the problems stemming from controversy regarding patenting genetic material).

22. See discussion *infra* Part II (examining the language of Section Five of the TRIPS Agreement and arguing that the burdens on research and consumers should outweigh the exclusive rights).

that has led to inconsistent rights at a national level.²³ Part IV advocates for an amendment to the TRIPS Agreement that would explicitly exclude genetic material from patentability.²⁴

I. BACKGROUND

Maintaining substantive intellectual property rights is integral to assuring that inventors are able to reap the fruits of their labor.²⁵ At the same time, the World Trade Organization (“WTO”) has begun shifting toward health-focused benefit-sharing in order to both foster intellectual property development and to encourage cooperative international research.²⁶ Although gene patents have been issued for nearly three decades, concerns over the legality and public policy implications of issuing gene patents have increased only in recent years.²⁷

23. See *id.* (evaluating the inefficiencies in global governance when individual action by Member States is required).

24. See discussion *infra* Part III (asserting that an amendment to the TRIPS Agreement is necessary to ensure global intellectual equality in the areas of research, innovation, and consumer protection).

25. See Eric D. Zard, Comment, *Patentability of Human Genetic Information: Exploring Ethical Dilemmas Within the Patent Office and Biotechnology’s Clash with the Public Good*, 6 U. ST. THOMAS L.J. 486, 494 (2009) (referring to the Supreme Court’s acknowledgment that the original purpose for granting patents was to incentivize invention though temporary exclusivity rights).

26. See WTO, Ministerial Declaration of 14 November 2001 ¶¶ 4-5, WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration] (affording flexibility to the implementation of the TRIPS Agreement for the purposes of protecting public health); Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1679 (2001) (arguing that genetic patents should be freely licensed to promote international scientific collaboration). *But see* Novartis AG v. Union of India, 2007 A.I.R. 24759 (Mad.), 4 Madras L.J. 1153, available at <http://judis.nic.in/chennai/qrydisp.asp?tfnm=11121> (depicting the Indian government’s refusal to grant a patent to Novartis on the grounds that its drug was not an “invention” because it was a known substance and did not enhance efficacy).

27. See generally Brief for American Medical Ass’n et al. as Amici Curiae Supporting Plaintiffs, Ass’n for Molecular Pathology v. United States Patent & Trademark Office, 669 F. Supp. 2d (S.D.N.Y. 2009) (No. 09-4515), 2009 WL 3269106 (arguing that: (1) Myriad’s gene sequence claims are products of nature; (2) Myriad’s correlation claims are laws of nature; and (3) both, necessarily, are unpatentable subject matter); Michael Crichton, Op-Ed, *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, at A23 (asserting that “gene patents block innovation [and]

A. INTELLECTUAL PROPERTY RIGHTS UNDER THE TRIPS AGREEMENT

The seminal treaty related to international intellectual property rights is the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS").²⁸ The WTO has 153 member and 30 observer states.²⁹ The TRIPS Agreement created detailed protections for six specific types of intellectual property: (1) Copyright and Related Rights,³⁰ (2) Trademarks,³¹ (3) Geographical Indications,³² (4) Industrial Designs,³³ (5) Patents,³⁴ and (6) Layout-Designs (Topographies) of Integrated Circuits.³⁵ Additionally, TRIPS includes specific provisions for protecting undisclosed information and controlling anti-competitive behavior in contractual licenses.³⁶

1. Patentable Subject-Matter Under the TRIPS Agreement

Section Five of the TRIPS Agreement provides that patents shall be available either to products or processes, "provided that they are new, involve an inventive step, and are capable of an industrial application."³⁷ Patentability is subject to qualification under only three independent criteria. While no subject matter is explicitly excluded, TRIPS allows—but does not require—Member States to exclude from patentability: (1) inventions – provided the exclusion is

inhibit research" as exemplified by the delayed research of SARS due to patent concerns); Who Owns Your Body?, Nobel Laureate Opposes Gene Patents, <http://www.whoownsyourbody.org/sulston.html> (last visited Jan. 7, 2010) (quoting Dr. John E. Sulston, 2002 Nobel Prize in Medicine winner, who stated that "a genome sequence is a clear-cut case of public domain material").

28. See TRIPS Agreement, *supra* note 2; MATTHEWS, *supra* note 3, at 11 (identifying previous failed attempts to amend existing international intellectual property conventions, which led to the negotiation and adoption of the TRIPS Agreement in order to provide a mechanism to enforce intellectual property rights).

29. WTO, Members and Observers, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Jan. 7, 2010) (identifying the parties in the WTO as of July 23, 2008).

30. TRIPS Agreement, *supra* note 2, pt. II, § 1.

31. *Id.* pt. II, § 2.

32. *Id.* pt. II, § 3.

33. *Id.* pt. II, § 4.

34. *Id.* pt. II, § 5.

35. *Id.* pt. II, § 6.

36. *Id.* pt. II, §§ 7-8.

37. *Id.* pt. II, § 5 art. 27.

necessary for public order or health, the protection of life, or the environment;³⁸ (2) diagnostic, therapeutic and surgical methods;³⁹ and (3) plants and animals—other than micro-organisms.⁴⁰

The TRIPS Agreement was intended to create a standard, a minimum level of protection for intellectual property that would obligate Member States to make patent protection available for all inventions.⁴¹ However, TRIPS provides no uniform standard or definition of what constitutes an “invention.”⁴² This lack of a uniform standard or definition of the term “invention” has led to individual Member States carving out their own idiosyncratic definitions,⁴³ which need only adhere to the basic framework provided in Article 27(1).⁴⁴

38. *Id.* pt. II, § 5 art. 27(2).

39. *Id.* pt. II, § 5 art. 27(3)(a).

40. *Id.* pt. II, § 5 art. 27(3)(a).

41. *See, e.g., id.* pt. II, sec. 5 (noting the basic requirements of patentability).

42. *See* TRIPS Agreement, *supra* note 2, art. 27 n.5 (providing the only language alternatives for patentability: “the terms ‘inventive step’ and ‘capable of industrial application’ may be deemed by a Member to be synonymous with the terms ‘non-obvious’ and ‘useful’ respectively”); MATTHEWS, *supra* note 3, at 46–47 (“Article 1.1 [of the TRIPS Agreement] makes clear that TRIPS is not intended to be a harmoni[z]ation document since Members are free to determine the method of implementing the Agreement within their own legal system and practice.”).

43. *Compare, e.g.,* The Patents (Amendment) Act, No. 15 of 2005, India Code (2005), § 3(d), *available at* http://ipindia.nic.in/ipr/patent/patent_2005.pdf, *with* *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). The Patents (Amendment) Act defines unpatentable material as

[t]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus.

The Patents (Amendment) Act, § 3(d). On the other hand, *Diamond* indicates that naturally-occurring materials as well as theories are unpatentable subject matter:

The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none.”

Diamond, 477 U.S. at 309 (internal citations omitted).

44. *See* TRIPS Agreement, *supra* note 2, art. 27(1) (requiring that patents be issued for inventions that are “new, involve an inventive step, and are capable of industrial application”).

Section Five of the TRIPS Agreement is silent with regard to naturally occurring material and does not list genetic material as an exception to patentability.⁴⁵ The WTO has not addressed any patentable subject-matter challenges under the TRIPS Agreement and it is unclear how it would rule.⁴⁶ Individual Member States of differing economic and social development levels therefore struggle with addressing complex patentability issues on a case-by-case basis.⁴⁷

45. See *id.* art. 27(1)-(3); see also MARTIN KHOR, INTELLECTUAL PROPERTY, BIODIVERSITY AND SUSTAINABLE DEVELOPMENT: RESOLVING THE DIFFICULT ISSUES 70 (2002) (quoting Argentine law professor Carlos Correa as saying that “the TRIPS Agreement does not specify what an ‘invention’ is, and since there is no ‘universal’ concept of what it means, countries can, within certain limits, opt for various alternatives”).

46. See Graeme B. Dinwoodie & Rochelle Cooper Dreyfuss, *International Intellectual Property Law and the Public Domain of Science*, 7 J. INT'L ECON. L. 431, 435 (2004) (noting that there are no WTO decisions addressing Article 27 subject matter exclusions directly, but relying on the WTO's “tend[ency] to hew closely to the text when resolving disputes”); SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY, NAT'L INST. OF HEALTH, PUBLIC CONSULTATION DRAFT REPORT ON GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS FOR PUBLIC 69 (2009) [hereinafter NIH REPORT] (addressing the lack of guidance from the WTO, as there have not been any cases requiring subject-matter interpretation, and attempting to predict the position of the WTO if faced with a patentable subject-matter challenge under Article 27, namely, that the exclusion of genes from patent-eligibility would not violate U.S. obligations under TRIPS).

47. See, e.g., *Novartis AG v. Union of India*, 2007 A.I.R. 24759 at ¶¶ 8, 19 (enforcing the validity of the Indian Patent Amendments Act of 2005, which deemed patent-eligible inventions must be more than the “mere discovery of a new form of a known substance” and must instead “enhance[] the known efficacy of that substance”); *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, No. 09-4515, 2010 U.S. Dist. LEXIS 30629 (S.D.N.Y. Mar. 29, 2010) (holding that the genetic material patented by Myriad Genetics is not “markedly different” from the native DNA and therefore is necessarily unpatentable); WORLD HEALTH ORGANIZATION [WHO], GENETICS, GENOMICS AND THE PATENTING OF DNA: REVIEW OF POTENTIAL IMPLICATIONS FOR HEALTH IN DEVELOPING COUNTRIES 21, 24–29, 32, 35, 37 (2005) [hereinafter WHO GENETICS, GENOMICS AND THE PATENTING OF DNA] (identifying key differences and emphasizing that there is “no common approach” on the patentability of genes by developing nations like India, China, and Brazil). See also Rajnish Kumar Rai, *Patentable Subject Matter Requirements: An Evaluation of Proposed Exclusions to India's Patent Law in Light of India's Obligations Under the TRIPS Agreement and Options for India*, 8 CHI.-KENT J. INTELL. PROP. 41, 51 (2008) (identifying limitations of the TRIPS Agreement with regard to the abilities of Member States to distinguish and interpret patentability standards and exclusions).

B. THE GROWING PROBLEM WITH PATENTING GENETIC MATERIAL

For the greater part of the last century, scientists and scientific professionals across the globe have researched, documented, and developed technologies from genes and genetic material.⁴⁸ For many developed countries, the expansion and exportation of lucrative intellectual property has become a cornerstone of what are now known as “service economies.”⁴⁹ It was dependence on these intellectual property industries that led to the development of the TRIPS Agreement.⁵⁰ The intended purpose of TRIPS was to secure minimum standards of protection for various categories of intellectual property and to create greater incentives for research and development across the world.⁵¹

In 1980, however, intellectual property rights and protections began to change with the precedent set by the United States Supreme Court in *Diamond v. Chakrabarty*.⁵² In *Diamond*, the U.S. Supreme

48. See generally *The History of Genetics*, BBC NEWS, May 30, 2000, http://news.bbc.co.uk/2/low/in_depth/sci_tech/2000/human_genome/749026.stm (last visited Feb. 25, 2010) (providing a historical timeline of genetic research, including the description of the structure of DNA by James Watson and Francis Crick in the early 1950s).

49. See Richard Abel, *Forecasting Civil Litigation*, 58 DEPAUL L. REV. 425, 440–41 (2009) (“Post-industrial service economies increase the value of skilled labor and intangible property.”); Thomas J. Manley & Scott M. Hobby, *Globalization of Work: Offshore Outsourcing in the IT Age*, 18 EMORY INT’L L. REV. 401, 401–02 (2004) (discussing the contribution of outsourcing to the disruption of the manufacturing base and the shift to service economies in many developed countries).

50. Cf. MATTHEWS, *supra* note 3, at 45 (postulating that the TRIPS Agreement was spearheaded by the economically powerful and diplomatically aggressive United States); see also Charles T. Collins-Chase, Comment, *The Case Against TRIPS-Plus Protection In Developing Countries Facing AIDS Epidemics*, 29 U. PA. J. INT’L L. 763, 765 (2008) (observing that developed countries—notably, the United States—now pursue bilateral trade agreements with intellectual property protections in excess of the TRIPS minimums).

51. See TRIPS Agreement, *supra* note 2, art 7 (explaining that the protections afforded by the TRIPS Agreement “should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”); see also Understanding the WTO, *supra* note 1 (stating that the TRIPS Agreement establishes minimum standards to protect intellectual property rights).

52. 447 U.S. 303 (1980).

Court ruled that genetically-modified or engineered products are patentable so long as the patentee produces a product that “is not nature’s handiwork, but his own.”⁵³ Relying heavily on *Diamond*, the United States Patent & Trademark Office (“USPTO”) began granting patents to a wide array of previously unpatentable subject matter, including human genes.⁵⁴ A mere two years after *Diamond*, the USPTO granted its first gene patent to the Regents of the University of California.⁵⁵ Similarly, the Japan Patent Office and European Patent Office began granting patents related to genes in the 1990s.⁵⁶ From 1980 to 2001, the USPTO granted patents to over 8,000 genes, genetic material, or gene sequences.⁵⁷ Between 1996 and 2002, U.S. patent applications involving biotechnology increased by 154%.⁵⁸ A 2005 study revealed that twenty percent of the approximately twenty to twenty five thousand genes in the human body had been granted patents in the United States.⁵⁹ The worldwide numbers are even more significant with patents on over half a million living organisms, genes, or gene sequences filed or issued by 2000.⁶⁰

In the United States, this massive increase was furthered by the passage of the Bayh-Dole Act⁶¹ in 1980, which enabled universities, small businesses, and non-profits that received federal funding for their research to pursue rights to inventions with precedent over the

53. *Id.* at 310 (explaining that it was because the applicant changed the naturally occurring product into something “with markedly different characteristics from any found in nature” that the result became patentable).

54. *See Gene Patents and Global Competition Issues: Protection of Biotechnology Under Patent Law*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS, Jan. 1, 2006, <http://www.genengnews.com/articles/chitem.aspx?aid=1163&chid=0> (last visited Apr. 23, 2010) (discussing the evolution of the U.S. patent system and its transformation from a government-based licensing and ownership system to a significantly more private one after *Diamond*).

55. *See id.* (identifying that the first gene patent was granted in 1982 to the Regents of the University of California for the construction of a plasmid contained in a bacterium).

56. *Id.*

57. Paradise, *supra* note 12, at 133 (specifying further that at least 1,500 were claiming sequences of human genetic material).

58. *Gene Patents and Global Competition Issues*, *supra* note 54.

59. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCI. 239, 239 (2005).

60. *See KHOR*, *supra* note 45, at 23 (specifying that 161,195 were whole or partial human genes).

61. 35 U.S.C. §§ 200-12 (2009).

government.⁶² This shift toward the privatization of research and patent-application did not go unnoticed, and in the last ten years, the U.S. Congress has made two attempts to restrict patentable subject matter and exclude genetic material from its ranks.⁶³

C. MYRIAD GENETIC'S PATENT OF BRCA

The vague language in the TRIPS Agreement has caused nuanced differences in the domestic patent laws related to genetic material.⁶⁴ Member States have varied in their interpretation and implementation of domestic patent law in an attempt to comport with international law while maintaining personalized national regulations.⁶⁵ Specifically, the European Union, Canada, and the

62. See Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J. L. SCI. & TECH. 393, 401 (2006) (emphasizing that prior to Bayh-Dole, “[t]he general aim of the agencies was to achieve widespread dissemination of the results obtained in laboratories operating with federal money and to encourage wide development and usage through dedication to the public domain and nonexclusive licenses”).

63. See Genomic Research Accessibility Act, H.R. 977, 110th Cong. (2007) (describing measures to exclude human genetic material from future patentability); Genomic Research Accessibility Act, H.R. 3967, 107th Cong. (2002) (proposing limits on the scope of patentable subject matter to exclude genetic material for research, general diagnostic testing, and federal and federally assisted patents); see also Press Release, Congressman Xavier Becerra, Reps. Becerra & Weldon Introduce Bill to Ban the Practice of Gene Patenting (Feb. 9, 2007), available at <http://becerra.house.gov/HoR/CA31/News/Press+Releases/2007/02-09-07+REPS+BECERRA+WELDON+INTRODUCE+BILL+TO+BAN+THE+PRACTICE+OF+GENE+PATENTING.htm> (indicating that the bill was intended to fix a mistake in regulation and that genes are unpatentable).

64. Compare The Patents (Amendment) Act, *supra* note 43, § 3(d) (narrowing the scope of patentable material in India, by rejecting the patentability of “new form[s] of . . . known substance[s]” without that substance creating a new and unique product), with 35 U.S.C. § 101 (2009) (granting patent application rights to “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”). See WHO GENETICS, GENOMICS AND THE PATENTING OF DNA, *supra* note 47, at 26–27, 29 (noting that Brazil affords ambiguous protection; it has two laws that suggest genes are not patentable, but it provides patentability for chemical products if “the criteria of novelty, utility and non-obviousness” are met). China permits gene patents, but “life forms” may not be patented, and India does not allow patents on genes or cells. *Id.*

65. See WHO GENETICS, GENOMICS AND THE PATENTING OF DNA, *supra* note 47, at 29 (recognizing that between Brazil, China, and India, “there is no common approach” on how to address the genetic material of humans); see also Jerome H. Reichman, *Harmonization Without Consensus: Critical Reflections on*

United States have questioned whether only the processes or also the genes themselves may be patented.⁶⁶

The European Patent Office (“EPO”) granted Myriad’s patent application for the BRCA1 gene in 2001.⁶⁷ Myriad’s patent was subsequently challenged in the European Union on the basis that it did not satisfy the requirements set forth in the European Patent Convention—that the patent be novel, involve an inventive step, and be prone to industrial application.⁶⁸ In 2004, the EPO revoked one of Myriad’s patents on that basis,⁶⁹ only to amend and reinstate it in the fall of 2008; but excluding the actual gene from the patent.⁷⁰

Myriad was granted its BRCA gene patents in Canada between October of 2000 and April of 2001.⁷¹ From the time the patent was issued, all of the Canadian provinces adopted differing methods of testing for the BRCA genes.⁷² However, Myriad began enforcing their patents in 2001 and provincial testing ended.⁷³ Major Canadian

Drafting a Substantive Patent Law Treaty, 57 DUKE L.J. 85, 89 (2007) (highlighting the disparities that exist between different Member States regarding requirements of patentability).

66. See Sirpa Soini et al., *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues*, 16 EUR. J. HUM. GEN. S10, S15 (2008) (reiterating that, after fierce opposition, the European Patent Council revoked and later amended Myriad Genetics’ BRCA1 and BRCA2 patents to limit the scope of each); Willison & MacLeod, *supra* note 10, at 260 (observing that the government of Ontario refused to honor Myriad’s patent claim on genetic material); see also Laura Eggertson, *Ontario Defies US Firm’s Genetic Patent, Continues Cancer Screening*, 166 CAN. MED. ASS’N J. 494, 494 (2002) (explaining that the Health Minister of Ontario found no violations of Myriad’s patents by funding predictive genetic testing).

67. EPO Decision, *supra* note 9.

68. See Convention on the Grant of European Patents art. 52(1), Oct. 5, 1973, 1065 U.N.T.S. 255-520.

69. See Etheridge, *supra* note 9, at 3 (reporting that the EPO revoked Myriad’s BRCA1 patent which included a patent on a specific portion of the gene itself).

70. See EPO Decision, *supra* note 9 (clarifying that the amended patents only cover the testing for certain BRCA gene mutations, and do not cover the BRCA genes themselves).

71. Canadian Cancer Society, Background on the Patenting of BRCA1 and 2 Genes, http://www.cancer.ca/Canadawide/How%20you%20can%20help/Take%20action/Advocacy%20what%20were%20doing/Gene%20patenting/Breast%20cancer%20genes/Background%20on%20the%20patenting%20of%20BRCA1%20and%202%20genes.aspx?sc_lang=en (last visited Apr. 23, 2010).

72. See generally Williams-Jones, *supra* note 18, at 140–42 (identifying the differing approaches by each Canadian province).

73. Caroline Mallan, *Gene Test for Cancer Won’t Stop*, TORONTO STAR, Sept.

leaders spoke out emphasizing the importance of the test for women and the unjustifiable cost for the Canadian government.⁷⁴

The United States began issuing BRCA gene patents to Myriad in 1998.⁷⁵ In the years after the first BRCA patent was issued, Myriad established a history of anticompetitive, exclusive behavior, refusing to grant research licenses and enforcing their patents to ensure the exclusivity of their BRCA gene diagnostic tests.⁷⁶ In May 2009, a group of medical associations, medical professionals, organizations, and patients filed suit against Myriad and the USPTO in federal court, challenging the legality and constitutionality of the patent claims on human genes.⁷⁷ The lawsuit challenged the validity of Myriad's genetic patents on the basis that BRCA genes are "Natural Human Genes" with natural mutations, and that the genes may have other, different effects in addition to being associated with a higher risk of breast and ovarian cancer.⁷⁸ In late March 2010, the United

20, 2001, at A3 (describing the actions of Canadian provinces after the cease and desist orders were sent and the subsequent refusal to accept the orders by Ontario hospitals).

74. See Williams-Jones, *supra* note 18, at 143 (characterizing Former Ontario Premier Harris' staunch opposition to gene patents and concern for women's healthcare); Michelle Swenarchuk, *Of Harvard Mice and Prairie Farmers: Canadian Patents on Life*, in WHOSE CANADA?: CONTINENTAL INTEGRATION, FORTRESS NORTH AMERICA, AND THE CORPORATE AGENDA 481, 488 (Ricardo Grinspun & Yasmine Shamsie eds., 2007) (quoting Ontario Minister of Health and Long-Term Care Tony Clement as saying that the practice of patenting genes was "abhorrent," and asking whether the product of human genetic research would "come down to a series of monopolies setting exclusive prices for tests which most of Canada—indeed most of the world, especially the poorer countries—cannot afford").

75. See U.S. Patent No. 5,710,001 (filed June 7, 1995) (patenting "methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene (BRCA1), some mutant alleles of which cause susceptibility to cancer, in particular breast and ovarian cancer"); U.S. Patent No. 5,747,282 (filed June 7, 1995) (patenting additional methods to isolate and detect BRCA1 mutations).

76. See Holman, *supra* note 18, at 347 (identifying Myriad pushing the University of Pennsylvania out of the market); Canadian Cancer Society, *supra* note 71 (reporting the cease and desist letter that Myriad sent to the government of Ontario regarding the province's utilization of their genetic testing mechanism).

77. See Complaint ¶¶ 7-18, *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, 699 F. Supp. 2d 365 (S.D.N.Y. 2009) (No. 09-4515), 2009 WL 1343027 (listing the plaintiffs challenging the patentability of genetic material and enumerating the claims against the defendants).

78. See *id.* at 15-16 (explaining the specifics of human genes and gene

States District Court for the Southern District of New York partially granted the plaintiffs' motion for summary judgment and invalidated seven of twenty-three challenged Myriad patents on the grounds that human genes were not patentable subject matter under 35 U.S.C. § 101.⁷⁹ Myriad Genetics plans to appeal the District Court decision.⁸⁰

II. ANALYSIS

The broad language of the TRIPS Agreement allows individual Member States to enact national intellectual property laws that grant patents to human genes.⁸¹ While the very status of genes as valid patentable subject matter is controversial,⁸² the silence of TRIPS on the subject has serious consequences.⁸³ The failure of the TRIPS Agreement to protect research necessary for advancements in innovation, regulate anticompetitive behavior, oversee the integration of disparate national laws, and mandate protection against licensing and transaction costs proves that the Agreement's inadequacies must be resolved.

A. THE TRIPS AGREEMENT'S SILENCE ON THE PATENTABILITY OF GENETIC MATERIAL IMPEDES RESEARCH AND HARMS CONSUMERS

The TRIPS Agreement's failure to exclude genetic material from patentability thwarts research and has a detrimental effect on consumer prices for products produced using patented genes.⁸⁴

mutations).

79. *See Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, No. 09-4515, 2010 U.S. Dist. LEXIS 30629, at *121, *147, *163 (S.D.N.Y. Mar. 29, 2010) (holding that the patents were invalid under 35 U.S.C. § 101 because isolated and/or purified BRCA sequences contained no "markedly different" characteristics to naturally occurring DNA). Instead of focusing on the physical composition of the sequence, the court focused on its function. *See generally id.*

80. *See Pollack, supra* note 11 (reporting Myriad's plan to appeal).

81. *See* TRIPS Agreement, *supra* note 2, art. 27(1) (listing the basic requirements of patentability as the product being "new, involve an inventive step, and [be] capable of an industrial application").

82. *See, e.g., Willison & MacLeod, supra* note 10, at 259 (clarifying that while patenting life is a contentious idea, it is "well established in law").

83. *See, e.g., Williams-Jones, supra* note 18, at 137-38 (examining whether gene patents create monopolist licensing regimes and harm consumers with exorbitant prices).

84. *See* JOHANNA GIBSON, INTELLECTUAL PROPERTY, MEDICINE AND HEALTH: CURRENT DEBATES 182 (2009) (suggesting that pricing of products with exclusive

Supporters of gene patenting maintain that there is no evidence that gene patents thwart innovation or unnecessarily restrain trade by inflating costs or enabling predatory pricing.⁸⁵ Yet while the purpose of patents was to incentivize innovation, evidence indicates that patents do not increase innovation⁸⁶ and there are significant numbers of outspoken opponents to patenting genes.⁸⁷ Allowing the patenting

rights is profit-driven, with little concern for the quality or benefit of the product, thus affecting developing countries and national healthcare programs); *see also* Gitter, *supra* note 26, at 1626 (highlighting the concerns of a University of Pennsylvania bioethicist who has “warned that [a gene patent], and [the patent holder’s] attendant right to collect royalties from subsequent researchers working on the gene, will impede others from developing therapeutics based on the gene”).

85. *See* Gregory C. Ellis, *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents*, 15 RICH. J. L. & TECH. 1, 5 (2008) (maintaining that there is no empirical evidence to support a conclusion that gene patents impede research and development); *see also* Pilar N. Ossorio, *Legal and Ethical Issues in Patenting Human DNA*, in A COMPANION TO GENETHICS: PHILOSOPHY AND THE GENETIC REVOLUTION 408, 418 (Justine Burley & John Harris eds., 2002) (arguing that critics of patenting “must [ask] why people who actually generate . . . knowledge do not deserve some compensation for their efforts and contributions; [and why] having a common interest in the genome does not necessarily mean that we can appropriate the fruits of other people’s labor”). *But see* GIBSON, *supra* note 84, at 83-84 (reasoning that the patent system can substitute further investment in research and development programs, which may lead to a reduction in innovation).

86. *See* MICHELE BOLDRIN & DAVID K. LEVINE, *AGAINST INTELLECTUAL MONOPOLY* 186-87 (2008) (explaining that the substantial increases in patent protections have not spurred similar increases in innovation and arguing that there is little historical evidence that supports the argument that intellectual property monopolies effectively increase innovation).

87. *See, e.g.*, MATTHEWS, *supra* note 3, at 113 (highlighting the high costs of complying with the TRIPS Agreement and how this negatively impacts developing countries); *see also* FRIEDRICH VON HAYEK, *THE FATAL CONCEIT: THE ERRORS OF SOCIALISM* 37 (W.W. Bartley III ed., 1989) (arguing that continued research does not show that the availability of patents “actually enhances the flow of new technical knowledge rather than leading to wasteful concentration of research on problems whose solution in the near future can be foreseen and where, in consequence of the law, anyone who hits upon a solution a moment before the next gains the right to its exclusive use for a prolonged period”); American College of Gene Testing, *Position Statement on Gene Patents and Accessibility of Gene Testing* (Aug. 2, 1999), http://www.acmg.net/StaticContent/StaticPages/Gene_Patents.pdf (last visited May 10, 2010) (expressing concern for the enforcement of patents on genes under the belief that gene testing “must remain widely accessible and affordable”).

of genetic material hinders research⁸⁸ and allows for monopolistic pricing behavior by patentees.⁸⁹

1. Researchers Face Significant Barriers Because the TRIPS Agreement Does Not Prohibit Patenting Genetic Material

Independent and follow-on research is negatively affected by genetic patenting.⁹⁰ In the past thirty years, the cost of independent research in pursuit of patents has doubled.⁹¹ Companies argue that without the assurances of patent protection, substantial investments into research and development are not financially worthwhile.⁹²

Furthermore, researchers have little incentive to conduct important follow-on research or develop more effective and comprehensive diagnostic tests because exclusive patents limit their ability to actually conduct the new tests, let alone market them to turn a

88. See, e.g., Crichton, *supra* note 27, at A23 (reporting that at the outset of the SARS epidemic, scientists initially refrained from conducting research due to patent license concerns).

89. See *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, 2010 U.S. Dist. LEXIS 30629, at *14-16 (S.D.N.Y. Mar. 29, 2010) (listing the grievances of women whose insurance was refused by Myriad and were unable to afford the test as an out-of-pocket expense); see also Mulcahy, *supra* note 18 (explaining that *Ass'n for Molecular Pathology* was filed by Myriad against the University of Pennsylvania for testing BRCA genes at nearly half the price of Myriad).

90. See Willison & MacLeod, *supra* note 10, at 260 (distinguishing between two types of innovation: new discoveries and those which improve upon existing discoveries); Kenneth G. Huang & Fiona E. Murray, *Does Patent Strategy Shape the Long-run Supply of Public Knowledge? Evidence from Human Genetics*, ACAD. MGMT. J. (forthcoming 2010) (manuscript at 13-14, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1249522) (acknowledging that research that seeks to build upon existing technologies is "follow-on" research).

91. See *Gene Patents and Global Competition Issues*, *supra* note 54 (reporting that from 1970 to the present, developing a new drug and getting approval by government agencies has grown from six years and costing less than \$10 million to often over 15 years and costing between \$500-800 million).

92. See *id.* (explaining that patent protection is the only justification for the significant expense of commercially developing new medical technologies); see also Rebecca S. Eisenberg, *Bargaining Over Proprietary Research Tools*, in *EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY* 222, 232-33 (Rochelle Dreyfuss, Diane Zimmerman, & Harry First eds., 2001) (suggesting that research companies will only engage in licensing rights when significant future revenue is projected).

profit.⁹³ Follow-on research is in decline as increasing research costs compete with ever fewer incentives to innovate.⁹⁴ Without the ability to conduct follow-on research, there is no impetus to improve upon the patented method, even if it has demonstrated flaws.⁹⁵ For example, in 2006, over ten years after Myriad patented the BRCA1 and BRCA2 genes and their respective diagnostic tests, researchers at the University of Washington published a study that found that Myriad's commercial BRCA test produced false-negative results on patients that actually carried a positive gene mutation.⁹⁶ Exclusivity on a genetic test limits the ability to conduct research integral to the development of more inclusive tests.⁹⁷ Gene patenting effectively

93. Cf. Suhwan Chang et al., *Expression of Human BRCA1 Variants in Mouse ES Cells Allows Functional Analysis of BRCA1 Mutations*, 119 J. CLINICAL INVEST. 3160, 3160 (Oct. 2009) (describing a new diagnostic test developed under Myriad's license to NCI); Allison Williams Dobson, NCI's New BRCA1 Test: Broader Utility and Another Challenge to Traditional Genetic Tests, *Genomics Law Report* (Sept. 20, 2009), <http://www.genomicslawreport.com/index.php/2009/09/30/ncis-new-brca1-test-broader-utility-and-another-challenge-to-traditional-genetic-tests/> (last visited Apr. 23, 2010) (asserting that Suhwan Chang's new test has many positive benefits, but may infringe on Myriad's patent and is far from commercially available).

94. See Nancy T. Gallini, *The Economics of Patents: Lessons from Recent US Patent Reform*, 16 J. ECON. PERSP. 131, 136 (2002) (highlighting that longer patent terms may lead to decreased innovation); Huang & Murray, *supra* note 90, at 40 (noting that follow-on research declines when patents on gene sequences are filed and granted).

95. See Nathan Seppa, *Defect Detector: Plugging Holes in a Breast Cancer-gene Screen*, *SCI. NEWS*, Mar. 25, 2006, at 181 (explaining that researchers in Europe and the United States have developed more expansive genetic testing for presence of a BRCA gene mutation, but the United States tests fail to detect mutations shown in the European test); see generally Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 JAMA 1379 (March 22-29, 2006) (reporting the discovery of positive gene mutations left undetected by the Myriad test).

96. See Walsh et al., *supra* note 95, at 1379-80 (explaining that Myriad Genetics tests failed to identify a mutation in patients who, in fact, carried a pathogenic BRCA1 or BRCA2 mutation and other limitations of current BRCA diagnostic testing).

97. See Mulcahy, *supra* note 18 (quoting Emory University's director of the Division of Medical Genetics and plaintiff in *Ass'n for Molecular Pathology*, stating that "[w]hen a gene patent and exclusive licensing situation create a genetic test monopoly, we are forced to avoid performing research for this particular disease and therefore cannot contribute our cutting-edge technologies to the improvement of clinical testing for this patient population"); Seppa, *supra* note 95, at 181 (contending that geneticist Mary-Claire King's alternative testing technique catches mutations overlooked by Myriad's commercial test, but Myriad's exclusive

excludes researchers from the market, forces them to pursue alternatives and ultimately less promising research paths because they are cheaper and more accessible.⁹⁸

*2. The TRIPS Agreement Injures Consumers by Allowing the
Creation of Closed-Market Monopolies*

The TRIPS Agreement fails to provide the adequate safeguards needed to ensure competition within markets: competition that could be a catalyst for innovation.⁹⁹ In addition, the TRIPS Agreement also lacks a provision that would mandate government action against monopolist pricing.¹⁰⁰ TRIPS relies on the antitrust theory that such regulation should not be necessary because both the market and competing innovation would check monopolistic activity.¹⁰¹

patent precludes laboratories from conducting any type of BRCA diagnostic tests); *see also* Chang et al., *supra* note 93, at 3160-69 (publishing the findings of the National Cancer Institute's new BRCA1 genetic test study and reporting its development of a new BRCA1 genetic test which theoretically detects *any* harmful BRCA1 variant); Dobson, *supra* note 93 (asserting that the NCI test may infringe upon one of Myriad's broad patents of the BRCA genes, and is not yet available on the market).

98. *See* Gitter, *supra* note 26, at 1652 (commenting that Myriad's patented test for breast cancer put all other American labs out of business and threatens labs in the UK); Paradise, *supra* note 12, at 149-50 (reporting that in a study of U.S. geneticists, "21% claim that [failing to obtain data] from another researcher has resulted in their abandonment of a promising line of research" and in a study of 200 genetic testing laboratories, "approximately 50% reported that they did not attempt to develop new tests because of commercial constraints brought on by a patent"); Willison & MacLeod, *supra* note 10, at 260 (remarking that 35% of geneticists interviewed reported a decrease in data sharing, and that nearly 50% of those interviewed were refused academic requests at least once, which led to an inability to conduct appropriate testing in nearly 30% of those cases).

99. *See* Susan DeSanti & William Cohen, *Competition to Innovate: Strategies for Proper Antitrust Assessments*, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY 317, 321 (Rochelle Dreyfuss, Diane Zimmerman, & Harry First eds., 2001) (finding that competition begets further innovation within a market, and interviewing a representative for 3M who explained that market position gained from innovation is "fleeting," and without further innovation, companies lose position in the market).

100. *See* TRIPS Agreement, *supra* note 2, art. 30(k), 40(2) (providing Member States with the ability to take action against anticompetitive practices so long as they consider relevant laws and do not infringe on the interests of patent holders and affected parties).

101. *Cf.* Hanns Ullrich, *Intellectual Property, Access to Information, and Antitrust: Harmony, Disharmony, and International Harmonization*, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY 365, 371 (Rochelle

However, allowing gene patenting effectively monopolizes the relevant market by granting the patent holder complete control of the market.¹⁰² Closing access to the market has foreclosed competition and allowed genetic monopolies to increase their profit margins at the consumers' expense.¹⁰³ Myriad's exclusionary conduct provides an example of how gene patents negatively impact both consumers and researchers.¹⁰⁴

B. THE BROAD LANGUAGE OF SECTION 5 OF THE TRIPS
AGREEMENT ALLOWS FOR INCONSISTENCIES IN THE NATIONAL
LAWS OF INDIVIDUAL MEMBER STATES

Section 5 of the TRIPS Agreement allows individual Member States to determine the patentability of genes, gene sequences, and a variety of other biotechnological products.¹⁰⁵ The resulting ambiguity has created significant disparities in the national laws of Member States.¹⁰⁶ Not only does this ambiguity create serious legal conflicts between Member States, but also between patent holders and the

Dreyfuss, Diane Zimmerman, & Harry First eds., 2001) (arguing that there is no contradiction between "the exclusivity provided for by intellectual property and . . . free competition").

102. See Oskar Liivak, *Maintaining Competition In Copying: Narrowing the Scope of Gene Patents*, 41 U.C. DAVIS L. REV. 177, 203 (2007).

As there is only one way to accurately draw a particular map, there is very nearly only one sequence for a particular gene. Because of this property, a broad patent claim to a gene sequence becomes not just a barrier to direct piracy, but a complete barrier to nearly all competition. In these cases, there will not be any competition because a broad claim leaves no room for non-infringing solutions to the problem.

Id.

103. See *id.* (explaining that gene patents are significantly more costly than patents on traditional subject matter due to the inability of innovators to enter the market created by a particular gene patent).

104. See BOLDRIN & LEVINE, *supra* note 86, at 69 (contending that monopolist companies "are willing and able to do anything legally and technically feasible to maintain their monopoly profits").

105. See TRIPS Agreement, *supra* note 2, pt. II, § 5 (identifying the minimum standards that member-states must adhere to in order to provide sufficient intellectual property standards).

106. See WHO GENETICS, GENOMICS AND THE PATENTING OF DNA, *supra* note 47, at 25-37 (2005) (identifying significant differences in the level of coverage granted to genetic material in the domestic patent law of various WTO Member States: Brazil's allowance of only gene sequence patents, the EC requirements of novelty, utility, and non-obviousness, China's allowance of gene patents but not life forms, and India's refusal to patent genes or cells).

governments themselves.¹⁰⁷ Additionally, under TRIPS, legal conflicts are only resolved based on challenges by individual Member States, thus eliminating the potential for an individual patent holder to file a WTO action for breach of the TRIPS Agreement.¹⁰⁸

The TRIPS Agreement only obligates Member States to acquiesce to a basic set of intellectual property rights that encourages heightened user protections at a national level.¹⁰⁹ But the Agreement provides no real option to reduce or eliminate any standard TRIPS protection. Without the application of appropriate maximum standards or exclusions for adequate balance on a global scale, the TRIPS Agreement's minimalist framework is an inadequate and impractical standard.¹¹⁰ The problems faced by individual Member States are emblematic of issues that will occur between Member States as incongruent national intellectual property laws are enacted, amended, and re-codified worldwide under the wide umbrella of the TRIPS Agreement.¹¹¹

107. See, e.g., *Myriad Wins European Patent Appeal on Cancer Test*, REUTERS, Nov. 20, 2008, <http://www.reuters.com/article/BIOTRX/id USN2041020920081120> (last visited Apr. 24, 2010) (describing the European Patent Office's modification of Myriad's BRCA patents following a four year conflict that began with patent revocation and ended with an amended, but reinstated patent).

108. TRIPS Agreement, *supra* note 2, arts. 63-64 (outlining dispute settlement procedures involving Member States only); see also GIBSON, *supra* note 84, at 160 (examining the history of Swiss company Novartis' litigation in India and explaining the unlikelihood that the Swiss government would take legal action against India under TRIPS and before the WTO out of respect for the judicial assertions of other countries).

109. See TRIPS Agreement, *supra* note 2, art. 27(2)-(3) (identifying permissible limitations on patentable subject matter at the national level); Rochelle Cooper Dreyfuss, *TRIPS Round II: Should Users Strike Back?*, 71 U. CHI. L. REV. 21, 22 (2004) (arguing that the TRIPS agreement encourages countries to increase patent protections, which in turn makes them susceptible to a WTO challenge for any reduction of those protections).

110. See Katherine J. Strandburg, *Evolving Innovation Paradigms and the Global Intellectual Property Regime*, 41 CONN. L. REV. 861, 896 (2009) (recognizing that the TRIPS Agreement's failure "to incorporate any standards of maximum intellectual property protection also reflects a paradigm of innovation in which follow-on innovation is either unimportant or occurs within an industry structure in which *ex ante* licensing is an effective means to structure it").

111. See, e.g., Q. Todd Dickinson, *Patentable Subject Matter: The Debate Reignites – Or Did It Ever Really Go Away?*, LANDSLIDE, Nov.-Dec. 2008, at 30, 35 (identifying skepticism regarding the expansion of patentable materials in India and Brazil); Reichman, *supra* note 65, at 89 (confirming that TRIPS "left ample room for national variations and approaches").

The flexibility of each member state to interpret and define the language of the TRIPS Agreement results in national protections that vary significantly from state to state.¹¹² These variations are most visible in reviewing the disparate handling of Myriad Genetics' patents within the European Union,¹¹³ Canada,¹¹⁴ and the United States.¹¹⁵

112. Compare 35 U.S.C. §§ 101-03 (allowing patents to be granted to anyone who "invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," and specifying the criteria of nonobviousness), with Convention on the Grant of European Patents, *supra* note 68, arts. 52-53 (providing patentability for "any inventions which are susceptible of industrial application, which are new and which involve an inventive step," and excluding the patentability of "discoveries, scientific theories and mathematical methods," plants and animals, the patenting of items whose patenting would be "morally repugnant," or any "essentially biological processes"); and Canadian Patent Act, ch. P-4, §§ 27(3)(a)-(d), 27(7) (1985) (declaring that patents must specify the invention's use, steps of its process or construction, its principle or application, and any sequences necessary to distinguish the invention from others, and excluding the patentability of "any mere scientific principle or abstract theorem"). See WHO GENETICS, GENOMICS AND THE PATENTING OF DNA, *supra* note 47, at 25-37 (enunciating the different patent allowances of several countries: Brazil, which issues gene sequence patents, but not patents to genes; China, which only expressly refuses patents to "life forms"; and India, which does not patent either genes or cells).

113. See, e.g., EPO Decision, *supra* note 9 (reporting that Myriad's European patent was reinstated after it was amended to cover only the diagnostic test); Paradise, *supra* note 12, at 138-42 (describing opposition to Myriad's monopolistic gene patent from a wide array of European genetics societies and research institutes); *Scope of Breast Cancer Gene Patents 'Slashed'*, BIONEWS, Jan. 28, 2005, http://www.bionews.org.uk/pag_e_12236.asp (last visited Apr. 24, 2010) (reporting that after a recent amendment, there is now only one gene mutation protected by Myriad's BCRA patents).

114. See, e.g., Williams-Jones, *supra* note 18, at 142-43 (articulating that some Canadian provinces have rejected Myriad's patent claims, continuing to perform the BRCA screening at approximately 30% of the Myriad test cost); Willison & MacLeod, *supra* note 10, at 260 (explaining Ontario's continued testing for BRCA which government officials argued did not infringe Myriad's patent).

115. See, e.g., Ass'n for Molecular Pathology v. United States Patent and Trademark Office, No. 09-4515, 2010 U.S. Dist. LEXIS 30629 (S.D.N.Y. Mar. 29, 2010).

C. THE TRIPS AGREEMENT THWARTS INNOVATION AND HURTS CONSUMERS BY NOT REQUIRING COMPULSORY LICENSING OR BENEFIT-SHARING FOR GENETIC MATERIAL

Article 31 of the TRIPS Agreement allows for the compulsory licensing of TRIPS-protected intellectual property¹¹⁶ but does not mandate that a member state address a patent holder's anti-competitive actions.¹¹⁷ For example, Myriad has regularly refused to license its BRCA gene tests, preferring to exercise its exclusive rights to the detriment of consumers and researchers alike.¹¹⁸ Myriad has issued testing licenses only to necessary subsidiaries in other countries and companies explicitly authorized to conduct supplemental testing only.¹¹⁹ Such exclusivity has caused individual Member States to take concerted action against Myriad.¹²⁰ Still, women in the United States have been unable to obtain second opinions on the tests because Myriad has not authorized any other facility to conduct them.¹²¹ The Canadian government has also faced

116. See TRIPS Agreement, *supra* note 2, art. 31 (identifying certain limited exceptions to exclusivity of the patent holder, and permitting the granting of patent rights by compulsory license to individuals other than the patentee).

117. See *id.* art. 31(k) (permitting Member States to grant compulsory licenses in order to "correct [certain] anti-competitive practices," without mandating that states utilize such licensing).

118. See *Ass'n for Molecular Pathology*, 2010 U.S. Dist. LEXIS 30629, at *14-16 (identifying the plaintiffs, including a woman who was unable to obtain a second opinion of a BRCA gene test conducted by Myriad due to the company's unwillingness to license its gene patents, and a number of women who were unable to obtain the test due to Myriad's discretionary acceptance of insurance); Chang et al., *supra* note 93, at 3160 (describing a new BRCA screening test, which suggests that the Myriad test may be insufficient to completely rule out a dangerous mutation); Walsh et al., *supra* note 95, at 1380 (publishing results of a BRCA screening test that caught mutations missed by Myriad's test, but which was never commercially available to consumers); E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 13 (2008), available at http://papers.ssrn.com/sol/papers.cfm?abstract_id=1260098 (asserting that Myriad's actions gave the impression that it was ready to thwart scientific research to expand its profit and prevent researchers from improving upon or critiquing the quality of Myriad's tests, or developing new tests and therapies for BRCA indicated cancers).

119. See Gold & Carbone, *supra* note 118, at 14 (emphasizing that Myriad would generally provide the comprehensive testing at its Utah laboratory and require its local licensees to provide the less expensive single-mutation tests).

120. See discussion *supra* Part I.C. (discussing the actions of the EPO, Canada, and the United States against Myriad).

121. See Holman, *supra* note 18, at 347 (recognizing Myriad's exclusive behavior when it refused to allow the University of Pennsylvania to conduct breast

significant barriers with Myriad, forcing policy modifications resulting in different approaches within its provinces.¹²² While financial burdens are heavier on the shoulders of developing nations,¹²³ even countries with extensive financial resources, like Canada, have been unable to afford the monopolist prices demanded by patent holders.¹²⁴

Myriad's refusal to license its test in the United States has had a significant effect on consumers and researchers.¹²⁵ First, because Myriad has refused to license the testing, individuals who have tested positive for a BRCA gene mutation have had no ability to obtain a second opinion on their test results and must rely on the Myriad lab's conclusions.¹²⁶ Additionally, Myriad's prohibition on alternative

cancer gene screening); Willison & MacLeod, *supra* note 10, at 260 (describing Myriad's declaration that a number of Canadian provinces were violating their exclusive patent). *But see* COLEMAN & TSONGALIS, *supra* note 17, at 551 (referring to Myriad's licensing exception for the National Cancer Institute, which consisted of only a reduced fee and some additional favorable terms).

122. *See* Paradise, *supra* note 12, at 138 (explaining that each province in Canada deals with BRCA gene-testing in different ways; noting Ontario completely ignores Myriad's patent claim and conducts its own testing, Alberta conducts the testing through Myriad in Utah, and British Columbia used to conduct the test through Myriad); Heather Kent, *BC Sidesteps Patent Claim, Transfers BRCA Gene Testing to Ontario*, 168 CAN. MED. ASS'N J. 211 (Jan. 21, 2003) (reporting that British Columbia transferred its BRCA cancer gene testing to Ontario); Eggertson, *supra* note 66, at 494 (reporting Ontario's continued screening of women for the presence of a BRCA gene). Quebec does not conduct the genetic testing at all because of its cost-prohibitive nature. Paradise, *supra* note 12, at 138.

123. *See generally* GIBSON, *supra* note 84, at 12 (elaborating on how intellectual property innovation disadvantages developing countries by limiting access to medicines).

124. *See* Swenarchuk, *supra* note 74, at 488 (comparing similar testing procedures in Canada against Myriad's gene test to show that Canada's test cost approximately \$1,300 and Myriad's was nearly three times that, at approximately \$3,850).

125. *See* Complaint, *supra* note 77, ¶¶ 7-26 (questioning the patentability of genetic sequences and material, and citing to the resulting harm to medical associations, professional, and patients by limiting research and access); Mulcahy, *supra* note 18 (specifying that scientists are forced to avoid researching diseases with exclusive patents and licensing consequently stifling the development of technologies for improving testing); *see also* Dobson, *supra* note 93 (considering the potential legal ramifications of the development of a more comprehensive BRCA diagnostic test that is unable to enter the market because of Myriad's exclusive gene patent).

126. *See* Ass'n for Molecular Pathology v. United States Patent and Trademark

testing centers in the United States has excluded individuals with undesirable health insurance coverage, minimal health insurance coverage, or no health insurance coverage at all.¹²⁷ These individuals who have been refused by Myriad have been left with no viable testing alternatives; forced to pay for the test themselves, a daunting task with high out-of-pocket costs, or live without the valuable medical knowledge that the test would provide.¹²⁸

For these reasons, the TRIPS Agreement should more than just allow Member States to grant compulsory licenses for genetic material.¹²⁹ Consumer harm of this magnitude requires compulsory licensing, which the TRIPS Agreement allows only under very specific circumstances.¹³⁰ But Article 31 allowances are insufficient safeguards for consumers and researchers because they place the burden of taking action on the member state itself.¹³¹ Mandatory compulsory licenses for gene patents in all Member States would allow licenses to be granted to other laboratories, thus increasing competition and innovation while reducing consumer costs.¹³²

Office, No. 09-4515, 2010 U.S. Dist. LEXIS 30629, at *15 (S.D.N.Y. Mar. 29, 2010) (depicting the struggle of Genae Girard, who was blocked from obtaining a second opinion on her BRCA screen conducted by Myriad).

127. *See id.* at *14-16 (identifying those individuals excluded from Myriad's testing because Myriad refused to accept their insurance, including Medicaid); *see also* Myriad Genetics, Payment and Insurance, <http://www.bracnow.com/consideringtesting/payment-insurance.htm> (last visited Apr. 24, 2010) (reporting that BRCA testing patients are typically responsible for paying ten percent of the test price out-of-pocket).

128. *See* Mulcahy, *supra* note 18 (estimating current Myriad testing prices at over \$3,000).

129. *See* TRIPS Agreement, *supra* note 2, art. 31 (explaining that when a member state's own laws allow for the unauthorized grant of exclusive intellectual property rights, the government may permit use under specific circumstances and after meeting specific provisions).

130. *See* TRIPS Agreement, *supra* note 2, art. 31(a) (allowing compulsory licenses to be issued only after a review on the merits of each proposed use of the subject matter of a patent); GIBSON, *supra* note 84, at 162 (explaining that communicable diseases are the usual target of most grants of compulsory licenses).

131. *See* TRIPS Agreement, *supra* note 2, art. 31 (allowing the grant of compulsory licenses only when the laws of a member state already permit their issuance).

132. *See* BOLDRIN & LEVINE, *supra* note 86, at 73-75 (lamenting the detrimental economic impact of monopolistic patents and emphasizing the near impossibility of developing technologies like new computer software without infringing on "some patent held by someone else"); *see also* GIBSON, *supra* note 84, at 146-47 (identifying positive aspects of compulsory licenses and indicating that the

Without mandatory compulsory licensing, licenses to conduct innovative research are often prohibitively expensive, if they are granted at all.¹³³ Gene patents, like other exclusive rights, have an inherent tendency to restrict competition.¹³⁴ Indeed, the cost of challenging a patent is often prohibitively expensive and may chill competition.¹³⁵

Gene patents supporters argue that exclusive rights create so-called “legal monopolies” or monopolies in name only, which do not dominate the market.¹³⁶ They argue that simply because these patentees hold exclusive rights does not mean they do not compete with similar products that may produce the same functions and meet the same demand.¹³⁷ But the very process of information gathering and innovation would cease to exist as we know it if researchers were entirely unable to share knowledge and build upon it in hopes of creating new inventions.¹³⁸

flexibilities of the TRIPS Agreement allow for Member States to contract out of compulsory licensing provisions often necessary in establishing access to intellectual property in developing countries).

133. See Eisenberg, *supra* note 92, at 231-33 (examining transaction costs license negotiations, which may add significant time and monetary costs to research teams and noting that attempts to license between heterogeneous institutions can result in significant demands and expectations); see also Gold & Carbone, *supra* note 118, at 13 (analyzing the effects of certain cease and desist letters sent by Myriad to companies who were conducting BRCA screening, and Myriad’s refusal to license any laboratory for commercial testing).

134. See NUNO PIRES DE CARVALHO, *THE TRIPS REGIME OF ANTITRUST AND UNDISCLOSED INFORMATION* 139 (2008) (illustrating the prevailing opinion that patents are inherently anticompetitive due to the exclusive rights they award the patent holder); see also Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS*, 34 N.C. J. INT’L L. & COM. REG. 371, 381-82 (2009) (observing that while patents may be justified by their innovations to society, they “exclude others” and allow patent owners to “charge a premium price” for patented objects).

135. See Holman, *supra* note 18, at 347 (providing that quick dismissals of patent litigation creates a “chilling effect” due to patent-challenge reluctance).

136. See PIRES DE CARVALHO, *supra* note 134, at 34 (arguing that patents do not “provide immunity against competitive market forces” and that patents are “legal monopolies” like other exclusive property rights).

137. See *id.* at 36 (contending that while “[a] patent covers a solution for a technical problem . . . [the problem] may be solved by means of different solutions”).

138. See Dreyfuss, *supra* note 109, at 22 (concluding that there would be no expansion of knowledge unless innovators are allowed to research, learn from, and expand upon the work of earlier inventors); see also Paradise, *supra* note 12, at

Exempting genetic material from exclusive licensing will expand innovation in both developing and economically-developed Member States.¹³⁹ Developing countries are already at an inherent disadvantage with respect to groundbreaking innovation, and increasing intellectual property rights simply widens the gap between the wealthy and the disenfranchised as knowledge becomes ever more expensive.¹⁴⁰ In fact, problematic discrepancies exist between the percentage of research focused on illnesses and diseases affecting industrialized nations, as opposed to afflictions that impact people in poorer countries.¹⁴¹ Eliminating the exclusive licensing of genes would remove the economic disparities inherent in costly licensing arrangements¹⁴² and incentivize innovation in developed countries by eliminating steep transactional costs involved in negotiating licensing deals.¹⁴³

149 (observing that improvements to the diagnostic methods currently employed are unlikely to be made due to the inability of researchers and physicians to use the BRCA1 gene itself).

139. See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation?: The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698-701 (1998) (warning that increases in intellectual property rights, without proper licensing safety nets, could lead to the underuse of limited resources because the right holder has the ability to block others).

140. See Dreyfuss, *supra* note 109, at 29.

Educating a [developing country's] citizenry to the level where it is technically and culturally sophisticated enough to innovate at globally competitive levels may become prohibitively expensive once intellectual property rights are recognized [and] unless some concession is made to user interests, any nation that is now behind will likely stay there.

Id.; see also Peter K. Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 382-83 (2006) (indicating that unbalanced intellectual property systems would harm developing countries more than developed ones, due in part to less developed countries having fewer resources to overcome a breadth of economic disadvantages).

141. See GIBSON, *supra* note 84, at 83 (noting that if research is primarily motivated by market demand, there may be significantly less research into "rare and tropical diseases" in favor of more widespread and thus lucrative alternatives).

142. See Eisenberg, *supra* note 92, at 232-33 (examining the high transaction costs inherent in negotiating licensing deals with patent holders and noting that the licenses may take months, if not years, to negotiate, which can force the licensee to incur even more costs).

143. See *id.* at 234 (clarifying that patent-holder negotiations are often lengthy and costly because the rights holder will not see any profit from the development of a new product unless they are able to preserve some value after the product's development).

III. RECOMMENDATIONS

The TRIPS Agreement's minimum standards, even when viewed in the more flexible light of the 2001 Doha Declaration, are an inadequate and vague means of establishing standard criteria for patentability.¹⁴⁴ The World Trade Organization should amend Section 5 of the TRIPS Agreement to specifically prohibit the patenting of naturally occurring things, including genetic material.¹⁴⁵ In the absence of such an amendment, the WTO should develop guidelines that establish basic definitions of requirements for patentability.¹⁴⁶ If the development of guidelines proves untenable, the WTO should mandate compulsory licensing and fair-use standards to spur development of gene-based innovation and decrease consumer costs.¹⁴⁷

A. THE WORLD TRADE ORGANIZATION SHOULD AMEND SECTION 5 OF THE TRIPS AGREEMENT TO INCLUDE ACCESS TO AND EXCLUDE PATENTABILITY OF GENES AND NATURALLY OCCURRING GENETIC MATERIAL

An amendment to Section 5 of the TRIPS Agreement to prohibit the patenting of genetic material would provide the most sweeping and immediate change to global patent protections.¹⁴⁸ Amending

144. Compare TRIPS Agreement, *supra* note 2, art. 27 (providing the minimum protection standards required of patents in all Member States without defining the term "invention") with Doha Declaration, *supra* note 26, ¶ 5(a) (encouraging Member States to interpret the TRIPS Agreement in a light favorable to the promotion of research and innovation).

145. See S. Aymé et al., *Patenting and Licensing in Genetic Testing: Recommendations of the European Society of Human Genetics*, 16 EUR. J. HUM. GEN. S3, S3 (2008) (recommending to "limit[] the breadth of the claims in genetic patents and, more practically, to reduce the number of patents by limiting the patentable subject matter, thereby improving the quality of the patents that will eventually be granted").

146. *Contra* Reichman, *supra* note 65, at 89 (noting the purpose behind the ambiguity of the TRIPS agreement structure was to allow for differences and flexibilities).

147. See generally PIRES DE CARVALHO, *supra* note 134, at 139-45 (examining the requirements of Article 31 of the TRIPS Agreement and analyzing the flexibilities required to mandate compulsory licensing or fair-use standards in particularized situations).

148. See Understanding the WTO, *supra* note 1 (outlining components of the TRIPS Agreement, including sections on patents, and exposing portions of the Agreement susceptible to amendment).

TRIPS would alleviate the problems currently faced by many individual Member States in the struggle to address patentable material at the domestic level.¹⁴⁹ Clarifying TRIPS via amendment would provide a more secure structural framework for interpretation in the event of future patentable subject-matter challenges.¹⁵⁰ An explicit exclusion of genetic material from patentability would ensure that human genes continue to assist researchers in the development of groundbreaking vaccines and numerous other preventative health care measures.¹⁵¹ Allowing private companies to patent genetic material such as human genes and gene sequences has been detrimental to the research field by placing a premium on patentability of individual gene sequences that may or may not lead to any innovation.¹⁵²

149. See, e.g., *Novartis AG v. Union of India*, 2007 A.I.R. 24759 at ¶ 19 (upholding the Indian Patent Amendments Act of 2005 which defined “invention” and stipulated that patents would not be granted to discoveries, unless the product had notably different practical value or application); *Ass’n for Molecular Pathology v. United States Patent and Trademark Office*, No. 09-4515, 2010 U.S. Dist. LEXIS 30629 (S.D.N.Y. Mar. 29, 2010) (holding that the genes patented by Myriad are necessarily un-patentable because they are not markedly different from what occurs in nature); WHO GENETICS, GENOMICS AND THE PATENTING OF DNA, *supra* note 47, at 25-37 (identifying the lack of a cohesive approach to the patenting of genes and genetic material by developing nations like India, China, and Brazil).

150. See generally NIH REPORT, *supra* note 46, at 80-81 (2009) (noting that it is unclear how TRIPS would be interpreted because there have been no member state challenges of the patentability of genetic material like DNA on the basis that it occurs naturally).

151. See, e.g., Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES, Apr. 16, 2006, <http://www.nytimes.com/2006/04/16/magazine/16tissue.html> (describing medical innovations obtained through research conducted with genetic materials (e.g. tests for polio, H.I.V. and smallpox)). The Fox Chase Cancer Center and Nobel Prize winner Baruch Blumberg developed the first Hepatitis B vaccine after Ted Slavin provided them with his unique tissues that contained “extremely high concentrations of valuable hepatitis B antibodies.” *Id.*

152. David Ewing Duncan, *What’s the Point in Patenting Genes?: Whatever the Outcome of the ACLU vs. Myriad Case, a New Effort is Needed to Turn Genetic Testing into a Useful Diagnostic Tool*, TECH. REV., May 27, 2009, <http://www.technologyreview.com/biomedicine/22704> (last visited Apr. 24, 2010) (suggesting that the Myriad litigation avoids the true problem of gene patenting, which is the existence of “thousands of biomarkers . . . languishing in databases” and waiting to be clinically validated).

B. THE WORLD TRADE ORGANIZATION SHOULD ESTABLISH
GUIDELINES FOR INTERPRETING THE BASIC REQUIREMENTS OF
PATENTABILITY AND EXCLUDING GENES

First, TRIPS should be interpreted with deference to the objectives outlined in Article 7.¹⁵³ Interpreting TRIPS as a vehicle for innovation as much as for protection is permissible and would expand the scope of the 2001 Doha Declaration¹⁵⁴ and greatly increase basic flexibility in TRIPS outside of the narrow focus outlined in the Declaration.¹⁵⁵ Section 5 should be clarified to explicitly exclude the patentability of any naturally occurring subject matter, which is consistent with the domestic patent protections of many Member States.¹⁵⁶ Additionally, paragraph two of Section 5 should be interpreted to permit Member States to exclude genetic material from patentability on a general public health exception.¹⁵⁷ This exclusion is justified because patenting the material endangers public health by stifling the development and marketability of diagnostic tests, pharmaceuticals, and other medical necessities.¹⁵⁸

Finally, Article 30, which allows for exceptions to conferring patent rights, should be interpreted to allow research and fair-use access to genes, genetic material, and gene sequences.¹⁵⁹ The WTO

153. See MATTHEWS, *supra* note 3, at 49 (explaining that the objectives enunciated in Article 7 were to alleviate the concerns of developing countries during TRIPS negotiations).

154. See generally Doha Declaration, *supra* note 26, ¶ 5(a) (emphasizing the importance of reading “each provision of the TRIPS Agreement . . . in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles”).

155. See *id.* ¶ 4 (providing flexibility under the TRIPS Agreement with regard to public health and specifically “access to medicines for all”).

156. See, e.g., Convention on the Grant of European Patents, *supra* note 68, art. 52(2)(a) (excluding “discoveries” from patentability); Canadian Patent Act, *supra* note 112, § 27(8) (excluding “mere scientific principles” from patentable subject-matter).

157. See TRIPS Agreement, *supra* note 2, art. 27(2)-(3) (identifying permissible exceptions from patentability such as “diagnostic, therapeutic, and surgical methods”).

158. See Swenarchuk, *supra* note 74, at 488 (discussing Ontario’s Minister of Health and Long-Term Care, Tony Clement’s disapproval with gene patenting when it hinders further development of diagnostic innovations, arguing that it is contrary to public interest and fails to promote a competitive market for diagnostic testing).

159. See TRIPS Agreement, *supra* note 2, art. 30 (bestowing members with the

could interpret Article 30 to exempt gene patents from conferring exclusive rights upon the patent holder.¹⁶⁰ A liberal interpretation of Article 30 would comport with the objectives of the TRIPS Agreement and the 2001 Doha Declaration, while still supporting educational access and innovation.¹⁶¹

C. THE WORLD TRADE ORGANIZATION SHOULD MANDATE
COMPULSORY LICENSING TO ENGENDER FAIR-USE STANDARDS IN
GENETIC INNOVATION

Article 31 of the TRIPS Agreement addresses “Other Use Without Authorization of the Right Holder,” which includes the grant of compulsory licenses.¹⁶² Compulsory licenses may be granted by individual governments, regardless of the interest of the right holder, when “the public interest requires that others than the patent owner exploit the invention or as a remedy against the utilization of the patent rights in an abusive manner.”¹⁶³ As with many regulations under TRIPS, however, compulsory licenses are simply suggested for use by Member States and no mechanism exists to require them.¹⁶⁴ Mandating compulsory licensing of gene patents would ensure the availability of patented materials for research and additional innovation.¹⁶⁵

ability to provide exemptions within TRIPS so long as the use grant does not unreasonably conflict with the rights of the patentee).

160. *See id.* (detailing the requirements for granting non-exclusive licenses to patent holders).

161. *See id.* art. 7 (stressing that patent protections should help increase innovation); Doha Declaration, *supra* note 26, ¶ 4 (citing the important public health and welfare concerns that permit flexible interpretations of the TRIPS Agreement by Member States in need of relaxed patent protections).

162. *See* TRIPS Agreement, *supra* note 2, art. 31 (allowing Member States to grant licenses to individuals or groups other than the rights holder under specific circumstances).

163. PIRES DE CARVALHO, *supra* note 134, at 141 (explaining the role and purpose of compulsory licenses and their requirement in order to benefit the public good or provide redress against abuses).

164. *See* TRIPS Agreement, *supra* note 2, art. 31 (providing Member States with the option to grant compulsory licenses in antitrust and other circumstances).

165. *Contra id.* (detailing the necessary requirements for the grant of a compulsory license to a member state and mandating no specific products be granted compulsory licenses automatically).

CONCLUSION

Intellectual property rights and protections are integral to ensuring that innovators have appropriate incentives to develop, research, and create. The TRIPS Agreement, however, has established only a minimum standard of protection that encourages additional exclusivity at the national level, and provides no mandates to ensure that Member States promulgate maximum protections to spur development. The Myriad Genetics example clearly illuminates the problems caused by these inadequacies. It is necessary for the WTO to develop clear and definitive regulations in order to avoid such disparities between Member States. The TRIPS Agreement must be amended to explicitly exclude genes and natural or unmodified genetic sequences as patentable subject matter under Article 27(1). If TRIPS is not amended, the WTO should draft guidelines to encourage the interpretation of the Agreement to exclude gene patents or mandate compulsory licensing of genes.