

CONTRIBUTOR BIO



CAITLYN MORRISON is an undergraduate senior studying Political Science with an independent concentration centralized in Public Policy. Academically, she is primarily interested in international relations, specifically in Chinese politics and social policies on homelessness and poverty. Caitlyn's inspiration for this paper came from two case studies she encountered in lecture, which followed two women's personal struggles to afford patented healthcare testing with no ability alternative. This illustration struck Caitlyn as an obvious and outright human rights violation, bringing her to examine how access to medicine and treatment are viewed through a human rights perspective in the international realm. After she graduates, Caitlyn aims to pursue a career in public policy and public affairs in Washington D.C.

THE HUMAN RIGHTS PERSPECTIVE BEHIND PATENT LAWS

Caitlyn Morrison

Abstract

The reasons for the lack of access to essential healthcare policies and medicines are manifold, but in many cases the high prices of drugs create a barrier to needed treatments in developing countries.¹ These prohibitive drug prices are often the result of corporations in industrialized nations holding patents on the technology to produce their recently discovered medicine. Strong intellectual property rights were developed for pharmaceutical companies who invested in the creation of new medicines to receive the maximum profit from their innovation. However, the monopolization of these medicines' production gives the corporation the ability to sell their product at a high cost, often unreachable for poor countries to afford. Governments in these developing countries have attempted to bring down the prices of medicines yet been blocked by industrialized countries who formulated the World Trade Organization Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement to set strong standards for the protection of intellectual property,

¹ Ellen Hoen, "TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond," *Chicago Journal for International Law*, Vol. 3, no 1 (Spring 2002).

including patents for pharmaceuticals.² In addition, patents on genes, such as the case of Myriad Genetics' ownership of the BRCA1 and BRCA2 genes restrict diagnostics, therapies, drug development and identification of related cancers to be done solely by Myriad preventing patients from obtaining a second diagnostic opinion from an independent laboratory. Article 25 in the Universal Declaration of Human Rights states that "everyone has the right to a standard of living adequate for the health and well-being of himself and his family including medical care and the right to security in the event of sickness and disability."³ Therefore denying individuals access to available lifesaving medicine for the sake of maximizing corporations profit is causing citizens in developing countries to suffer from a lack of adequate standard of health. To understand why patent laws have been predominantly looked at as a political economy issue and remain disproportionately unexamined under the human rights scope leads me to ask the following research question: Why are human rights laws not being applied to the restrictions imposed by global patent law?

Real-World Observation

On April 27, 2015 the Royal Society of Medicine held a conference in London and produced a report stating that five billion people do not have access to safe, affordable surgical and anesthesia care when needed.⁴ Access is the worst in low-income and lower-middle-income countries, where nine of ten people cannot access basic surgical care.⁵ This conference was held to examine how global surgery will be shaped in the future, publishing their findings in *The Lancet* journal in order to educate developed countries on the role they ought to play to help combat this issue.⁶ Their research stated that progress in global health over the past 25 years has not been uniform internationally with mortality and morbidity from common conditions

² *Ibid.*

³ The United Nations, *Universal Declaration of Human Rights*. 1948

⁴ Donald McNeil, "Routine Operations Could Save Millions of Lives, If They Were Available," *The New York Times*, April 27, 2015.

⁵ Meara John, "Global Surgery 2030: Evidence and Solutions for Achieving Health, Welfare, and Economic Development." *The Lancet*, 386.9993 (2015): 569-624.

⁶ "Global Surgery, Anesthesia, and Obstetrics: Shifting Paradigms and Challenging Generations," *The Royal Society of Medicine*, 2015.

needing surgery growing in the world's poorest regions.⁷ In the absence of surgical care, fatality rates are high for common, easily treatable conditions including appendicitis, hernia, fractures, obstructed labor, congenital anomalies, and breast and cervical cancer.

Low and middle income countries are facing the burden of infectious disease, maternal disease, non-communicable diseases, and injuries all of which surgical and an anesthesia care are essential for treatment. When viewing the large projected increase in the incidence of cancer, road traffic injuries and cardiovascular diseases in these low and middle income countries, the need for surgical services in these regions will continue to rise substantially from now until 2030.⁸ Despite the growing need, surgery was considered too complicated and expensive to be an integral part of public health in developing countries. Therefore, the Royal Society of Medicine decided to bring light to this issue. The World Bank estimates that universal access to 44 procedures would prevent 6% to 7% of all preventable deaths in low and middle income countries.⁹ With surgeries new found recognition as a cost effective public health intervention, providing access to essential surgical services and safe and timely medical care can only be achieved by addressing the weaknesses within the health care system.

The reasons for the lack of access to essential healthcare policies and medicines are manifold, but in many cases the high prices of drugs create a barrier to needed treatments in developing countries.¹⁰ These prohibitive drug prices are often the result of corporations in industrialized nations holding patents on the technology to produce their recently discovered medicine. Strong intellectual property rights were developed for pharmaceutical companies who invested in the creation of new medicines to receive the maximum profit from their innovation. However, the monopolization of medicines' production affords corporations with the ability to sell their product at a high cost, often unreachable for poor countries to afford. Governments in

⁷ *Op. Cit.*, fn. 5

⁸ *Op. Cit.*, fn. 5

⁹ The World Bank, "Surgery Could Save Millions of Lives in Developing Countries," March 26, 2015.

¹⁰ Ellen Hoen, "TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond," *Chicago Journal for International Law*, Vol. 3, no 1 (Spring 2002).

these developing countries have attempted to bring these prices down, yet have been blocked by industrialized countries who formulated the World Trade Organization Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which set strong standards for the protection of intellectual property, including patents for pharmaceuticals.¹¹ Article 25 in the Universal Declaration of Human Rights states that “everyone has the right to a standard of living adequate for the health and well-being of himself and his family including medical care and the right to security in the event of sickness and disability.”¹² Therefore, denying individuals access to available lifesaving medicine for the sake of maximizing corporations profit is causing citizens in developing countries to suffer from a lack of adequate standard of health. To understand why patent laws have been predominantly looked at as a political economy issue and remain disproportionately unexamined under the human rights scope leads me to ask the following research question: Why are human rights laws not being applied to the restrictions imposed by global patent law?

Conventional Wisdom

International conventional wisdom arrives at the same consensus, that people believe human rights should be a higher priority on the international agenda. This consensus is displayed through the non-partisan poll conducted by World Public Opinion, which states that majorities in all nations surveyed express support for the United Nations playing an active role in promoting human rights and reject the argument that their intervention would be an improper interference in the internal affairs of a country.¹³ Publics in most countries favor the UN playing a larger role than it presently does to promote human rights. In a second World Public Opinion survey, data suggests that a majority of individuals in 17 of the 21 nations polled say their government should abide by international law and reject the view that governments are not obliged to follow international laws when they conflict with the national

¹¹ *Ibid.*

¹² The United Nations, *Universal Declaration of Human Rights*. 1948.

¹³ “Polls Find Strong International Consensus on Human Rights,” *World Public Opinion*, December 7, 2010.

interest.¹⁴ This data proves an authoritative claim that the international community supports human rights laws as an international movement.

However, current practices suggest that patent laws are restricting human rights through infringing on an individual's right to health as stated in the Universal Declaration of Human Rights. Patents allow for monopolistic control over substances that are essential to research, medicine and patients – all things crucial in human rights plans.¹⁵ The last decade has seen a dramatic expansion of intellectual property protection standards, both in their subject matter and scope of economic interests they protect. Due to the TRIPS agreement, intellectual property rights have been an economic issue in the world trading system with unexamined implications in a public health, education, or human rights sectors.¹⁶ The surge of the human rights movement during post-World War II placed international patent law interests in the shadows while other issues emerged to the movement's forefront, leaving them relatively unexplored. This paper brings light to pharmaceutical patent laws under the scope of international human rights to identify the restrictions imposed by these intellectual property interests and the global implications they create.

Methodology and Evidence

To illustrate the impact of patent laws on the field of international human rights, this paper will use qualitative methodology in the form of case study research. These case studies will examine two specific restrictions imposed by patent laws: access to medicine and access to healthcare. This paper will mostly utilize primary sources in order to obtain non-bias evidence to support my research findings. Examples of primary sources that will be included in this paper will be government reports, United Nations' reports, World Bank reports and World Health Organization reports. My secondary evidence will be drawn from sources including the New York Times, The Washington Post and scholarly journals.

¹⁴ "People in 17 of 21 Nations Say Governments Should Put International Law Ahead of National Interest," *World Public Opinion*, November 2, 2009.

¹⁵ Daniel Kevles, "Can They Patent Your Genes?," *The New York Review*, March 7, 2013.

¹⁶ Laurence Helfer, "Toward a Human Rights Framework for Intellectual Property," *UC Davis L. Rev.*, Vol. 40 (2006): 975.

Theoretical Paradigm

The theory that best explains and frames my research question is international legal realism. In international law, legal realism's core assumption is that rules and law that govern interstate behavior are based on the distribution of power between states.¹⁷ This paradigm emphasizes that world politics are driven by the relative power positions of states and the laws they create.¹⁸ According to the theory's founder Hans Morgenthau, "universal moral principles cannot be applied to the actions of states in their abstract universal formulation, but they must be filtered through the concrete circumstances of time and place."¹⁹ This analysis of the relationship between legal realism and ethics explains that realists are aware of the moral significance of political action but are also aware of the tension between morality and the requirements of successful political action. Morgenthau introduces rationality to this theory defining rationality as a process of calculating the costs and benefits of all alternative policies in order to determine their utility and ability to maximize power.

Given these assumptions, international legal realism will help explain my research question and research findings. The primary assumption of international legal realism being that politics are driven by the relative power of states frames the dynamic of developed nations' power over developing nations in creating international patent laws. Realism's assumption of states political power as the driving force for all outcomes in world politics helps to frame this papers examination of states laws effect on international human rights. The theory's aspect of rationality helps to examine international patent law as a political economy issue due to its innate relation to cost-benefit analysis.

Conventional wisdom thinkers use the theoretical paradigm of liberalism to frame and explain their opinion on human rights issues and international intervention. The fundamental principle of liberalism is that special interests rather than state interests prevail and that peace and cooperation are in the best interest of every state.²⁰ The founders of liberalism, Immanuel Kant and

¹⁷ Professor Shelley L. Hurt, "Theoretical Paradigms of International Law," POLS 426-01 course reader (Spring 2015).

¹⁸ *Ibid.*

¹⁹ Julian Korab-Karpowicz, "Political Realism in International Relations", *The Stanford Encyclopedia of Philosophy* (Summer 2013 Edition), Edward N. Zalta (ed.).

²⁰ *Op. Cit.*, fn. 16

Adam Smith, emphasize the importance of interdependence of states and non-state actors in implementing international institutions and reform.²¹ This theory explains the conventional wisdoms rational of believing that human rights should be put before the states own interest. The theory's belief in interdependence between states frames these thinkers' desire for increased action for human rights and United Nations intervention. Liberalism helps explain an ideal way of handling human rights issues while international legal realism frames the actual situation occurring due to the restrictions imposed by patent laws.

Restrictions Imposed: Access to Medicine

The Office of the United Nations High Commissioner for Human Rights convened an expert conference on October 11, 2010 in Geneva, Switzerland to "exchange views on human rights considerations relating to the realization of access to medicines as one of the fundamental elements in achieving the full realization of the right of everyone to the highest attainable standard of physical and mental health."²² During this conference Craig Mokhiber, speaking on behalf of the UN Human Rights office, stated that "human rights law provides standards for access to medicine requiring that they are safe, affordable, of appropriate quality, and made available without discrimination."²³ He listed a number of steps that could be taken to achieve health as a fundamental human right including expanding access to off-patent drugs and price control.

The acknowledgement of patent protections as impeding access to medicine and therefore human rights standards is a central issue initially imposed by the 1994 TRIPS agreement. The agreement states that all World Trade Organization (WTO) member states are obliged to grant patents to medical inventions to encourage innovation by assuring compensation to

²¹ Juliet Kaarbo and James Ray, *Global Politics* (Boston: Cengage Learning, 2010).

²² United Nations Human Rights Council, "Promotion and Protection of All Human Rights, Civil Political, Economic, Social and Cultural Rights, Including the Right to Development," 12th Session. October 12, 2009.

²³ United Nations Human Rights, "Access to Medicines – Fundamental to the Right to Health," November 5, 2010.

recoup the high cost of developing new medicines.²⁴ These patents on medicines give drug companies the right to prevent others from manufacturing their innovation, meaning that only brand name drugs are available for 20 years from the filing date. Therefore during these 20 years, artificially high prices can be charged.²⁵ Some developing countries have viewed the TRIPS agreement as a barrier in their attempt to combat public health problems by restricting drug availability due to high cost of unaffordable medicine in countries whose health-care systems are often overwhelmed by HIV/AIDS and other infectious diseases.²⁶ Without patent protection, the production of generic drugs drives the prices of medicines down to affordable levels. For example, Prozac which during its patent period sold for \$2.50 per pill was produced by a generic manufacturer for only \$0.25 a pill after its patent ended.²⁷ This large increase in the price of medicines due to patent law has a large effect on people in developing countries who cannot afford to buy these drugs, leaving many suffering from treatable diseases. This displays the conflict between patent law and human rights due to restrictions on access to medicine through heavily increased prices, leaving millions of people in developing countries unable to achieve their right to health. The Doha Declaration was intended to be a shield for developing countries against the repercussions of universalized intellectual property standards to drug access however; pharmaceutical patents are still creating a barrier.

The Doha Declaration was a 2005 amendment to the TRIPS agreement stating that developing countries could use compulsory licenses in situations of a national emergency to access life-sustaining medicines.²⁸ Compulsory licenses are issued by governments to authorize the use or production of a

²⁴ Ian F. Fergusson, "The WTO, Intellectual Property Rights, and the Access to Medicine Controversy," (online report, U.S. Library of Congress, Congressional Research Service, December 12, 2006).

²⁵ Wendy H. Schacht and John R. Thomas, "Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984," (online report, U.S. Library of Congress, Congressional Research Service, January 10, 2005).

²⁶ *Op. Cit.*, fn. 22

²⁷ Barry Robson and O.K. Baek, "The Engines of Hippocrates: From the Dawn of Medicine to Medical and Pharmaceutical Information," (Wiley, 1 edition, 2009): 475.

²⁸ *Op. Cit.*, fn. 22

patented item by a domestic party other than a patent holder in cases of extreme urgency or national emergency.²⁹ Article 31 of the agreement limits the scope and duration of a compulsory license to address the circumstances for which the license is authorized and restricts production authorized by the compulsory license to the domestic market.³⁰ According to former European Union trade negotiator Pascal Lamy “we have solved about 10% of the problem of access to medicines in developing countries through the WTO’s action.”³¹ Even with this amendment in place, developing nations have seldom made use of the flexibility of the TRIPS agreement. Even though a developing country with no manufacturing capability may use a compulsory license to obtain a product for a generic manufacturer in another country, the generic manufacturer in the second country may have no incentive to produce such limited quantities to poor countries. In addition, under many of the proposals the product would have to use distinguishable packaging with identifiable characteristics to avoid trade diversion to other markets.³² Under such restrictions, it is not certain that a generic producer would undertake the development and formulation costs for such a limited market.³³ Thus, even though a compulsory license may be issued, the drugs may never be manufactured.

Thailand provides an excellent example of why other countries have been reluctant to utilize compulsory licensing. When the country issued a number of compulsory licenses for antiretroviral drugs by Abbott’s Kaletra, the large pharmaceutical company was angered at Thailand for ‘ignoring the patent system.’ In response, Abbott Kaletra announced it would not be applying for license to sell seven of its newest products in Thailand.³⁴ Thailand has since been repeatedly placed on a U.S. Trade Representative ‘priority watch

²⁹ *Op. Cit.*, fn. 22

³⁰ World Trade Organization, “Trade-Related Aspects of Intellectual Property,” 2015, p. 333.

³¹ “WTO Drug Pact Lifts Trade Talks,” *Wall Street Journal*, September 2, 2003.

³² Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Note from the Chairman, Paragraph 2(b)(ii), December 16, 2002.

³³ UK Commission on Intellectual Property, “Integrating Intellectual Property and Development Policy,” September 2002, p. 45-46.

³⁴ “Abbott to Withhold New Drugs from Thailand in Retaliation for Kaletra Compulsory License,” *Aidsmap*, March 15, 2007.

list' of countries seen to be committing intellectual property piracy.³⁵ Due to the repercussions larger developed nations have the potential to impose; compulsory licensing has had little effect on widening developing countries access to medicine.

Even with a compulsory license provision in place, patents are still placing restrictions on international access to medicine. Although patents have expired on a number of first-line AIDS drugs making them available cheaply from generic makers, patents still exist on most new and second-line medicines complicating the provision of HIV treatment. This is problematic as newer antiretroviral drugs are generally less toxic, making it easier to take and more effective at fighting HIV.³⁶ Drugs used to combat resistance are called second-line drugs and although the number of people in need of these drugs is expected to increase, the price of second-line drugs remains on average six times higher than drugs commonly used for first-line regimens.³⁷ One limitation of TRIPS is that the new, better drugs are only available in countries that have the capacity to cover the high cost, widening the access to treatment gap due to profit margins of large pharmaceuticals being put before public health.

In February 2009, a shipment of second-line generic antiretroviral drugs was confiscated by Dutch customs authorities. The 49kg of Abacavir sulfate tablets produced by an Indian company, Aurobindo, were bound for a treatment program in Nigeria.³⁸ The tablets were later released but the seizure highlights the tensions between the European Union's rules on intellectual property rights and World Trade Organization rules concerning the production of generic medicines.

Legal showdowns have begun to arise against the drug industry in recent years highlighting the struggle for global health equity in this patent war. This is highlighted in the 2013 landmark decision by the Indian Supreme Court whose ruling blocked global pharmaceutical giant Novartis' effort

³⁵ "U.S. Trade Representative Places Thailand on Priority Watch List in Annual Report," *Kaiser Health News*, May 1, 2007.

³⁶ "HIV/AIDS, TRIPS and Second-Line Therapy," *AVERT*, 2014.

³⁷ World Health Organization, "HIV Drug Resistance Fact Sheet," April 2011.

³⁸ "NIGERIA: Seizure of Drug Shipments Threatens ARV Access," *IRIN PlusNews*, March 13, 2009.

to patent an updated version of its leukemia-treating drug.³⁹ This decision cleared the way for mass production of a much cheaper generic version to supply lifesaving medicines for much of the developing world. However, larger currently pending agreements such as the Trans-Pacific Partnership Agreement (TTP), a free trade agreement involving the U.S. and 11 other Pacific-Rim countries, contains intellectual property provisions designed to preempt trade barriers that protect access to medicine.⁴⁰ If signed, the TPP would force all countries to grant additional drug patents, extending monopolies on medicines beyond 20 years which will delay lower-cost versions of these medicines from entering the market.⁴¹ According to Rohit Malpani, Director of Policy and Analysis at Doctors Without Borders Access Campaign, “the intellectual property provisions of the TPP completely undermine the Obama Administration’s stated public health goals.”⁴² In addition, this would pave the way for drug industry giants to avoid the kind of public interest challenges at issue in the Indian court.⁴³ Today, 26 million people worldwide are still without access to proper treatment, and the World Health Organization has recently pressed wealthy donor states for a major infusion of aid for medical treatment programs to meet their right to health.⁴⁴ Yet, those same programs are sliding on a collision course with powerful pharmaceutical monopolies from patents. Under the global intellectual property protections, the world’s poorest patients, who line up to vaccinate their children from diseases that better-off countries eradicated generations ago, are priced out of a medical market that thrives on the desire for wealth.

Restrictions Imposed: Access to Healthcare

According to a 2005 study by the National Center for Biotechnology Information, nearly 20 percent of our approximately 23,000 human genes

³⁹ Rama Lakshmi, “India Rejects Novartis Drug Patent,” *The Washington Post*, April 1, 2013.

⁴⁰ “TPP Trade Deal Will Be Devastating for Access to Affordable Medicines,” *Doctors Without Borders*, January 26, 2015.

⁴¹ *Ibid.*

⁴² *Ibid.*

⁴³ Michelle Chen, “Patents Against People: How Drug Companies Price Patients out of Survival,” *Dissent Magazine*, Fall 2013.

⁴⁴ *Ibid.*

have been patented.⁴⁵ One particularly famous case involves Myriad Genetics patent ownership of two genes, BRCA1 and BRCA2, whose mutations can dramatically increase a woman's chance of developing breast or ovarian cancer.⁴⁶ Myriad was granted seven patents in 1997 over the sequenced BRCA1 and BRCA2 genes, associated mutations and associated diagnostic tests to detect their presence.⁴⁷ These patents allowed Myriad to monopolize the diagnostic tests to look for such mutations as well as give the company a virtual lock on research and diagnostics of the BRCA1 and BRCA2 genes. Since the patent system was designed to grant certain rights to inventors in order to reward and encourage human inventiveness, existing law during this patents enactment allowed this infringement upon people's access to healthcare solely because this was being looked at as an economic issue versus an ethical issue.

In order to clarify and simplify U.S. law, the Patent Act of 1952 was created. This act states that in order to qualify for a patent, an inventor must show that their innovation is useful, novel and nonobvious and something that is a process, machine, manufacture or composition of matter.⁴⁸ In 1980, the Supreme Court of the United States decision in *Diamond v. Chakrabarty* set an important precedent for areas of patentability by ruling that laws of nature, physical phenomena, and abstract ideas are not patentable however, "manifestations of nature" are.⁴⁹ Following this ruling's guidelines, the Patent and Trademark Office (PTO) was able to begin issuing patents on three different versions of DNA isolated from the body to meet this manifestation of nature requirement. The first is "complementary DNA" or cDNA which is constructed of only the gene's base pairs which produce some of the amino acids that assemble into the body's proteins placed in the same order as they occur in the native gene omitting the other gene's base pairs.⁵⁰ The other two

⁴⁵ Kyle Jensen and Fiona Murray, "Intellectual Property Landscape of the Human Genome," *Science* 310(5746):239-240 (October 14, 2005).

⁴⁶ Wendy H. Schacht and John R. Thomas, "Gene Patents: A Brief Overview of Intellectual Property Issues," (online report, U.S. Library of Congress, Congressional Research Service, July 18, 2013).

⁴⁷ *Op. Cit.*, fn. 15

⁴⁸ *Op. Cit.*, fn. 46

⁴⁹ *Diamond v. Chakrabarty*, 417 U.S. 303 (1980).

⁵⁰ *Op. Cit.*, fn. 46

patented versions of DNA comprised isolated fragments or the whole of the raw DNA in a gene. Myriad was granted patents meeting the “composition of nature” requirement due to its findings of the chemical structure of the BRCA genes as well as “method” claims covering processes for diagnosing breast cancer.⁵¹ Myriad’s patents encompass every conceivable use of the three types of DNA, including diagnostics, therapies, drug development and the identification of other cancers involving either of the genes.⁵² However, these patents soon developed controversy over the ethical issue that Myriad’s monopolization on all aspects of research and diagnostic testing interfered with the progress of science and the delivery of healthcare services.

In May 2009, the Association for Molecular Pathology (AMP) along with the American Civil Liberties Union (ACLU) and nineteen other plaintiffs filed a lawsuit against Myriad Genetics Corporation seeking to overturn the patents on DNA isolated from two human genes, BRCA 1 and BRCA 2.⁵³ The plaintiff’s lawyers approached the suit as though it were a civil rights case, reaching beyond the technicalities of patent law to emphasize the human rights issue that the patents created which enabled Myriad to infringe the rights of biomedical scientists, physicians and patients. They contended that BRCA DNA, and by implication all human DNA, should not be eligible for patents as a matter of law since patients had suffered harm from Myriad enforcing its BRCA patent in clinics and laboratories stopping others from using the genes for cancer research.⁵⁴ Myriad’s monopolization prevented patients from obtaining a second diagnostic opinion from an independent laboratory and enabled it to charge a list price of almost \$4,000 for a BRCA gene evaluation test, a price that many women can’t afford.⁵⁵ Women were forced to trust one laboratory performing a single test to secure a diagnostic and inform treatment. Additionally, limiting gene-sequence based test services

⁵¹ Timothy B. Lee, “You Can’t Patent Human Genes. So Why Are Genetic Testing Companies Getting Sued?” *The Washington Post*, July 12, 2013.

⁵² *Op. Cit.*, fn. 15

⁵³ John R. Thomas, “Mayo v. Prometheus: Implications for Patents, Biotechnology, and Personalized Medicine,” (online report, U.S. Library of Congress, Congressional Research Service, November 6, 2012).

⁵⁴ *Op. Cit.*, fn. 15

⁵⁵ Andrew Pollack, “After Patent Ruling, Availability of Gene Tests Could Broaden,” *The New York Times*, June 13, 2013.

to a single provider interferes with medical training, practice, research, the advancement of medical knowledge and enhancement of public's health.⁵⁶ This was not in the public interest since no other laboratory could assess the reliability of its tests, improve upon their speed or cost reducing the quality of genetic testing.⁵⁷ The effects of this patent law blocked people's ability to utilize the health care service that was developed by Myriad in the first place, leaving it unavailable to many patients and unable to be further developed by outside research.

Once the result of these patent's human rights violations against people's ability to receive health care were brought to the forefront, the court reconsidered its rationale for allowing human genetics to be patented. The Department of Justice backed the plaintiff's argument by filing a friend-of-the-court brief pointing out that DNA extracted from the body was no more patent-eligible than any of the natural elements in the periodic table that had to be separated chemically from the compounds in which they occur in the earth.⁵⁸ The case was brought to the Supreme Court who decided in June 2013 that genomic DNA is ineligible for patenting under the "product of nature" doctrine holding that preexisting substances found in the wild may not be patented and that Myriad had "not created anything."⁵⁹ The court took a more favorable view of cDNA observing that it is a distinct form of DNA from which it was derived and could therefore be patented. This decision against the patenting of human genes ruled that five out of Myriad's seven patents were not eligible. Additionally, more than 8,000 genes patents have the potential to be at risk due to this decision.⁶⁰ This ruling is expected to make it difficult for inventors to protect early, gene-related discoveries through the patent system. In particular, how the courts will apply this decision to other biologic products. This ruling is a win for patients now having greater access to genetic testing and benefiting from scientists ability

⁵⁶ Michelle K. Lee, "Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena and Natural Products," College of American Pathologists, June 22, 2014.

⁵⁷ *Op. Cit.*, fn. 51

⁵⁸ *Op. Cit.*, fn. 46

⁵⁹ *Ibid.*

⁶⁰ *Op. Cit.*, fn. 55

to now engage in research on these genes without fear of being sued.⁶¹ This was the first case to examine patent laws under a human rights scope and once the restrictions that these laws created were brought to court, the court unanimously decided against the ability to patent human genetic material.

The Myriad holding will have far-reaching and long-term implications for international patent law. The United States being a global hegemon, especially in holding patent laws, means that its Supreme Court decision on the Myriad matter is likely to be a leader for other jurisdictions to follow similar standards. This decision sets the United States apart from economic rivals when it comes to rules on patenting genes. For example, the European Patent Office (EPO) grants patents for inventions related to gene sequencing as long as applicants can demonstrate the industrial application of the sequence.⁶² Australia, Canada and Japan have similar rules, allowing the patenting of human genes as long as they are isolated and the patent application explains how the genes are useful.⁶³ These jurisdictional differences means that the U.S. Supreme court decision does not directly impact patents in these jurisdictions, however the ruling has already made other countries reconsider their patent standards. In 2014, a Canadian Children's Hospital of Eastern Ontario filed a court challenge with the ultimate goal of invalidating patents on human genes, the first court challenge to the country's Patent Act, which is hoping to follow the U.S. Supreme Court's case rational for striking down these patents.⁶⁴ The global implications of the Myriad decision create a new revelation of viewing patent laws as having the potential to be viewed as a human rights issue which could greatly affect the way all patents are seen.

So What? Research Implications

The implications of my research findings display that there is a crucial need to re-evaluate the effects that intellectual property rights impose. The technology is available to provide developed and developing nations with access to medicines and treatments that could save millions of suffering

⁶¹ Emma Barraclough, "What Myriad Means for Biotech," *World Intellectual Property Organization*, August 2013.

⁶² *Ibid.*

⁶³ *Ibid.*

⁶⁴ Sheryl Ubelacker, "Human DNA Patents Challenged By Canadian Hospital," *The Huffington Post*, November 3, 2014.

lives, yet it is unutilized to its full extent due to intellectual property laws giving corporations the right to maximize its profit. The ability to invalidate patents, as well as their human rights restrictions, when examining the effects they impose on peoples access to treatment displays that this new method of evaluation could have a large influence on what is patentable internationally. The development of a human rights framework for intellectual property can provide government officials, international jurists, and states an opportunity to influence the framework's substantive content and the procedural rules that mediate relationships between these two components.

The International Covenant on Economic, Social and Cultural Rights (ICESCR) has been a major international human rights instrument addressing the issue that patent laws should allow everyone to both “enjoy the benefits of scientific progress and its applications” and “enjoy the benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production.”⁶⁵ This research brings to light how patent laws are beginning to be looked at as human rights issues yet, still have a ways to go to ensure that access to health is achieved for everyone. The trend of examining the importance of human rights has been on the rise since World War II. With increased knowledge from globalization on these issues coupled with this research's implications of restrictions on health, these findings have the ability to reshape international law and increase access to the benefits of scientific innovations.

⁶⁵ International Covenant on Economic, Social and Cultural Rights, adopted 16 December 1966, 993 U.N.T.S. 3 (entered into force 3 January 1976), G.A. Res. 2200 (XXI), 21 U.N. GAOR Supp. (No. 16), p. 49, U.N. Doc. A/6316 (1966).