

RETHINKING GENE PATENTS

By Richard A. Spinello and Sarah Cabral

1 Introduction

The dispute over gene patents has intensified in recent years thanks to several prominent legal cases and an anticipation that genomics will soon deliver on its promises of new drugs and therapies. We propose to analyze this debate primarily from a moral perspective. We also consider the policy perspective and in particular the suitability of international intervention. Are the stakes high enough to warrant adjustment to the international intellectual property trade agreement known as TRIPS in order to prevent further patenting of the human genome? We maintain that while gene patents are legally and morally suspect, such multilateral intervention would be inadvisable. The complexities of this issue cannot be sorted out without understanding something about human genomics, and so we begin with this topic.

Cells are the basic units of all living organisms. Within cells are the nuclei or life force of the cells. DNA and RNA are the nucleic acids found in an organism's cells, and DNA is the molecule that stores genetic material. There is about six feet of DNA within the nucleus of every cell. DNA is composed of genes, which are really “stretches” or strains of that DNA. Genes are organized into chromosomes and it is through chromosomes that genetic information is transmitted. A human's chromosomes contain approximately 30,000 genes, and this complete set of genes is known as the human genome [Klug and Cummings, 1996]. These genes contain the biological information necessary for making certain proteins. In effect, each gene is analogous to a sentence with a four-letter alphabet, A, T, C, and G (representing the nucleotide bases that form the genes: adenine, thymine, cytosine, guanine) which combine in pairs to communicate with the cell and instruct its development in certain ways. It's this genetic information, for example, that instructs cells to make black hair instead of brown hair [Mitchell, 2004].

The Human Genome Project mapped and sequenced these genes. This effort has enabled genetic testing and also created opportunities for various gene therapies. Through a blood test or tissue sample it is possible to determine aspects of an individual's genetic status, which, in conjunction with the human genome map, will allow doctors to determine if an individual has defective genes that predispose that individual to a chronic illness. For example, researchers have isolated two genes, BRCA 1 and 2, which function to suppress breast tumors. When a problem or mutation occurs with either of these genes, breast cancer can be the result. Once genetic diseases have been diagnosed the goal is to develop therapies that correct the mutation. Consider the disease known as phenylketonuria that is triggered by a mutation to a gene that breaks down the molecule called phenylalanine which can cause brain damage if it builds up in the bloodstream. The optimal cure is to repair this defective gene so that the person's metabolism is restored to a normal state [Zimmer, 2012].

Cancer has been at the forefront of genetic research and medicine since the mapping of the human genome was completed and published in 2003. Scientists are now convinced that cancer is a genetic disease: it originates in a genetic mutation that is promoted by environmental factors. Genomics has led to limited success in cancer treatment such as PLX4032 which inhibits the activity of mutated proteins in patients with melanoma and causes those cells to die [Carr, 2010]. Many similar therapies are on the horizon and the whole biotech industry stands to gain, but who appropriates the value from these discoveries depends to a large extent on how the issue of gene patents is resolved.

2 Patenting the Genome: Precedents and Antecedents

Patents are controversial but necessary. Most forms of technological investment require significant investment and inventors need the reward of a patent, or some sort of protection for their investment as an inducement to commit capital. Patents give inventors a property right in their innovation so that they can appropriate the value of their added value without interference from free riders. Without patents, competitors would enter the market and free from the burden of paying for research costs force the price down to the marginal cost of production, making it exceedingly difficult for the innovator to recover his costs. Thus, the patent system prevents others “from reaping where they have not sown” and thereby promotes research and development investment [Dam, 1994]. While it is generally admitted that patents enhance social welfare by encouraging ingenuity, there are costs associated with the patent system such as impediments to cumulative innovation along with foregone consumer surplus associated with economic rents. There is also the social cost associated with administering the patent system. The objective of policy makers should be a balanced patent policy that rewards technological innovation while also minimizing these costs by ensuring that patents are awarded prudently.

According to the U.S. Patent Act [U.S.C., 2006] a patent is to be awarded to “whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof.” Thus, a patent eligible invention must satisfy the criteria of novelty and utility, and it must fall under the category of a process, machine, manufacture, or composition of matter. Over the past few decades the scope of patent protection has been expanding to include, software, surgical procedures, research tools, and business methods. Even living organisms are now patentable subject matter under certain conditions. In the famous *Diamond v. Chakrabarty* [1980] case the judges opined that the patent statute should cover “anything under the sun that is made by man.” The Court ruled that genetically altered life forms such as plants and animals could be patented. This ruling in conjunction with the *Moore v. Regents of University of California* [1990] case, which stated that people do not own their DNA and that such DNA can be owned by researchers, opened the door for the patenting of genetic material.

There are, however, still exceptions to patentable subject matter, most notably, laws of nature, physical phenomena, and abstract ideas. Thus, algorithms and formulas, existing material elements, and plants and animals cannot be patented since they are discovered

rather than invented. Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none” [Funk Brothers v. Kalo, 1948]. However, if a naturally occurring substance is altered, perhaps through the introduction of genetic material, the new result would typically be a “non-naturally occurring manufacture or composition of matter – a product of human ingenuity,” and therefore something eligible for a patent. The focal issue or “relevant distinction” is between products of nature and human made inventions. In the Chakrabarty case human intervention resulted in bacteria that had markedly different characteristics from nature and “the potential for significant utility” and so was deemed to be patent eligible. On the other hand in Funk Brothers [1948] the Supreme Court ruled that a patent for multiple naturally occurring bacterial strains was invalid. According to the guidelines put forth in that case, an invention that “serves the ends nature originally provided” is most likely unpatentable subject matter but an invention that expands the “range of utility” when compared with nature is apt to be patent eligible.

In keeping with legal precedent and the apparent wishes of Congress, the U.S. Patent and Trademark Office (PTO) has issued patents for DNA molecules (or genes) for the past thirty years. Over 2,600 patents for isolated DNA have been awarded over that period. The U.S. Congress has not yet taken any action to curtail such patents. As a result, the Courts have been reluctant to nullify these patents and so typically rely on the clear and flexible precedent of cases such as Funk Brothers and Chakrabarty to analyze patent claims and to determine whether or not there is some expansion of utility when compared to nature.

While many gene patents have been granted, the validity of such patents has been the subject of intense debate. Discussion has polarized between those who claim isolated DNA is a product of nature and those who see this isolated and purified substance as a legitimate invention. Several high profile law suits have contested the validity of these patents. At issue in these cases is whether or not isolating DNA from its native environment amounts to an invention. Or does it remain a product of nature? The isolated human gene or DNA differs from the native gene to the extent that the extraction process results in changes to its molecular structure. The native genes are chemically bonded to other genes and proteins. The isolation process not only separates out impurities but also changes the chemical bonds so that the isolated DNA is no longer connected to thousands of additional nucleotides as it is in its native state. Perhaps the most critical question in this dispute hangs on whether cleaving those bonds to isolate a gene transform that isolated gene into different and hence patentable material? Those who support gene patents argue in the affirmative and claim to have science firmly on their side. However, even if we concede that isolated DNA is chemically different, does it have a new utility (as required by Funk Brothers, 1948) or does it just serve the same ends intended by nature, that is, to function as a gene encoding a protein sequence?

Aside from the technical and scientific questions, there are obviously social and moral issues at stake. Opponents of gene patents insist that these isolated genes are products of nature and maintain that they these unwarranted patents cause “inexcusable and intolerable societal harms” [Eli, 2011]. They cite the many problems with “oppressively

monopolistic patents,” including the detrimental exclusionary effects of this enclosure of the genome [Eli, 2011]. Supporters, on the other hand, offer utilitarian arguments based on the necessity of patent protection to induce biotech innovations. They also point to firm legal precedent and the cloud of uncertainty that would envelop the biotech industry if these patents were now invalidated.

3 The Myriad Genetics Case

There have been several high profile cases involving gene patents or medical testing patents. In *Amgen, Inc v. Chughai Pharmaceuticals Co.* [1991] the court validated a claim that isolated DNA encoding human erythropoietin was eligible for patent protection. Although the U.S. Supreme Court has not yet directly address this issue in 2012 it invalidated Prometheus Laboratories process patents that help doctors determine drug doses for patients with Crohn’s disease. Prometheus’ patents combined a law of nature about how the body metabolizes certain drugs with a set of routine steps for applying that knowledge. The Court said that the patents merely “recited” laws of nature, and since the laws of nature are not patentable neither can the claimed process or tests be eligible for patent protection [Mayo v. Prometheus Laboratories, 2012]. Legal scholars believe that this decision could have ramifications for the gene patent issue.

But the most relevant case for our purposes is clearly *Association for Molecular Pathology v. United States PTO* [2010, 2011]. The patent holder in this case, a company called Myriad Genetics, claimed an isolated piece of DNA containing the nucleotide sequence that translates into either the BRCA1 or BRCA2 protein. Relying on DNA samples from families with inherited breast cancer, Myriad had identified this DNA sequence that codes for these proteins. It was awarded patents in 1997 covering these isolated DNA sequences and associated diagnostic methods.

These patents have a “preemptive effect,” since they exclude anyone from working with the BRCA genes without permission. Only Myriad can commercialize this discovery through the development of diagnostic screening tests, gene therapies, or other products. In addition to the patenting of this isolated DNA, the patent holder also claimed a product called cDNA, which is the “mirror image” of the DNA sequence. cDNA does not normally exist in the human body, and is naturally created only through the operation of certain retroviruses. Transforming normal DNA into cDNA, however, provides a more efficient tool for researchers and health care professionals who wish to study, diagnose, and treat the disease associated with a gene.

Along with its patents for the BRCA genes, Myriad was also awarded a patent for the method of determining whether a person is predisposed to the relevant form of cancer by comparing the person's gene sequence to the sequence in nature that codes for either BRCA1 or BRCA2. Finally, Myriad received a patent for the method of determining whether a particular cancer therapy is efficacious by growing cells containing the

relevant gene and determining whether those cells grow more slowly when subjected to that therapy.

A lawsuit by a group of genetic researchers contested the validity of these patents, arguing that the BRCA genes are “natural human genes” or products of nature. As such, they are unpatentable subject matter and hence invalid under statute § 101. The plaintiffs also maintained that the monopoly of these genes enabled by the patent interfered with the capability of patients to obtain better cancer screening tests. The District Court agreed with the plaintiffs and rejected all of the Myriad patents reasoning that since the purification of natural DNA does not alter its inherent characteristics, isolated DNA remains a product of nature. The court concluded that “because the claimed isolated DNA [was] not markedly different from native DNA as it exists in nature, it constituted unpatentable subject matter” [Association for Molecular Pathology v. United States PTO, 2010]. The court also invalidated Myriad’s method claims.

On appeal, the Federal Appeals Court ruled in favor of the patent holder, reversing the decision of the lower court. Following the framework laid out in the Supreme Court’s decisions in *Chakrabarty* and *Funk Brothers*, this court reach a different set of conclusions. It reasoned that due to human intervention the isolated DNA did exist in a distinctive chemical form and therefore was different from DNA in the human body (or native DNA). Isolated DNA has been cleaved or severed from chemical bonds so that it consists of just a fraction of the naturally occurring DNA molecule. Since isolated and purified DNA has this “markedly different” chemical structure it is eligible for a patent. Moreover, after decades of genetic patents and a pattern of firm judicial precedent, including *Chakrabarty* and *Moore*, the court concluded that it could not now call isolated DNA as non-patentable and thereby disrupt the “settled expectations” of the scientific community [Association for Molecular Pathology v. United States PTO, 2011]. The court also rejected plaintiff’s argument that isolated DNA and native DNA are not different because they have the same genetic function of transferring information. According to the court, it’s not the use of this isolated DNA that determines patent eligibility but its distinctive nature. As result, the Court declined to extend the “laws of nature” exception to include isolated DNA sequences. At the same time, the Appeals Court affirmed the two method patents, one for comparing and analyzing DNA sequences and the other for screening potential cancer therapeutics by way of changes in cell growth rates. It criticized the District Court for creating this sweeping rule that isolated genes are not patentable, and quoted the Supreme Court which has more than once cautioned lower courts not to “read into the patent laws limitations and conditions which the legislature has not expressed” [Diamond v. Diehr, 1981].

4 Legal and Normative Analysis of BRCA Patents

Arguably, a more balanced and legally nuanced outcome would have supported the patentability of the cDNA claims, and the patentability of the method claims, while holding that isolated DNA sequences or BRCA gene patents should be voided. By

simply isolating the BRCA genes through extracting them from their natural location and incidentally changing their molecular structure in the process seems an insufficient basis for a patent. It is certainly dubious that the cleaving or breaking of chemical bonds transforms the isolated genes into a new substance as the Court has supposed. Thus, this innovation appears to still fall on the side of products of nature as something discovered but not invented. As an amicus curiae brief for the plaintiff stated, awarding a patent for the discovery of the BRCA gene is like awarding a patent for the discovery of a chemical element such as lithium. On the other hand, cDNA cannot be isolated from nature but must be created in the laboratory so it should be patent eligible. Similarly, assuming that the method claims meet the general criteria for method patents, they too should be considered patent eligible so that researchers can reap the rewards from the application of its discoveries [Bilski v. Kappos, 2010]. Such a solution balances the innovator's reward with the preservation of open access to the human genome for the sake of future research.

Hence, researchers or biotech companies like Myriad should not be able to obtain patent rights to isolated and purified DNA sequences on the legal basis that this does not constitute patentable subject matter. Although different in molecular structure, those DNA sequences have not been sufficiently modified, so they are still fundamentally the same entities as they were in their natural state. Also, why isn't the issue of utility relevant in this case as it is in other patent cases? Isolated DNA offers no new utility, since it serves the same function it did in nature.

Patents will mean that other researchers are pre-empted from using these mutant genes for their own scientific work. As one dissenting judge in the Molecular case stated, "broad claims to genetic material present a significant obstacle to the next generation of innovation in genetic medicine—multiplex tests and whole genome sequencing" [Association for Molecular Pathology v. United States PTO, 2011]. The purpose of patent protection is to stimulate innovation but sometimes too much protection can impede rather than promote innovation. Given these valid preemption concerns and the proximity of these modified genes to native DNA, the justification for BRCA patents appears to lie on tenuous legal ground.

How should this decision be assessed on purely normative grounds? A utilitarian analysis is probably indeterminate, since it would be difficult to resolve this debate on the basis of cost benefit analysis. A Lockean analysis, on the other hand, holds more promise for probing the moral issues in this case. Recall the essentials of Locke's theory. A person has a property right, that is, the right to exclude others, in his person, in his actions and labor, and in the products of that labor. Thus, Locke relies on a labor theory justified by this thesis of self-ownership to demonstrate why property rights are warranted when someone adds his or her labor to what is held in common. As Locke explains, "Man has a Property in his own person. This no Body has any right to but himself. The Labor of his Body and the Work of his Hands we may say are properly his. . . Whatsoever then he removes out of the State that Nature had provided. . . he hath mixed his Labor with and joined to it something that is his own, and makes it his Property [Locke, 1988]. There have been many discussions of Locke demonstrating how this theory applies both to

physical and intellectual property, since production of the latter also involves creative effort and labor. As Easterbrook [2005] points out, “intellectual property is no less the fruit of one’s labor than is physical property.”

On the surface, it may seem that a property right is well deserved in this case given that there is substantial labor involved on common property. The laborious and time consuming efforts in mapping the physical location of the BRCA genes (with the help of DNA samples), the determination of the exact nucleotide sequences, and the cleaving and purifying efforts to isolate the DNA seem to warrant a property right of some sort. Also, although this research is initially based on DNA samples, those who provide these samples have no ownership claims. Ownership was the central issue in *Moore v. Regents of the University of California* [1990]. John Moore filed suit against researchers at the University who patented a cell line from the tissues derived from his diseased spleen once it was surgically removed from his body. The California court ruled against Moore’s claim of any proprietary right over this genetic material. Similarly, in *Greenberg v. Miami Children’s Hospital Research Institute* [2003] a Federal District Court found that the patent for the gene for Canavan’s disease which was discovered from Greenberg’s tissue sample did not violate the rights of the donor since that donor has “no cognizable interest in body tissue and genetic matter. . . .”

Despite these factors, however, there are two reasons why patents are not warranted according to Locke’s framework. First, for Locke, labor gives rise to a property right only when it transforms and adapts something from the state of nature. This standard should have a higher threshold for intellectual (as opposed to physical) resources. The creator awarded an intellectual property right must create something new and distinct from the public domain, something that goes beyond what already exists there as an intellectual object (such as an idea or formula) or a naturally occurring substance. There is some question in this case whether the labor of researchers like Myriad is transformative enough to warrant a property right since, as we have seen, some argue that isolated DNA is not “markedly different” from native DNA. Locke is always insistent that labor must put a “distinction” between what is worked upon and the commons. In discussing how the collection of apples or acorns from the commons bestows a property right on the collector Locke says: “That Labor put a distinction between them [acorns and apples] and common. That added something to them more than Nature, the common mother of all, had done; and so they became his private right” [Locke, 1988]. But does the discovery and isolation of a DNA segment (such as the BRCA gene) create a decisive distinction by adding something “more than nature” to create the type of property boundary required by Locke’s theory? Didn’t Myriad discover these genes, which are part of our bodies and which contain fundamental information about humanity, rather than actually invent them? Does the purification and cleaving process really result in a new, distinct substance or composition of matter? As the dissent points out in the *Association for Molecular Pathology* [2011] case, “there is no magic to a chemical bond that requires us to recognize a new product when a chemical bond is created or broken.” The breaking of these bonds and other purifying efforts do not result in structural or utility difference between the native BRCA gene and the gene in its isolated state. If patents were awarded for these genes,

why not for chemical elements like lithium which also must be isolated for industrial applications but which is the same element whether it is in the earth or isolated.

Second, even if it could be argued that isolated DNA is distinct enough from native DNA, a patent would still be inappropriate when scrutinized through the lens of Locke's theory. While Locke believed in property rights based on labor he did not support unlimited rights. Locke insists on an important condition limiting the acquisition of property which is referred to as the sufficiency proviso. According to this principle, one cannot appropriate an object from the commons through labor unless there remains enough resources of the same quality for others to appropriate. According to Locke, "For this Labor being the unquestionable Property of the Laborer, no Man can have a Right to what that is once joined to, at least where there is enough, and as good, left in common for others" [Locke, 1988]. This proviso, which should apply to both physical as well as intellectual property, clearly limits the right to appropriate property. Appropriators, therefore, must leave sufficient resources and "equal opportunity" for others, though some commentators on Locke have suggested a more flexible limitation such that an appropriation should not worsen the situation of others [Waldron 1988].

Moore [2004] frames this proviso in terms of weak Pareto superiority, which permits individuals to better themselves through the appropriation of property so long as no one is made worse off in the process. In cases where no one is harmed by such an appropriation, it is "unreasonable to object to a Pareto-superior move." Thus, if the acquisition of an intangible work or patentable subject matter makes no one worse off in social welfare terms, compared to how they were before the acquisition, then an intellectual property right is valid. For most intangible works such as novels or poems, no one is made worse off by the acquisition (provided that the presumptive property right is given to the expression of ideas and not the ideas themselves), and the labor creates a prima facie property claim to that work.

However, this is not the case with the patenting of isolated DNA sequences which cannot pass the Pareto superiority test. The patenting of the BRCA genes is not consonant with even this more flexible interpretation of Locke's proviso, because it does make others worse off by preempting them from using these valuable genetic resources. These preemption concerns, which gave rise to the plaintiff's law suits against Myriad, signal a problem from a Lockean perspective. When patents inhibit future discoveries and innovation by locking down natural phenomena or laws of nature they must be inconsistent with Locke's proviso. In this case, Myriad's BRCA patents do not leave sufficient resources for other potential appropriators. When genes are patented, researchers are constrained from studying the genetic basis of a disease such as Canavan's disease without the payment of a steep licensing fee to the patent holder. In some cases, companies refuse to license their patents and products, and thereby foreclose research all together. Myriad itself has been accused of this exclusionary behavior [Holman, 2007]. Myriad does not allow others to perform diagnostic tests that reveal increased risk of breast cancer and its patents foreclose research opportunities for the development of improved tests. Also, it is alleged that

these gene patents impede the development of tests for other diseases, since the BRCA mutation may be responsible for certain chronic afflictions other than breast cancer [Eli, 2011]. By enclosing this genetic information through these broad claims to genetic material, Myriad precludes others from making their own appropriations, such as the invention of new diagnostic tests for breast and other cancers, or from even sequencing BRCA genes, through their own productive labor. Hence, despite the arduous labor involved, the patents awarded in this case lack a moral foundation since many others are made worse off through this initial appropriation and subsequent exclusion.

Patents for diagnostic methods and therapies, on the other hand, have a much better chance of satisfying a Pareto-based proviso, if they are awarded properly and do not involve patenting or “reciting” laws of nature in ways that tie up the future use of those laws. The criteria for process or methods patents is beyond the scope of our discussion, but the U.S. Supreme Court has recently clarified those guidelines insisting that a process is not patentable “unless that process has additional features that provide practical assurance that the process is more than a drafting effort to monopolize the law of nature itself” [Mayo Collaborative Services v. Prometheus Laboratories, 2012]. Assuming they meet these criteria, companies like Myriad should be allowed to patent the applications of their discoveries of the BRCA genes such as diagnostic tests, so long as these patents are not preemptive and, in the spirit of Locke’s proviso, they leave sufficient resources for others.

The Appeals Court that decided the most recent Myriad case validating their gene patents asserted that it is not their duty to re-write the law or change policy. Courts should defer to the legislators who are elected to make laws. However, there is certainly ambiguity about whether or not patents for DNA molecules, which are the physical embodiment of nature’s laws, are consistent with the precedent of Chakrabarty and Funk Brothers. This ambiguity should be resolved, and U.S. patent policy should be adjusted to preclude this type of broad gene patent, based on reasoning that takes into account the normative demands suggested by Locke’s theory which point to the harm caused by the dangerous preemptive effects of these patents.

5 The International Controversy: Human Gene Patents and TRIPS

Concurrent with the debate going on in the United States over human gene patents is an international debate regarding whether or not there should be a specific exclusion of human genes from patentability in the World Trade Organization’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The intellectual property agreements often referred to as TRIPS consist of provisions protecting copyrights, trademarks, geographical indications, industrial designs, patents, integrated circuit layout designs, and undisclosed information and trade secrets. Since the WTO, including TRIPS, went into effect in January 1995, some of the most controversial provisions of TRIPS have been those regarding patent protection, a subject covered in Articles 27 through 34. According to these Articles, every member nation must protect patents for twenty years after the patent is filed (Art. 33). Although patents apply to any invention,

product and/or process that is novel, inventive and applicable to the relevant industry (Art. 27.1), there are three types of inventions that can be excluded from patentability, including inventions contrary to morality, diagnostic, therapeutic, and surgical methods for the treatment of humans or animals, and plants and animals other than microorganisms (Art. 27.2, Art. 27.3a, Art 27.3b). In addition, compulsory licensing and government use without the authorization of the patent holder are allowed under certain conditions (Art. 31). The language of TRIPS Article 27.3(b) is ambiguous, such that member nations can either exclude gene patenting, allow gene patenting, or allow for “purpose-bound protection,” which protects the specific use of the gene disclosed in the patent but not the gene, itself [Carlos, 2007].

At its meeting in March 2002, the TRIPS council surveyed representatives of member nations, regarding their own national patenting practices. Although no question on the survey explicitly raised the issue of human gene patenting, representatives addressed patenting isolated DNA sequences in their responses to what is and is not patent-eligible in their country. The following countries identified that while it is not possible to obtain a patent covering subject-matter identical to that found in nature, it is possible to patent biological material which is isolated from its natural environment: Bulgaria, Canada, Australia, Switzerland, Czech Republic, European Communities, Estonia, Hong Kong, Iceland, Japan, Norway, Poland, and the United States [WTO IP/C/W/273, 2003].

6 Should the WTO Amend TRIPS Article 27.3(b)?

Although citizens of the developed world are advocating for the WTO to amend TRIPS to exclude gene patenting, by and large, the representatives of developed nations on the TRIPS council are against increasing specificity in the TRIPS agreement, in order to maintain flexibility in the application of the agreements. However, the representatives of many developing and least-developed nations on the TRIPS council, especially Bolivia, hold that the patentability of life forms ought to be explicitly excluded.

Though many WTO representatives of developing and least developed nations are eager for an amendment to TRIPS, it was the representative of Bolivia who sent a memorandum in February 2010 to all the member nations of the TRIPS council highlighting the “need to urgently review Article 27.3(b) to prohibit the patenting of all life forms, including plants and animals and parts thereof, gene sequences, microorganisms as well as all processes including biological, microbiological and non-biological processes for the production of life forms and parts thereof” [WTO IP/C/W/545, 2010]. The representative of Bolivia reasoned that 1.) Patent holders and applicants are from developed countries, 2.) Patents prevent those in developing countries from using patented material, and 3.) The patenting of life forms is “unethical, as it is against the moral and cultural norms of many societies and indigenous people” [WTO IP/C/W/545, 2010].

At the June 2010 TRIPS council meeting, the memorandum from the representative of Bolivia became the subject of a debate on human gene patenting. The representative of Bolivia began the conversation, claiming that Article 27.3(b) actually encouraged the

patenting of genes and gene sequences [WTO IP/C/M/63, 2010]. He also addressed the ethical dimension of human gene patenting again, noting that “the patent system had turned into a tool for the privatization and commercialization of life itself on a scale and magnitude that warranted concern” [WTO IP/C/M/63, 2010]. Representatives from developing and least-developed countries, including Brazil, Venezuela, Ecuador, Pakistan, Zimbabwe, Holy See, Nigeria (on behalf of the African Group), and Angola (on behalf of the Least-Developed Countries Group) aligned themselves with the Bolivian representative.

Many representatives of developed nations of the WTO, including representatives from Switzerland, the United States, the European Union, Japan, and Australia, and Canada, argued that there should be no amendment to Article 27.3(b) of TRIPS. The representatives of Switzerland and the United States defended their position, by pointing to the stimulation of investment and the generation of benefits to mankind due to patent rights. The United States representative went on to state that “life forms and methods related to life forms should be patentable if they [meet] the requirements of patentability, especially novelty, inventive step and industrial applicability” [WTO IP/C/M/63, 2010]. It is not surprising that the United States, Switzerland, and the European Union are upholding strong patent protection for biotechnology inventions, since these nations are home to almost all of the top 100 biotechnology firms [MedAdNews, 2007].

There was no action plan established to amend Article 27.3(b) after the debate that occurred at the June 2010 meeting of the TRIPS council. A large constituent, those against amending TRIPS, noted that the patentability of life forms, as they exist in nature, are excluded through the application of TRIPS, as it now stands. The representative of Chile noted that “the three essential requirements for patentability set forth in Article 27.1 of the TRIPS agreement, i.e. novelty, inventiveness and industrial application, should be applied and respected in full, and, if this [is] the case, there should be no contradiction or conflict with misappropriation of naturally occurring life forms” [WTO IP/C/M/63, 2010]. However, the controversy still remains, since “novelty” and “inventiveness,” as they relate to human gene patents, are left up to each member nation’s interpretation. It is, therefore, up to national judicial systems to determine what is patent-eligible or patent-ineligible.

One suggested solution for achieving a more consistent application of TRIPS is to create an international, comprehensive database of patents. This was suggested by the representatives of Chile and Japan. The representative of Chile said that it was “essential” that “national and regional patent offices have access to all the information available to avoid granting erroneous patents that did not comply with the patentability requirements” [WTO IP/C/M/63, 2010]. The rationale behind the database is that precedents would be set for the international community, regarding what is and is not a novel or inventive use of life forms.

7 Conclusion

In this paper we have demonstrated why gene patents, such as those awarded for the BRCA genes, are unwarranted. Their legal justification is dubious, since it is questionable that isolated DNA is an invention rather than a discovery and a product of nature. A normative analysis confirms this judgment. While utilitarian reasoning is indeterminate, a Lockean analysis strongly suggests that these patents cannot be justified because they are inconsistent with Locke's proviso due to their preemptive effects. Although we argue isolated DNA is patent-ineligible, we do not think it necessary that the TRIPS council amend article 27.3(b), so that it explicitly excludes human gene patenting. However, we do think that the TRIPS council should offer specific recommendations encouraging member nations to view isolated DNA patent-ineligible for the reasons delineated in this paper. There is support for excluding human gene patentability among the citizens of many developed nations, and that support includes some government officials, members of medical associations, geneticists, patients, and human rights and consumer activists actively engaged in advocating against the patenting of human genes. If public pressure continues to mount against gene patenting, we are reservedly confident that the judicial and legislative branches of developed nations will soon disturb the "settled expectation" of the biotech industry.

8 References

- Amgen, Inc v. Chughai Pharmaceuticals Co. (1991) 927 F.2d 1200 (Fed. Cir.)
 Association for Molecular Pathology v. United States PTO (2011). F. 3d 1329 (U.S. App).
 Association for Molecular Pathology v. United States PTO (2010). 702 F. Supp. 2d 181 (U.S. Dist).
 Bilski v. Kappos (2010). 130 U.S. 1238.
 Carr, G. (2010), Special report on the human genome. *Economist*, June 19, 3-7.
 Correa, C. (2007), Patenting Human DNA: What Flexibilities Does TRIPS Allow? *Journal of World Intellectual Property*. 10, 419-437.
 Chakrabarty v. Diamond (1980). 447 U.S. 303.
 Dam, K. (1994). The Economic Underpinnings of Patent Law, *Journal of Legal Studies*, 23, 247-271.
 Diamond v. Diehr (1981). 450 U.S. 175.
 Eli, L. (2011). When Myriad Genetics Prohibited a Myriad of Options. 21 *DePaul Journal of Art, Technology and Intellectual Property* 357.
 Easterbrook, F. (2005). Intellectual Property is still Property, in Moore, A. (ed.) *Information ethics*, University of Washington Press, 113-122. .
 Funk Brothers v. Kalo Inoculant Co. (1948). 333 U.S. 127.
 Greenberg v. Miami Children's Hospital Research Institute (2003). 264 F. Supp.2d 1064 (S.D. FL.)
 Klug, W. and Cummings, M. (1996). *Essentials of genetics* 2nd ed., Prentice-Hall.
 Holman, C. (2007). The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation," 76 *UMKC Law Review* 295.
 Locke, J. (1988). *Second treatise of government*, Laslett, P. (ed.), Cambridge University Press.

- Mayo Collaborative Services v. Prometheus Laboratories (2012). 566 U.S. 181.
- MedAdNews (2007). Top 100 Biotechnology Firms.
- Mitchell, B. (2004). The New Genetics and the Dignity of Humankind, in Colson C. and Cameron, N. (eds) Human dignity in the biotech century, Interscience Press, 60-74.
- Moore v. Regents of the University of California (1990) 793 P.2d 479 (Cal. S. Ct.).
- Moore, A. Intangible Property: Privacy, Power, and Information Control, Information ethics, 176-180.
- U.S.C. (2006) 35, § 101.
- Waldron, J. (1988). The right to private property, Oxford University Press.
- World Trade Organization (2010). Review of Article 27.3(b) of TRIPS Agreement: Communication from Bolivia. IP/C/W/545, 1-5.
- World Trade Organization (2010). Minutes of Meeting on 8-9 June 2010. IP/C/M/63, 3-22.
- World Trade Organization (2003). Review of the Provisions of Article 27.3(b): Illustrative List of Questions. IP/C/W/273, 13-32.
- Zimmer, C. (2011). Hope, Hype, and Genetic Breakthroughs, The Wall Street Journal March 11, C6.