Transforming Gene Patentability and Removing the Need for Courtroom Genetics

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I. Introduction

The American legal literature is brimming with differing court opinions that have slowly shaped most all of this nation's bioethical debates.[1] On the one hand, American case law has been more reactive than directive in tackling topics such as the right to abort a fetus, the right to die, or the general right to privacy within the physician-patient relationship.[2] On the other hand, the interpretation of these topics is complicated by the simple fact that they call for wide interdisciplinary coverage.[3] Most recently, the leading bioethical and legal debate revolves around genetics, specifically, the right to patent genes as well as the diagnostic tests that detect the presence of those genes.[4]

The questions raised by human gene patents are some of the most difficult to answer in the fields of law, medicine and bioethics today. Patent rights over genetic material are important because they provide necessary incentives for researchers to invest time and money to discover the very fabric that makes up the inner structure and function

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[1] Roe v. Wade, 410 U.S. 113 (1973); Cruzan v. Director, Missouri Department of Health, 497 U.S. 261 (1990); Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 883 (1992); Washington v. Glucksberg, 521 U.S. 702 (1997).

[2] Stephen Latham. (2014) *U.S. Law Basics*. Seminar on Law & Bioethics. New Haven, CT: Yale University.

[3] *Id.*

[4] Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329 (2011); Mayo v. Prometheus, 556 U.S. 10-1150 (2012); Association for Molecular Pathology v. Myriad Genetics, 569 U.S. 12-398 (2012).

of our being.[5] In the context of genetic diagnostics, these incentivized discoveries are aimed at detecting inherited qualities that influence predictive or latent conditions so that patients can prepare for their future health and wellbeing.[6] However, the law's normative conclusion is that the ultimate purpose of patents is to promote and foster innovation.[7] That said, the present patent system is lacking an appropriate balance between patient access to these diagnostic materials and incentives for innovation.[8] By looking through certain ethical lenses, we can see the need to custom-create a patent structure specific to genetic material that stimulates ambitious and costly innovation, yet also provides adequate patient safeguards to accessing these biotechnologies.[9] It will become clear that

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[5] *Patenting Genes: Pros and Cons*, GENETICS GENERATION: EDUCATION IS OUR MOTIVE, *available at* http://knowgenetics.org/patenting-genes-pros-and-cons/, ("[Patent protection] encourages research and development in private industry. Patents support innovation and invention by giving companies rights to gene sequences. The lure of potential patent drives and pushes researchers to think creatively and work harder in order to obtain a patent for their work. […Patents] provide opportunities for investment in research and development. Companies, as well as individuals, can invest in a patented gene. This provides financial support for the development of useful innovations. It can take hundreds of millions of dollars to introduce a new drug to the market. Most companies do not have this money and rely on financial assistance.").

[6] Yanming Fend, et al., *Improved Molecular Diagnosis by the Detection of Exonic Deletions with Target Gene Capture and Deep Sequencing*, AM. COLLEGE OF MED. GENETICS AND GENOMICS, 1 (2014), *available at* http://www.nature.com/gim/journal/vaop/ncurrent/pdf/gim201480a.pdf, ("Recent advancements in massively parallel sequencing (MPS) technologies has redefined the practice of molecular diagnosis of human genetic diseases in clinical settings. Because 85% of all known mutations are located in the coding regions and the intron/exon junctions, capture-based target gene enrichment followed by MPS analysis is a cost-effective way to identify point mutations […] MPS with consistent exonic coverage can potentially provide an opportunity for concurrent detection of deletions and point mutations in patients with inherited disorders.").

[7] U.S. CONST. art. I, § 8, cl. 8.

[8] Kristen Jakobsen Osenga, *Get the Balance Right! Squaring Access with Patent Protection*, UNIV. OF RICHMOND SCHOLARSHIP REPOSITORY, 309, 314 -15 (2012), ("While the patent side of the conflict is focused on discovering, developing and commercializing new technologies, the hallmark of human rights is access. […] But even if patents were abolished, human rights concerns of access and availability would persist. As just one simple example, providing access also requires distribution. Distribution of pharmaceutical or other technologies faces an uphill battle in some cases, far and above the barrier caused by the existence of patents. At the very least, there must be management of the distribution process and infrastructure to effectuate it. […] While there may be […] truth to the story that intellectual property rights interfere with global access to food, shelter and the like, by looking at the rest of the story it is clear that not all patents are bad, and not all that is bad is caused by patents.").

[9] Susan Cartier Poland, *Genes, Patents and Bioethics – Will History Repeat Itself?* BIOETHICS RESEARCH LIBRARY AT GEORGETOWN UNIV., 1, 5 (2010), *available at* https://repository.library.georgetown.edu/handle/10822/556895, ("The bioethical issues concerning gene patenting are complex and interwoven with other bioethical issues- e.g. informed consent, the body as

having a patent just for the sake of having a patent or for any incidental cost-earnings to the patent holder without properly working the patent to its fullest potential is ethically and legally impermissible since it is inconsistent with the Constitutional goals of a patent system and it does not promote any far-reaching public interest goals, such as access to these informative technologies.

This paper will advance through a series of sections all aimed at expressing the inflexibility of the current Patent Act in adjusting for industry-specific reliance on patent protection. This shortcoming has limited patient access to genetic diagnostics and does not promote aggressive innovation that is essential to the success of this particular industry. The first section will explain American patent law and its theoretical basis. The second section will examine the ethical framework that supports prompting the legislature to compose a specific law regarding human gene patents. The third section will discuss the statutory revelation that occurred when the Supreme Court interpreted the Patent Act to cover biological and genetic material. This section will also address the distinction the Court draws between natural and synthetic biological materials when interpreting the Patent Act. The fourth section will summarize how the industry-specific characteristics of gene patents suggest that some policy proposals may be better than others. The final section will summarize why a different, congressionally-established patent system for the genetic industry is justified.

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property, animal rights, and xenotransplantation. […] Gene patenting is the unbundling of genetic property rights, such as the right to possession, the right to use, the right to sell, the right to dispose. Gene patenting thus presents a challenge to society's definition of reproduction. […] What are the limits for credit or responsibility?").

II. The Source of American Patent Law, Its Goal, and Finding the Balance

Early forms of intellectual property protections date back to ancient Greece and have since then been adopted in various forms all over the world.[10] The United States has some of the strongest patent protections amongst developed and developing nations and works very hard to convince the international community to adopt infrastructure just as robust as ours.[11] The American patent system has layers upon layers of laws that codify how intellectual property protection is granted and insulated from free riders as well as how the government may dissolve those protections in the interest of greater access. Taking just a glimpse at the American Patent system will guide our further discussions about ethics, access, and the future.

A. Introduction to Patents and Applicable Constitutional Language and Law

A patent is a legal title that a nation gives an owner for a limited time that grants them a commercial advantage not to *use* but rather to *exclude* others from using, making, selling, offering to sell, or importing the invention during the patent term.[12] The very first

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[10] *Intellectual Property: History of Intellectual Property*, STANFORD ENCYCLOPEDIA OF PHILOSOPHY, *available at* http://plato.stanford.edu/entries/intellectual-property/#HisIntPro, ("One of the first known references to intellectual property protections dates from 500 B.C.E., when chefs in the Greek colony of Sybaris were granted year-long monopolies for creating particular culinary delights."); Kristina Lybecker, *The Economic Case for Strong Protection for Intellectual Property*, IPWATCHDOG, *available at* http://www.ipwatchdog.com/2014/05/02/the-economic-case-for-strong-protection-for-intellectual-property/id=49376/, (Professionals who study economic trends identify strong intellectual property laws, most notably patent enforcement laws, as necessary for a nation's economic development and growth. "The bottom line is that decades of study and scores of researchers demonstrate that a robust intellectual property rights regime is beneficial to economic development.").

[11] Anne Boring, *Does Foreign Patent Protetion Increase the United States' Trade of Pharmaceuticals with Developing Countries?* (2010) *available at* http://www.uq.edu.au/economics/documents/jobmarketpapers/jmpboring.pdf, ("The United States has been pushing for the implementation of intellectual property rights in developing countries, through the World Trade Organization and bilateral or regional free trade agreements.").

[12] 35 U.S.C. § 271(a); Cynthia M. Ho, *Inoculation Inventions: The Interplay of Infringement and Immunity in the Development of Biodefense Vaccines*, 8 J. OF HEALTH CARE L. & POL'Y 111, 123 (2005), *available at* http://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1096&context=jhclp.

Article of the U.S. Constitution endows Congress with the authority to create patent laws.[13] It reads that Congress shall have the power, "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[14] This language suggests that patents are not merely awards given to secure patent originators' their exclusive rights, but rather that such patent rights are dedicated to fostering and encouraging innovation that is generally useful.[15] Imagine a balancing scale with a central pillar and a pan on each of its sides. The pillar represents this goal to promote science and the useful arts. On one of the pans on either side are patent originators' exclusive rights over their innovation. This is a very heavy pan. What could be put on the other pan to level the scales at equilibrium? The other scale would have to include scientific progress itself since it is an important goal of the research and development. But what if that is not enough to offset the exclusive rights? What else would raise the owners' scale? Actual access to these beneficial innovations would likely tip the scale to equilibrium.

Given how many science and the useful arts may exist, Congress created the U.S. Patent Act, a code that has four main parts, constituting 37 chapters, that deals with topics ranging from trademarks, plant patents, pharmaceuticals, and biotechnology.[16] The part

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[13] U.S. Const. art. I, § 8, cl. 8, *supra* note 7.
[14] *Id.*
[15] *General Information Concerning Patents,* U.S. PATENT & TRADEMARK OFFICE, *available at* http://www.uspto.gov/patents/resources/general_info_concerning_patents.jsp, (The following information relates to *infra* note 14 and beyond. "In the language of the statute, any person who 'invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent,' subject to the conditions and requirements of the law.[…] The patent law specifies that the subject matter must be 'useful.' The term 'useful' in this connection refers to the condition that the subject matter has a useful purpose and also includes operativeness, that is, a machine which will not operate to perform the intended purpose would not be called useful, and therefore would not be granted a patent. Interpretation of the statute by the courts have defined the limits of the field of subject matter that can be patented, thus it has been held that the laws of nature, physical phenomena, and abstract ideas are not patentable subject matter.").
[16] 35 U.S.C. §1-376.

of the U.S. Patent Act that concerns the span of our project most is 35 U.S.C. §101. It reads, "Whoever invents or discovers any new or useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[17] The language of this section informs a patent-seeker which inventions are patent eligible subject matter.[18]

American patent law has not developed in a vacuum. In fact, the United States has adopted many regulations that are governed by their participation in international organizations, most relatedly here, the World Trade Organization ("WTO"). The United States has been a member of the WTO since 1995.[19] As a member of the WTO, the United States must comply with the Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), a substantive set of minimum patent rights that member nations have to provide to patent holders.[20] The World Trade Organization created TRIPS in 1994 as a way to integrate intellectual property law in the international arena. For instance, TRIPS Article 27 defines patentable subject matter as "new, involve[s] an inventive step and [is] capable of industrial application."[21] Also, Article 33 says a patent term starts twenty

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[17] 35 U.S.C. §101.
[18] U.S. PATENT & TRADEMARK OFFICE, *supra* note 15.
[19] *United States of America and the WTO*, WORLD TRADE ORGANIZATION, *available at* http://www.wto.org/english/thewto_e/countries_e/usa_e.htm.
[20] Ester Ferrara, *Access to Medicine: Patent, Price Regulation and Prizes*, ILSP L. J., 14 (2013), (" The TRIPS agreement […] is an international framework for protecting trademarks, copyrights, and aptents that required all the State Members to provide mandatory minimum standards of intellectual property (IP) protection."); Ho, *supra* note 120, at 118, ("In addition to considering current patent laws and the Constitutional parameters that would govern any changes, constraints based on international agreements that the United States has signed are also important to examine. The most important agreement is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is the first international agreement to mandate minimum levels of patent protection for all member states of the World Trade Organization, including the United States.").
[21] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, URUGUAY ROUND AGREEMENTS, art. 27,*available at* http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

years from the date of application, but nations may extend it if they so desire.[22] Additionally, Article 62.2 requires patent applications be examined within a reasonable time.[23]

In the United States, the patent timeline is not only compliant with these minimum requirements outlined in TRIPS but the timeline often gets pushed back to afford more time on the market for successful patent applicants.[24] For instance, the length of the patent term given to a successful patent applicant generally exceeds the TRIPS twenty-year requirement that begins from the date of application because the United States has a relatively long pre-grant stage.[25] It takes time for the application to be reviewed by the United States Patent and Trade Office ("USPTO"). So, even if an invention satisfied the criteria for patent subject matter eligibility, a patent does not exist unless and until a patent application is filed and granted by the USPTO.

Patent applications for products or developments such as pharmaceuticals and medical devices are typically approved by the USPTO before the applications for regulatory approval from the Food and Drug Administration ("FDA") are provided

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[22] *See Id.*

[23] PETER TOBIAS STOLL, ET. AL., W*TO: Trade Related Aspects of Intellectual Property Rights*, 788 (2009), ("The purpose of Art. 62 is that the acquisition and maintenance of intellectual property rights shall not be impeded in such a way as to render useless the material standards and rules of enforcement. Applying this, procedures and formalities should not be so complicated or expensive as to make the majority of applications uneconomic. Members may decide within their margin of discretion which procedures and formalities to implement, while respecting the principles laid down before.").

[24] U.S. DEP'T OF HEALTH & HUMAN SERVICES, U.S. FOOD & DRUG ADMIN., *What is the maximum amount of time that the patent can be extended?, available at* http://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069959.htm, ("[…] human drug products, medical devices, food additives, or color additives, and animal drug products are eligible for patent extension. […] In all cases, the total patent life for the product with the patent extension cannot exceed 14 years from the product's approval date, or in other words, 14 years of potential marketing time. If the patent life of the product after approval has 14 or more years, the product would not be eligible for patent extension.").

[25] Cynthia M. Ho, *Current Controversies Concerning Patent Rights and Public Health In a World of International Norms, available at* http://www.luc.edu/media/lucedu/law/faculty/pdfs/ho/current_patent.pdf, ("The patent term in many TRIPS-plus agreements goes beyond the TRIPS requirement that the term not end before twenty years from the date of application. In particular, many agreements allow for extension of the patent term if there are 'unreasonable delays' in the patent examination.").

because the patent-applicant will want to ensure their product idea is applied for while it is still considered "new."[26] The FDA is charged with the job of making sure that the patented products are safe and effective such that they should enter the market.[27] The Patent Office evaluates whether inventions are patentable, and often, inventions can be new and nonobvious even if it will infringe on a prior patent.[28] This is most common for incremental improvement patents on old inventions, a concept called ever-greening or considered life cycle management.[29] A real world example of this plea for patent protection over an incremental improvement reached Canada's Supreme Court when the justices struck down Canada's old drug regulatory regime that allowed brand-named pharmaceutical firms to obtain an automatic 2-year extension on their patent term by filing new patents for only marginal product changes.[30] Patent originators defend patents

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[26] Dennis S. Fernandez & James T. Huie, *Strategic Balancing of Patent and FDA Approval Processes to Maximize Market Exclusivity*, DRUG DISCOVERY TODAY (2004), *available at* http://www.iploft.com/PTO-FDA.pdf, ("Patents are crucial to protect a company's ideas while FDA approval is necessary to legally market their products. […] Patents require novelty, utility, and unobviousness. […] If the innovating company begins FDA process before USPTO filing, then it runs the risk of another company patenting the invention before them. […] Furthermore, issued patents drive FDA approval, speeding up the process.").

[27] U.S. DEP'T OF HEALTH & HUMAN SERVICES, U.S. FOOD & DRUG ADMIN., *FDA Fundamentals, available at* http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm, ("The FDA is responsible for protecting the public health by assuring the safety, effectiveness, quality, and security […].").

[28] Ho, *supra* note 25, at 8, ("Often referred to as 'life cycle management,' or 'evergreening' this occurs when multiple patents are obtained related to the a single commercial product based on slight variations after an initial patent on the underlying chemical compound. […] subsequent patents issued to the same patent holder may be for new uses of the same compound or new dosing mechanisms.").

[29] *Id.*

[30] Wayna Kondro, *Supreme Court Rules Against Drug Patent "Evergreening"*, 12 CMAJ (2006), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1660583/, (" […] patents of an altogether marginal nature, such as the shape, dosing range or colour of a pill, and then claiming infringement on its original patent should not have been allowed under Canada's old drug regulatory regime. This latest decision overturned a lower-court ruling to quash Apotex Inc.'s notice of compliance to market a knock-off of the AstraZeneca pronton-pump inhibitor, omerprazole, which was sold in Canada from 1989 to 1996. The drug was removed from the market and its patent expired in 1999 but AstraZeneca used the regulatory system to successfully trigger a series of successive 24-month 'stays' to prevent Health Canada approval of a lower-cost generic equivalent.").

on small improvements by claiming they contribute to patient health and that such patents are legal so long as the improvements meet the other patent requirements.[31]

Although this particular patent approach is highly beneficial for patent applicants, it is certainly concerning for those who view patents as a potential way to block public access to innovation or advancements in research, or both.[32] Ever-greening influences access to patented inventions insofar as these improvements may allow an entirely new patent term to begin for a technology that has already been protected for nearly twenty-years. Ever-greening will allow the patented innovation to maintain its edge against competitors who will soon be able to market their versions of the older invention that does not include this new improvement.[33] This may prove to be a significant impediment to the access of the innovation for two main reasons. First, this newly improved and approved patent will mean the originator has a right to decide whether to enter the market with the product or not while still fending off any other product competitors.[34] Secondly, if the patent originator does not seek to license the innovation but simply exclude others from benefiting from the invention, there is no benefit to the public consumers.[35]

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[31] Roger Collier, *Drug Patents: The Evergreening Problem*, 9 CMAJ (2013), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/, ("But what if the new product improves patient safety? Or reduces adverse effects? Or increases adherence? 'I agree that if it doesn't provide the slightest advantage to patients, it does not deserve protection. You can't merely take a molecule and paint it a different colour,' says [Paul] Herrling, [chair of the board of the Novartis Institute for Tropical Diseases in Singapore.]").

[32] *Monopoly Extension or "Evergreening"*, PATENT OPPOSITION DATABASE, *available at* http://patentoppositions.org/about, ("[Patent originators] have a clear interest in extending their patent monopolies on profitable [inventions] for as long as possible. To fulfill this goal, many use the patent system to delay the entry of competitors in to the market.").

[33] Cynthia M. Ho, (2014). *Global Access to Medicine: Week 5, Beyond Patents: Protecting Drugs through Regulatory Law*, ("[…] companies often seek to make incremental changes to drugs that may have only modest social utility, but may help extend commercial profits. Patent linkage may increase this evergreening phenomena by providing an incentive for companies to sequentially patent different aspects of a commercial drug to extend the time before generic manufacturers can enter the market.").

[34] *See Id.*

[35] *Id.*

Although once a patent is awarded the patent originator has the complete authority to either exercise their patent rights or not, there is one important exception to this usual rule. This exception occurs when the government exchanges a royalty payment to a patent owner so to legally break the patent owner's rights to the patented invention by way of licensing the innovation out to another manufacturer irrespective of the patent originator's resistance.[36] This is called a "compulsory license," because it is a government-required use of the patent that would otherwise constitute infringement.[37] However, the royalty the patent originator receives in exchange for the government's use is slight by comparison to what the market price would likely be.[38] This legally permissible government right to intrude on an owner's intellectual property rights suggests that patent rights are not an end in themselves but rather a means to a greater end that may justify dissolving a patent owner's rights in some situations.[39]

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[36] *Compulsory licensing of pharmaceuticals and TRIPS*, WORLD TRADE ORGANIZATION, *available at* http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm, ("Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property […]."); Carlos Maria Correa, *Compulsory Licensing: How to Gain Access to Patented Technology*, CHAPTER NO. 3.10, *available at* http://www.iphandbook.org/handbook/ch03/p10/, (" A compulsory license is an authorization given by a 'national authority' to a natural or legal person for the exploitation of the subject matter protected by a patent; the consent of the patent title holder is not necessary. Compulsory licenses may be required to import or produce a given product, or to use a patented technology for research. They are especially important when there are no close substitutes for a product or process and a research exception is not available or is too narrow.").

[37] Howard B. Abrams, *Copyright's First Compulsory License*, 26 SANTA CLARA HIGH TECH. L. J. (2009), ("[…] these [are] statutorily sanctioned but otherwise infringing uses of copyrighted material as exemptions or exceptions.").

[38] Eric Bond and Kamal Saggi, Compulsory Licensing, Price Controls, and Access to Patented Foreign Products, (2012), *available at* http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_4_12/wipo_ip_econ_ge_4_12_ref_saggi.pdf, ("Our analysis shows that the option to use compulsory licensing necessarily […] either lowers the licensing fee that is paid to the […] patent-holder or it causes a switch from licensing to entry thereby improving the quality of the good available to […] consumers.").

[39] *More Thoughts on Patents and Copyrights*, CTR. FOR ECONOMIC & PUBLIC RESEARCH (June 25, 2013), *available at* http://www.cepr.net/index.php/blogs/beat-the-press/more-thoughts-on-patents-and-copyrights, ("[…] these are government policies designed to meet a public purpose (i.e. promoting innovation and creative work), not natural rights that are an end in themselves. […] The constitution authorizes Congress to create monopolies for limited periods of time 'to promote the Progress of Science and useful Arts.' In this sense, patents and copyrights are explicitly linked to a public purpose. […] Once we recognize that

The only requirement a country has is to notify the patent owner before issuing a compulsory license, unless it is an emergency.[40] TRIPS Article 31 says that this exception to the rule must be a small deviation from usual patent rights, it does not unreasonably conflict with normal exploitations of the patent, and it does not unreasonably prejudice the legitimate interests of the patent owner and taking into account the legitimate interests of third parties.[41] No country is required to use compulsory licenses, and in fact the U.S. is highly unlikely to ever issue them in the case of an emergency or because of any other excusable reason under TRIPS Article 31 because there is such a long tradition and duty of valuing the protected properties of patent holders.[42] However, if a compelling interest needs to be met, such as a nation-wide health interest, and a patent is current and enforceable, the government likely has a competing duty to protect the interests of the public.

India is a nation that is known to only meet the very minimum TRIPS requirements for intellectual property protection because of their government's goal of providing inexpensive patented products to its citizens.[43] In fact, the Indian government relies on the threat of compulsory licensing to ensure that their patentees actually put the patent to use and benefit the public.[44] India's Patent Act says, "The patentee must work the invention, or have another work the invention, on a commercial scale and the fullest

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patents and copyrights are policies to promote innovation and creative work then the question is whether they are the best policy and if so, are they best structured now for this purpose. Neither assumption is obvious and I would argue that the latter is almost certainly not true.").

[40] TRIPS Art. 31, ("This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.").

[41] *Id.*

[42] TRIPS Art. 31.

[43] Suresh Koshy, *The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective*, 1 BOSTON UNIV. J. OF SCIENCE A& TECH. L. (1995), ("Like many developing countries, India currently maintains weak patent laws in order to provide inexpensive products to its citizens. […] Nonetheless, in the interest of furthering patent harmonization, India signed the [TRIPS…]. Among other things, TRIPS requires minimum levels of patent protection.").

[44] *Id.* at 5, quoting Patents Act, 1970, 27 INDIAN A.I.R. MANUAL 450 (1979), §83(a).

extent reasonably practicable without undue delay."[45] Recently, India's Intellectual Property Appellate Board ("IPAB") upheld the country's first compulsory license on a pharmaceutical product.[46] The compulsory license was issued to Hyderabad-based Natco Pharma Ltd, an Indian generic drug manufacturer, which sells a much cheaper version of the German pharmaceutical company Bayer AG's kidney and liver cancer drug called Nexavar.[47] Justice Prabha Sridevan made the final decision in which she cited affordability and product access as the reasons for upholding the compulsory license.[48] By contrast, the United States has never issued a compulsory license due to access issues.[49] In fact, "The United States has often granted compulsory licenses as a remedy for violations of antitrust laws, reflecting the value of free enterprise and competition in the United States."[50] The role of compulsory licenses may be key for making sure that patents are actually being used in a way that is benefiting the public, and not just for

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[45] *Id.*
[46] Patralekha Chatterjee, *India's First Compulsory License Upheld, But Legal Fights Likely to Continue*, INTELLECTUAL PROPERTY WATCH, *available at* http://www.ip-watch.org/2013/03/04/indias-first-compulsory-licence-upheld-but-legal-fights-likely-to-continue/.
[47] *Id.*
[48] *See Id.*
[49] Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 NORTHWESTERN J. OF INT'L L. & BUS., *available at* http://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1244&context=njilb.
[50] *Id.* at 670, (For example, compulsory licenses were granted as remedies for anti-trust violations in United States v. Hartford-Empire Co., 46 F. Supp. 541 (N.D. Ohio 1942), where the Ohio federal court said, "There is no question but that the patentee has the exclusive right to license his patents to others to make, use or vend the patented article." However, when Defendant chose not to license others to make or vend its machines, but instead had a plan for licensing the use of its machines where the licensees had to abide by certain restrictions which they consequently did not, the court held that issuing compulsory licenses so to minimize their monopoly that was increasing price on glassware and other items they had patented was legal. Since compulsory licenses are issued in the name of public interest, the fact that the United States consistently issues compulsory licenses to protect free market economics illustrates how the United States generally trusts that the market is the medium that determines successful practical application.).

consumer access reasons, but as a way to remove any restrictions on outside research and development done to improve or further any given area of innovation.[51]

Contrary to this view is a strong opposition against compulsory licensing in the United States ranging from technical legal arguments to basic practical arguments against their issuance.[52] For instance, some may argue that patents are comparable to contracts insofar as an agreement has been made between the patent holder and the government that the former will reveal their innovation and the means to use it in exchange for the government's return promise of a time-restricted monopoly on the very production of the innovation.[53] However, when a compulsory license is issued, this is a breach of contract.[54] A less technical challenge to compulsory licenses simply relies on the argument that patents are the ultimate incentives to develop new technology, and if patent originators feel threatened by the issuance of these licenses then innovation is sure to halt because inventors would feel less secure about exposing their research to the scientific community under a false promise of protection.[55] However, it is not likely that compulsory licenses would be such a huge disincentive for innovation because it only would be issued when a patent holder does not use their patent to benefit the public in the way they are otherwise required, they would still receive royalty payments, and the

[51] Maria Correa, *supra* note 36, ("Compulsory licenses may be needed when patents restrict the freedom to operate in a given field of R&D. Such licenses are subject to several conditions, notably that the licensee must remunerate the patent holder.").
[52] Cynthia M. Ho, *Global Access to Medicine: The Influence of Competing Patent Perspectives,* 34 FORDHAM INT'L L. J. 680, (2014).
[53] *Id.*
[54] Fauver, *supra* note 49, at 681, ("Under this theory, compulsory licenses may constitute a taking. Even if compulsory licensees do not acquire the constitutional dimensions of a taking, they still have been consider a 'totally inappropriate expropriation of private property.").
[55] *Id.* at 684, ("Some would argue that a nation's position in technological production is determined more by effective incentives for innovation than by licensing, an that compulsory licenses reduce those incentives.").

benefits of being issued a patent would be present before the compulsory license is issued, such as a strong market presence compared to the licensed competitor.[56]

B. Looking at a Spectrum of Patent Views That May Help Reach Equilibrium

The U.S. patent system has long had its fair share of debated concerns, including the breadth of protection provided to innovators, the inadequacy of umbrella rules, and erroneous judicial applications of these rules.[57] At the foundation of many of these debates is a general disagreement on the actual role of patents in the totality of the law.[58] The disagreement is not likely centered on whether or not patents should exist, but rather *how* patents are to be operated in a way that promotes innovation. The question to be asked is, "are patents the means of innovation or are there ways that patents ought to be used to promote innovation?" This question can be answered with a spectrum of views on the role of patents.[59] On one end of this spectrum is the view that a patent is a privilege

[56] *Id.* at 676, ("It is not certain, however, that compulsory licensing would lessen the incentive to invent. First, the original patentee would have established a market before the grant, which would put it at an advantage over competitors have to 'start from scratch' to develop the product. […] Third, some compulsory licensing systems provide flexible royalty rates […] the patentee can receive not only a fair return on its investment under this system, but may retain the advantage of an established market position as well. […] It is likely that compulsory licenses would not lessen a patentee's motivation to invent, and also the public benefits by reducing the patentee's enjoyment of monopoly profits. Such a windfall is of particular harm to consumers when the demand for a product, like medicine, is inelastic because the consumer in such a situation has little market choice. In sum, the harm which compulsory licenses inflict on incentives to invent is probably outweighed by the resulting public benefits.").
[57] Alan Devlin, *Systematic Bias in Patent Law*, 61, 57 DEPAUL L. REV. 57-63 (2012).
[58] *Id.* at 60, ("Like any ideologically driven controversy, the patent debate features arguments of varying nuance and scope. Some advocate the wholesale abolition of the patent system from the U.S. economy- a position that critics typically advance without a strong empirical foundation or a nuanced regard for the likely economic effect of such a monumental transformation in the law. Others counsel incremental adjustment in doctrine to effect change in a more responsible manner. […] Given the fact that different stakeholders invariably take conflicting, entrenched positions on any patent issue of note, how should policymakers identify optimal adjustments in the law and achieve the requisite level of consensus to facilitate their creation?").
[59] Ho, *supra* note 52, ("[…] a major hurdle to actually addressing access issues is that there are fundamentally different vies of patent policy ('patent perspectives') that have a significant impact on how facts, laws, and proposed solutions are viewed.").

that is subject to public interest.[60] This will be referred to as the access view on the purpose of patents. On the polar opposite side of this spectrum is the view that patents are the ultimate property right and should rarely, if ever, be disregarded.[61] This will be called the innovation view on the purpose of patents. These two views can be placed on either pan of the scale that was illustrated earlier in this section. The innovation view would be on the pan holding the exclusive ownership rights of patent owners. The access view would be on the other end, where patent rights alone are not considered to be the ultimate way to promote the scientific innovation and useful arts.

In the big picture, the access view considers the role of patents in promoting innovation to be one of only many public goals.[62] The public interest considerations that the access view thinks are key to assessing the purpose of patents include several goals for making sure that patents are actually providing an incentive to innovate and do not impede subsequent innovation.[63] For instance, if something is patented that is integral to further innovation and other inventers or scientists in the field cannot work around it, then that patent is likely hindering further innovation.[64] This is a hurdle that comes up in

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[60] *Id.* at 4, ("On the one end of the spectrum, there is a view of patents as privilege granted by the state and inherently subject to limitations- especially if necessary to promote other social policies, such as access to medicine […].").

[61] *Id.* at 29, ("This alternative perspective views patents as a very strong property right that should in fact be stronger than most property rights, such that it will be referred to as an 'uber-right.' […] In other words, the uber-right perspective […] views patents as a special type of property right, but in a very different manner that the [other] view. Patents are considered special in that they are much more limited in time, such that the strength of patent rights during that limited term is considered paramount.").

[62] U.N. Econ. & Soc. Counsel, Sub Comm'n on Promotion and Prot. Of Human Rights, *The Impact of the Agreement on TRIPS on Human Rights*, Para. 14, U.N. Doc. E/CN.4/Sub.2/2001/13 (June 27, 2001), (This sections suggest that rights under TRIPS are secondary to more universal human rights, such as the right to health.).

[63] Paul Belleflamme, *Patents and Incentives to Innovate: Some Theoretical and Empirical Economic Evidence*, 13 ETHICAL PERSPECTIVES: J. OF THE EUROPEAN NETWORK 271, (2006), ("[IP law] grants exclusive use of the protected knowledge or creative work to the creator. Thereby, IP law provides creators with the necessary incentives to produce new knowledge and solves the *underproduction* problem that would have resulted from the non-excludability of knowledge.").

[64] Bhaven Sampat and Heidi L. Williams, *How do patents affect follow-on innovation?* MIT ECON. 2 (2014), ("[…] if patents discourage follow-on research, reforms to the patent system may be appropriate.").

the context of human gene patents when laboratories and researchers want to learn more about the patented gene or DNA sequence, but are precluded from doing so for fear of patent enforcement.[65] Another public interest consideration is to limit the patentable subject matter criteria to the point where what is actually incentivized through patents are ambitious, pioneering scientific discoveries and not things like ever-greened innovations.[66] Lastly, in the context of health care, individuals with this view would want to increase access to what is patented so that health and wellbeing become more universally available.[67]

The innovation view holds that patents are the ultimate property right and should rarely be infringed since the reward of intellectual protection promotes innovation that benefits society at large.[68] The trust and reliability of the patent-holding institution, if you will, would be at stake if a patent holder's rights were not respected.[69] One commonly cited reason for why patents are the ultimate incentive for innovation is that given how expensive investments in scientific pursuits are, patents are the light at the end of the tunnel for all innovators.[70] So, without patents, incentives to innovate would likely dissolve for those industries that require a lot of investment before they reap success for

[65] Jon F. Merz and Mildred K. Cho, *What are Gene Patents and Why Are People Worried about Them?*, 8 COMMUNITY GENET. 203, 204 (2005), ("Clinical as well as research laboratories typically pay royalties for the use of patented technologies. […] Disease gene patents vary in significant ways from these more typical patented tools that are used by laboratories for testing for a variety of specific disease genes. Critically, since a disease patent claims all methods of testing for a specific gene, there is no plausible way of working around these patents and the patents may be used to monopolize a test.").
[66] Poku Adusei, PATENTING OF PHARMACEUTICALS AND DEVELOPMENT IN SUB-SAHARAN AFRICA: LAWS, INSTITUTIONS, PRACTICES, AND POLITICS (2013), ("[…] patent examiners should be trained to interpret patentability requirements strictly before granting pharmaceutical patents. Indian for instance has raised the criteria for patentability so as to prevent 'evergreen patents' from being registered.").
[67] Ho, *supra* note 52, at 27.
[68] *Id.* at 30, ("Although the uber-right may recognize that patent rights have the potential to create challenges to accessing patented drugs in the short-term, these challenges are considered less important than maintaining long-term innovations.").
[69] *See Id.*
[70] *Id.* at 28.

their patent. Holders of this view may argue that being able to exercise a time-limited exclusionary authority over an invention is a necessary reward that fuels access to important innovation even if not everyone can access it at the same time.[71]

These two views on the role and purpose of patents are increasingly important as debates regarding the current status of intellectual property protections on certain innovations, such as the right to patent human genes and the diagnostic tests that detect the presence of those genes, are getting more heated. Considering the importance of these two perspectives in predicting future conflicts concerning innovation that is capable of detecting serious illnesses earlier than infection may help drive policy considerations in any change that is made to the United States' Patent Act. Even without any changes to the law, these perspectives can lend a hand in determining when the United States government should exercise its current rights to intervene by way of issuing a compulsory license, for example, when the patent holder does not properly meet the goals of access to innovation.

III. Ethical Lens Creating the Vision for A Different Patent Law Future

Examining the ethical implications of patents on human genes can be a bit of a challenge because it requires coordinated efforts between the scientific experts, ethicists, and lawyers, often times *after* the patent claims are awarded protection. The steadfast pace of genomic research and all that stems from it makes it especially difficult for ethicists and lawyers to get out in front of the technology and identify what ought or must be done to promote and protect all relevant rights. In the meantime, the public perception

[71] *Id.* at 31, (" Although an uber-right view of patents recognizes that access to affordable medicine may be limited during the patent term by prices set by patent owners, they suggest that strong patent rights nonetheless benefit all.").

of patents on human genes has lead to many objections to the resulting biotechnologies, such as patents on genetic diagnostic tests.[72] These objections to patents on human genes often branch from a concern over violating the principle against human ownership and the slippery slope effect of creating an industry that commercializes human material.[73] Relatedly, there exists a *common heritage* objection that says by virtue of genes being a natural and universally shared trait of our species, the human genome should be collectively owned and not conferred private ownership through a patent.[74]

From the outset, it should be noted that current U.S. patents on human genetic material in fact do not justify the ownership of one person by another.[75] This is because it is not the pure, raw, natural material that is fundamentally human that is considered patentable subject matter.[76] Only through a lot of effort and technical skill can the raw human genetic material be manipulated and considered innovative before being awarded a patent.[77] Therefore, the patented and manufactured product is very different from the

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[72] Annabelle Lever, *Is It Ethical To Patent Human Genes?*, THEORIES OF JUSTICE AND INTELLECTUAL PROPERTY (2008), ("Indeed, if patenting-rights are assumed to be absolute […], so that patent-holding can prevent the use or commercial development of inventions, however useful and desirable, there might be very strong moral objections to the idea that human genes are legally patentable.").
[73] Timothy A. Caufield, *From human genes to stem cells: new challenges for patent law?* TRENDS in Biotechnology, Vol. 21, No.3 (2003).
[74] Arthur L. Caplan and Robert Arp, *Is It Ethical to Patent or Copyright Genes, Embryos or Their Parts?* 139 Contemporary Debates in Bioethics, First Edition (2014).
[75] Lever *supra* note 72, at 8, ("It is hard to find a published source for this belief, but it occurs frequently enough in oral arguments about patenting to merit attention by (Crespi, 1997, pp. 219-223). *See*, in particular, Crespi p. 225; also Ossorio, p. 411. However, Jeremy Rifkin claims that 'genetically altered human embryos and fetuses as well as human genes, cell lines, tissues, and organs are potentially patentable, leaving open the possibility of patenting all of the separate parts, if not the whole, of a human being.' (Rifkin, 1998, pp. 44-45)."
[76] Caplan and Arp, *supra* note 74, at 139; Michael Franco, *How Gene Patents Work*, HOW STUFF WORKS, *available at* http://science.howstuffworks.com/life/genetic/gene-patent.htm, (The U.S. courts have gone through a lot of effort to make sure that naturally occurring DNA is not patentable subject matter. The distinctions between natural occurring and synthetic will be taken up more in a later section. However, for now, "It is important to note that genes can count as altered products of nature only if they have been removed from the body and processed in some way.").
[77] Caplan and Arp, *supra* note 74, at 139.

naturally occurring, universal thing it once was, and therefore qualifies as something new, useful, nonobvious, and worthy of patent protection.[78]

A. Setting the Scene & The Real Moral Dimensions

The process of patenting certain genetic information is long, complicated, and requires fluency beyond basic Mendelian genetics. Ultimately, genes can only be patented if further work was done to change their natural form.[79] Gene manipulation starts with extracting DNA cells from the body.[80] All DNA uses the same four nucleotides: adenine, guanine, thymine and cytosine.[81] However, complementary DNA, called cDNA, does not have introns like naturally occurring DNA.[82] To get cDNA isolated and purified, there is a long process of transcription that takes place in isolation from the rest of the genome.[83] Because of this long process, cDNA is patent eligible while naturally occurring DNA is not.[84]

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[78] *Id.*
[79] *Gene Patenting*, ROCHE (2006) 6, ("They can be patented only if further work is done to change the gene. In other words, an inventive step is needed to make it unobvious. Such extra work may include isolating, purifying and identifying the gene or gene sequence. Plus, all the other general requirements for getting a patent must be met.").
[80] *DNA Extraction*, LEARN GENETICS: GENETIC SCIENCE LEARNING CENTER, *available at* http://learn.genetics.utah.edu/content/labs/extraction/.
[81] Bruce Alberts, et al., MOLECULAR BIOLOGY OF THE CELL, (2002), *available at* http://www.ncbi.nlm.nih.gov/books/NBK26837/, ("Because all DNA molecules consist of an approximately equal mixture of the same four nucleotides, they cannot be readily separated, as proteins can, on the basis of their different charges and binding properties.").
[82] Jason Rantanen, *Myriad: Isolated DNA out, cDNA in*, PATENTLYO, (June 13, 2013), *available at* http://patentlyo.com/patent/2013/06/myriad-isolated-dna-out-cdna-in.html, ("cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. […] creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring. Petititoners concede that cDNA differs from natural DNA in that 'the non-coding regions have been removed" […] the lab technician unquestionable creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it is derived. As a result, cDNA is not a 'product of nature' and is patent eligible under § 101 […].").
[83] Alberts, *supra* note 81.
[84] *See Id.*

The actual moral dimensions of current patents on human genetic material frame the dual goals of promoting the rights of patent holders to exclude others from claiming to be the original source of the innovation and upholding the professed purpose of patents to benefit the public.[85] The professed purpose of patents is namely to confer exclusionary rights only to those who have innovated something of great value so that they can and will disclose the innovation to benefit the public and continue to encourage greater advancement.[86] However, the monopolistic behaviors of patent-owning entities in this particular discipline have called into question these exclusionary rights in ways that highlight the obligations inherent in having such power.

The ethical considerations and significance of patents on human genes certainly go beyond just genetic diagnostic tests and into other areas such as stem-cell ethics and embryo research ethics.[87] For the purposes of this paper, we identify the ethical imperative of better balancing the goals of intellectual property rights that protect and permit inventors of these products to create tests that can capture one's predisposition to

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[85] *Quoting* Sony Corp. of Am. V. Universal City Studios, Inc., 464 U.S. 417, 429 (1984), ("[T]he monopoly privileges hat Congress may authorize are …[not] primarily designed to promote a special private benefit. Rather, the limited grant is a means by which an important public purpose may be achieved. It is intended to motivate the creative activity of authors…by the provision of a special reward." (some alteration in original)).

[86] Lawrence M. Sung, *It is Ethical to Patent or Copyright Genes or Embryos*, CONTEMPORARY DEBATES IN BIOETHICS, 144 (2003).

[87] Insoo Hyun, *Stem Cells*, HASTINGS CENTER BOOK, *available at* http://www.thehastingscenter.org/Publications/BriefingBook/Detail.aspx?id=2248, ("The main ethical and policy issues with stem cells concern the derivation and use of embryonic stem cells for research. […] Embryonic stem cell research is especially controversial for those who believe that five-day-old-preimplantation human embryos should not be destroyed no matter how valuable the research may be for society. […] to bypass this ethical controversy, the President's Council on Bioethics recommended in 2005 that 'alternative sources' of pluripotent stem cells be pursue. […] But embryonic stem cell research will remain necessary because there are some questions only embryonic stem cells have the potential to answer."); Insoo Hyun and Kyu Won Jung, *Human Research Cloning, Embryos, and Embryo-Like Artifacts*, THE HASTINGS CENTER REPORT (Sept.-Oct. 2006) *available at* http://www.thehastingscenter.org/Publications/HCR/Detail.aspx?id=2538, ("[Some argue that] human research cloning carries an added moral burden because it would involve the deliberate (and subsequent destruction) of burgeoning human life solely for biomedical research, and because it would enliven the dreaded possibility of human reproductive cloning.").

genetically inherited diseases with access to the best tests that have the ability to serve this diagnostic need. At the foundation of the following argument is a general trust that patents on human genes are ethically permissible, desirable and valuable insofar as they can balance temporary, exclusionary rights with promoting innovation that will benefit society by essentially improving and advancing human health.[88] To the extent that patents are not accomplishing their intended goal, as they may not be in the realm of human genetic patents, there is a need to reevaluate the way patents are awarded to make sure they are living up to the above criteria.

B. Ethical Principles and Arguments Undermining Intellectual Property Law and How They May Relate to Patents on Human Genes

Ethical arguments against intellectual property ("IP") range from technical critiques of the law that supports it to bold calls to action to do away with the entire institution. By understanding the ethical principles against, as well as in support of, IP law, the goal is to feature a fuller account of the ethics surrounding the debate regarding patent protection over genes. The arguments against IP law push directly against the very foundational assumption that this paper is relying on, which is that patents on human genes are ethically permissible, desirable and valuable insofar as they can balance access with exclusionary property rights. However, even just a brief chronicling of these many ethical arguments for and against IP law may amount to a treatise length analysis. For this reason, the immediate focus will be on two particularly philosophically creative

[88] Geoff Watts, *The Locked Code: Despite Numerous Attempts to Prevent it, Patenting of Genes is Still Legal*, 334 GENE PATENTS, 1032 (2007) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1871761/pdf/bmj-334-7602-feat-01032.pdf, ("Given that the patent system is long established and generally agreed to be socially desirable, why should its application to genes have proved so contentious?").

arguments against IP law. The first one is David Koepsell's liberty/commons argument.[89] The second is James Wilson's harm argument.[90] Together, these arguments explore a lot of the looming objections that exist at the very foundation of the institution of IP law that continue to pervade the debates surrounding the approval of specific patents, such as those on human genes.

Koepsell's argument transitions through a couple fundamental axioms followed by several premises that relate to the ethical problems of all intellectual property rights before concluding that intellectual property laws are an ethically impermissible restriction on freedom and expression.[91] Without outlining Koepsell's argument in great detail in the body of this section, we will briefly consider what Koepsell says about how the category of intellectual property law may not actually be considered eligible for legal protection if we were to redo all of institutional law.[92]

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[89] David Koepsell, WHO OWNS YOU? THE CORPORATE GOLD RUSH TO PATENT YOUR GENES, (2009); *The Ethical Case against IP (Transcription)*, HXA ARTICLES, *available at* http://www.hxa.name/articles/content/ethical-case-against-ip_koepsell_2009.html, (Koepsell's argument is centered on John Stuart Mill's liberty principle. The idea here is that liberty should promote and secure individualism, because individualism is connected with the nature of man as a being who seeks social and personal progression. Koepsell writes, "According to J.S. Mill, we have unrestricted liberty except to the extent that it injures someone else. So this is the notion of the liberty principle- a basic, fundamental notion of liberal democracies."); John Stuart Mill, ON LIBERTY (1859) , *in The Collected Works of John Stuart Mill*, vol. xvii: *Essays on Politics and Society*, Part 1, ed. John M. Robson, 213 (1977); *What is Mill's Liberty Principle? Does it correctly set out the grounds on which government interference with individual lives is justified?*, UNIV. OF OXFORD- DEP'T. OF CONTINUING EDUCATION, *available at* http://plaza.ufl.edu/ioannis.p.pappas/site%20files/assignment_2.pdf.

[90] James Wilson, *Could There be a Right to own Intellectual Property? 28* L. &PHILOSOPHY, 393 (2009), *available at* https://www.academia.edu/1016889/Could_There_be_a_Right_to_Own_Intellectual_Property; HXA ARTICLES, *supra* note 26; *Deductive and Inductive Arguments*, INTERNET ENCYCLOPEDIA OF PHILOSOPHY, *available at* http://www.iep.utm.edu/ded-ind/, (Wilson's harm argument moves through a series of premises that inductively support the conclusion that there are no intrinsic moral rights to own intellectual property. "A deductive argument is an argument that is intended by the arguer to be […] valid, that is, to provide a *guarantee* of the truth of the conclusion provided that the arguments premises are true. […] An inductive argument is an argument that is intended by the arguer merely to establish or increase the probability of its conclusion. In an inductive argument, the premises are intended only to be so strong that, if they were true, then it would be unlikely that the conclusion is false.").

[91] David Koepsell, lecture (Oct. 10, 2000). (Transcript available at http://www.hxa.name/articles/content/ethical-case-against-ip_koepsell_2009.html).

[92] *Id.*, (Koepsell's first axiom is based on Mill's standard liberalism, which is that humans have fundamental rights to their autonomy of their minds and bodies. The second axiom, still related to Mill's

Essentially, legal rights of ownership, Koepsell argues, are only just if they would be valid in a world without institutions, what he refers to as a brute world.[93] For instance, this very keyboard I am typing on is an object. Even without the social or legal conventions that currently dictate to me that I own this keyboard, I know that I possess this thing excluding it from the possession of another who cannot possibly occupy this same small space at the same time as I am writing this paragraph without violating my just possession. This is a brute fact. So, even in a pre-institutional world, even if we are not using or thinking about institutional-legal terms like ownership, we understand possession and want protections for physical title.[94] Koepsell firmly asserts that the justice of laws that enable us to exert our rights over physical property are also grounded in brute facts. The brute fact of one's possession over something is what makes laws that enable that person to sue when someone takes it away from them warranted and just.[95] Unlike land and moveables, IP laws are not grounded in any brute facts of possession, and therefore are unjust.[96]

Koepsell claims that there are parts of the world that cannot justly be owned.[97] He looks specifically at the problem of patents based on human genes.[98] Koepsell's position

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liberty principle, is that humans have fundamental rights to freedom of expression. The premise that follows is an ontology of patentable subject matter. Koepsell says that the categories of patent law are describing expressions that, if we were to redo all of institutional law, would not likely be considered eligible for legal protection.).

[93] *Id.*

[94] *See Id.*

[95] The author of this article recognizes that Koepsell's argument tends to overlook general civil tort law categories of harms such as intentional infliction of emotional distress and defamation. It is not the goal of this section to pick away at the opposing's sides view, rather it is important to see the ethical case against intellectual property protection.

[96] *Id.*, ("Intellectual property law is a pragmatic response to the logical problem of the fact that you can't possess an idea type to the exclusion of others; and it is an attempt to try to create an economy, to try to deal with this to spur innovation through increasing project for those who have monopolies.").

[97] *Id.*

[98] *Id.*, (Koepsell gives a description of DNA, cDNA, and transcription before making his argument. The author of this article thinks it is beneficial for us to quote this here so that the reader can get more familiar

is that a patent on cDNA is not a novel thing because it is naturally occurring and therefore not a legally valid claim let alone an ethically valid one.[99] He asks whether there are parts of the world that cannot be possessed in any meaningful way because they cannot be enclosed in order to have grounds for possession?[100] If so, these are called "commons-by-necessity."[101] Examples of these include sunshine, elements in the atmosphere, and laws of nature. Basically, these are parts of the universe that are incapable of being enclosed to the exclusion of others.[102] Koepsell argues that the human genome is a commons by necessity.[103] When people try to patent genes they are attempting to enclose an un-enclosable space to the exclusion of others and this is an ethical wrong.[104] It is unethical because it is an attempt to curtail our autonomy over our

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with the scientific process of gene isolation and purification that was mentioned in the earlier section. Koepsell writes, "A gene is an arrangement of nucleotides that codes for a protein- a little bit of science: its action involves the creation of proteins by mRNA- messenger RNA- which, as it creates the protein, reads the beginning and end of the gene and leaves out the introns. Now, this is a natural process; this is how you are mad: you are composed of proteins that are read through this process, and producted in different cells according to differentiation of those cells, again, through the instructions of your DNA. It is the same mechanism as that which scientists use to create what they call isolated cDNA. That's important. A patent on cDNA is, I argue, not different than a patent on a gene itself: there is nothing new about the cDNA.[…].") *; See* Koepsell WHO OWNS YOU? *supra* note 27.

[99] *Id.*

[100] *See Id.*

[101] *Id.*; David Koepsell, *Naturally Occuring Genes and the Commons By Necessity*, GENEWATCH, *available at* http://www.councilforresponsiblegenetics.org/genewatch/GeneWatchPage.aspx?pageId=305, ("There is simply no natural way to exclude others from using ideas. But not all ideas can become the subject of patents. The courts have long recognized that laws of nature and abstract ideas, for instance, cannot be eligible for patent protection. I contend that this is simply a good, pragmatic idea, but rather in accord with natural law. Abstract ideas and laws of nature are incapable of enclosure or exclusivity because they belong quite clearly to what I call the 'commons-by-necessity.' […] Attempts by states, through patent laws or other means, to exclude anyone from utilizing commons-by-necessity, or to grant exclusive uses to anyone over these sorts of commons, are unethical. […] Abstract ideas, natural phenomena, and natural laws cannot be contained, cannot be exclusively controlled, and no rights may inhere for any one individual over them. Unlike the rights that inhere over real property, there is no manner in which anyone may claim an exclusive right over the commons-by-necessity. Instead, we all necessarily share equal rights of access to these commons, not because some sovereign says we do, but because we are entitled to free, equal and open access to instrumental use of nature's parts so long as that use does not interfere with anyone else's rights. […].").

[102] GENEWATCH, *supra* note 101.

[103] Koepsell, *supra* note 91, (It is a constantly evolving object that involves every member of the species and like the atmosphere, it cannot be enclosed to the exclusion of others simply as a matter of necessity.).

[104] *See Id.*

own genome.[105] Koepsell concludes that IP law is an attempt to enclose a commons-by-necessity just like the laws that allow for the patenting of genes.[106]

Next, Wilson's argument suggests that intrinsic moral rights to intellectual property do not exist.[107] Intrinsic moral rights are those that are justified by features of the moral right holder, which are important to protect when considered on their own.[108] To show that there is an intrinsic moral rights claim, which Wilson calls the "Rights Justification Principle," one must be able to show first that violating this right would result in either a wrongful harm or other significant wrong to the holder of the right, and second that the wrongful harm or other wrong in question is independent of the existence of the intrinsic right one is trying to justify.[109]

Wilson answers both of these concerns by highlighting how intellectual property is unique in two ways.[110] First, intellectual property is inherently nonrivalrous, meaning that people can come up with the same ideas without ever obstructing the thought process

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[105] *Id.,* ("You and I has as much right to investigate what makes us up as anyone else- and this goes back to the axioms I explored early on in the talk. What Myriad owns with these patents is a right to exclude you from finding out about what is in you; and they're exercising their right to our common detriment- in fact it does violence to you when they exercise their right, in much the same way as if [someone] ripped [a] book from my hand." Furthermore, Koepsell says that typically when the law says you can't make a certain expression, it has to do with preventing physical harm, but IP laws do not prevent physical harms as required to be a justified limitation on Mill's liberty principle. His fourth premise says that IP rights are exclusionary rights that prevent the unauthorized expression of protected idea types. "And I've come to the conclusion that all intellectual property law is some form of government restriction on expression having nothing to do with physical harms [… as required by Mill's liberty principle.]"); *Supra* note 96, (Koepsell's argument tends to overlook general civil tort law categories of harms such as severe emotional distress and defamation).

[106] *See Id.*

[107] Wilson, *supra* note 90, at 393, ("Intellectual property typically involves claims of ownership of types, rather than particulars. In this article I argue that this difference in ontology makes an important moral difference. In particular I argue that there cannot be an intrinsic moral right to own intellectual property.").

[108] HXA ARTICLES, *supra* note 89.

[109] Wilson, *supra* note 90, at 1.

[110] *Id.* at 403, ("The argument depends on two sub-claims: first, a claim about a particular property which intellectual property goods as a kind have, namely that they can be enjoyed nonrivalrously. And second, a claim about the necessary conditions for the justification of intrinsic moral rights- namely that we cannot be justified in positing the existence of an intrinsic moral right to [someone] unless we can point either to some wrongful harm, or some other significant wrong which will typically occur to those whose putative moral right to [someone] is violated.").

of others.[111] He writes, "But each intellectual property good is nonrival, and so by its nature abundant: there is no physical reason why each person should not make use of a particular idea."[112] Second, imposing an intrinsic moral right to intellectual property means that we can impose moral duties on other agents that are supported by justification.[113] Wilson says, "Rights have their basis in the protection of individuals, and also involve impositions on what otherwise are the freedoms of other agents."[114] The idea here is that we should be able to point out the way in which someone would be harmed if they were not allowed to have their right to something. Wrongful harm, however, is based on falling below a normative standard of harm, not some extraordinary standard.[115]

Wilson determines that there are only three ways in which someone might be wronged that would meet the criteria set in the "Rights Justification Principle."[116] First, the creator is wronged by being excluded from the use of what she has created.[117] Second, the creator is wronged by being prevented from excluding others from what she

[111] *Id.* at 404.
[112] *Id.*
[113] *See Id.* at 405; HXA ARTICLES, *supra* note 89.
[114] Wilson, *supra* note 90, at 405.
[115] *Id.* at 406, ("Slave owners were made worse off by losing the legal right to own slaves, and were thus harmed relative to a historical baseline by the legislative changes. But I take it that this would not represent a cogent argument in favour of an intrinsic moral right to own slaves. In general, when someone has no entitlement to a particular advantage, they cannot use the mere fact that they would be made worse by losing that advantage as an argument in favour of them having an intrinsic moral right to that advantage. So, in order to ground an intrinsic moral right, a person would have to be made worse off than the relevant normative baseline by having their right violated. I shall not specify here what the relevant normative baseline should be: I shall simply assume that there is such a baseline […]."); HXA ARTICLES, *supra* note 27; Wilson, *supra* note 90, at 408 (Lastly, Wilson says there must be something other than the moral right or the possible wrongful harms which to explain why there ought to be such a right. The reason for this is to avoid a circular argument that would hold that intrinsic moral rights are in reference to wrongful harms that then justify those moral rights. Wilson's refined Rights Justification Principle now reads. "Any justification of an intrinsic moral right must show that violating the right would typically result in either a wrongful harm or other significant wrong to the holder of the right, which is independent of the existence of the moral right we are trying to justify.").

[116] *See Id.* at 414.
[117] *Id.*

has created.[118] And third, the creator is wronged by others benefiting unfairly from her creative effort.[119] Wilson argues that none of these apply to show that there may be an intrinsic moral right to IP.[120]

C. The Ethical Principles Supporting Intellectual Property Law

Even though Koepsell and Wilson's ethical arguments against intellectual IP laws as they stand now are clear and hit on a lot of common criticisms, completely overhauling this legal institution would be very shortsighted given the various ethical support for IP laws. Arguments based on justice and rule utilitarianism lend a lot of ethical support for the reliability of this institution.

Garret Hardin's *The Tragedy of the Commons* is a strong basis for an argument supporting IP laws from a distributive justice lens.[121] Although *The Tragedy of the Commons* has traditionally been used as a defense of either privatization or governmental regulation of the environment, and generally problematized by economists like Nobel Prize winner Elinor Ostrom, it serves a very important purpose in defending intellectual property law. Essentially, the establishment of a patent system is justified because it would be unfair to allow people a 'free ride' at the expense of others who apply

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[118] *Id.*
[119] *Id.*
[120] HXA ARTICLES, *supra* note 89; Wilson, *supra* note 90, at 414, 415, 426 (With regard to the first way in which someone might be wronged, the property right over a nonrival good will not delete it nor will it stop anyone else from using it or thinking the same idea. Next, being prevented from economically benefiting by excluding others from accessing the innovation does not constitute a wrongful harm that is independent of the intrinsic moral right to exclude others from their work. Lastly, Wilson holds that it is not unfair to breach economic rights that are created by intellectual property law since they this does not impose a cost on the person providing the good. He says, "Economic rights cannot be intrinsic moral rights, as they cannot meet the conditions set down by the *Rights Justification Principle*.").
[121] Garret Hardin, *The Tragedy of the Commons,* 162 SCIENCE, 1243 (1968) *available at* http://www.sciencemag.org/content/162/3859/1243.full.pdf&embedded=true.

themselves to the act of inventing.[122] Imagine a commonly shared piece of property, one where individuals come to do a lot of different things, such as raise sheep and crops, but no one ever takes care of the commons such that it may remain usable to others after they have finished their work.[123] Since no one is forced to take care of the commons so that its use is sustainable, it would be against an individual's interest to not overuse the commons. That does not change the fact, however, that individuals who use the commons greatly benefit from it and would hate to see it go. In fact, individuals would be open to something like a tax or some sort of a rule, what Hardin calls mutual coercion, which they mutually agree to, to ensure that this commons was available to be used by all.[124] This concept can be useful for understanding the ethical permissibility of intellectual property laws. The idea is that if there is a lack of incentive to promote research, development, and ultimately innovation, then these things will not be shared for fear of abuse by others who will simply free ride.[125] The establishment of a patent system is justified because it would be unfair to allow individuals to free ride but also because it

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[122] Sigrid Sterckx, *The Moral Justifiability of Patents*, 13 ETHICAL PERSPECTIVES: J. OF THE EUROPEAN ETHICS NETWORK, 245, 255 (2006), *available at* https://www.academia.edu/243631/The_moral_justifiability_of_patents.

[123] *An Alternative: The Commons-Based Peer Production model*, THE ETHICS OF INTELLECTUAL PROPERTY, *available at* http://classes.soe.ucsc.edu/cmpe080e/Spring05/projects/ip, ("The most serious problem was the difficulty in getting the users of the land to decide what amount of cattle each grazer should be allowed to use in order not to over-work the land. Here we encounter the 'free rider' problem, where no matter what everyone else does, you are better off acting on your own to maximize your profits. […] As a result of depleting resources, much of the land formerly available to commoners was enclosed and made private in order to maintain it.").

[124] Hardin, *supra* note 121, ("The social arrangements that produce responsibility are arrangements that create coercion, of some sort. […] To say that we mutually agree to coercion is not to say that we are required to enjoy it, or pretend we enjoy it. Who enjoys taxes? We all grumble about them. Bu we accept compulsory taxes because we recognize that voluntary taxes would favor the conscienceless. We institute and (grumbly) support taxes and other coercive devices to escape the horror of the commons.").

[125] Ferrara, *supra* note 20, ("The consequence is that the absence of any form of control leads to a lack of adequate incentive to promote further research and development. However, the idea that by ensuring a patent holder an exclusive right over the results of his research represents an answer to the tragedy of the commons […].").

would otherwise risk the necessary sharing of research and innovation that is so germane to scientific development.[126]

Rule-utilitarianism deems an act morally right based on whether or not it falls under a correct moral rule.[127] If adopting a rule maximizes the net utility for everyone affected, then the rule is morally justified.[128] "Generally, actions are to be judged in reference to rules and rules in reference to the consequences. The only time particular acts are tested directly is when there is no rule which covers the act or when two rules conflict."[129] It has been generally accepted that IP law positively influences the amount of innovation and social utility that results from properly incentivized innovation.[130] Therefore, rule utilitarianism suggests that IP law generally improves the progress of science overall, even if we may come across certain instances where patents seem inappropriate.

D. The Utilitarian Purpose of Patent Law

Neither the harms nor the benefits of DNA patents for clinical genetic testing are quite clear. However, a large concern about approving patents that rely on research done with entire genes or expressed gene sequences is that they easily have the potential to

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[126] Victoria Stodden, *Why Public Access to Data is So Important (and why getting the policy right is even more so)*, NAT'L ACADEMY OF SCIENCES PUBLIC COMMENT MEETING, *available at* http://sites.nationalacademies.org/xpedio/groups/dbassesite/documents/webpage/dbasse_083204.pdf.
[127] Adam Moore, *Intellectual property, Innovation, and Social Progress: The Case Against Incentive Based Arguments, 26* HAMLINE L. REVIEW 602, 609 (2003), *available* at http://faculty.washington.edu/moore2/mooreIP.pdf.
[128] *Id.*
[129] *Id.*
[130] *Id.*, ("In terms of 'justification,' modern Anglo-American systems of intellectual property are easily modeled as rule-utilitarian. Typically, it is argued that adopting the systems of copyright, patent and trade secrets leads to an optimal amount of intellectual works being produced and a corresponding optimal amount of social utility.").

hinder scientific progress in the area of genomic research.[131] This fear is warranted; especially in light of a recent 2002 Federal Circuit court case that held academic institutions could be liable for patent infringement even in nonprofit research.[132] Relatedly, many are fearful that patent holders could also create an anti-commons effect where researchers may avoid certain areas of interest that are characterized with having patent thickets.[133] Patent thickets are an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees.[134] These obviously discourage researchers from competing and pursuing ambitious breakthroughs or new cures for diseases that may be far better than whatever is currently patented.[135] Furthermore, these concerns highlight the ethical importance of bestowing patents to promote innovation and protect the integrity of the sciences.

The U.S. patent system has a very utilitarian function.[136] By granting one owner exclusionary rights over others, the Patent Office is saying that the innovator has given to

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[131] Timothy Caufield, et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1092 (2006), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2701726/, ("Much of the policy debate has focused on the seemingly quantifiable and practical concerns about the effect of patents on access to useful technologies in both the context of research and the clinic."

[132] Madey v. Duke Univ, 307 F.3d 1351 (2002); Robert Cook-Deegan, *Gene Patents*, 15 FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS, 69, 69-72 (2008), *available at* http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/gene%20patents%20chapter.pdf.

[133] Keyvan Vakili, *Strategic Patenting and the Tragedy of the Anticommons: A Closer Look at Firms Patenting Behavior*, DRUID SOCIETY, *available at* http://druid8.sit.aau.dk/acc_papers/7ysnj11t301va2jbnulm61x9a4ih.pdf, ("[…] a dense web of overlapping patents owned by too many individual players in a technology area leads to subsequent underinvestment in cumulative innovation and a decline in the patenting rate of firms in that area.").

[134] Merz and Cho, *supra* note 65, (" [..] a patent thicket is created that can lead to difficulties in securing licenses and expenses in paying multiple 'stacked' royalties to multiple patent owners.").

[135] *Id.*, ("A strong argument can be made that the research exemption should be much broader, encompasing research aimed at better understanding the claimed invention, such as how it works and whether it works as taught by the patent, how to improve upon it and how to work around it.).

[136] Alan Devlin and Neel Sukhatme, *Self-Realizing Inventions and the Utilitarian Foundationg of Patent Law*, 51 WILLIAM AND MARY L.R. 897, 913 (2009), ("[…] academic commentators have resoundingly

society a bounty of information and innovation that resulted from his or her endeavors into the useful arts that will in turn be used to push forward more science. Patents ensure the common, intellectual good of the society in which they are exercised because the patent-protected researchers are encouraged to disclose their innovations to their intellectual community without fear that their innovations may not be protected.[137] It allows more research into the area that tests the theory, criticizes it, or likely improves on it in a remarkably novel way. Therefore, patents are not an end in themselves but rather a means to pursuing other ends such as more innovation, improvements to public health, and expanding our creative capabilities.

> "[…] the underlying premise [is] that patient rights inherently foster innovation by demanding public disclosure of inventions in exchange for a temporary term of exclusivity. Perhaps unprecedented is the pervasive readiness to disavow this quid pro quo between the public and the inventor when the disclosed invention culminates in a product or process that achieves market demand."[138]

Absolute patent rights that prevent the use, continued research or commercial development of inventions that are useful and desirable are morally indefensible because they are not executing the professed purpose of patents.[139] This is the juncture where we find patents on human genes today. Predatory patenting behaviors that limit the scope of research into important, life-saving technologies based on human genes are ethically problematic under the utilitarian standards of patent law.[140]

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embraced the position that patent law exists to promote purely utilitarian concerns. More importantly, the U.S. Supreme Court has consistently reaffirmed the same view on several occasions.").

[137] Sung, *supra* note 86, at 140.

[138] *Id.* at 144.

[139] Lever, *supra* note 72, at 8.

[140] Sung, *supra* note 86, at 144 "[…] A copyright or a patent is only a means to an end, and as such, they constitute a societal good only to the extent the intended goals are achieved. The ugly truth is that intellectual property rights policy is largely unconcerned with whether an author or inventor obtains a reward for his or her work or invention. The crux instead is whether the government grant of intellectual property rights is an efficient tool for driving national creativity and innovation. At the heart of this consideration is the public disclosure of the seeds of individual imagination to grow the fruits of societal knowledge."

Although a patent warns others to not infringe on the owner's rights, studies suggest that patents have a relatively minor impact on basic research since those have rarely been the subjects of lawsuits and because researchers generally tend to not have patents dictate their agendas.[141] Therefore, it is key to realize that patents can only have real impact on those who use it to compete with a patented product on the market. A patent that is not asserted will not likely have an impact on research, and subsequently, the public interest.[142] Some scholars believe that a useful measure of the impact of a gene patent is the amount of litigations revolving around this issue, however a more accurate measurement would also take into account the number of laboratories or researchers that self-proclaim to have halted research for fear of infringing on a patent and being susceptible to litigation.[143]

E. The Research Standstills that Result from Patents on Human Genes

When scientists encounter a patent-protected gene, they are faced with three options: (1) avoid researching the particular gene; (2) become authorized under a license to the rights to research the gene from the patent originator; or (3) expose their research activity to patent enforcement by continuing their research.[144] Findings suggest that

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[141] *Id.* at 306;Walsh et al., *View from the Bench,* 309 SCIENCE, 2002 (2003), *available at* http://www.sciencemag.org/content/309/5743/2002; Corrine Langinier, Pool of Basic Patents and Follow-*up Innovations,* (2006), *available at* http://www2.econ.iastate.edu/faculty/langinier/documents/LanginierPool.pdf, ("In the are of biotechnology, follow-up innovations are often build on several basic innovations, and cannot be developed without them. Inventions such as methods to isolate and locate gene sequences possess the characteristics of public goods.").

[142] Christopher Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation,* 76 UMKC L. R. 295, 306 (2007), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1090562.

[143] *Id.* at 3030, (Dr. Holman believes that patent litigation is the best measure.).

[144] Andrew S. Robertson, *The Role of DNA Patents in Genetic Test Innovation and Access,* 9 NORTHWESTERN J. OF TECH. AND INTELLECTUAL PROPERTY 377, 384 (2011), *available at* http://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1007&context=njtip.

researchers are most likely to elect the third option. Many have interpreted this choice as an indication of how patents do not necessarily hinder innovation and science because a patent holder must have the desire to enforce their patent before stifling others studies. "Studies have shown that these patents have had a relatively minor impact on basic research, due in large part to the fact that researchers simply choose to remain ignorant of the patents, or at least do not let the existence of patents dictate research agendas"[145] However, the mere threat of a lawsuit clearly has the potential to impede follow-on research given the great deal of research laboratories that have said they stopped their research for fear of infringement.[146] "Laboratories would rather not offer a test than risk expensive litigation, even if the laboratory has a good chance at prevailing. The fact that all issued patents are presumed valid furthers this harm."[147] These gene patents have led 25% of labs surveyed to stop performing a genetic test and 53% reporting that they were unable to develop a new test because of patents.[148] This inability to research or invent around a patent is especially problematic given the professed purpose of patents is to promote and foster innovation. Therefore this relates to the first option available, namely to avoid researching that particular gene altogether, which many laboratories evidently do for fear of the punitive consequences of patent enforcement.[149]

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[145] Holman, *supra* note 142, at 305.
[146] Langinier, *supra* note 141; Adam Jaffe, et al., *Real Impediments to Academic Biomedical Research*, *8* INNOVATION POLICY AND THE ECONOMY 1, 8 (2009), ("[…] Where innovation is cumulative, the assertion of patents on key upstream discoveries may significantly restrict follow-on research.").
[147] Sapna Kumar, *Life, Liberty, and the Pursuit of Genetic Information*, 65 ALABAMA L. R. 626, 640 (2014), *available at* http://www.law.ua.edu/pubs/lrarticles/Volume%2065/Issue%203/2%20Kumar%20625-681.pdf.
[148] Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, J. MOLECULAR DIAGNOSTICS, Feb. 2003, at 3-8 *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1907386
[149] Kumar, *supra* note 147, at 640, ("[…] laboratories will cease research in the face of a patent, even one of dubious validity, rather than risk costly litigation.").

This leaves one viable option for researchers to elect; obtaining a license from the patent originator.[150] A significant issue that may come up in this case however is when a patent originator does not seek to license out its patent to others, and rather wants to simply exclude others from making, using, or selling the invention.[151] Courts generally will still find in favor of the patent originator in the event of a lawsuit due to the rights conferred onto a patent owner when the USPTO approves their application.[152] Finding in favor typically means issuing an injunction, which means that competitors researching the patented product would be required to cease and desist. This is even the case when the patent originator does not have a market share and therefore is not losing any sales.[153] Public policy goals about whether a patent is used should play a role in the decision about whether or not an innovation deserves court-ordered patent protection.[154] What is the purpose of having a patent if it is not going to benefit the world with its presence? Having a patent just for the sake of having a patent and not working it to its fullest potential is

[150] *Id.* at 646.
[151] *Id.* at 648.
[152] *Id.* at 633; Golan v. Holder, 132 S. Ct. 873, 878 (2012).
[153] Sarah R. Wasserman Rajec. *Tailoring Remedies to Spur Innovation*, 61 AM. UNIV. L.R. 733, 755 (2012), *available at* http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1661&context=aulr.
[154] *Id.* at 747, ("The balance struck by the patent grant rests on the assumption that the public will benefit from the disclosure of the invention and from the invention's entry into the market."); *Public Policy*, THE SCOPE OF PROTECTION OFFERED BY INTELLECTUAL PROPERTY LAW, *available at* http://nationalparalegal.edu/public_documents/courseware_asp_files/patents/IntroIP/Scope.asp; *What will happen if someone sues me for patent infringement?*, UNITED STATES PATENT AND TRADEMARK OFFICE, *available at* http://www.uspto.gov/patents/litigation/What_is_Patent_Infringement.jsp, ("The court may conclude that the patent claim is not valid if it is shown that the claimed invention was disclosed in a prior patent or patents, a book, a magazine, a newspaper, a television show or movie, a webpage or other published work before the date of the claimed invention. Also, the court may conclude that the patent claim is not valid if it is shown that application for the patent was filed. In addition, the court could find the patent invalid because it does not meet their other statutory requirements, such as a sufficient written description of the invention, or because it does not describe the subject matter that is patent eligible.").

ethically impermissible since it is inconsistent with the Constitutional goals of a patent system and it does not promote any public interest.[155]

This sort of patent-hoarding behavior is not part and parcel to the very professed purpose of patents that we acknowledged in the beginning. Patents offer a time-restricted right to exclude others from using, making, selling the disclosed patent information.[156] However this time offered is assumed to be used by the patent originator to either license out the invention or produce it themselves so to benefit the public by granting it access to the innovation before the patent expires.[157] When this does not happen, a wealth of knowledge is not made available in exchange for protection that cannot be overcome without a compulsory license. There is an ethical imperative to better balance the rights of patent owners to patent and exclude others from making, using and selling their technologies with the professed purpose of patents, which is to benefit society with this innovation.

F. The Ethics of Patient Autonomy and Informed Decision Making In Health Care Choices

As we have seen, arguments supporting patents are built on around a case that they deserve the highest intellectual property protection so that further innovation can be adequately guaranteed. However, the consequences of granting such protection without ample patient safeguards may directly endanger patient autonomy when making health

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[155] *See* U.S. CONST. ART. I, § 8, cl. 8, *supra* note 7, (Proclaiming that the constitutional policy of patent law is to promote the progress of science and art by securing rights to inventors for their respective discoveries.").
[156] Charles Frederick Seyboldt, *Attributes of protection,* A BIT ABOUT PATENTS, *available at* http://www.walaw.com/patent.html.
[157] Wasserman Rajec, *supra* note 153, at 755.

care choices.[158] The bioethical principle of respect for patient autonomy demands that each rational, competent person be given the right to make medical decisions that affect his or her life.[159] Respecting autonomy ensures that patients have given their free, informed consent for treatment. The goal of the genetic counselor-patient relationship is to provide information that the patient can use to make a decision guided by his/her own values.[160] "The presumption […] guiding the actual conduct and methods of clinical genetics work is that autonomy […] can flourish only in a purely factual environment."[161] Patient choice of genetic tests that give them the facts they need to make informed medical decisions moving forward are at the mercy of patent holders of genetic diagnostic tests.[162] This is the reality because a patent conferred on one inventor who may or may not license it out means the patient's ability to elect a test to assess his or her genetic predispositions is seriously limited. This is further exacerbated by the potential for only one laboratory being licensed to perform the genetic diagnostic test, and this test may not be the best actual diagnostic researched. This means there will not be any secondary opinion testing, and the testing that is available will be more limited than it *needs* to be.[163]

Take for instance a patient who seeks a second opinion about whether or not they are predisposed to breast cancer. As we saw above, fear of patent enforcement and the

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[158] Kumar, *supra* note 147, at 681.
[159] Jennifer A. Parks and Victoria S. Wike, THEORIES AND VALUES IN BIOETHICS, 18 (2010).
[160] Arthur L. Caplan, *Neutrality is Not Morality: The Ethics of Genetic Counseling*, from Prescribing Our Future: Ethical Challenges in Genetic Counseling (1993), reprinted in *Theories and Values in Bioethics* (2010), 63.
[161] *Id.*
[162] Kumar, *supra* note 147, at 627, ("In the past year, much attention has been paid to how diagnostic testing can help patients make informed medical decisions. For example, in May 2013, Angelina Jolie announced in a *New York Times* op-ed that she chose to have a double mastectomy after learning that she carries the BRCA 1 genetic mutation.").
[163] *Id.* at 661, ("Patent holders may limit the scope of available testing and prevent individuals from obtaining secondary testing. In extreme cases, a patent holder may be unable to unwilling to offer the analogous test.").

hassles of patent thickets limit the ability and incentive for research laboratories to pursue further research in areas that require much ambition, such as genetics.[164] We know that just because something is patented, does not mean it is the top-of-the line in its class. So, when this patient goes to their physician to seek a genetic diagnostic examination to assess his/her genetic traits and predispositions, they may believe that what they are seeking and going to be tested with is considered by the scientific community to be the best available resource for achieving this diagnostic goal. In fact, implicit in a patent award is this very notion, that what is being patented is the best of its kind given the available prior art. For a long time, Myriad Genetics, a patent holder over the BRCA1 and BRCA2 genes, had a patent only on one of the many possible diagnostics tests to assess the genetic predispositions to breast and ovarian cancer.[165] However, because of their broad patents over these genes, which included all of their polymorphic nucleotides, they were the only provider for this diagnostic assessment. Also, because Myriad was the sole provider for BRCA testing, there was no incentive for them to provide advanced testing techniques for allowing patients to confirm their original test results because this would be considered market cannibalization.[166] Basically, there is no incentive for Myriad to create another more advanced test while their patent is still young because this would divide their own market presence as being the only BRCA diagnostic test available

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[164] Stephen A. Merill, *Effects of Intellectual Property Practices on Research*, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH, *available at* http://www.ncbi.nlm.nih.gov/books/NBK19862/, ("A patent on an upstream discovery may be an impediment to downstream research if it results in lack of access by downstream researchers not in need of exclusivity or to foundational discovery or indispensable research took […] or if it renders access to multiple patented technologies excessively different or costly (the 'thicket' or 'anti-commons' problem).").

[165] Robertson, *supra* note 144, at 386.

[166] *Id.;* Wasserman Rajec, *supra* note 153, ("Any new product a company considered introducing would be competition with its other products, and thus the company would stand only to divide market share it already had among multiple products, while losing the cost of introducing the innovation. This phenomenon is known as 'cannibalization' of the market.").

between the original test and this confirmatory test. Furthermore, if Myriad had decided to pursue confirmatory tests, the theory of market cannibalization suggests that Myriad may not have continued with their existing product development because they would commit their resources to develop this newer test that seems to have a great demand.[167] Instead, what happened was that patients would take the same diagnostic test multiple times to see if the results were consistently positive or negative. However, the test Myriad was offering was incomplete compared to what another laboratory at Yale University had innovated, which also included large genetic rearrangement testing.[168] If we are going to limit the availability of market competitors based on approved patent applications, it is in the public's best interest to have patented that which is considered at the time of application to be the best in its class.

Furthermore, the exorbitant costs associated with patents on diagnostic tests such as the ones Myriad had over the BRCA genes mean that not everyone can afford to access their genetic information to make more medically informed decisions about their health.[169] The patents held by Myriad give them a monopoly on the tests and without the market competition there exists no need to reduce their prices. In 2008, the cost to individuals was upwards of $3,000, the cost to Myriad to provide the test was $32

[167] Wasserman Rajec,*supra* note 153, at 769.
[168] Kumar, *supra* note 147, at 676, ("[…] Where the diagnostic test being offered is incomplete compared to what another laboratory could offer, as we saw with Myriad failing to offer large rearrangement testing when Yale had the capability to do so.").
[169] (The author of this article recognizes that not everyone can afford medical care in general. However, the American legal system is reforming the law's impact on the health care industry so that costs of health care delivery are overall minimized while access to care is improved. Access to diagnostic testing does not have a therapeutic or curative benefit, however, like most services rendered do. It is purely diagnostic. Nonetheless, in the context of minimizing health car costs, maximizing quality of patient care and improving access to care, exorbitantly priced diagnostic tools that may allow for cheaper preventative medicine instead of chronic, urgent or emergency care is antithetical to the very goals we have set up as a nation to combat increasing health care delivery costs. Furthermore, genetic diagnosis that may confirm or rule out a suspected genetic condition is important given the inheritability of these traits that may be passed on to current and future children.)

million, but Myriad profited in the range of $222 million.[170] When addressing the purpose of patents above, not once did we say that the right of a patent owner includes making a profit. Making a profit is merely incidental to the exclusionary rights that are conferred onto the individual who innovates something of great social worth.

> "[…] A copyright or a patent is only a means to an end, and as such, they constitute a societal good only to the extent the intended goals are achieved. The ugly truth is that intellectual property rights policy is largely unconcerned with whether an author or inventor obtains a reward for his or her work or invention. The crux instead is whether the government grant of intellectual property rights is an efficient tool for driving national creativity and innovation. At the heart of this consideration is the public disclosure of the seeds of individual imagination to grow the fruits of societal knowledge."[171]

The profit margins that are pursued are creating a justice issue because access to this resource is being greatly determined by one's ability to pay. Justice theory traditionally holds, "Persons deserve to be treated like those to whom they are similar and unlike those to whom they are dissimilar, that is, who differ from them in morally significant ways (such as need, merit or social contribution)."[172] Here, all individuals who seek the same genetic diagnostic information ought to be treated similarly by either unilaterally being granted access to such technology or not. Social worth and ability to pay seem to factor in far too much in being able to access a test that informs a patient on how to engage in future medical decision making.[173]

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[170] Ass'n for Molecular Pathology v. U.S Patent and Trademark Office, 702 F.Supp.2d 181 (2010), citing to Myriad Genetics, Inc., Annual Report (form 10-K), at 27 (Aug. 28, 2008).
[171] Caplan and Arp, *supra* note 74, at 144.
[172] *Patents Introduction*, CHAPTER 2- FIELDS OF INTELLECTUAL PROPERTY PROTECTION, *available at* http://www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch2.pdf, ("A patent is a document, issued, upon application, by a government office (or a regional office acting for several countries), which describes an invention and creates a legal situation which the patented invention can normally only be exploited (manufactured, used, sold, imported) with the authorization of the owner of the patent. "Invention" means a solution to a specific problem in the field of technology. An invention may relate to a product or a process. The protection conferred y the patent is limited in time (generally 20 years).").
[173] *Infra* Section IV of this article. The issues of access to health care due to unaffordability are tied to these issues as well.

This unjust access issue goes to show that there is an ethical interest in amending the current patent infrastructure in the United States to account for both a more nuanced appreciation for the privilege of conferring intellectual property protection onto a patent originator as well as show why granting more research freedom and access to health-maintaining technology is warranted in an age of austerity. There seems to be a huge disconnect between what the actual goals of patent law are, namely incentivizing increased innovation and access where profits are merely incidental, and the primary benefits that patent holders view patent law as granting, which is overwhelmingly large profit margins.

IV. Litigious Dangers of DNA Diagnostic Tests in a Competitive Market

Over one million people in the U.S. population are lawyers.[174] It comes to no surprise, then, that we have a very litigious society. The average patent lawsuit costs each side approximately $2 million in legal fees and related expenses and the amount increases around 15% each year.[175] The first patent awarded on a recombinant DNA method was granted in 1980, only six months after the Supreme Court decided that life could be patented.[176] There are between 3,000 and 5,000 U.S. patents on human genes and 47,000 on inventions involving genetic material. The following is a cursory overview of a

[174] *We are the world's most litigious society,* THE TELEGRAPH, *available at* http://www.thetelegraph.com/opinion/columnists/article_53dbee4f-d60f-5558-83bb-3763573a887c.html.
[175] Mark A. Glick, et al., INTELLECTUAL PROPERTY DAMAGES: GUIDELINES AND ANALYSIS, (2003) 1, 20.
[176] Cook-Deegan, *supra* note 132, (The first patent on a recombinant DNA method was granted in December 1980, just six months after the United States Supreme Court rules in *Diamond v. Chakrabarty* that a life form could be patented" Gene patents were an extension of the legal doctrines that permitted patents on hormones, vaccines and other natural products that had taken some ingenuity to become newly useful things.).

fraction of the handful of case law that has controlled the patent eligibility of life forms, such as human DNA.

A. Judicial Review Drawing the Line in the Sand Between What Is and Is Not Patentable Subject Matter

The next issue at hand is where human gene patents fall within the category of patentable subject matter. In general, laws of nature, physical phenomena, and abstract ideas have been held not patentable.[177] Two specific U.S. Supreme Court cases outline what the Court believes are important parameters of the patentable subject matter requirements.[178] Together, these cases explain why certain DNA patents are subject to patent protections while others are not. In both cases, the judicial interpretation of 35 U.S.C. §101 establishes that genetically engineered organisms or inventions are patent eligible because through scientific manipulation, the entity is no longer "naturally occurring."[179]

The Supreme Court has emphasized an implicit division found in the Patent Act between naturally occurring phenomenon, most specifically living things, and human innovation concerning a topic other than DNA.[180] In *Diamond v. Chakrabarty*, the issue was whether the creation of a bacterium capable of breaking down crude oil was

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[177] Diamond v. Chakrabarty, 447 U.S. 303 (1980), (citing to Parker v. Flook, 437 U.S. 584, 98, S. Ct. 2522, 57 L.Ed.2d 451 (1978)).
[178] Diamond v. Chakrabarty, 447 U.S. 303 (1980); Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F. 3d 1329 (2011).
[179] Michael Powell, *Supreme Court rules that a naturally occurring DNA segment is not patent eligible, but cDNA may be patent eligible*, ASS'N OF CORPORATE COUNSEL, *available at* http://www.lexology.com/library/detail.aspx?g=c9022fa6-7323-4063-a751-80e73b66e7f3, ("A naturally occurring DNA segment is a product of nature and not patentable merely because it has been isolated." The Supreme Court's holding rests on 'an important implicit exception' to §101: 'Laws of nature, natural phenomena, and abstract ideas are not patentable.' In explaining that isolated BRCA genes are not new compositions of matter, the Court relied on its […] previous decision concerning 'laws of nature' and 'natural phenomena": *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)[…].").
[180] *See Id.*

protected under 35 U.S.C.§101 as "compositions of matter" or whether Congress' Plant Variety Protection Act of 1970 ("PVPA") precluded such protection.[181] The PVPA authorized patent protection for asexually produced plants in 1930 and some sexually reproduced plants in 1970, but specifically excluded bacteria.[182] Petitioner Diamond claimed the passage of the PVPA indicated that Congress did not expressly authorize patent protection for bacteria and was joined with Justice Brennan in finding it is within Congress' purview, not the Court, to decide what constitutes patentable subject matter.[183] However, given that respondent Chakrabarty's claim was based on a natural phenomenon, the opposing party argued that could not be afforded patent protection as it does not constitute a "manufacture, or composition of matter."[184]

Nonetheless, the U.S. Supreme Court found in favor of respondent Chakrabarty's invention because the patent claim was for a bacterium not found in nature that "constitutes a 'manufacture' or 'composition of matter' within that statute."[185] Chief Justice Burger wrote for the majority and found that the bacteria in this case was clearly a

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[181] Diamond v. Chakrabarty, *supra* note 180; PLANT VARIETY AND PROTECTION ACT, Pub. L. 91-577, Dec. 24, 1970, 84 Stat. 1542-1559.
[182] PLAN VARIETY AND PROTECTION ACT, *supra* note 184, at §42 (a).
[183] D. Chakrabarty, *Patentability of Micro-organisms*, 14 AKRON L. R. 341, 343-44, (Justice Brennan was actually in the dissent for the this case which upheld Chakrabarty's patent. However, Justice Brennan felt that it was within Congress' purview to broaden the categories to make this clear. "Justice Brennan expressed his concern, in a dissenting opinion, whether Chakrabarty should be 'able to secure a monopoly on the living organism itself.' He stated that he believed that the majority was extending the coverage of the patent system, even though, in his view 'Congress plainly has legislated in the belief that §101 does not encompass living organisms. It is the role of Congress, not this Court, to broaden or narrow the reach of patent law. This is especially true where, as here, the composition sought to be patented uniquely implicated matter of public concern.'").
[184] Diamond v. Chakrabarty, *supra* note 180, at 307.
[185] *Id.*, at 303; D. Chakrabarty, *supra* note 186, at 347 ("The court, in its decision, limited itself as much as possible to a determination of 'whether respondent's micro-organism constitutes a 'manufacture' or a 'composition of matter' within the meaning of the statute.' A key factor for the Court in seeking to determine the congressional intent behind section 101 was the fact that Congress retained the use of the word 'any' in modifying both manufacturer and composition of matter in the 1952 re-enactment; that if Congress had wished to place restrictions on the meaning of these words, it would not have said 'any.' Another factor that the Court felt was compelling was the statement made during the hearings on the bill that these words referred to 'anything under the sun developed by man.'").

man-made invention, and therefore patentable subject matter.[186] The relevant distinction in this case was between products of nature and human made inventions, the latter being patentable subject matter because they are a result of human ingenuity and research and fall neatly within the requirements of 35 U.S.C. §101.[187] Therefore, this case made it clear that genetically engineered live organisms *can qualify* as patentable subject matter if they are decidedly unlike anything that naturally exists.[188]

Writing for the dissent in *Chakrabarty* was Justice Brennan who disagreed with the majority's decision to not defer to the very language of the PVPA. Justice Brennan believed the court extended the patent system to cover living organisms against Congress' dominant opinion that these were not patentable subject matter even under 35 U.S.C. §101.[189] The very exercise of judicial review that took place in *Chakrabarty* is not unique to patent litigation, but probably indicates the special legislative need Congress must satisfy by generating specific language in future rules or amend past language regarding patentable subject matter so that what is defined can account for the whole range of scientific innovation. The proverbial ball was left in Congress' court after the *Chakrabarty* ruling. Since Congress is constitutionally designated for the task at hand, they must decide what to do next: either override the Court's decision by introducing new law or do nothing and allow this interpretation to govern. At this point in time, Congress chose the latter. However, this suggestion of amending the actual legislation will be taken up later on in the paper when discussing the literature about the future of gene patents.

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[186] Sharon McAuliffe and Kathleen McAuliffe, LIFE FOR SALE (1981).
[187] D. Chakrabarty, *supra* note 186, at 348, (Quoting the Supreme Court," 'The relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.'").
[188] Diamond v. Chakrabarty, *supra* note 180, at 303.
[189] *Id.* at 322.

The climate that surrounded *Chakrabarty* as well as the result was highly unprecedented.[190] What would have been the consequences of the Court deciding the case the other way? For one, there would not have been such high support for inventors to apply for patents on innovations that are a result of manipulating natural phenomena. During the time in which the *Chakrabarty* patent was first applied for, there was also another application for a biologically pure strain of bacteria that produces the antibiotic lincomycin filed by a party named Upjohn.[191] For both of these applications, the USPTO denied the applications for the bacteria because they considered them living organisms and not patentable subject matter.[192] Then in the spring of 1979, the Court decided to examine these patents after a long appeals process by the USPTO.[193] However, before the Court got this opportunity, Upjohn's patent claim was withdrawn.[194] Many believe this was because Upjohn's bacterium was only a refinement of a natural antibiotic-producing bug, and although it can not be found in nature, Upjohn feared it was not too far from

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[190] Audrey R. Chapman, UNPRECEDENTED CHOICES: RELIGIOUS ETHICS AT THE FRONTIERS OF GENETIC SCIENCE, 132 (1999), ("In *Diamond v. Chakrabarty* the Court ruled, in a narrow 5-4 decision, that a genetically modified strain of bacteria capable of degrading components of crude oil and thus useful in cleaning up oil spills was patentable as a new and useful manufacture or composition of matter. Although Ananda Chakrabarty, a microbiologist then working at General Electric, had acknowledged that he used commonplace methods to exchange genetic material between bacteria, the Court held that 'his discovery is not nature's handiwork but his own' and 'the result of human ingenuity and research.' While the decision affirmed that phenomena of nature in their natural state are not patentable, the Court identified a major exception: goods that have been transformed from their natural state through human intervention.").
[191] Daniel J. Kevles, *Ananda Chakrabarty wins a patent: Biotechnology, law, and society*, 1972-1980, 25 HSPS 111, 127 (1994), ("In December, the Upjohn lawyers amended their patent application to omit the product claim on […] purified lyncomycin- a move that rendered the company's case moot and saved it the not inconsiderable cost of an appeal to the Supreme Court. Roman Saliwanchik later explained that the company thought its claim for the purified natural fungus was weak and might drag Chakrabarty's case, which was much stronger […].") ; Sheldon Mak Rose & Anderson, *Obtaining Patents for Manufactured Products of Naturally Occurring Substances*, USIP, *available at* http://www.usip.com/pdf/Article_Patents/substanc.pdf, (" 'Whether the claimed pure materials are novel as compared with less pure materials of the reference, ' the Court stated, '… pure materials necessarily differ from less pure or impure materials and, if the latter are the only ones existing and available as a standard of reference, as seems to be the situations here, the 'pure' materials are 'new' with respect to them.' Similarly, in In re Bergy […] held that a biologically pure culture of the Streptomyces microorganism was not a 'product of nature.' It was therefore patentable over the microorganism as it existed in nature.").
[192] LIFE FOR SALE, *supra* note 189, at 199.
[193] *Id.*
[194] *Id.*

being a product of nature to withstand high patent scrutiny. Chakrabarty's bacterium, on the other hand, was definitely a man-made organism that was created using fusion techniques. However, Upjohn, unlike Chakrabarty, had the intention to market the bacterium if the Court were to find in their favor. The *Chakrabarty* case was simply an attempt to see what the Court would say and if favorable, would then open up the gate for a highly lucrative industry.

Had the Court decided the case in the other direction, there would likely have been an incredible amount of disincentive to go through the patent process. Most companies would have been more likely to guard their research on life forms as trade secrets instead of proceeding through the arduous, albeit more rewarding, patent application process. Trade secrets are usually considered the best protection for patent originators in technology sectors that are fast-paced and constantly evolving because they find going through the expense and formality of the patent application is a waste of precious time.[195] However, not using the patent system and instead relying on such things such as trade secrets would be less than optimal for encouraging innovation on a macro scale.[196] The justifiable paranoia over protecting trade secrets would hinder creativity

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[195] Dean W. Russel, et al., *Choosing Between Trade Secret and Patent Protection*, INTELLECTUAL PROPERTY DESK REFERENCE: PATENTS, TRADEMARKS, AND RELATED TOPICS 215, *available at* https://clients.kilpatricktownsend.com/IPDeskReference/Documents/Trade%20Secret%20or%20Patent%20Protection.pdf, at 217, ("With the increasing importance of technology and the corresponding increase in infringements, misappropriation […] it is important to understand the costs and benefits of, and the steps to implement, each form of protection to choose correctly from the various alternatives. Proper selection is further complicated by the fact that some forms of protection, such as trade secret and patent protection overlap. […] By contrast, trade secret protection is potentially unlimited in duration: it continues so long as competitors do not reverse engineer or independently develop the subject matter of the trade secret, or so long as it is not disclosed For instance, The Coca Cola Company has maintained its famous formula for the Coca Cola beverage as a trade secret for decades. If the owner had patented the formula, it would have become publicly available and usable after the patent's expiration.").

[196] Miles J. Feldman, *Toward a Clearer Standard of Protectable Information: Trade Secrets and the Employment Relationship*, BERKLEY LAW, *available at* http://www.law.berkeley.edu/journals/btlj/articles/vol9/Feldman/html/text.html, ("Trade secret protection may, however, limit or discourage innovation.").

within and across disciplines because the non-disclosure of research interests on patent databases would mean lack of transparency amongst the profession that could result in many foreseeable impediments such as pursuits of frivolous or already accomplished scientific goals. The scientific community benefits from disclosure and from peer review, and trade secrets would likely hinder innovation compared to patent protections. Public interest clearly does favor patents on innovation over the other intellectual property protections available for these very reasons.

B. Scientific Discoveries vs. Patentable Inventions: Isolated Human DNA as Patent Ineligible Subject Matter

The ruling in *Association for Molecular Pathology ("AMP") v. Myriad Genetics, Inc.*, was the first to directly address the patentability of DNA sequences.[197] Representing claimant AMP was the American Civil Liberties Union ("ACLU").[198] The ACLU honed their attack on Myriad, the patent originator for two specific genes in question, as well as the USPTO for conferring Myriad with the original patent.[199] The procedural posture of this case spans several years and various stages of appeals, but the final Supreme Court decision was well worth the wait. The Court held that since isolated DNA involves a naturally occurring segment of DNA, DNA is precluded from patent eligibility and

[197] Ass'n for Molecular Pathology v. Myriad Genetics, *supra* note 4.
[198] *Association for Molecular Pathology v. Myriad*, AMERICAN CIVIL LIBERTIES UNION, *available at* https://www.aclu.org/free-speech-technology-and-liberty-womens-rights/association-molecular-pathology-v-myriad-genetics, ("On June 13, 2013, the U.S. Supreme Court invalidated patents on two genes associated with hereditary breast and ovarian cancer in response to a lawsuit filed by the American Civil Liberties Union and the Public Patent Foundation (PUBAT) on behalf of researchers, genetic counselors, patients, breast cancer and women's health groups, and medical professional associations representing 150,000 geneticists, pathologists, and laboratory professionals.").
[199] Ass'n for Molecular Pathology v. Myriad Genetics, *supra* note 4.

protections, however synthetically created DNA ("cDNA") is patent eligible because it is non-naturally occurring.[200]

The issue that the Court took up that is of particular interest for the scope of this paper is whether or not a segment of human DNA is patent eligible under 35 U.S.C. §101 when it is isolated from the remaining natural DNA sequence. Defendant Myriad discovered the location and sequence of two genes, BRCA1 and BRCA2, which, if displaying a mutation, can dramatically increase the risk of breast and ovarian cancer.[201] This discovery allowed Myriad to develop diagnostic tests useful for detecting these genetic mutations so that patients can accurately assess their risk for breast and ovarian cancer.[202] Furthermore, because testing for the BRCA mutations usually involves using reagents consisting of fragments of BRCA genes, Myriad's rights over the mutations enabled them to exclude all others from doing this diagnostic testing.[203]

Justice Thomas delivered the opinion of the Supreme Court and dedicated a significant portion of the decision to harkening back to the previous Federal Circuit Court's opinion on isolated DNA.[204] With regards to cDNA, three Supreme Court Justices were in agreement that such innovation met the patent eligibility requirements.[205] Justice Thomas wrote, "The central dispute amongst the panel members was whether the

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[200] *Id.* at 2109 and 2120.
[201] *Id.* at 2112.
[202] *Id.* at 2109.
[203] Robertson, *supra* note 144, at 383, ("In essence, the patents granted to Myriad gave the company the exclusive right to perform diagnostic tests on the *BRCA1* and *BRCA2* genes and to prevent any researcher or individual from insolating and studying the genes without first getting permission from Myriad. […] *Myriad* illustrates the core issues surrounding gene patents- namely, their effect on research and development (innovation) and on clinical healthcare (access).").
[204] Ass'n for Molecular Pathology v. Myriad Genetics, *supra* note 4, at 2114-2115, ("On remand, the Federal Circuit affirmed the District Court in part and reversed in part, with each member of the panel writing separately. They reasoned that Myriad's actions against him [Petitioner Dr. Harry Ostrer] and his stated ability and willingness to begin BRCA1 and BRCA2 testing if Myriad's patents were invalidated were sufficient for Article III standing.").
[205] *Id.* at 2115.

act of isolating DNA- separating a specific gene or sequence of nucleotides from the rest of the chromosome- is an inventive act that entitles the individual who first isolates it to a patent."[206] Justice Thomas recognized that each of the judges on the panel had a very different view on this particular question concerning the difference between the patent eligibility of cDNA compared to DNA.[207]

Just as in *Chakrabarty* the 35 U.S.C. §101 standard of "new and useful […] compositions of matter," was the rule against which the Court assessed Myriad's patents.[208] Justice Thomas notes that Myriad's patent descriptions only address the process of discovering the locations of these genes, and do not explicitly disclose any information other than their research process. Justice Thomas said,

> "It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes […] the question is whether this renders the genes patentable.[209]

Justice Thomas concluded that Myriad's biggest contribution was uncovering the BRCA1 and BRCA2 genes, but discovery alone does not by itself satisfy the §101 inquiry.[210] Judge Lourie from the United States Court of Appeals for the Federal Circuit rejected the claim that isolated DNA was patent eligible subject matter because the DNA molecule is

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[206] *Id.* at 2114.
[207] *Id.*
[208] *Id.* at 2116, ("We have 'long held that this provision contains an important implicit exception [:] Laws of nature, natural phenomena, and abstract ideas are not patentable." […] As the court has explained, without this exception, there would be considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.' […] This would be the very point of patents, which exists to promote creation. *Diamond v. Chakrabarty*, 447 I.S. 303, 309, 100 S.Ct. […].").
[209] *Id.*
[210] *Id.* at 2110, ("Myriad's patent descriptions highlight the problem with its claims: They detail the extensive process of discovery, but extensive effort alone is insufficient to satisfy §101's demands. Myriad's claims are not saved by the fact that isolating DNA from the human genome severs the chemical bonds that bind gene molecules together.").

held together by chemical bonds that require chemical alteration, therefore make the DNA molecule a non-naturally occurring substance worthy of protection.[211] The chemical bonds that Judge Lourie had decided were dispositive were considered trivial by Justice Thomas given that Myriad did not rely on the chemical changes that result from the isolation of a section of DNA, their claims only focused on the genetic information that was encoded in the two genes.[212]

With regards to cDNA, Justice Thomas relied on the scientific methods required to synthetically derive DNA. He began his opinion by noting that only some DNA nucleotides code for amino acids, known as exons, while others do not, known as introns.[213] Only naturally occurring DNA contains both while cDNA on the other hand, contains only exons.[214] Justice Thomas says, "[Even though cDNA is dictated by nature] the lab technician unquestionably creates something new when cDNA is made."[215] This very inventive step is what the Supreme Court has now claimed is so integral before declaring something as patentable subject matter.

The *AMP* decision properly reminds us that there are limits to what can be protected under patent law and what can possibly become a market commodity.[216]

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[211] *See Id.* at 2115.
[212] *Id.* at 2118.
[213] *Id.*, at 2111-2112, ("Sequences of DNA nucleotides contain the information necessary to create strings of amino acids, which in turn are used in the body to build proteins. Only some DNA nucleotides, however, code for amino acids; these nucleotides are known as 'exons.' Nucleotides that do not code for amino acids, in contrast, are known as 'introns.'").
[214] *Id.*
[215] *Id.* at 2119, (Justice Tomas goes on to say, "cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a 'product of nature' and is patent eligible under §101, except insofar as very sort series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.").
[216] *Action Alert, Now the FDA is Going After Vitamin C!, available at* http://www.anh-usa.org/action-alert-now-the-fda-is-going-after-vitamin-c/, (Recall that there is a difference between patentability and market exclusivity. Patentability is something that the USPTO handles, while market entry is subject to the

Relatedly, we can now more accurately define what is a legitimate human gene patent. Although a gene is defined as genetic material that encodes for a protein, a gene patent is often a claim over molecular constructs that do not exist in nature, but that instead merely corresponds to, or is derived from, naturally occurring genes.[217] The human gene patents that are especially problematic are the ones that are solely covering isolated human genes. By contrast, synthetic human DNA is something that requires ingenuity, and as the Supreme Court has said, patentable subject matter. Hours after the Court struck down the isolated gene claims under 35 U.S.C. §101 Ambry Genetics began to offer the gene testing for BRCA mutations at significantly lower prices.[218]

C. Myriad Asserts Injunction Against Ambry Due to Threat to Market Exclusivity

From both *Chakabarty* and *AMP* we have seen that living bacteria and synthetic DNA, respectively, can be patented if and only if the subject matter over which the patent claims exclusionary power is innovative and not simply a discovery of something that occurs in nature. The ruling of *AMP* that claimed isolated natural DNA is not patent eligible resulted in Myriad asserting its diagnostic patent claims over other genetic diagnostic providers throughout the course of their original patent term. This sparked

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determination of safety and efficacy by the FDA. For instance, vitamins are naturally occurring, and therefore not patent eligible, but will be go through FDA approval before hitting the shelves.).

[217] Holman, *supra* note 142, at 307, ("The ambiguity of the term is becoming increasingly clear the word 'gene is used in a variety of divergent ways, and often has dramatically different meanings for scientists working in different disciplines. In fact, many patents routinely referred to as 'gene patents' actually claim molecular constructs that do not exist in nature, but that instead merely correspond to, or are derived from, naturally occurring genes.").

[218] *See, e.g.*, Bradley J. Fikes, *Pathway Genomics offers BRCA Cancer Test,* U-T SAN DIEGO, *available at* http://www.utsandiego.com/news/2014/jun/03/pathway-brca-cancer-test/, ("[…] Ambry Genetics of Aliso Viejo, began offering the test on the day of the decision.").

some high-profile litigation as well as interesting discussions regarding the dangerous threats affording a patent over human DNA have on access to affordable testing.[219]

The procedural and substantive arguments asserted in the preliminary injunction asserted in *University of Utah Research Foundation, et al. v. Ambry Genetics Corporation* shine light on the complexities found in gene patent litigation.[220] First off, the preliminary injunction stage of a patent infringement lawsuit does not answer the question of whether or not a patent is valid but instead evaluates the persuasiveness of Plaintiff's evidence without all the evidence that may come out at trial.[221] The Plaintiff's burden of production, in this case Patentee University of Utah, a licensee of Myriad, is to adequately demonstrate the validity of their patent in order to enjoin the alleged infringer Ambry from selling the genetic tests related to the patented DNA sequences.[222] To obtain a preliminary injunction, Plaintiff Myriad must show the following four factors: 1) that it is likely to succeed on the merits, 2) that it is likely to suffer irreparable harm in the absence of preliminary relief, 3) that the balance of equities tips in its favor, and 4) that an injunction is the public interest.[223]

The initial burden of production falls on the alleged infringer Ambry to provide the Federal District Court with evidence of patent invalidity, however the burden then quickly shifts to the patentee Myriad to persuade the District Court that they are

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[219] E. Richard Gold, *Myriad Genetics: In the eye f the storm*, GENET. MED., (2010), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3037261/pdf/nihms-203462.pdf, (The poor public opinion of Myriad did this truly festered.).
[220] Univ. of Utah v. Ambry Genetics, WL 931057 (2014).
[221] 35 U.S.C.A. §§282(a), 283, ("A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.").
[222] 35 U.S.C.A §§283, 282(a), 101.
[223] Univ. of Utah v. Ambry Genetics, *supra* note 223, at 30.

nevertheless likely to succeed at trial on the issue of their patents' validity. In this case, Myriad failed to adequately assert their likelihood to succeed on the merits because Defendant Ambry successfully questioned whether Myriad's patent claims were directed to products of nature or abstract ideas, both of which are not patentable subject matters under 35 U.S.C. §101.[224] The District Court's Judge Shelby noted that on the very same day they issued the *AMP* ruling, the USPTO provided new criteria regarding awarding patents concerning naturally occurring DNA. It read,

> "As of today, naturally occurring nucleic acids are not patent eligible merely because they have been isolated. Examiners *should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not,* as being ineligible subject matter under 35 U.S.C. §101. Claims clearly limited to non-naturally-occurring nucleic acids, such as a cDNA or a nucleic acid in which the order of the naturally occurring nucleotides have been altered (e.g., a man-made variant sequence), remain eligible. Other claims, including method claims, that involve naturally occurring nucleic acids may give rise to eligibility issues and should be examined under the existing guidance in MPEP 210, Patent Subject Matter Eligibility."[225]

Therefore, even though the USPTO had previously awarded human gene patents on naturally occurring gene sequences in isolation, the practice is no longer appropriate. Consequently the District Court favored Defendant Ambry's assertion that such patents lack merit.

The District Court decided that Myriad adequately established the second element that they were most likely going to suffer irreparable harm if an injunction did not issue because Myriad would lose the remainder of their exclusive patent term.[226] Myriad

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[224] *Id.* at 39. ("The court need not decide whether the Supreme Court's refusal in *AMP* to defer to the UPSTO's past practice of awarding gene patents weakens the initial presumption of subject matter eligibility for Plaintiff's patent claims. Even if the presumption applies, the court concludes that Defendant has persuasively come forward with evidence to overcome it.").

[225] *Id.*

[226] *Id.* at 36, ("Thus, even if Plaintiffs have not sued every company that has announced an intent to conduct BRCA1 and BRCA2 testing, this does not mean that Plaintiffs cannot show irreparable harm here. Moreover, it appears that Plaintiffs have been diligent, and not indifferent, in enforcing their patents through litigation in the recent aftermath of the Supreme Court's decision in *AMP* just a few months ago.

actually asserted four separate claims as to why they would suffer irreparable harm, but only the fact that they would lose the rest of their patent term was convincing for the court.[227] Judge Shelby found it especially convincing that Myriad was diligent in enforcing their patents through litigation even in the aftermath of the earlier Supreme Court decision in *AMP* and that such efforts gesture to the likelihood of suffering irreparable harm in the absence of injunctive relief.[228]

The next issue was whether or not the balance of equities or hardships favored issuing a preliminary injunction against Ambry. Judge Shelby decided that although Myriad would suffer irreparable harm without an injunction due to the loss of the remainder of their exclusive patent term, the Court found Ambry's argument overwhelmingly compelling. Ambry claimed that they would likely be forced out of business if the Court issued an injunction, and that this tips the balance in their direction rather than to Myriad. "In advance of its announcement that it would offer genetic testing, including BRCA1 and BRCA2, Defendant invested an estimated $46.7 million in capital resources, expanding its laboratory and hiring an additional 110 employees."[229] Although past case law has essentially asserted that notions of fairness are not offended when the potential patent infringer bears the risk of potential patent enforcement, the Court here

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[…] By all indications, Myriad and the other Plaintiffs are actively defending their patent exclusivity. The court finds that the Plaintiffs' claimed harm from the loss of exclusivity of Myriad's patent terms bolsters Plaintiff's showing that they will likely suffer irreparable harm without injunctive relief.").

[227] *Id.* at 31, (The other claims regarding possible irreparable harm that Myriad would endure included price erosion, loss of market share, and reputational harm.).

[228] *Id.* at 36, ("[…] Plaintiffs have been diligent, and not indifferent, in enforcing their patents through litigation in the recent aftermath of the Supreme Court's decision in *AMP* just a few months ago.).

[229] *Id.* at 55.

found that the threats to Ambry's business were especially persuasive given their successful challenge to the subject matter eligibility of Myriad's patents.[230]

The last issue was whether or not an injunction against Ambry favors public interest.[231] This element by far was given the smallest amount of attention by the District Court. If the courts were to dedicate primary concern over this element before all others, then they would likely reach the most just and accurate patent decisions more efficiently and effectively given the true purpose of affording patent protection over innovation.[232] Here, Myriad asserted that there generally exists a public interest in upholding patent rights to exclude others from making, using, or selling their innovation because the patent system encourages advancements in technology that would better society in exchange for monopoly rights.[233] However, the District Court's response to Myriad's argument was especially exciting for those who were hoping that there would not be another impediment to accessing low-cost DNA diagnostic tests. The District Court said in response to this argument, "But the public's interest in preserving patent rights will not always trump other considerations, especially when public health issues are at stake."[234]

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[230] *Id.* at 56, ("[…] Defendant here has succeeded in raising a substantial question concerning the subject matter eligibility of Plaintiff's asserted patent claims. […] The court finds that Defendant appears to have acted with some caution in timing its BRCA testing launch after the conclusion of the *AMP* litigation. Further the court has concluded that Defendant's belief in the appropriateness of its launch following the Supreme Court's *AMP* ruling was not misplaced. In view of the foregoing, the court concludes that Defendant's potential hardship in losing its entire business outweighs the hardship Myriad may suffer in terms of price erosion, lost market share, and the loss of the remainder of its patents' exclusive terms, which begin to expire in the coming months.[…] Notwithstanding the court's conclusion that Plaintiffs will suffer irreparable injury without an injunction, the court nevertheless concludes that the balance of hardships factor tips slightly in Defendant's favor, and provides further reason not to impose a preliminary injunction at this time.").

[231] *Id.*

[232] Kumar, *supra* note 147, at 39, ("Article 8 allows for this right to be balanced against public safety, health and morals. IN this regard, Article 8 is similar to the protection for fundamental liberty rights that has evolved in the U.S. common law.").

[233] Univ. of Utah v. Ambry Genetics, *supra* note 223, at 56.

[234] *Id.*

The District Court held that although Myriad demonstrated that they were likely to suffer irreparable harm if the injunction were not issued, Ambry successfully questioned the merit of the patents and they found the balance of hardships weighed against issuing a preliminary injunction in favor of Myriad.[235] This preliminary injunction suit was a last ditch effort by Myriad to protect their patent rights before their rights expired over the BRCA1 and BRCA2 genes.

The amount of time, money, and energy tied up in these two above cases litigating gene patents was incredible. Together they go to show that there may be a difference between securing a gene patent and claiming an exclusive right to a diagnostic technique. In fact, by reading these opinions together, we can see that the justice system is not fond of delaying the development of improved diagnostic techniques by upholding broad patents on isolated genes such as BRCA1 and BRCA2.[236] A huge reason for this is because it is clear that doing so would delay an incredible amount of scientific progress.[237]

V. One-Size-Fits-All Patent System Is Less than Optimal

There is a wide range of industries that are covered by the U.S. patent system including pharmaceuticals, chemicals, biotechnology, and information technology. Industry specific considerations that take into account these sectors' diverse goals, the

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[235] *Id.*

[236] Christopher Lee, *Cease or Persist? Gene Patents and the Clinical Diagnostics Dilemma*, YALE COLLEGE LIBRARY, *available at* http://www.library.yale.edu/prizes/applebaum/papers/lee.pdf/.

[237] *Id.* at 30 and 70, ("Ultimately, the broad scope of the BRCA1/2 patents would undermine the development of improved diagnostic techniques by preventing academic labs from applying them in clinical studies. […] Delaying the application of techniques such as whole-exome sequencing in order to protect existing patents on BRCA1/2 and other genes is not the way to ensure continued scientific progress. With the coming of personalized medicine, an increasing number of patients will rely on more comprehensive genetic tests to determine whether they have a hereditary predisposition for not just breast cancer, but a myriad of other chronic diseases.").

amount of initial investment and the speed of advancements admittedly complicates the current unitary patent system we have but it may be the most appropriate legislative choice to make in light of these considerations. Given the varied categories of innovation that patents protect, it may be sensible to create policy that is at least sensitive to the peculiarities of these fields so that the Patent Act is aptly incentivizing applicants within those fields to innovate. A comparison between the several aforementioned patent fields and genetic diagnostic tests within the field of biotechnology illustrates why the Patent Act may need new standards that are capable of distinguishing between the different innovations. Furthermore, reflecting on how certain types of patent infringement remedies may be more suitable to a patent originator's interests may also facilitate innovation instead of threatening its continuation.

A. Human Genetic Diagnostic Tests Merit Separate Policy Consideration Because They may Lack The Hallmarks that Warrant Exclusive Ownership Rights

Congress has generally modeled patent law in a neutral way insofar as the law is one collective series of regulations and rights that currently apply to a whole host of industries displaying distinct and varied goals. However, as Dan L. Burk and Mark A. Lemley have disclosed in their article "Policy Levers in Patent Law," patent law is highly technology-specific in application.[238] As we saw in the earlier section describing the case law, patent holders will often seek judicial intervention when infringement becomes an issue. However, the courts are currently interpreting the laws that Congress alone is entrusted to create in ways that take into account the particularities of technologies but

[238] Dan L. Burk and Mark A. Lemley, *Policy Levers in Patent Law*, 8 VIRGINAL L. R., 3 (2003), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=431360.

that are not clearly set out in that way in the law.[239] Burk and Lemley agree that "[the courts have] consciously or not, been applying industry-specific legal rules for some time- and getting the rules wrong." This use of judicial review may be less efficient and accurate than a whole new statutory change to the Patent Act.

It is important to not lose sight of the goal of our patent system. Congress has offered a limited reward to inventors for investing in innovation that is to be balanced against the duty of the patent holder to disclose the innovation to the public.[240] Through this Congressional encouragement, new technologies protected under patents are to be given to the public. The originator benefits through their exclusive property rights that will continue to regularly encourage greater advancements. However, strong patent protection is less important when an industry requires less research and development costs, has significant non-patent incentives to innovate, and is less risky in terms of success. Patents on human genetic material are unique in these three ways and they are a prime example of why the Patent Act's protections and goals may be best served if these characteristics were taken into account. By comparing patents on genes to the patents in other industries, it is clear why the Patent Act may benefit from an amendment. The amendment would have the goal of ensuring that there is not a dichotomy between incentives to innovate and adequate access to patient health care. It would have to remedy

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[239] *Mandated Simplification of Patent Litigation- Judicial Trends and a new Model Order*, DORSEY, *available at* http://www.dorsey.com/eu_ip_patent_litigation_simplification/, ("To avoid judicial intervention that may have detrimental consequences, patentees should consider designing cases to avoid judicial impatience with perceived unnecessary complexity. […] Patentees and their lawyers should take note of this risk of judicial simplification and how it may impact the value of patent rights."

[240] Burk and Lemley, *supra* note 241, at 7-8, ("There is virtually unanimous agreement that the purpose of the patent system is to promote innovation by granting exclusive rights to encourage invention. […] The consensus position has been that such legal constraints on patentable inventions are justifiable if they offer a net benefit to society, trading the disutility of restricted output and higher prices for some greater social utility of inventions that might otherwise have never been produced. There is no unanimity, however, about whether the patent system actually serves this goal, and if so how well.").

the current trade-off between not granting confirmatory testing to patients who have been told they are genetically predisposed to certain diseases with the incentives to develop new genetic tests. The remedy would allow patients to make more informed health care decisions for themselves and their families while still promoting the goals of patent law.

Research and development costs vary greatly depending on the industry and this is a relevant characteristic for considering the overall function of patents on genes.[241] Although the pharmaceutical industry rarely cites actual figures of their capital investments, it is unquestionably true that this industry requires the most ingenuity, financing, and patent protection amongst the industries.[242]

> "Industry observers estimated in 2003 that the average cost of developing a candidate drug and bringing it to market was $802 million. Some high-end estimates have been to the tune of almost $2 million per drug. More skeptical, left-leaning observers have posited a lower, though still considerable, figure of $110 million. […] ongoing innovation in the pharmaceutical industry is contingent on investors being able to appropriate a sufficient degree of their marketed drugs' social value."[243]

A major additional part of the costs associated with the pharmaceutical industry has to do with the gamble the researchers take on experimenting with several compounds before finally identifying a possible drug that is deemed safe and effective by market regulators at the FDA.[244] The chemical industry also requires a large capital investment to fund

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[241] *See e.g., Id.* at 86, ("The software industry […] has relatively low fixed costs and a short time to market. […] While the costs of writing software have increased substantially over time as programs have become more complex, the costs of writing and manufacturing computer programs are remain low relative to the fixed costs of development in many industries.").

[242] *See* John R. Graham, *Crisis In Pharma R&D: It Costs $2.6 Billion to Develop a New Medicine; 2.5 Times More than in 2003,* FORBES, *available at* http://www.forbes.com/sites/theapothecary/2014/11/26/crisis-in-pharma-rd-it-costs-2-6-billion-to-develop-a-new-medicine-2-5-times-more-than-in-2003/, ("Last December, Deloitte and Thomson Reuters examined newly introduced drugs from the twelve pharmaceutical companies with the largest research and development (R&D) budgets. It cost $1.3 billion to bring a newly discovered compound to market.).

[243] Devlin, *supra* note 57, at 68.

[244] Burk and Lemley, *supra* note 241, at 11, ("But a major additional part of the costs stems from the uncertainty of the R&D efforts. Pharmaceutical companies may try hundreds of compounds before identifying a possible drug, and they may not know for years whether they have chosen the right one for testing.).

research.[245] Perhaps those industries that require the most time, energy, and monetary investments in research and development generally have the greatest need for patent protections.[246]

Continuing with a comparison between pharmaceutical drug research and development costs and marketing approval procedures to genetic patenting suggests that there is a huge discrepancy in the effort, money, and overall investment between the industries that will likely to continue to widen. For instance, early stage drug discovery is estimated to be around $335 million in capitalized costs per marketed drug, with less than 5% of compounds screened making it through the preclinical/animal model phase.[247] On the other hand, once a gene is researched, which admittedly does require substantial investment, genetic tests are designed rather than discovered, which will result in the costs of advancements significantly reduced.[248] "As technology and techniques continue to advance, the price of early stage discovery in genetic testing will continue to plummet."[249]

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[245] *Id.*, at 210, ("While most […] chemical inventions require broad patent protection because of their high cost and uncertain development process, in the case of software development the opposite is true.").
[246] *See* Id. at 90, (Burk and Lemley go through a lengthy analysis to conclude that software may be patent eligible, but should have a narrower application of protection given the speed of the improvements on prior innovation and the low cost investment compared to industries like pharmaceuticals and chemicals . They say, "Because innovation is relatively low-cost but rapid, the need for patent protection is generally modest. Patent protection for such incremental software inventions should be relatively easy to acquire, but should be narrow. In particular, software should not generally extend across several product generations." In the same vein, the author of this article proposes that if we analyze how patents on certain biotechnologies, such as those on human gene patents that are used to protect innovations such as diagnostic tools, may warrant a narrower patent protection as well.).
[247] Robertson, *supra* note 144, at 391, ("Drug candidates fail to achieve FDA approval for a variety of reasons. Approximately 39% of failures are caused by biopharmaceutical issues […] Another crucial factor is lack of efficacy, which is responsible for about 29% of failures. […] The final price tag for this step [early-stage drug development] in the drug development pipeline is estimated to be around $335 million in capitalized costs per marketed drug, with less than 5% of compounds screened making it through to the preclinical/animal model phase.").
[248] Kathryn A. Phillips et al., *Diagnostics and Biomarker Development: Priming the Pipeline*, 5 NATURE REVS. DRUG DISCOVERY 463, 464 (2006).
[249] Robertson, *supra* note 144, at 392.

With regards to gaining FDA marketing approval, pharmaceuticals are more likely to end in failure than in success at this stage post-patent approval with the average time to reach the market being around twelve to fifteen years.[250] The FDA's regulatory and market approval for genetic tests varies depending on whether the diagnostic is an *in vitro* diagnostic device or laboratory-developed test.[251] The latter are the most prevalent form of genetic diagnostic tests on the market and they fall out of the regulatory authority of the FDA.[252] The reason for this is because the chemical that conducts the genetic analysis are analyte specific reagents which are purchased from biological or chemical suppliers that are not produced under FDA assured manufacturing quality control.[253] Therefore the costs for market entry are so much lower for genetic diagnostic tests than for pharmaceuticals. Furthermore, because these products may fall outside of the FDA's jurisdiction, the patent holder does not have any incentive at this point to ensure that their tests are of high quality and that they effectively and accurately identify genetic mutations.

Whether or not an industry has non-patent incentives to innovate is also a relevant characteristic for determining the overall necessity of a long patent term. Like pharmaceutical and chemical innovation, biotechnological innovation requires a lot of capital investment as well as a lot of associated risks.[254] Also like these industries, patent protection is currently an important driver of innovation for this field because it means potentially significant rewards in the market and it lowers the perceived risk in investing

[250] *Id.* at 393, ("At present, genetic tests are used in one of two separate forms: *in vitro* diagnostic devices (IVDs) or laboratory developed tests (LDTs). FDA regulation of genetic tests varies significantly depending on the manner in which these tests are produced and sold.").
[251] *Id.*
[252] *Id.*
[253] *Id.*
[254] *Id.* at 22.

in a product that requires money, time and talent.[255] As we saw in the *Ambry* case, Myriad was very worried about their market share as well as the brand recognition they have established when they were once the sole manufacturers of the BRCA1 and BRCA2 diagnostic tests. However, unlike pharmaceuticals and chemicals, the government funds a significant amount of capital into biotechnological innovation.[256] Nearly two-thirds of all existing DNA patents have resulted from publically funded research.[257] Innovators in this sector do not need additional incentives to commercialize genetic information.[258] Therefore, this is a huge non-patent incentive to innovate that warrants a separate policy consideration over these genetic diagnostic tools.

Another factor to consider that may suggest stronger patents are more warranted for certain innovation compared to others, such as patents on genes, includes the

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[255] *Id.* at 14, ("The systematic variation R&D expenditures across industries naturally affects the need for patent protection; industries that must spend more time and money in R&D generally have a greater need for patent protection.").

[256] *See* Maureen E. Boyle, *Leaving Room for Research: The Historical Treatment of the Common Law Research Exemption in Congress and the Courts, and Its Relationship to Biotech Law and Policy*, 12 YALE J.L. & TECH. L. REV. 111, 159 (2010).

[257] UNITED STATES PATENT AND TRADEMARK OFFICE PUBLIC HEARING ON GENETIC DIAGNOSTIC TESTING, transcript *available at* http://www.uspto.gov/aia_implementation/120216-genetic_transcript.pdf, at 187; Krista L. Cox, *Public Hearing on Genetic Diagnostic Testing*, KEI STATEMENT AT USPTO PUBLIC HEARING ON GENETIC DIAGNOSTIC TESTING, *available at* http://keionline.org/node/1364, ("[…] a report done by the Department of Health and Human Services Advisory Committee on Genetics, Health, and Society concluded that DNA patents were not necessary to provide incentives for research or development of clinical testing. Nearly two-thirds of all existing DNA patents have resulted from publicly funded research. […] The cost of developing a diagnostic test has been shown to be several orders of magnitude less than the cost of developing a new drug. With the majority of identification and isolation of DNA occurring as a result of federal funds and the low cost of creating a diagnostic test, monopoly rights over the DNA is unnecessary in this field."); *Brown and Michael's Budget Estimator for Patents, available at* http://www.bpmlegal.com/patfees.html, ("The following fees are broad ballpark estimates based on past experience, and assume that you have supplied a detailed description and (if appropriate) drawings of your invention. […] Biotech […] may be expected to cost upwards of $7,500 with the required DNA sequence listings, etc."); Graham *supra* note 241, (Compare this to the figure quoted earlier, "Last December, Deloitte and Thomson Reuters examined newly introduced drugs from the twelve pharmaceutical companies with the largest research and development (R&D) budgets. It cost $1.3 billion to bring a newly discovered compound to market.").

[258] USPTO PUBLIC HEARING ON GENETIC DIAGNOSTIC TESTING, *supra* note 260, at 187.

industry's susceptibility to reverse engineering and free-riding.[259] Reverse engineering is the process of extracting knowledge or design information by disassembling the component, like a chemical, and analyzing its features and reconstructing the component.[260] Generic drug manufactures only need to prove bio-equivalency to the originator drug before entering the market.[261] A generic manufacturer relies on clinical data that the originator submits during the regulatory approval process so to establish a bioequivalent version of the drug with regards to the active ingredient and dosage.[262] It is for this very reason that the United States has other protections in place for the pharmaceutical industry such as data exclusivity.[263] Data exclusivity is a type of regulatory protection that prevents a generic company from this sort of free riding that may become possible by reverse engineering.[264] Regulatory agencies may not even accept applications for generics of the original drug during data exclusivity periods, which consequently provides the original drug a longer period of market exclusivity to be sold at a high price while the generic's approval is pending. The chemical industry is similarly susceptible to the free riding phenomenon due to reverse engineering.

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[259] *Id.* at 214, ("[…] reverse engineering is critically important to progress in the software industry, but patent law lacks any explicit reverse engineering provision. […] This does not mean that reverse engineering a patented product is necessarily illegal under patent law.").
[260] *Decompilation and Reverse Engineering*, *available at* http://www.program-transformation.org/Transform/DecompilationAndReverseEngineering, ("The colloquial use of 'reverse engineering' and the formal one are somewhat different. [Some] speak of 'reversing' a program, when they talk about a quick, focused exploration of an executable program. Not the in-depth analysis (usually starting with the source code) that is traditional reverse engineering.").
[261] Cynthia M. Ho., *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. R. 419, 432 (2014), ("[…] although a generic still needs FDA approval, it only needs minimal testing to be approved. The generic only needs to have testing that shows that it is 'bioequivalent' to the previously approved brand drug, such that the FDA can infer that the earlier clinical tests for safety and efficacy of the brand name drug also apply to the generic.").
[262] *Id.*
[263] *Id.* at 494, ("In particular, regulatory laws provide important complementary protections to patents for the pharmaceutical industry. […] 'patent linkage' and 'data exclusivity' could be modified to reduce overprotection of incremental innovation to promote more breakthrough innovation.").
[264] *Id.* at 498, ("Data exclusivity can be rationalized as granting the originator necessary protection to prevent freeriding by a second entrant who does not bear the costs.").

Another relevant characteristic that weighs heavily on the overall utility of a patent is whether the patented innovation is in an industry that speedily develops. An example of an industry that does not benefit a great amount from patents is the information technology industry.[265] "Innovators in these industries routinely denounce patents as a major impediment to their work. Some researches have even estimated that the patent premium in these areas may be insignificant- even negative. If true, this means that patents are encumbering, rather than spurring [innovation]."[266] Being awarded a patent here is not sought after because it is not suitable for the goals of advancing this industry.[267] Although information technology requires a lot of expertise, the industry moves a mile a minute, meaning the time invested in the innovation is considerably less than in developing a new drug or chemical compound.[268] Genomic research that results in greater understanding of the properties of a gene and how it can be useful for personalized medicine, like how patents on the BRCA1/2 mutations resulted in diagnostic tests to assess individuals exposure to breast and ovarian cancer, is another booming area that can be stifled with the use of patents. The patent system was not designed to stifle innovation, it was meant to inspire them. Although such innovation is worthy of some protection, overprotecting an innovation that is in the context of a largely booming project has consequences on access and further innovation.

Gene patents essentially deny inventors access to vital genetic information that cannot be invented around. Therefore, gene patents discourage rather than encourage

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[265] Devlin, *supra* note 57, at 26.
[266] *Id.* at 77.
[267] *Id.* at 27, ("[…] innovation in IT is extraordinarily rapid, being characterized by continuous incremental improvements over the prior art.").
[268] Burk and Lemley, *supra* note 241, at 12, ("In the computer industry, […] while debugging a new program is still a significant undertaking, writing such a program takes considerably less time than developing a new drug or producing a computer chip.").

inventors to provide greater amounts of genetic tests. As we saw in an earlier section, the threat of patent infringement litigation stops researchers from developing new tests that could directly benefit patients. All of this is directly counterproductive to part of the professed purposes of patent rights as a medium that protects innovation and promotes science. Patents on genes and the diagnostic tests that result from them have disincentivized second opinion genetic testing and patients' access to these tests is completely hindered. In fact, a study done by the Department of Health and Human Services' Advisory Committee on Genetics, Health and Society concluded that DNA patents were not necessary to provide incentives for research or development of clinical testing. Genetic diagnostic testing that is done in the biotechnological sector certainly has other incentives and protections guaranteed to innovate that are essentially lacking in the other riskier industries such as pharmaceuticals and chemicals. Since there are differences across the patent industries, it is time to propose differing legal remedies that ought to be available to these industries in the event of a successful patent infringement lawsuit both under the current law and potentially under some amended law.

B. Appropriate Infringement Remedies That Benefit Instead of Stifle Innovation Under The Current Patent System

Given the interest of this paper is human genetic patents and how they have helped create an industry of diagnostic biomarkers that detect predispositions to certain diseases, the influence of these patents on personalized medicine is potentially boundless. Kyle Jensen and Fiona Murray famously discovered how many patents are currently out

on the human genome and came out with a startling 20%.[269] Furthermore, genes are very difficult to invent around and pose significant threat to downstream innovation.[270] The following are suggestions to improving access to genetic diagnostic tests under the current Patent Act. First, the United States should issue more compulsory licenses instead of having the courts decide whether or not a patent is legitimate. Second, if the courts should have to make a decision, they should issue more legal remedies instead of equitable remedies when the benefits of greater access to the technology outweigh the private property interests of patent owners. Third, have the courts use the public interest factor as a primary element that needs to be met before moving on to assessing other factors in determining whether the patent is legally effective.

Currently, the federal government has the right to issue compulsory licenses under 28 U.S.C§1498.[271] These licenses grant the federal government the authority to create a contract with a lab or other manufacturer to produce the product the patent holder has exclusive rights to and this agreement will protect the manufacturer from infringement liability.[272] There may be three circumstances that would warrant issuing compulsory licenses over genetic diagnostic patents. "The first circumstance would be where a diagnostic test is not made available at all by the patent holder […] The second circumstance would be where the diagnostic test being offered is incomplete compared to

[269] Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, SCIENCE, Oct. 14, 2005, 239.
[270] Delvin, *supra* note 57, at 75.
[271] 28 U.S.C. §1498, *available at* http://www.law.cornell.edu/uscode/text/28/1498.
[272] *Compulsory Licensing, Chapter II: Government Use Under 28 USC 1498, available at* http://www.cptech.org/ip/health/cl/us-1498.html, ("Under this statute the US government does not have to seek a license or negotiate for use of a patent or copyright. […] The right owner is entitled to compensation, but cannot enjoin the government or a third party authorized by the government, to prevent the use. Any contractor, subcontractor, person, firm, or corporation who receives authorization from the federal government to use patents or copyrights is construed as use by the federal government, and cannot be sued for infringement.").

what another laboratory could offer, as we saw with Myriad failing to offer large rearrangement testing when Yale had the capability to do so. The third circumstance would be where only a single laboratory is offering the testing, with no availability for confirmatory testing […]."[273]If anything, a patent covering the BRCA1 and BRCA2 gene, as was the case in *Myriad*, would likely only have been useful as a licensing tool for researchers and other innovators to simply pay forward as an investment for their own projects.

That said, the United States does not have a strong history of issuing compulsory licenses.[274] Furthermore, these policy suggestions are not likely to be welcomed with open arms by members of the biotechnological industries. Many who view the professed purpose of patents to be purely protections and incentives for innovation say that this is an uncompensated taking in violation of the Constitution's 5th Amendment. Tom Kowalski, an intellectual property professor and a regular USPTO Public Hearing speaker said,

> "[…] genetics should not be watered-down by an unconstitutional compulsory uncompensated licensing for independent second opinion diagnostic testing […] for a number of reasons, including because access to patented technology is available under current law, and moreover because the issues of access to patented technology – especially on their face in the *Myriad* case—are not issues of patent law. They are issues of health care or health reform."[275]

However, the goal of patent law is not at all divorced from the goals of access to the patented product.[276] A policy change would need to highlight these interrelated aspects of

[273] Kumar, *supra* note 147, at 676.
[274] *See supra* section III:A.
[275] USPTO PUBLIC HEARING ON GENETIC DIAGNOSTIC TESTING, *supra* note 260, at 41.
[276]Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUSTON L. R. 1047, 1055 (2009), ("If patents were conceived as a tool to promote innovation as one among many societal goals, exceptions to ensure that the patent purpose is served would seem reasonable. In particular, while patents are assumed to provide an incentive to innovate, to the extent that patents fail to provide appropriate incentives, or actually interfere with additional innovation, modifications are necessary. Accordingly, under the view of patents as privilege, a nation would limit or craft exceptions to typically patent remedies if doing so would promote

patents better so that patent originators do not separate themselves from their duty to make sure they balance access with innovation.

Relatedly, others have also said that the U.S. government should exercise its march-in rights under the Bayh-Dole Act to alleviate the health and safety needs that the patent holders are not reasonably satisfying by having monopoly rights over human genes. The Bayh-Dole Act of 1980 allows the government to "march in" and require that licenses be granted or actually grant the license themselves when the patent holder does not effectively achieve the practical application of the invention.[277] At a USPTO public hearing on genetic diagnostic testing, even those individuals who perceive patents from their perspective as having the sole importance of encouraging greater innovation and not access have said that it would be preferable for the federal government to use their march in rights rather than amend the entire Patent Act in a way that would create limitations on the exclusive rights of owners. However, the lack of past government intervention in the form of licenses suggests that this is not a very likely event to occur.

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greater innovation, such as the use of patented inventions by researchers. In the area if health care and access to medicine, the idea that patents are a privilege has particularly dramatic consequences. One possible view is that 'the lives of patients have to come before the patents of drug companies,' such that substantial modifications of patents are appropriate, particularly if a nation places a premium on the right t health through programs such as universal access to essential drugs […]." What Professor C.M.Ho says here about the impact of this view on wider access issues is key and will come up again in a short while where the author of this article examines how the Australian courts decision to uphold the validity of the naturally occurring and cDNA in isolation was not significant given their single payor, public health system.).

[277] Barbara M. McGarey and Annete C. Levey, *Patents, Products and Public Health: An Analysis of the CellPro March-In Petition*, 14 BERKELEY TECH. L. J., *available at* http://www.law.berkeley.edu/journals/btlj/articles/vol14/McGarey/html/reader.html, ("To exercise this march-in right, the government must determine that such action is necessary: because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use; to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or the licensees; […] Although march-in, as a safeguard of the public interest, is a purely governmental authority, the legislative history of the act indicates that Congress anticipated that third parties […] would inform the federal government of the possible need for march-in.").

Injunctions are the typical reward given to patent holders who successfully bring forward an infringement suit.[278] Issuing equitable remedies in the form of injunctions to patent owners of genetic diagnostic tests when legal remedies would shift greater weight to properly accommodating public interest in affordable diagnostic testing can be very dangerous. Injunctions are most appropriate for patents because the benefit conferred onto a patent holder is their grant of exclusive power to bar all others from making, using, selling or offering to sell their claimed innovation. Sarah R. Wasserman Rajec accurately details the following disadvantages to the public in granting a patent over a highly valuable invention:

> (1) a monopoly rent can be extracted because of the lack of competition, and thus fewer people may be willing or able to purchase the invention;
> (2) other inventions that build on the patented invention may be delayed or not occur, thus depriving both putative future innovators of the ability to innovate and the public of access to a future innovation; and
> (3) the patent holder may choose not to bring the invention to market at all.[279]

Given the gravity of these disadvantages when enjoining an infringer to quit engaging in their activity is quite steep, it may be especially judicious to grant a legal remedy of high royalty payments instead when their infringement is actually doing more social good than patent enforcement. A related suggestion here is for the courts to grant injunctions only to those actors that are most likely to be the best innovators or will be more likely to respond to this remedy by innovating more.[280] That said, the concern over avoiding

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[278] *Supreme Court Holds Traditional Injunction Test Applies to Patent Cases*, MCKEE, VOORHEES, & SEASE, *available at* http://www.ipmvs.com/content/supreme-court-holds-traditional-injunction-test-applies-patent-cases. ("[…] the general rule in patent cases is that once an infringement is found, an injunction should issue.").
[279] Wasserman Rajec, *supra* note 153, at 740.
[280] *Id.* at 763, ("The analysis until now has assumed that decisions about how to allocate permanent injunctions must inolve some analysis as to which actors are the best innovators- or those who will respond to the availability of the equitable remedy by innovating more.").

market cannibalization would still be there even if the courts more carefully award injunctions.[281]

Court decisions concerning the rights between private parties in patent infringement suits will affect the availability and prices of products to the public. "When an invention is practiced, it is likely to be available to the public at some price, and thus available to other innovators who wish to purchase and use it."[282] If a court finds in favor of a patent originator who does not seek to license nor manufacture its product, then the public has no access to the innovation during the patent period until and unless the originator decides otherwise. A public interest analysis would be especially beneficial for courts to use in identifying cases where injunctions would not serve the goals of patents. Wasserman Rajec writes,

> "Public health concerns have led courts to deny permanent injunctions in some cases on the basis of the public interest; however, this is the extent of use of the public interest factor in the denial of injunctions. For the most part, the public interest is considered to favor a strong patent system with the strong remedy of an injunction to support it."[283]

Although courts generally presume that the validity of the patent system stems from the public interest idea that patents endow society with more advancements because they are incentivized by temporary exclusionary patent periods, if the courts were to assess whether or not public interest is adequately served with the protection of this patent during each injunction suit, concepts of justice and fairness would be less likely offended. If the courts were to ask themselves what is in the interest of the public at this time

[281] *Id.* at 769. (Basically, there is no incentive for the patent originator to create another more advanced product/complete further innovation while their patent is still young because this would divide their own market presence as being the only product protected and likely available for consumers to purchase. Furthermore, the theory of market cannibalization suggests that the patent originator may not continue producing their existing product development because they would commit their resources to develop this newer test that seems to have a great demand.)
[282] *Id.* at 775.
[283] *Id.* at 778; *See, e.g.*, Smith & Nephew, Inc. v. Synthes, 466 F. Supp. 2d 978, 985 (W.D. Tenn. 2006).

concerning this patented invention, they would be more likely to decide accurately whether or not public interest would be served in this case.

C. Big Picture Steps to Fix the Whole System: Proposing a Congressional Amendment to the Patent Act In Light of these Issues and Controversies

Given Congress' power to exclude subject matter as it sees fit from patent protection, the goal may be to amend the Patent Act in ways that take into account how biotechnology sectors, including genetic diagnostic tests, have other incentives besides patents to guarantee innovation. The current law is inadequate at bridging the gap between innovation and access and we need a change to the law that will better balance these two considerations. The first suggestion is to have Congress specifically outline what qualities or characteristics of human genes are patent eligible. The second suggestion is to reorganize how the government publically funds for this type of biotechnology depending on whether or not this is an ever-greened technology or something brand new. The third suggestion is to have an experimental use exception for researchers interested in the genetic sequences that are part and parcel to the patented innovation. Together, these changes will create a patent law better calibrated to the peculiarities of genetic diagnostic tests.

Before diving into these three suggestions, understanding why previous attempts at eliminating the legal patentability of genes in the past have not worked and why such prohibitions are not warranted if other protections on patient access are strengthened. Congressmen Dr. Dave Weldon and Xavier Becerra sponsored the ultimately unsuccessful Genomic Research and Accessibility Act ("GRAA") in hopes of ending the

patenting of genes back in 2007. This bill was motivated by concerns over gene patents that were addressed in the earlier sections, but the scope of its proposed bar extended to patenting any "nucleotide sequence or its functions or correlations, or the naturally occurring products it specifies."[284] However, Congress and the Courts have both a long tradition of never wanting to place specific limitations on patentable subject matter for fear of limiting innovation, and for good reason. "Congress and the courts have steadfastly refused to enact any subject matter specific limitation on patentable subject matter- even attempts to ban the patenting of genetically engineered mammals (including human beings) and human cloning have failed to win congressional approval."[285]

If such a limitation such as the one proposed in GRAA was successfully implemented, the legal interpretation would likely have rendered a ban on any claim that involves the use of a polynucleotide, genetic information, or a biological correlation. Such a blanket ban on human gene patents could chill any progress in genetic testing and is not warranted given that there is so much progress and good to come of these technologies. Furthermore such a ban would even limit other inventions that only tangentially involve DNA. [286] The GRAA is simply far too overbroad and it fails to distinguish between naturally occurring and non-naturally occurring nucleotide sequences and between genetic and non-genetic uses of DNA.[287] "The push to ban the patenting of human genes, or DNA in general, is implicitly based on an assumption that, for this

[284] H.R. 977, 110th Cong. (2007), *available at* http://thomas.loc.gov/cgi-bin/query/z?c110:H.R.977:.
[285] Holman, *supra* note 142, at 296.
[286] *Id.* at 359-60, ("The relatively modest impact of human gene patents in the context of genetic testing and research tools, at least as measured by the rate of enforcement and litigation outcome, simply does not warrant the GRAA's sweeping prohibiting on the patenting of DNA and DNA-related inventions. The ban would encompass too many important inventions involving DNA and other 'nucleotide sequences' that have nothing to do with genes, or even biology.").
[287] *Id.* at 360, ("In my view, the GRAA is overly broad, for example, in failing to distinguish between naturally and non-naturally occurring nucleotide sequences, and between genetic and non-genetic uses of DNA.").

particular category of technology, the overall cost of patents exceeds any positive benefit."[288] Congress passed the Genetic Information Nondiscrimination Act of 2009 ("GINA") as a prohibition against discrimination on the basis of genetic information with respect to health insurance and employment.[289] This is describing one particular use of information that may be generated from biotechnology that Congress has acknowledged could be detrimental to the public welfare.[290] Small protections such as these that recognize the nuanced dangerous uses of sensitive information are more likely to be calibrated to the issues.

Congress must outright identify what is considered natural and what is considered synthetic for the purposes of having an exclusive patent statute for genetic diagnostic biotechnology. A common opposing argument to this proposal however holds that statutorily changing the gene patent system, including the creation of any exemptions from liability for the infringement of patents on genes would be more harmful than helpful to patient access and to the quality of innovative genetic diagnostics.[291] Holders of this view tend to overlook the fact that many physicians self-disclose that they are often significantly limited by contractual and financial barriers placed on them by their institutions or their insurers in selecting tests for their patients.[292] Furthermore, the members of the court are not geneticists, physicians, lab-technicians or chemists. They

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[288] *Id.* at 361.
[289] *Genetic Discrimination*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE: NATIONAL INSTITUTES OF HEALTH, *available at* http://www.genome.gov/10002077, ("GINA protects Americans from discrimination based on their genetic information in both health insurance (Title I) and employment (Title II). Title I amends the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHSA), and the Internal Revenue Code (IRC), through the Health Insurance Portability and Accountability Act of 1996 (HIPPA), as well as the Social Security Act, to prohibit health insurers from engaging in genetic discrimination.").
[290] Holman, *supra* note 142, at 302.
[291] USPTO PUBLIC HEARING ON GENETIC DIAGNOSTIC TESTING, *supra* note 260, at 75.
[292] *Id.*

would benefit from more direct statutory language that they can then interpret and use to decide future cases. The distinctions made between cDNA and DNA are important, but not necessarily dispositive of what the future of genetic research may bring. Congress would benefit from collaborating this goal with experts in the field to understand the manner by which DNA is no longer a naturally-occurring substance.[293]

Other countries have also looked closely at this very intersection of gene patenting and human health, most notably Australia.[294] Australia's Law Reform Commission conducted an intense study of the impact of gene patenting on the availability of medical services in Australia called, "Genes and Ingenuity Report: Gene Patenting and Human Health."[295] The report concluded that there was no firm evidence of increased costs, limited access to genetic testing, lower quality of health care services, or lower levels of clinical research and development.[296] All in all, the Australian study refutes all of the concerns that we have outlined above about the effects of aggressive enforcement of gene patents. However, that does not mean the Australian public does not worry about the impact these gene patents will have on their access to medicine. In fact, the Australian public shares similar concerns as the American public with regards to balancing access with incentives to innovate in genetics.[297] That said, there is a key

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[293] The author of this article would like to point out that Congress may not be able to make these changes fast enough to keep up with oncoming patents on human genes. In fact, Congress is behind already in recognizing any distinction on these two forms of DNA that the Court has decided drive the divide between patentable subject matter and ineligible subject matter. Congress needs to efficiently and effectively decide on what the relevant characteristics of patent eligible genes and by defining these dimensions of patentability, greater protections on both innovation in this area and access would be possible.

[294] *See Id.*

[295] *Id.*

[296] *Id.*

[297] Dianne Nicol, *Balacning Innovation and Access to Healthcare through the Patent System- An Australian Perspective*, COMMUNITY GENETICS 228, 229 (2005), *available at* http://hinxtongroup.files.wordpress.com/2010/10/balancing-innovation-and-access-to-healthcare-through-the-patent-system-an-australian-perspective.pdf, ("Similar to other countries, there are worries in Australia about gene patents. The providers of genetic testing services in Australia are particularly concerned about

difference between Australia's health system and the United States' health system, namely that Australia has a single payer health system that in general likely mitigates the issues of access to genetic testing.[298] Australia's Medicare is available for people of all ages, not just those who are over 65-years-of age, with a disability, or End-Stage Renal Disease.[299] The importance of this difference is that Australia does not share issues with the United States about insuring their population or establishing wide patient access to health services. This likely has a significant impact on why the Australian Full Federal Court ruled unanimously that gene patenting is permissible, completely opposite of how the U.S. Supreme Court ruled.[300]

With regards to the second suggestion, it is especially important to not fund for evergreened patents on these diagnostics. As we saw before, two-thirds of all existing DNA patents have resulted from publically funded research.[301] Incremental improvements on a patented product that does not result in significant improvement in diagnostic testing ability is not worthy of patent protection let alone other interests outside of patents, namely public funding. It may be wise to create a sort of

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the impact of gene and other research tool patents on their research work and on their delivery of clinical testing services.").

[298] James A. Baker III, *What the U.S. can learn from Australian Health Care*, BAKER INSTITUTE FOR PUB. POL'Y AT RICE UNIV. BLOG, *available at* http://blog.chron.com/bakerblog/2012/04/what-the-u-s-can-learn-from-australian-health-care/.

[299] *Id.*

[300] Philippa Brice, *Implications for BRCA testing as Australian court upholds gene patents*, PHG, *available at* http://www.phgfoundation.org/blog/16277/, ("The Full Federal Court of Australia has ruled unanimously that isolated DNA and RNA are patentable subject matter. […] The ruling diametrically opposed the final position of the US Supreme Court, which after a long wrangle concluded that naturally occurring DNA sequences are a product of nature and not patent eligible merely because they have been isolated. This invalidated the US patents for the *BRCA1 and BRCA2* gene sequences held by Myriad Genetics, Inc. […] Patients who want tests might fear patenting would restrict their access. But to date, in Australia, that doesn't appear to have been the case. Unlicensed BRCA testing costs around AU$500, whereas testing via Genetic Technologies is closer to $2000. Whilst some years ago they made attempts to enforce their legal monopoly for genetic testing, the company backed down after public protests.").

[301] USPTO PUBLIC HEARING ON GENETIC DIAGNOSTIC TESTING, *supra* note 260, at 187, ("Nearly two-thirds of all existing DNA patents have resulted from publicly funded research. […] Researchers and companies do not need additional incentives to commercialize genetic knowledge.").

reimbursement system full of checks and balances where the government hires professionals to makes sure that the public's dollars are not spent on gene patents that do not result in actual new, nonobvious, and useful innovation as required.

In Sapna Kumar's article, *Life, Liberty, and the Pursuit of Genetic Information,* she suggests that the biggest complicating factor in the debate currently is that academic biotechnological research is prone to commercialization.[302] Therefore, a research exemption should be explicitly legislated and it should be limited to patents with medical applications to allow researchers to expand on diagnostic tests under patent protection. This would promote innovation that is honed in on improving patient's access to the most effective and accurate diagnostic test. These changes to the patent law will foster innovation and will encourage access in ways that the current law does not.

VI. Conclusion: The Ethics of the New System

Patents are clearly considered a necessary stimulus for innovation, and by extension, patents can be considered necessary for consumers to access the innovation that otherwise would not have been. Technology has increased our ability to understand our own bodies, and in an era where health care delivery costs must be reduced for overall sustainability of an entire industry, the ability to detect diseases sooner and potentially adopt preventative health care choices is increasingly important. Furthermore, the *Myriad* decision showcased just how much of an impact bodily information can have

[302] Kumar, *supra* note 147, at 678, ("At its root, the problem is that academic research in biotechnology can be commercialized […] Even when the original patented work was funded by government grants, researchers can still patent- and therefore commercialize- their work. Consequently, current protection for experimental use is practically non-existent.").

on a patient's ability to make a medical choice.[303] Patient autonomy in making medical decisions is inextricably linked to ensuring they are informed about their health and possible outcomes.[304] Diagnostic tools such as the ones that Myriad had for the BRCA1/2 genes are especially suited for this purpose. There is an ethical pressure to increase access to these diagnostic tools so that patient's medical decisions are more informed.

In the past, the weight of public benefits has not equaled that of incentivizing innovation. It is time to bring these two goals to equilibrium, and patents on human genetic material may prove to be the appropriate outlet. The ethics of justice, utility, and autonomy highlight the contrasting perspectives on the goals of patents as either avenues for innovation and necessary protections on property rights or patent protections as secondary to public interest goals of access. Given the continuum of patent perspectives, the role of patents and patent law is to balance innovation with consumer access since both are important drivers for the success of entire enterprises that thrive from patent protections.

Seeing this balance come to fruition is possible even under the current patent law in the United States, but it may require holding the federal government and its various associated agencies accountable for making sure this balance is struck. Under the current law, issuing more compulsory licenses when a patent is not properly worked and exercising the government's march-in rights under the Bayh-Dole Act is one road not often traveled that would improve the issues of consumer access. Issuing legal instead of

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[303] *Id.* at 659, "(Numerous women filed declarations in the district court stating that they could not make informed decisions to have mastectomies and hysterectomies without knowing whether they carried a BRCA mutation. BRCA is only the tip of the iceberg, there are many other diseases that can be diagnosed through genetic testing, leading to better medical treatment."

[304] Vikki A. Entwistle et al., *Supporting Patient Autonomy: The Importance of Clinician-Patient Relationships,* 25 J. GEN INTERN MED. 741, (2010), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881979/.

equitable remedies may be warranted when the patent originator does not seem to have any intention on working the patent to its fullest potential. Lastly, encouraging the courts to adopt public interest as a primary threshold factor for assessing the legal validity of a patent after it has been issued may signify the important weight that needs to be given to consumer access.

However, the unjust access issues related to the affordability of these tests and the harm done on further research into genetics emphasize the need for a new law so that innovation and patient health can improve in tandem.[305] Adopting congressional changes to that go beyond the current law include an amendment to the Patent Act that includes actual language that dictates what the proper dimensions of gene patent eligibility are so that the USPTO properly awards patents and the Courts do not have to continue interpreting a law that was constructed many decades before the Human Genome Project. If Congress were to explicitly add language to the Patent Act that draws some brighter line between the patent eligible gene qualities and ineligible gene qualities, the courts can point to this law instead of winding through logical pretzels trying to interpret the current Patent Act. Another suggestion would be to eliminate the non-patent incentive of federal funding for ever-greened biotechnologies that have exhibited only marginal improvements on previous diagnostics and do not warrant the financial support. Lastly, a

[305] Ho, *supra* note 276, ("If patents were conceived as a tool to promote innovation as one among many societal goals, exceptions to ensure that the patent purpose is served would seem reasonable. In particular, while patents are assumed to provide an incentive to innovate, to the extent that patents fail to provide appropriate incentives, or actually interfere with additional innovation, modifications are necessary. Accordingly, under the view of patents as privilege, a nation would limit or craft exceptions to typically patent remedies if doing so would promote greater innovation, such as the use of patented inventions by researchers. In the area if health care and access to medicine, the idea that patents are a privilege has particularly dramatic consequences. One possible view is that 'the lives of patients have to come before the patents of drug companies,' such that substantial modifications of patents are appropriate, particularly if a nation places a premium on the right t health through programs such as universal access to essential drugs […].").

suggestion for the future is to amend the Patent Act to also include language of experimental use so that scientific development is not hindered by patents on genes that cannot be experimented around without fear of patent infringement and enforcement.