ARTICLE

ARE ALL GENES EQUAL?

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> "The myopic viewpoint thinks of a *human gene* as merely another chemical compound, composed of various bases and sugars. But history and science teach us otherwise."
> -James D. Watson[†]

INTRODUCTION

The year 2013 can aptly be called the "year of genes" at the Supreme Court. From the *Monsanto* gene patents case[1] to the genetic fingerprinting of arrestees,[2] the Court grappled with difficult questions arising out of an increasing application of genetics to various aspects of our society. Then came *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the much-publicized case involving the patentability of human genes.[3] Amicus curiae briefs representing hundreds of organizations and interest groups,[4] combined with extensive academic commentary and voluminous media coverage, undoubtedly made this one of the most controversial patent law cases in the recent past.[5] The case posed a simple question: "Are *human* genes

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[†] Brief for Amicus Curiae James D. Watson in Support of Neither Party at 8, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) (No. 10-1406) (emphasis added).

[1] Bowman v. Monsanto Co., 133 S. Ct. 1761 (2013).

[2] Maryland v. King, 133 S. Ct. 1958, 1976 (2013).

[3] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

[4] This is based on the Author's Westlaw search of filings of briefs conducted on April 6, 2013.

[5] *See* Samantak Ghosh, *Gene Patents: Balancing the Myriad Issues Concerning the Patenting of Natural Products*, 27 BERKELEY L. TECH. J. 241, 262-264 (2012); Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 707 (2004); Michael Crichton, Op-Ed., *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, at A23 ("YOU, or someone you love, may die because of a gene patent."); *Special Feature: Gene*

patentable?"[6] A unanimous Court answered in the negative.[7]

But before delving into the Court's answer, it is important to pause for a moment on this question to understand what it asked, and more importantly what it did not ask. The question did not ask whether genes in general—regardless of whether they are human genes—should be patentable. It did not ask whether other human biological materials such as proteins, vitamins, and cells could be patented. Similarly, it did not consider the patent-eligibility of non-genetic materials obtained from non-human sources, such as plants, animals, and bacteria. But given the unitary nature of patent law, the Court's answer would have broad implications for patents involving all products of nature, genetic or non-genetic, human or non-human.

This leads us to the question this Paper explores: "Are all genes equal?" To pose the question conversely, "Are human genes special?" Would we have the same concerns about, for example, patents on bacterial genes, or even human non-genetic material, as we have for patents on human DNA? It is worth thinking about why, when a majority of patents cover genes from non-human sources, the case that finally landed before the Court involved human genes.[8] We have not seen as much debate and outcry over these other patents as we have witnessed over the issue of human DNA patents. Is human DNA unique in some respect, and therefore more deserving of protection from patent monopoly? If so, should we be concerned that a case involving human genes essentially lays the doctrinal foundation for the patent-eligibility of other biological products?

Let us rephrase this question in another context. *Diamond v. Chakrabarty* was a landmark patent case that has been widely credited with opening the floodgates of biotechnological innovation in this country.[9] *Chakrabarty* upheld a patent on genetically modified chimeric oil-eating bacteria.[10] Three decades

Patenting Symposium, SCOTUSBLOG, http://www.scotusblog.com/category/special-features/gene-patenting-symposium/ (last visited Apr. 23, 2013).

[6] Petition for Writ of Certiorari at i, *Myriad*, 133 S. Ct. 2107 (No. 12-398) (emphasis added); *see Ass'n for Molecular Pathology v. Myriad Genetics, Inc*, 133 S. Ct. 694, 695 (2012) ("Petition for writ of certiorari to the United States Court of Appeals for the Federal Circuit granted limited to Question 1 presented by the petition.").

[7] *See Myriad*, 133 S. Ct. at 2120.

[8] Gregory D. Graff et al., *Not Quite a Myriad of Gene Patents*, 31 NATURE BIOTECHNOLOGY 404, 408 (2013).

[9] Diamond v. Chakrabarty, 447 U.S. 303 (1980); *see* Douglas Robinson & Nina Medlock, *Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents*, 17 INTELL. PROP. & TECH. L.J. 12, 12 (2005) ("Chakrabarty has affected the lives of virtually everyone in the United States, having contributed to a revolution in biotechnology that has resulted in the issuance of thousands of patents, the formation of hundreds of new companies, and the development of thousands of bioengineered plants and food products.").

[10] *See Chakrabarty*, 447 U.S. at 303.

later, the Supreme Court rejected a patent on human genes in *Myriad*. What would have happened if the species between the two cases were swapped? If instead of a chimeric bacteria, *Chakrabarty* had considered the patentability of a chimeric human, and instead of a human gene, *Myriad* had considered the patentability of a bacterial gene? Would the results have remained the same?

There are reasons to be skeptical, and subsequent legal developments suggest a different outcome if we tried patenting chimeric-human beings today. Since the Weldon Amendment to the recently passed Patent Reform Act bans patenting of human organisms, it would most likely prevent the patenting of chimeric-human beings as well.[11] However, patent law on its face appears to be generally agnostic to whether the patented biological products are found in human beings. Indeed, the Supreme Court's opinion in *Myriad* does not even mention the issue. Instead, the Court based its conclusions primarily on the fact that the patentee merely isolated genes and did not invent them.

The battling policy arguments attempting to win over the Court were primarily utilitarian. Those opposed to human gene patents warned of the danger of patents tying up basic tools of scientific research and inhibiting future innovation.[12] Those in favor argued that without patents there would not be enough incentive to invest in the discovery of genes.[13] The Court's conclusion is essentially based on the adoption of the former position. This Paper does not suggest that this is necessarily an unjustified position.[14] But the

[11] *See* Kevin E. Noonan, *Dr. James Watson: Human Genes Should Not be Patented*, PATENT DOCS (July 12, 2012), http://www.patentdocs.org/2012/07/dr-james-watson-.html ("[T]he portion of the Leahy-Smith America Invents Act having to do with patenting inventions comprising the human body (codifying the Weldon Amendment) were introduced and passed with assurance from its sponsors that the provisions were not intended to affect patenting of human DNA.")

[12] *See, e.g.*, Kane, *supra* note 5, at 707 ("By scientific and historical criteria, the genetic code can be characterized as a law of nature and as an essential component of the public domain in molecular biology . . . . [P]atenting of genes results in constructive preemption of genetic code, a result that is contrary to the Supreme Court's dictate."); *see also* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1292 (2012) ("[B]ecause th[e]se laws and principles are 'the basic tools of scientific and technological work,' there is a danger that granting patents that tie up their use will inhibit future innovation.").

[13] *See, e.g.*, Brief of the American Bar Association as Amicus Curiae in Support of Respondents at 18a-19a, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 12-398) ("The exclusion of isolated DNA as patent-eligible subject matter would dramatically impact the investment into biotechnology and slow, if not disable, future innovation.").

[14] In fact, the Author's own Paper critiquing the lower court decision has questioned the argument that gene patents are necessary to stimulate their discovery. *See* Ghosh, *Gene Patents*, *supra* note 5. In a sense, the Author feels vindicated because the Court's ruling is exactly for what he had argued: invalidate patents on human genetic sequences and uphold

problem is that the empirical investigation of both these theories has so far eluded any conclusive answers.[15]

The lack of conclusive answers does not mean that either of these utilitarian theories is inoperable; instead, it opens an opportunity for other moral considerations to play a role. There is a rich body of literature on the ethical and moral issues surrounding human gene patents.[16] However, the fact that human genes raise a different and unique set of considerations than non-genetic materials or materials obtained from non-human sources has been largely sidelined in the ongoing academic commentary and ignored by the courts.

Yet these considerations are important for a number of reasons. If human genes are exceptional biological products, is a human gene patents case the best vehicle for developing the patent-eligibility doctrine of all other natural products? After all, as the old adage goes, "hard cases make bad law."[17] One can question the Justices' indifference to the heightened concerns raised by patents on *human* genes as opposed to patents on *bacterial* genes. In addition, the *Myriad* opinion's oversight of these distinctions only adds to the speculation about the case's scope. Thus, these considerations could provide future judicial and legislative efforts with a richer context in which to address some of the complicated questions raised by patentable subject matter.

This Paper endeavors to understand and elaborate on some of these issues. In doing so, this Paper investigates the salience of this intuitive understanding of public moral sensibilities by conducting a survey. After all, information is better than intuition. Surprisingly, while there has been extensive commentary about the moral and ethical dimensions of human gene patents, there has been very limited probing of the public opinion. This is a substantial gap in the current literature. While scholars, judges, and government agencies play an important role in influencing societal perceptions and even social norms, it is inane to ignore public opinion in a representative democracy.

This Paper attempts to fill some of this gap through a survey of 215 college-educated participants. The survey, conducted by the Author and discussed in

patents on cDNA. *See id*. at 266; *see also Myriad*, 133 S. Ct. at 2107. Yet questions remain about the ramifications of this case.

[15] *See infra* Parts I-III.

[16] *See, e.g.*, David K. Chan, *Should Human Genes Be Patented?* 12 PHIL. IN THE CONTEMP. WORLD 30, 30-36 (2005); Timothy R. Holbrook, *The Expressive Impact of Patents*, 84 WASH. U. L. REV. 573,

588 (2006) (arguing that patents on human genes can result in expressive harms to a person's identity); Marilyn Martone, *The Ethics of the Economics of Patenting the Human Genome*, 17 J. BUS. ETHICS 1679, 1679-83 (1998); David B. Resnik, *DNA Patents and Human Dignity*, 29 J.L. MED. & ETHICS 152, 157 (2001).

[17] N. Sec. Co. v. United States, 193 U.S. 197 (1904).

Part III, suggests that most people are opposed to patents on natural products, regardless of whether the patents are obtained from human beings or bacteria. At the same time, the survey suggests that patents on human genes raise greater concern than patents on other natural products. Most participants in the survey opposed patents on human genes more than patents on genes of plants, animals, or bacteria. Similarly, participants showed greater opposition to the patenting of human genetic material than to patenting non-genetic material, exhibiting the hallmark of genetic exceptionalism.

The survey indicates that patents on human genetic materials and biological products may raise additional public concerns than those on non-human biological products. There could be a number of reasons for this. First, any patent-enforced restrictions on individual control over human bodily material will have to confront notions of personal property, human rights, human dignity, and privacy. Similarly, concerns that human gene patents may block access to genetic diagnostic tests may also be fueling some of the opposition to these patents. These concerns are less pronounced going down the species ladder from humans to animals to plants and bacteria. Finally, since human DNA is a unique molecule both biologically and culturally, any private monopoly on human genetic material raises concerns not necessarily shared by non-genetic materials.

Part I of this Paper begins by reviewing the *Myriad* decision. Part II reviews the empirical evidence on the impact of gene patents on innovation, concluding that the evidence supports neither the proponents of gene patents nor the opponents. Finally, Part III discusses the survey of public opinion on human and non-human biological materials, including genetic materials. It suggests that the survey results cannot be explained by sole reliance on impact on innovation, the only factor explicitly cited by the Supreme Court in *Myriad*. The human-ness of the patented products also appears to be a significant factor impacting the public discomfort with these patents.

I. THE *MYRIAD* DECISION

A. The Battle over the BRCA Genes

The *Myriad* decision is the culmination of a battle that started long before the American Civil Liberties Union and the Public Patent Foundation filed the first complaint against Myriad Genetics in May of 2009.[18] As early as 2001, the French Institut Curie opposed Myriad's breast cancer related gene patent, EP0699754, in Europe.[19] Subsequently, various hospitals, genetic societies,

[18] *See* Complaint, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 1:09cv04515).

[19] *See* Jordan K. Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy:*

and patient-advocacy groups from a number of European countries joined together to oppose Myriad's other patents on breast cancer related genes.[20] These oppositions successfully brought the European Patent Office to revoke one of the patents limit the scope of related patents in Europe.[21]

The growing international controversy over the breast cancer gene (the "BRCA" gene) patents also inspired legislative efforts in the U.S. Congress.[22] In 2002, Representative Lynn Rivers introduced a bill that would have granted exemptions from the enforcement of gene patents to physicians conducting genetic diagnosis and prognosis.[23] Another bill, the Genomic Research and Accessibility Act of 2007, would have prohibited the patenting of genetic material.[24] Strong opposition from the industry successfully stalled these bills.[25]

But the public concern surrounding gene patents did not subside. Recognizing the "perfect storm" that could result from patents in genomics and proteomics stifling downstream research and development, a 2006 National Academy of Science report recommended exemptions for conducting research on these types of patented inventions.[26] Myriad's patent monopoly gave rise to further disquiet when reports indicated that Myriad's genetic tests failed to identify about twelve percent of women whose BRCA mutations made them susceptible to breast cancer.[27] These concerns led to a provision in the Patent Reform Act of 2011 requiring the United States Patent and Trademark Office (the "USPTO") to study the effect of exclusively licensed patents on patients'

A Case Study of Myriad Genetics' BRCA Patent Controversy, 59 FOOD & DRUG L.J. 133, 139 (2004). Europe allows a type of legal procedure called "opposition" which permits third parties to challenge the validity of patents within nine months of their issuance. *See The Opposition Procedure*, EUROPEAN PATENT OFFICE (Sept. 9, 2008), http://www.epo.org/about-us/jobs/examiners/what/opposition.html.

[20] *See* Paradise, *European Opposition*, *supra* note 19.

[21] *See* Jordan K. Paradise, *Lessons from the European Union: The Need for a Post-Grant Mechanism for Third-Party Challenge to U.S. Patents*, 7 MINN. J. L. SCI. & TECH. 315, 320 (2005).

[22] *See* E. Richard Gold & Julia Carborne, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS MED. S39, S48 (2010).

[23] *Id*.

[24] *See* Samantak Ghosh, *Prometheus and the Natural Phenomenon Doctrine: Let's not Lose Sight of the Forest for the Trees*, 94 J. PAT. & TRADEMARK OFF. SOC'Y 330, 343 (2013).

[25] *See* Gold & Carbone, *supra* note 22.

[26] NAT'L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 14 (2006).

[27] Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 JAMA 1379, 1386 (2006).

opportunities to seek an independent diagnostic confirmation.[28]

B. The Drawn-Out Fight in U.S. Courts

Increased media coverage and academic commentary coupled with Myriad's aggressive enforcement of patents finally led to a group of patients, doctors, and advocacy groups joining hands to challenge the validity of the BRCA gene patents in the United States.[29] The petitioners argued that Myriad's breast cancer gene patents were invalid because they covered natural phenomena, which are patent-ineligible under 35 U.S.C. § 101.[30] Although the statutory language broadly grants patents on "any new and useful process, machine, manufacture, or composition of matter," the Supreme Court has long recognized that "laws of nature, physical phenomena, and abstract ideas" cannot be patented.[31] Granting summary judgment in favor of the petitioners, the district court found that the isolated DNA sequences covering breast cancer genes were patent-ineligible products of nature.[32] According to the court, the claimed products did not possess "markedly different characteristics" from their native form to satisfy the requirements of section 101.[33]

However, this lower court victory was short-lived as the Federal Circuit reversed the district court's judgment.[34] Following the Federal Circuit's reversal, the Supreme Court granted the petition for certiorari, vacated the Federal Circuit's judgment, and remanded the case in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Court's latest decision elaborating the natural phenomena exception.[35] On remand, the Federal Circuit maintained its original judgment on gene patents.[36] By a two to one majority, the court held that isolated human genes were patent-eligible.[37] Judge Lourie found the chemical cleavage of the DNA from the human

[28] *See* Ghosh, *Prometheus*, *supra* note 24.

[29] *See* Timothy Caulfield et al., *Myriad and the Mass Media: the Covering of a Gene Patent Controversy*, 9 GENETICS MED. 850 (2007); *see* Complaint, *supra* note 18.

[30] *See* Complaint, *supra* note 18, at 19.

[31] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 218 (S.D.N.Y. 2009).

[32] *Id*. at 232.

[33] *Id*. at 227.

[34] *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1358 (Fed. Cir. 2011).

[35] *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S.Ct. 2107, 2120 (2013); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694, 695 (2012).

[36] *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1337 (Fed. Cir. 2012).

[37] *See id*.

chromosome sufficient to confer it patentable distinctions.[38] Judge Moore concurred, not merely because of the alleged structural difference, but also because she found that the isolated DNA had additional utility not provided by the native form.[39] Judge Bryson, however, was not convinced. Finding the BRCA genetic sequences unpatentable, he observed that the chemical cleavage was incidental to the isolation of the DNA and did not overcome the structural similarity with the native form.[40]

Given the importance of the question and the Supreme Court's recent efforts to curtail the scope of patentable subject matter, the Court's decision to take the case was hardly surprising. A unanimous Court reversed the Federal Circuit on the patent-eligibility of human genes.[41] Writing for the Court, Justice Thomas reiterated the Court's opposition to patenting natural phenomena and found Myriad's claims to fall "squarely within the law of nature exception."[42] Justice Thomas explained that these "implicit exception[s]" to patentable subject matter arose out of a concern that patents on such "basic tools of scientific and technical work" would "tie up" their use and "inhibit future innovation premised upon them."[43] However, the Court recognized that "too broad an interpretation of this exclusionary principle would eviscerate patent law."[44] Ultimately, scientific innovation is best promoted by a patent policy that balances the incentivizing effects of patents with their preclusive effects.[45]

Applying these principles to Myriad's patent claims, the Court concluded that one could not get patents on genes simply by isolating them from their natural environment.[46]

Justice Thomas observed that Myriad had not created or altered the genetic information encoded in BRCA1 and BRCA2 genes; Myriad had merely discovered them.[47] Justice Thomas dismissed Myriad's claims that chemically cleaving the DNA necessarily created a non-naturally occurring molecule.[48]

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[38] *See id.* at 1328. For a critique of the majority's analysis, see Ghosh, *Gene Patents*, *supra* note 5. Judge Lourie understood chemical cleavage to mean that the DNA "had covalent bonds in its backbone chemically severed." *Myriad*, 133 S. Ct. at 2115.

[39] *See* Ass'n for Molecular Pathology v. U.S. Patent and & Trademark Office, 689 F.3d 1303, 1342-43 (Fed. Cir. 2012) (Moore, J., concurring).

[40] *See id*. at 1350-51 (Bryson, J., dissenting).

[41] *See Myriad*, 133 S. Ct. at 2111.

[42] *Id*. at 2117.

[43] *Id*. at 2116.

[44] *Id*.

[45] *Id*.

[46] *Id*. at 2117-19.

[47] *Id*. at 2116.

[48] *Id*. at 2118.

Finally, neither Myriad's extensive research efforts nor the usefulness of the isolated gene were sufficient to render it a patentable invention.[49] The Court noted that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."[50]

Importantly, while the question on certiorari was whether human genes are patentable, nothing in the Court's opinion appeared to limit the decision to human genes.[51] It is difficult to draw any principled species-based distinctions based on the policy considerations that the Court articulated, and the USPTO's preliminary guidelines following *Myriad* acknowledged as much.[52] Without making any distinction between human and non-human sources, the guidelines stated: "[N]aturally occurring nucleic acids are not patent eligible merely because they have been isolated."[53]

However, *Myriad's* ramifications on the patent-eligibility of *non-genetic* materials remain unclear. The principle that mere isolation from natural environment is insufficient to confer patent-eligibility can apply equally to purified non-genetic materials like proteins and vitamins to render them patent-ineligible. The principle's apparent breadth notwithstanding, the Court's elevation of the genetic information over the chemistry of the molecule leaves ambiguous implications for non-genetic materials. Commentators have lamented the Court's lack of guidance for the future,,[54] and Professor Dan Burk has suggested that future patent drafters might avoid *Myriad's* ambit by drafting their claims in terms of chemical composition rather than in terms of genetic information.[55] Whatever the merits of these interpretations, it is clear that *Myriad* casts a cloud on the patent-eligibility of all purified biological products, whether human or non-human, genetic or non-genetic.

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[49] *See id*. at 2117-18.

[50] *Id*. at 2117.

[51] *Id*. at 2120 ("We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.").

[52] *See* Jason Rantanen, *Myriad: The PTO's Preliminary Guidance*, PATENTLY-O, (June 14, 2013), http://www.patentlyo.com/patent/2013/06/myriad-the-ptos-preliminary-guidance.html.

[53] *Id*.

[54] Dennis Crouch, *Twenty Thoughts on the Importance of Myriad*, PATENTLY-O, (June 14, 2013), http://www.patentlyo.com/patent/2013/06/myriad.html (For example, Professor Timothy Holbrook of Emory Law noted that "the Court provided very little guidance as to future issues relevant to biotech, such as isolated/purified proteins or other organic chemicals.").

[55] *See id*.

II. INCONCLUSIVE EMPIRICAL EVIDENCE

A. Gene Patents: Good or Bad for Innovation?

The Supreme Court's rejection of gene patents was based on the application of a common law "natural phenomena doctrine" which is primarily a recognition of the consequentialist argument that a patent monopoly on natural phenomena would stifle future innovation.[56] On the opposite side are the supporters of gene patents, who argue that without the expectation of a patent, inventors would be unwilling to invest time and resources in the identification of genetic sequences.[57] The difficulty of determining which side is right can be traced back to the natural phenomenon doctrine's lack of a precise foundation.[58] As a common law doctrine, the natural phenomenon doctrine has no rigorous statutory basis, thereby leaving it up to the courts to delineate its boundaries.[59] Thus, depending upon which argument finds favor with a particular court, the doctrine's scope tends to be either under-inclusive or over-inclusive.

The divergent philosophies of the Federal Circuit and the Supreme Court with respect to the current patent-eligibility debate are a case-in-point.[60] The Federal Circuit appears to favor a narrow common law exclusion, preferring to rely on other statutory requirements such as novelty and non-obviousness to

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[56] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1292 (2012).

[57] *See* Brief of the American Bar Association as Amicus Curiae in Support of Respondents, *supra* note 13.

[58] Ghosh, *Prometheus*, *supra* note 24, at 333 ("Since the precise foundation of the natural phenomenon doctrine 'remains somewhat ambiguous [it] leaves the limits of the doctrine lacking proper delineation.'" (quoting Richard Seth Gipstein, *The Isolation and Purification Exception to the General Unpatentability of Products of Nature*, 4 COLUM. SCI. & TECH. L. REV. 2, 3 (2003))).

[59] *Id*. at 333, 336-38.

[60] Commentators have used colorful analogies to describe the current tension between the two courts. Professor Robin Feldman observes, "The conversation has the feel of an exchange between a teacher and a student, or perhaps between an adult and an adolescent, because after all, the Federal Circuit has been around only a few short decades." Robin Feldman, *A Conversation between the Supreme Court & the Federal Circuit*, SCOTUSBLOG (Feb. 5, 2013, 2:15 PM), http://www.scotusblog.com/2013/02/a-conversation-between-the-supreme-court-the-federal-circuit/. Noting the Court's increased interest in patent law, Professor Rebecca S. Eisenberg suggests, "The U.S. Supreme Court's relationship to patent law sometimes seems like that of a non-custodial parent who spends an occasional weekend with the kids. The custodial parent is, of course, the U.S. Court of Appeals for the Federal Circuit." Rebecca S. Eisenberg, *The Supreme Court and the Federal Circuit: Visitation and Custody of Patent Law*, 106 MICH. L. REV. FIRST IMPRESSIONS 28, 28 (2007).

weed out undesirable patents.[61] The current Supreme Court, on the other hand, favors a more robust "natural phenomena doctrine" manning the gates of patents.[62] The gene patents case is just another example of this ongoing tension. As the subsequent section notes, however, a review of the empirical studies on this subject does not conclusively support the consequentialist arguments of either side.

B. The Inconclusive Evidence

There have been a number of studies conducted on the impact of patents in the area of genetic research on biotechnological innovation. However, a review of these empirical studies does very little to end the debate. The studies neither conclusively support the argument of the proponents of gene patents, nor their opponents.

i. Do these patents promote innovation?

Let us first investigate the argument that patents are the major, if not the primary drivers of genetic discoveries. This contention is challenged by the fact that a substantial portion of these discoveries take place in academic research institutions, and patents do not appear to be a major motivating factor for academic researchers.[63] Studies have reported that about sixty-three percent of patents on genetic sequences have resulted from public funding.[64] Almost half of the top thirty owners of DNA-based patents are academic or non-profit organizations.[65] Yet patents are very low on the list of factors that incentivize academic researchers; they are generally more interested in publication and recognition. One study found that only seven percent of academic researchers

[61] The Federal Circuit downplayed the importance of patent-eligibility exclusions as nothing more than a "coarse eligibility filter." Research Corp. Techs., Inc. v. Microsoft Corp., 627 F.3d 859, 869 (Fed. Cir. 2010); *see* John W. Cox & Joseph Vandegrift, *The Supreme Court Is Paying Attention To Patent Law Again*, LAW 360 (Apr. 1, 2013, 11:54 AM), http://www.law360.com/articles/425426/the-supreme-court-is-paying-attention-to-patent-law-again ("Justice Breyer's dissent [in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*] had not persuaded Judge Randall Rader, who in dissent claimed that Justice Breyer had misapplied the 'useful, concrete, and tangible result' test . . . . [Judge Rader] further argued that public policy supported claims directed to diagnostic methods, [which] . . . should be encouraged through patent protection.").

[62] The Supreme Court believes that adopting the Federal Circuit's approach "would make the 'law of nature' exception to § 101 patentability a dead letter." Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303 (2012).

[63] *See* Ghosh, *Gene Patents*, *supra* note 5, at 267.

[64] *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 210 (S.D.N.Y. 2010); *see also* NAT'L RES. COUNCIL, *supra* note 25, at 104.

[65] *See* NAT'L RES. COUNCIL, *supra* note 26, at 104.

considered patents more than moderately important, while scientific importance, and personal interest affected more than ninety percent of research decisions in academia.[66]

These studies indicate that, at least in public research institutes, the absence of patents may not deter a substantial amount of genetic research. Even the Supreme Court in *Diamond v. Chakrabarty*, the seminal case for biotechnology patents, expressed doubts about the impact of patents on genetic research.[67] Observing that a large amount of research had already taken place in the absence of an assurance of patent protection, the Court noted, "The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks."[68]

Of course, these studies do not provide any insight into private companies, where patents may play a determinative role in research decisions. Given how easily genetic products can be reverse engineered, trade secret does not appear to be a viable alternative form of intellectual property protection.[69] Although it is debatable whether the patent system as a whole stimulates innovation, there is evidence that patents may play an important role in the biotechnology industry.[70] One study has found that a 10% increase of the patent premium received by a biotechnology company generally results in 10.6% increase in the company's research and development investment, which is much higher than the industry average of 6%.[71]

These studies suggest that whether patents influence decisions to undertake future research depends largely on the entity carrying out the research. Some industries, particularly the biotechnology industry, are more reliant on patents than academic research institutions.

ii. Do these patents stifle innovation?

Like their role in promoting innovation, there are mixed reports regarding

[66] *Id*. at 122.

[67] Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980).

[68] *Id*.

[69] For example, once a person possesses a kit containing DNA, the sequence of the DNA can readily be identified by standard DNA sequencing technologies. *See* E Petterson et al., *Generations of sequencing technologies*, 93 GENOMICS 105, 105–11 (2009).

[70] *See* SUBCOMM. ON PATENTS, TRADEMARKS AND COPYRIGHTS OF THE S. COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM, 80 (Comm. Print 1958) (Fritz Machlup) ("If we did not have a patent system, it would be irresponsible on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible on the basis of our present knowledge to recommend abolishing it.").

[71] Ashish Arora et al., *R&D and the Patent Premium* 48 (Nat'l Bureau of Econ. Research, Working Paper No. 9431, 2003), *available at* http://www.nber.org/papers/w9431.

the potential inhibitory impact of these patents on downstream research. Studies on how biotechnology patents affect downstream innovation hardly support the concern of gene patents stifling future innovation. For example, A survey conducted by Walsh *et al*. found that patents pose relatively few obstacles on downstream biomedical research because of the parties' ability to find "working solutions" to them.[72] Joseph Straus' study of the German industry reached similar conclusions.[73] An Australian survey showed that, although there was greater concern about the potential negative impact of gene patents than other types of patents, the Australian biomedical industry appeared to avoid the "anticommons" effect.[74] As Prof. Eisenberg in her excellent review of a number of empirical studies concluded,"[t]he results suggest that, overall, intellectual property has presented fewer impediments to research than policymakers may have projected on the basis of early salient controversies."[75] Professor Eisenberg cautions, however, that these studies have limited value as a test for the anticommons theory because the studies largely focus on the effects on the "research science community."[76]

There is also a possibility that the anticommons effect of gene patents may be more pronounced in one sub-sector of the biotechnology industry rather than in the industry as a whole. For instance, there are some reports of gene patents inhibiting the capacity of clinical labs to conduct diagnostic tests. Two studies have shown that about twenty-five to thirty percent of clinical laboratories abandoned or stopped developing diagnostic tests because of upstream patents.[77]

In sum, although certain studies have shown that gene patents may have negative impact on clinical diagnostics, there is otherwise very little evidence

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[72] *See* John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation, in* PATENTS IN THE KNOWLEDGE BASED ECONOMY 285, 328 (Wesley M. Cohen & Stephen A. Merrill, ed., 2003).

[73] JOSEPH STRAUS ET AL., GENETIC INVENTIONS AND PATENT LAW - AN EMPIRICAL SURVEY OF SELECTED GERMAN R&D INSTITUTIONS 15 (2004).

[74] DIANE NICOL & JANE NIELSEN, CTR. FOR LAW & GENETICS, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry*, OCCASIONAL PAPER NO. 6, xi-xii, 90 (2003), *available at* http://www.ipria.org/publications/reports/BiotechReportFinal.pdf. An anticommons effect occurs for patents when "the pace of innovation" is delayed because "it is necessary to enter into license negotiations over multiple patents." *Id*. at x.

[75] Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1061 (2008).

[76] *See id*. at 1098.

[77] *See* Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 5 (2003); Jon F. Merz et al., *Diagnostic Testing Fails the Test: The Pitfalls of Patents are by the Case of Hemochromatosis*, 415 NATURE 57 (2002).

to support the contention that gene patents inhibit downstream innovation in general.

iii. The data's limited explanatory scope.

Lastly, it is problematic to draw too many inferences about the validity of the consequentialist arguments at play here from these studies. Even if some studies demonstrate some inhibition of downstream innovation, they inadequately support the Supreme Court's reasoning for invalidating gene patents. The Court was concerned that the grant of gene patents "would 'tie up' the use of such tools [of scientific work] and thereby 'inhibit future innovation premised upon them.'"[78]All patents have some preclusive effect on downstream innovation. An argument that the issuance of these patents violates the utilitarian principles will be persuasive only with evidence that patents on natural products like genes inhibit downstream innovation more significantly than patents on other inventions.

Unfortunately, few studies have undertaken such a rigorous comparative analysis. Patents are likely to have both positive and negative effects on innovation. Studies conducted so far have largely focused on either the incentivization effect or the inhibitory effect, not both, making it very difficult to make an inference on the net impact on innovation.

In the absence of better empirical evidence, the impact of these patents on scientific innovation remains unclear. Yet, the absence of evidence is no reason to eschew these utilitarian considerations, but rather an invitation to conduct more and better studies. Admittedly, any empirical study on the net impact of these patents on social innovation is a challenging endeavor. Nevertheless, the dearth of any clear evidence on the utilitarian theories creates a fertile ground for other moral considerations to influence public opinion and the law. Part III is a modest attempt to understand what some of these considerations might be.

III. SURVEY AND EXPLANATION

This Part explores some of the questions raised previously in this Paper. It focuses on two main characteristics that may influence objections to patents on biological products: (1) whether the biological products are obtained from the human body, and (2) whether the biological products are genetic or non-genetic materials. Even though patent law overlooks these differences, it is likely that these distinctions influence public perceptions of patents covering biological products. This Part seeks first to assess the relevance of these distinctions through a survey and then tries to understand the implications for patent law.

[78] *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013).

A. The Importance of Surveys

While there has been extensive scholarship about the moral and ethical objections to gene patents, there has been very little investigation of the resonance of any of these objections with the public. The importance of seeking public opinion cannot be overstated. Public policy is expected to reflect the moral perceptions of the public in general, not just the convictions of judges, scholars, legislators, or patent examiners. Although surveys are not considered decisive *per se*, it is not uncommon for patent administrative agencies to seek public opinion on important questions of patent law. For example, the European Patent Office, the agency responsible for issuing patents in Europe, hinted in *Howard Florey* that surveys could be used to demonstrate moral objections against a particular class of patents.[79] The USPTO regularly solicits public opinion on proposed changes.[80] Even China recently sought public opinion on planned amendments to the country's patent law.[81]

Public opinion becomes even more pertinent in laws involving biotechnological innovation, which can have profound implications on our relationships with each other and the natural world. As one commentator noted, "[r]ight from the recombinant DNA controversy, the general public in the [United States] has been involved in the progress of biotechnology."[82] Public participation on an issue directly impacting human rights and human health is not only justified but also necessary.

That being said, nothing in this Paper should be interpreted as suggesting that public opinion should be determinative. Not only is it difficult to determine the public opinion correctly but also to ascertain whether the public

[79] *See* Taiwo A. Oriola, *Ethical and Legal Issues in Singapore Biomedical Research*, 11 PAC. RIM L. & POL'Y J., 497, 512 (2002) ("Obviously recognizing that the EPO is not the right institution to decide on fundamental ethical questions, the opponents requested that the EPO carry out a referendum to find out what the public in the Contracting States really wants to be patented. This request is refused since in opposition proceedings the burden of proof lies with the opponent-if they felt that such a survey might assist their case, it was up to them to carry it out." (quoting Howard Florey v. Fraktion der Grunen Im Europaischen Parlament; Lannoye, [1995] E.P.O.R. 541, 552))).

[80] *See, e.g.*, *Streamlined Patent Rexamination Proceedings Roundtable: Comments from the Public*, U.S. PATENT & TRADEMARK OFFICE, http://www.uspto.gov/patents/init_events/streamlinedreexam.jsp (last modified Jan. 4, 2012).

[81] Paolo Beconcini & Mani Chu, *China*: *Patent Law Reforms to Grant More Enforcement Powers to Patentees*, CARROLL, BURDICK & MCDONOUGH LLP, http://www.cbmlaw.com/news-resources/resources/emeabriefings/China-Patent-Law-Reforms-to-Grant-More-Enforcement-Power-to-Pantentees (last visited Apr. 23, 2013).

[82] KALYAN C. KANKANALA, GENETIC PATENT LAW & STRATEGY 130 (2007).

opinion is "correct." Aside from concerns about the tyranny of the majority, commentators have noted that a public of "cognitive misers" displaying "rational ignorance" may suffer from an "information gap" leading to shortsightedness.[83] In particular, determining public opinion in an area of law such as patent law, may be more difficult since patents may involve complex technology and intangible gains (in the form of information) in lieu of apparent deprivations (patent exclusions). In the end, neither an exclusive reliance on simplistic surveys of public opinion nor a complete ignorance of public opinion best serves policy formulations.

B. The Survey Results

Let us now turn to the survey conducted for this paper. Although there have been a number of studies surveying scientists and industry researchers about the impact of biotechnological patents on downstream research, only two surveys have thus far sought public opinion on DNA-related patents in the United States. It is unclear whether these surveys' results are contradictory or consistent since their wordings were somewhat different. A Biotechnology Industry Organization survey of "elite voters" found that fifty-one percent of respondents had reservations about DNA-based patents but could support these patents anyway for the good of the biotech industry's work on disease cures.[84] Genetic Engineering & Biotechnology News reported the results of another survey that found that "a near-majority of respondents (45.2%) called for doing away with gene patents."[85] However, neither of the surveys compared public opinion with respect to patents on genetic versus non-genetic materials, or biological products isolated from different sources.

The survey discussed in this Paper is the first of its kind, parsing out the public perceptions regarding different natural products. The survey was taken by 215 participants, with at least a college degree.[86] The participants were given a short explanation of patents and genes, and directed to additional

[83] Fred Cutler, *Jeremy Bentham and the Public Opinion Tribunal*, 63 PUB. OPINION Q., 321, 322 (1999).

[84] Donald Zuhn, *BIO Survey Shows Support for DNA-Based Patents Despite Some Reservations*, PATENT DOCS (Jan. 9, 2011), http://www.patentdocs.org/2011/01/bio-survey-shows-support-for-dna-based-patents-despite-some-reservations.html (Interestingly, the BIO-survey suggests that people respond more negatively to "gene patents" as compared to "DNA-patents.").

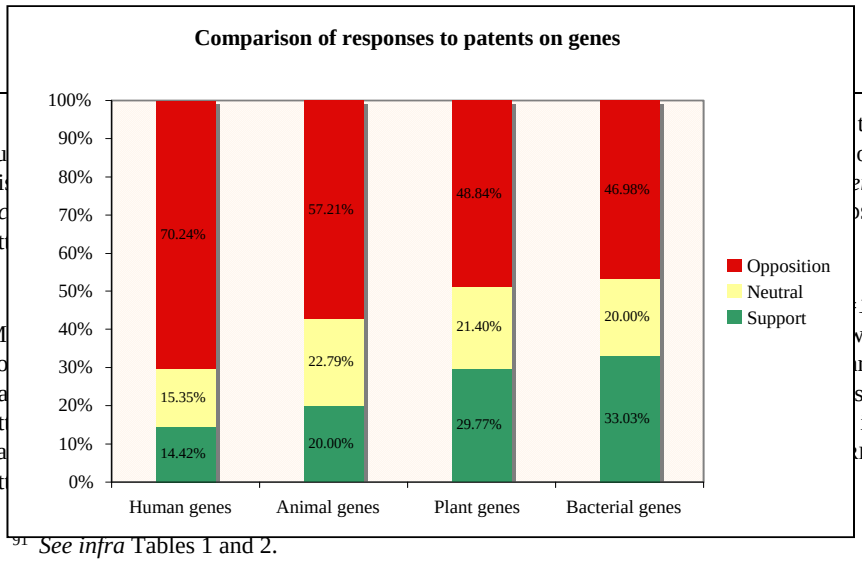
[85] *Recent Poll Results Highlight How Divisive Gene Patenting Is*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (Mar. 12, 2012), http://www.genengnews.com/gen-news-highlights/recent-poll-results-highlight-how-divisive-gene-patenting-is/81246482/.

[86] The survey participants were from all over the country. The male to female ratio was almost 1:1. Their ages ranged from 18 to 60. Their household incomes ranged from under $25,000 per year to $150,000 per year.

resources if they were interested. They were requested to provide their highest level of education, with the intention of screening out participants who do not have at least a college degree. The assumption is that participants with at least a college education would have a reasonably sophisticated understanding of biotechnology and patent law. The survey asked participants to indicate their support or opposition to patents on certain biological products in a five-point Likert scale: strongly support, support, neither support nor oppose, oppose, and strongly oppose.[87]

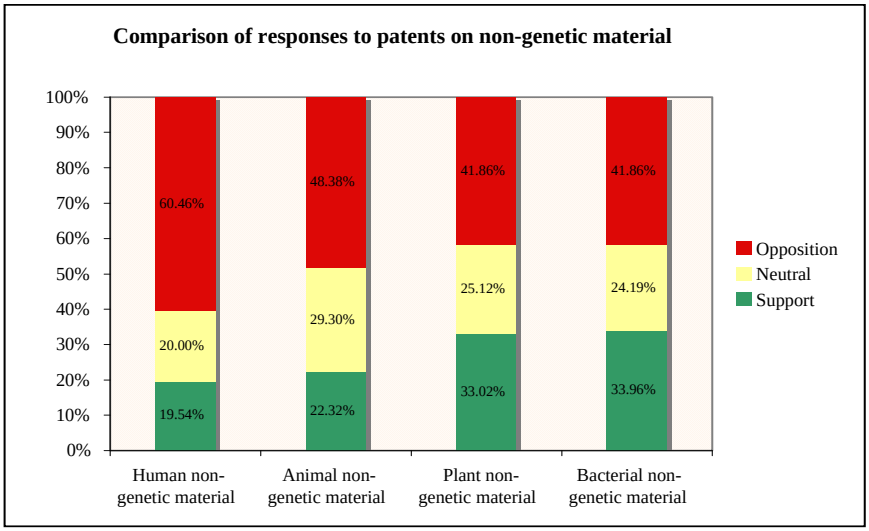
The survey results showed that in general, participants were opposed to the patenting of biological products regardless of the products' human origin.[88] These conclusions are statistically significant with p-values less than 0.0001[89]. However, there was a stronger opposition to patents on human biological products than for patents on biological products obtained from other sources, the opposition decreasing as one goes down the species ladder.[90] This variation across different species was observed independent of the genetic nature of products being patented.[91] An overwhelming majority of the participants (70.24%) opposed patenting human genes, while the lowest opposition was observed for patenting of bacterial genes (46.98%). Opposition to patents on animal genes (57.21%) and patents on plant genes (48.84%) lay in between. Conversely, the support for these patents increases as one goes from human beings to bacteria. The survey demonstrated a similar trend on patenting of non-genetic materials, with patents on human biological materials meeting the most resistance (60.46%), and patents on plants and bacterial non-genetic materials facing less opposition (41.86%).

Table 1



[91] *See infra* Tables 1 and 2.

Table 2



The survey also shows a difference between patents on genetic material versus non-genetic material.[92] These differences are statistically significant for patents on human biological materials, with a p-value of 0.016.[93] Thus, the survey suggests that people are more opposed to patents on human genes than

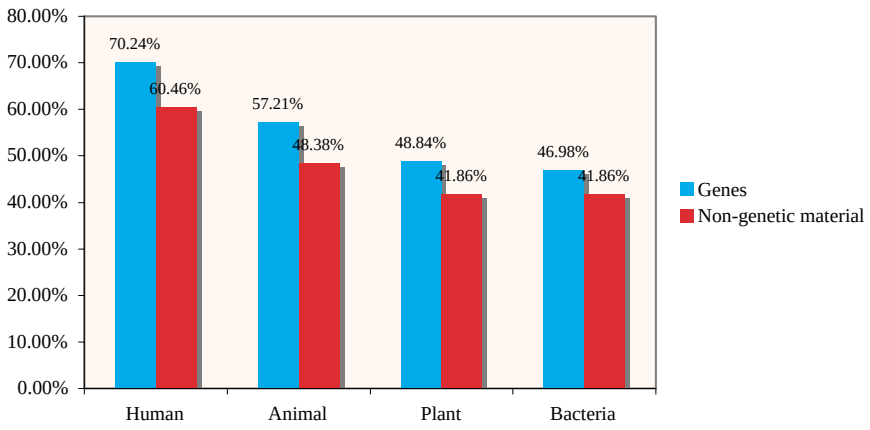
[92] *See infra* Table 3.

[93] *See supra* note 89.

to patents on human non-genetic materials. For other species, the difference in opposition is not statistically significant by conventional criteria. Hence, for animals, plants and bacteria although the survey shows some difference in opinion between genetic and non-genetic materials we cannot draw any statistically significant conclusion.

Table 3

Comparison of opposition to patents on genes and non-genetic material



In sum, although most participants were opposed to patents on biological products, we did see a species-based variation in their opposition. Also, when it came to human biological products, people were more opposed to patents on genes than non-genetic materials.

C. The Implications of the Survey Results

One of the key observations from this survey is that participants were not necessarily influenced by the dominant theories driving the ongoing debate in courts and academic circles. For instance, the utilitarian theory suggesting that these patents may impact downstream innovation does not explain the results. Even assuming that these patents inhibit downstream innovation more than patents on synthetic materials, there is no reason to believe that a human gene patent would impact downstream innovation more than, for example, a bacterial gene patent. Nor does an interest in preserving the public domain explain the preferential treatment of human genes over non-human genes or

human non-genetic materials.[94] In other words, there are additional considerations influencing the court of public opinion besides the narrow focus on innovation that guided the Supreme Court in *Myriad*.

While the Supreme Court focused on these patents' impact on innovation, the participants, not surprisingly, appear concerned about these patents' impact on human beings. This could partially explain the greater opposition to patenting human biological products than non-human biological products. First, granting private monopoly to human genes is antagonistic to the intuition that individuals have possessory rights to their genes. Simply put, people may feel that their genes belong to them and that no third party should have exclusionary rights to their genes.[95] This logic is evinced by media coverage from both before and after the gene patents ruling. For instance, the title of a Forbes article stated, "Myriad Genetics CEO Claims He Owns *Your* Genes."[96] Hailing the Supreme Court ruling, an ACLU opinion piece cheered, "VICTORY! Supreme Court Decides: Our Genes Belong to Us, Not Companies."[97] While some of this coverage may confuse exclusion with possession, a patent owner's exclusionary rights are by no means insignificant. As argued elsewhere, the power of a patent owner to prevent people from isolating and using their bodily products may even implicate the Takings Clause.[98] In addition, as some commentators have also argued, patenting of human biological products may be deemed offensive to human dignity and the right to a common human heritage.[99]

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[94] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (rejecting patents on a mixture of bacteria and noting "[t]he qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.").

[95] *See* Alison Tanner, *Human Genome Debate: SCOTUS to Decide Who Owns Your Genes*, POLICYMIC (Dec. 1, 2012), http://www.policymic.com/articles/19964/human-genome-debate-scotus-to-decide-who-owns-your-genes (Lisbeth Ceriani, a breast cancer survivor and plaintiff in the *Myriad* case argued, "My genes belong to me. Knowledge about my own body should not be held hostage by a corporation.").

[96] Steven Salzberg, *Myriad Genetics CEO Claims He Owns Your Genes*, FORBES (Apr. 13, 2012), http://www.forbes.com/sites/stevensalzberg/2013/04/13/myriad-genetics-ceo-owns-your-genes/ (emphasis added).

[97] Sandra S. Park, *VICTORY! Supreme Court Decides: Our Genes Belong to Us, Not Companies*, ACLU (June 13, 2013, 11:35 AM), https://www.aclu.org/blog/womens-rights-free-speech-technology-and-liberty/victory-supreme-court-decides-our-genes-belong.

[98] Samantak Ghosh, *The Taking of Human Biological Products*, 102 CALIF. L. REV. (forthcoming 2014).

[99] *See* Daniel J. Kevles & Ari Berkowitz, *The Gene Patenting Controversy: The Convergence of Law, Economic Interests, and Ethics*, 67 BROOK. L. REV. 233, 234 (2001) ("The controversy over gene patenting has swirled most turbulently around the claim that

Beyond the implications of a patentee's exclusionary claims, people may also be genuinely troubled by the impact of human gene patents on access to important genetic tests.[100] That healthcare access was a major driver of public anxiety is shown by the fact that a number of patient-advocacy groups[101] and groups like the American Medical Association lined up against human gene patents.[102]

Of course, the public unease with human gene patents may have been further exacerbated by some mischaracterizations of the rights conferred by patents. Some commentators have compared gene patent ownership with slavery[103] or suggested that gene patent owners can do whatever they want with other people's genes.[104] These misleading suggestions coupled with media hype may have contributed to a greater sense of apprehension about gene patents than is warranted.[105]

Whatever the concerns leading to an overwhelming opposition to human gene patents, it is quite clear that many of these concerns are much attenuated, or even non-existent, when considering biological products from other organisms. Human beings generally cannot claim some possessory rights to biological materials from non-human sources. Similarly, there would be little concern that patents on these products may impact access to human diagnostic tests. While animal rights activists may still argue for a greater recognition of

granting private intellectual property rights in parts of human genome violate a moral code because the genome, the common program for human life, belongs to us all."); Resnik, *supra* note 16, at 157.

[100] *See, e.g.*, Rachel Marshall, *Hands Off My Genes*, ACLU (Feb. 29, 2012, 5:21 PM), http://www.aclu.org/blog/womens-rights-free-speech/hands-my-genes (expressing concern that patent monopoly may stand in the way of getting genetic tests for hereditary spinal muscular atrophy).

[101] *See, e.g.*, Brief Amici Curiae of the National Women's Health Network et al. in Support of Petitioners at 7, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 12-398).

[102] *See, e.g.*, Brief of Amici Curiae American Medical Ass'n et al. in Support of Petitioners at 7, *Myriad*, 133 S. Ct. 2107, (No. 12-398).

[103] *See* Mike Adams, *U.S. Government Claims 100% Ownership Over all Your DNA and Reproductive Rights; Genetic Slavery is Already Here*, NATURALNEWS, (May 19, 2013), http://www.naturalnews.com/040400_ gene _patents_genetic_slavery_human_dna.html.

[104] *See* 153 CONG. REC. E315-05 (daily ed. Feb. 9, 2007) (statement of Rep. Becerra) ("[W]e have absolutely no say in what [patent owners] do with our genes.").

[105] Even Angelina Jolie's decision to undergo mastectomy was used as an opportunity to highlight Myriad's monopoly over the BRCA genes. *See* Gayle Sulik, *Why Jolie's Cancer Test Costs So Much*, CNN (May 28, 2013), http://www.cnn.com/2013/05/24/opinion/sulik-patented-genes (lamenting the high cost of BRCA genetic tests and ascribing it to Myriad's patent monopoly). Some have termed the media hype "genohype." *See* Caulfield, *supra* note 29.

dignity of animals, these claims get decreasing moral stridency as one goes down the species chain to lesser evolved species like plants and bacteria.[106] Thus, it is not surprising that the greatest difference in the measure of support for gene patents is observed between those of human and bacterial genes.

Similarly, the difference in public opinion between human genetic and non-genetic materials can be explained by the fact that genes are deemed special. There is a greater sense of value or respect associated with human genetic materials than non-genetic materials. Genetic exceptionalism is understandable.[107] Genetic information is unique in its capacity to simultaneously identify individuals separately and relationally. On the one hand, DNA fingerprinting is routinely used in solving crimes by identifying individuals. On the other hand, genetic information from individuals very often implicates relatives, and in some instances, even ethnic groups.[108] The longevity and multi-generational characteristics of DNA also lends to its unique status among natural products.[109]

For lower organisms, though DNA still retains its aura as a fundamental molecule of life, it does not raise many of the concerns implicated by human genetic information. For instance, privacy interests are very modest, if not virtually non-existent, for non-human species. This may explain why the survey did not show a statistically significant difference in the opposition between genetic and non-genetic materials for lower organisms.

An appreciation of these distinctions helps to understand why a case involving human gene patents is a questionable vehicle for developing a doctrine on the patent-eligibility of all natural products. As the survey shows, the human gene is an exceptional biological product because it is both a *human* biological material and a *gene*. After all, it is often said, "[H]ard cases make bad law."[110] Even Glanville Williams, a legal scholar who questioned this over-used legal maxim, was "certain . . . that cases in which the moral indignation of the judge is aroused frequently make bad law."[111] Just like the common man, it is possible that the *Myriad* Justices' moral outrage over the question of patenting human genes—although it found no expression in the *Myriad* opinion—may have been exceeded by their concern over patents on

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[106] *See* Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 422-423 (1988).

[107] However, we must be careful about the pitfalls of genetic essentialism. *See generally* DOROTHY NELKIN & M. SUSAN LINDEE, THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON 41-49(1995).

[108] *See* Ronald M. Green & A. Mathew Thomas, *DNA: Five Distinguishing Features For Policy Analysis*, 11 HARV. J.L. & TECH. 571, 580-87 (1998).

[109] *Id.*

[110] N. Sec. Co. v. United States, 193 U.S. 197, 400 (1905).

[111] BRYAN A. GARNER, A DICTIONARY OF MODERN LEGAL USAGE 398 (2nd ed. 1995).

other biological products. As Justice Holmes so eloquently put it:

> Great cases like hard cases make bad law. For great cases are called great, not by reason of their real importance in shaping the law of the future, but because of some accident of immediate overwhelming interest which appeals to the feelings and distorts the judgment. These immediate interests exercise a kind of hydraulic pressure which makes what previously was clear seem doubtful, and before which even well settled principles of law will bend.[112]

The *Myriad* gene patents case undoubtedly includes elements that could appeal to human feelings. Indeed, the very fact that it was such an emotive issue may explain why amongst so many patents on so many different biological products, the case ultimately challenged covered patents on human genes.

Finally, and perhaps more importantly, a nuanced understanding of these underlying policy considerations may help avoid the pitfalls of over and under-inclusiveness that appear to be a point of disagreement on patentable subject matter. Instead of lurking in the shadows of the dominant utilitarian concerns of innovation, these issues should be at the forefront, for they may provide a richer understanding of the concerns surrounding these patents. Bringing more granularity to the picture may help parse out the universe of biological products and facilitate a more tailored approach. Particularly, where the empirical evidence is unclear, these factors may influence legislative efforts on categorical patentable subject matter exclusions.

Public moral objections influencing patent law are not new.[113] American patent law contains a number of restrictions on patent-eligibility and the scope of patents based primarily on moral judgments rather than on their impact on scientific innovation. For instance, concerns about the harmful effects of patent incentive and disclosure of nuclear weapons technology lead Congress to ban patentability of such innovations in 1954.[114] Moral objection over the

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[112] *N. Sec. Co.*, 193 U.S. at 400-01.

[113] *But see* Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469 (2003) (criticizing the "patent first, ask questions later" approach of United States patent law and comparing it with other jurisdictions where morality plays a more explicit role in patent law).

[114] 42 U.S.C. § 2181 (2006) ("No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon. Any patent granted for any such invention or discovery is revoked, and just compensation shall be made therefor [sic]."); *see* Dresser, *supra* note 106, at 404 ("Congress preferred the possible knowledge loss resulting from its decision to

commodification of human beings was similarly instrumental in the incorporation of the "Weldon Patent Ban" into patent law, under which "no patent may issue on a claim directed to or encompassing a human organism."[115] The exception in patent law that health care providers cannot be held liable for the infringement of medical procedure patents is another example where ethical concerns expressed by the medical community forced the Congress to limit the scope of patent enforcement.[116]

Interestingly, in a debate over the patent-eligibility of biological products obtained from lower organisms, this study could provide ammunition to both opponents and proponents of patents. Opponents could point out that public opinion weighs against the granting of these patents.[117] On the other hand, proponents may rely on the fact that the participants were opposed these patents less than patents on human genes.[118] Besides, they could argue that public opinion is just one of the relevant factors, and not a determinative factor. It should be considered in conjunction with the incentivizing effect of patents, and the absence of evidence of these patents adversely impacting future innovation or healthcare access.

Given *Myriad*'s unclear guidance, these debates are likely to play out in the future. This Paper attempts to provide a richer context to these future debates over the patent-eligibility of natural products by providing another vantage point from which to explore these questions.

CONCLUSION

Human genes occupy a special status in our society, thereby raising special concerns over their monopoly. Whether this status and the concomitant concerns are justified or not is another question. But given *Myriad*'s potential of invalidating many more patents than just human gene patents, it merits asking whether the same concerns that elicited public disconcert over human gene patents are relevant to these patents over other biological products. The significance of these issues cannot be overstated. As the dust settles on the debate over the patenting of human genes, new questions about the patent-eligibility of other biological products are springing into life.

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restrict development of nuclear weapons technology to government-controlled programs over the dangers to national security patent availability would present.").

[115] Andrew Torrance, *Weldon Amendment Welded onto the Patent Act*, BIOLAW (Sept. 16, 2011), http://biolaw.blogspot.com/2011/09/weldon-amendment-welded-onto-patent-act.html.

[116] *See* Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NATURE REVS. GENETICS 803, 807 (2002).

[117] *See supra* text accompanying note 90.

[118] *See supra* text accompanying note 91.