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Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials

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Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials

*Gregory Dolin, M.D.**

ABSTRACT: Over the last twenty years, the legal and scientific academic communities have been embroiled in a debate about the patent eligibility of genetic materials. The stakes for both sides could not be higher. On one hand are the potential multi-billion dollar profits on the fruits of research (from newly discovered genes), and on the other is scientists' ability to continue and expand research into the human genome to improve patients' access to affordable diagnostic and therapeutic modalities. This debate is currently pending before the Supreme Court, which is considering a petition for certiorari in Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office.

Both sides have legitimate concerns. Given the unique nature of DNA, patents that broadly cover genetic materials and prevent their use (except by the license of the patentee) create insurmountable roadblocks for future research. However, denying exclusive rights to the fruits of laborious and costly research will remove the necessary incentives for investment in these endeavors, thus delaying scientific and medical discoveries.

To remedy these problems, this Article proposes a non-patent exclusivity system administered by the Food and Drug Administration. Under such a

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system, the innovators who bring new therapeutic or diagnostic products to market would receive exclusive rights to market their products for a limited time. This regime would provide sufficient market-based incentives to continue with the research and investment in this area. At the same time, because genetic sequences would no longer be broadly protected by patents, the public would be able to access these basic research tools without fear of infringement litigation. This approach addresses the concerns of both sides to the debate and leads to a cheaper, more predictable, and easier to administer system of exclusive rights.

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I. INTRODUCTION

In 1982, the United States Patent and Trademark Office (“USPTO”) “issued the first gene patent to the Regents of the University of California for work carried out” on a bacterium.¹ Since then, genetic research, gene isolation and purification, and genetic engineering have gained steam.² Concomitantly, attempts to obtain patents on the results of these new scientific endeavors have also skyrocketed.³ Applications on gene patents have been filed in the United States, Canada, Japan, and the European Patent Offices.⁴ The patents granted on these applications number in the tens of thousands.⁵ With all patents, the decision whether or not to permit patenting of a certain category of inventions generally rests with the national patent authorities⁶ and is based on considerations of public policy⁷ and whether patenting that category would be beneficial or detrimental to the

1. Edward Weck, Note, *Exclusive Licensing of DNA Diagnostics: Is There a Negative Effect on Quantity and Quality of Healthcare Delivery That Compels NIH Rulemaking?*, 31 WM. MITCHELL L. REV. 1057, 1062 (2005); see also U.S. Patent No. 4,363,877 (filed Apr. 19, 1978) (issued Dec. 14, 1982).

2. See, e.g., Larry I. Palmer, *Disease Management and Liability in the Human Genome Era*, 47 VILL. L. REV. 1, 20 (2002); Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 MINN. J.L. SCI. & TECH. 157, 190–91 (2010); Cara Koss, Note, *Oysters & Oligonucleotides: Concerns and Proposals for Patenting Research Tools*, 25 CARDOZO ARTS & ENT. L.J. 747, 754 (2007).

3. Omid E. Khalifeh, *The Gene Wars: Science, the Law and the Human Genome*, 9 LOY. L. & TECH. ANN. 91, 102 (2010); Cydney A. Fowler, Comment, *Ending Genetic Monopolies: How the TRIPS Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide*, 25 AM. U. INT'L L. REV. 1073, 1084 (2010).

4. See generally Melissa Wetkowski, Note, *Unfitting: Gene Patent Limitations Too Tight for United States' Biotechnology Innovation and Growth in Light of International Patenting Policies*, 16 SW. J. INT'L L. 181, 185–96 (2010) (discussing legal rules applicable to gene patents in the United States, Europe, Japan, Canada, Australia, and China).

5. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1625–26 (2003) (“Patentees have acquired thousands of patents on DNA sequences that cover specific genes or in some cases fragments of genes.”).

6. Gretchen Ann Bender, *Clash of the Titans: The Territoriality of Patent Law vs. the European Union*, 40 IDEA 49, 51–52 (2000) (“A patent is a statutory right granted to an inventor or the inventor’s assignee by a national government to exclude other people from practicing the invention disclosed and claimed in the patent specification. . . . Patent law, like all intellectual property law, has historically been based on the nation-state and the principle of territoriality. National governments grant patents to inventors.” (footnote omitted)).

7. See Marsha J. Ferziger, Comment, *Monopolies on Addiction: Should Recreational Drugs Be Patentable?*, 1994 U. CHI. LEGAL F. 471, 483 (“The debate over the ethical issues and public policy concerns inherent in granting patents on living organisms has direct applicability to the issue at hand. Commentators examining the patentability of biotechnological advances have recognized that Congress has the authority to limit patent rights in order to advance the general welfare.”); David S. Taylor, Note, *The Sinking of the United States Electronics Industry Within Japanese Patent Pools*, 26 GEO. WASH. J. INT'L L. & ECON. 181, 199–200 (1992) (“The grant of a patent monopoly and the rights thereby conferred with it are permitted because of the benefits derived from the full disclosure of the invention to the public.”).

advancement of science and human knowledge.⁸ The debate on this topic has raged in the pages of academic journals, in legislative committees, national patent offices, and the courts.⁹ This is not surprising for several reasons.

First, unlike other chemical entities, genetic materials are carriers of information,¹⁰ and that information is the same whether the relevant molecule is created by nature or by human effort.¹¹ Second, this information is conserved not only as between “naturally occurring” molecules and artificially engineered ones, but also across essentially all biological entities.¹² In other words, a genetic sequence carries the same information whether the sequence appears in a human or in a bacterium. Thus, allowing patents on any given genetic sequence potentially precludes the use of that sequence in not just humans, but in all future research.¹³

At the same time, laboratory-created genes are chemically and physically different from those that occur in nature, even if both sets have the same informational content.¹⁴ Focusing purely on the chemical structure, then,

8. *In re Tenney*, 254 F.2d 619, 623 (C.C.P.A. 1958) (“[U]nless the public so derives benefit, unless the patentee, by his disclosure, adds to the sum of human knowledge, . . . the policy of the patent laws would be frustrated.”).

9. See Gaia Bernstein, *In the Shadow of Innovation*, 31 CARDOZO L. REV. 2257, 2293–94 (2010) (discussing the debate on the propriety of allowing gene patents); David C. Hoffman, Note, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing a Broad Experimental Use Exception*, 89 CORNELL L. REV. 993, 1019 (2004) (noting that the National Institutes of Health’s (“NIH”) initial plans to file patent applications on genetic discoveries “spurred intense debate that has continued” to the present day (footnote omitted)).

10. See Reese McKnight, *RNA Interference: A Critical Analysis of the Regulatory and Ethical Issues Encountered in the Development of a Novel Therapy*, 15 ALB. L.J. SCI. & TECH. 73, 78 (2004).

11. Sean MacKenzie, Note, *Recognizing the Building Blocks of Life as Products of Nature: Association for Molecular Pathology’s Rightful Exclusion of Genetic Information from Patentable Subject Matter*, 32 WHITTIER L. REV. 367, 382 (2011).

12. See RICKI LEWIS, *HUMAN GENETICS: CONCEPTS AND APPLICATIONS* 310–11 (10th ed. 2012); Mary B. Mahowald, *Genes, Clones, and Gender Equality*, 3 DEPAUL J. HEALTH CARE L. 495, 504 n.48 (2000) (“[A]ll living species use the same genetic code.”); Marshall Nirenberg, *The Genetic Code*, Nobel Lecture (Dec. 12, 1968), in *PHYSIOLOGY OR MEDICINE 1963–1970*, at 372, 390 (1999) (“[M]ost, perhaps all, forms of life on this planet use essentially the same genetic language, and . . . the language is translated according to universal rules.”); William C. Mull, Note, *Using the Written Description Requirement to Limit Broad Patent Scope, Allow Competition, and Encourage Innovation in Biotechnology*, 14 HEALTH MATRIX 393, 397 (2004) (“[T]he basic chemical structure of DNA is the same for all species.”).

13. See Andrew S. Robertson, *The Role of DNA Patents in Genetic Test Innovation and Access*, 9 NW. J. TECH. & INTELL. PROP. 377, 383–85 (2011); Jennifer L. Davis, Comment, *The Test of Primary Cloning: A New Approach to the Written Description Requirement in Biotechnological Patents*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 469, 480–81 (2004); Krista Stone, Note, *Written Description After Ariad v. Eli Lilly: 35 USC § 112’s Third Wheel*, 11 J. HIGH TECH. L. 191, 193 (2010).

14. See generally *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad II)*, 653 F.3d 1329, 1358–73 (Fed. Cir. 2011) (Moore, J., concurring in part) (discussing the chemical and physical differences of laboratory-created DNA molecules versus naturally occurring DNA molecules), *vacated sub nom.* *Ass’n for Molecular Pathology v. Myriad Genetics*,

these artificial molecules should easily be eligible for patent protection as chemical entities.¹⁵ The problem, though, is that these molecules' chemical structure and their informational content are inseparable. Therefore, granting a patent to the innovators in this field may confer exclusive rights not just over the chemical structure, but also over the informational content¹⁶—all to the detriment of future research in genetics and genetic diseases.¹⁷

Of course, patent seekers in this area do not seek to patent random genetic sequences.¹⁸ Instead, they seek patent protection on genes that are

Inc., 132 S. Ct. 1794 (2012). The case is commonly referred to as “the *Myriad* decision,” after the name of the patent holder in question and one of the named defendants. See, e.g., Joshua D. Sarnoff, *Patent-Eligible Inventions After Bilski: History and Theory*, 63 HASTINGS L.J. 53, 55 (2011) (referring to the decision as “*Myriad* Genetics”). *Myriad I* was the district court decision that the Federal Circuit reversed. See Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad I*), 702 F. Supp. 2d 181, 222–32 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012). *Myriad II* was vacated by the Supreme Court on March 26, 2012, and remanded for reconsideration “in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, . . . 132 S. Ct. 1289 . . . (2012).” Ass'n for Molecular Pathology v. Myriad Genetics, Inc. (*Myriad III*), 132 S. Ct. 1794 (2012) (order granting petition for the writ of certiorari, vacating the decision below, and remanding for reconsideration). After remand, the same panel of the Federal Circuit that heard *Myriad II*, by the same 2–1 vote, reached an identical conclusion as prior to the remand. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad IV*), 689 F.3d 1303 (Fed. Cir.), *cert. granted in part*, 133 S. Ct. 694 (2012). Because the analysis in *Myriad IV* did not deviate from *Myriad II*, and because the opinion (especially Judge Moore's concurrence) in *Myriad II* is more scientifically comprehensive, the discussion in this Article will focus on the latter, rather than the former.

15. See *Myriad II*, 653 F.3d at 1349–55 (applying basic chemistry principles to laboratory-created DNA molecules and concluding that they are patent eligible); *id.* at 1358–73 (Moore, J., concurring in part) (same); *id.* at 1373–81 (Bryson, J., concurring in part and dissenting in part) (reaching the same result with respect to some, though not all, laboratory-created DNA molecules).

16. *Myriad I*, 702 F. Supp. 2d 181 (relying on the DNA's informational nature to conclude that patent claims on DNA cover the information contained therein and therefore cannot be sustained under the Patent Act); Debra Greenfield, *Intangible or Embodied Information: The Non-Statutory Nature of Human Genetic Material*, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 467, 476–77 (2009) (“[I]t is arguable that potential plaintiffs will be reluctant to question the legality of the subject matter of a patent on the informational content of DNA and DNA sequences.”); Janice M. Mueller, *Public Access Versus Proprietary Rights in Genomic Information: What Is the Proper Role of Intellectual Property Rights?*, 6 J. HEALTH CARE L. & POL'Y 222, 229 (2003).

17. See Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 796 (2000) (“There are sound policy reasons to be wary of permitting use of the patent system to capture the value of information itself. The traditional patent bargain ensures that patenting promptly enriches the information base, even as it slows down commercial imitation. This balances the interests of inventors in earning a return on past research investments against the interests of the larger public in promoting future research.” (footnote omitted)).

18. See Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY J. INT'L L. 1, 11 n.78 (2001) (noting that NIH abandoned attempts to patent certain genes when they could not identify their utility); Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and*

either known to produce certain proteins or the expression of which is found to be associated with a certain medical condition. For instance, a patent was sought on genes known as BRCA1/BRCA2¹⁹ because these particular genetic sequences are associated with a higher incidence of breast cancer.²⁰ The exclusive rights granted by the patent allow the patent-holder to limit the use and manufacture of these genes in testing or treating the disease,²¹ and for that matter, in future genetic research about breast cancer or other disease.²² The problem for the patentees is that the association between certain genetic sequences and corresponding conditions is a product of nature and is not an invention of anyone.²³ Though the search for these associations is laborious, expensive, painstaking,²⁴ and ultimately of significant importance to science and medicine,²⁵ the fruits of the search cannot be made exclusive to any person.²⁶ Nor can the genetic sequence, in and of itself—though it be newly found—be eligible for a patent, for that sequence is also a product of nature.²⁷

On the other hand, once the association between a certain genetic code and a condition is discovered, scientists can create smaller versions of

Antitrust, 16 BERKELEY TECH. L.J. 813, 840 (2001) (stating that under the PTO's standard, "the thousands of patent applications that have been filed on DNA sequences (and other genetic or protein information) of unknown function are likely to be rejected . . . [because] gene fragments of unknown function are not patentable").

19. See U.S. Patent No. 6,033,857 (filed Mar. 20, 1998); U.S. Patent No. 5,837,492 (filed Apr. 29, 1996); U.S. Patent No. 5,753,441 (filed Jan. 5, 1996); U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,710,001 (filed June 7, 1995); U.S. Patent No. 5,709,999 (filed June 7, 1995); U.S. Patent No. 5,693,473 (filed June 7, 1995).

20. Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737, 775 n.186 (2004) ("[Genes] BRCA1 and BRCA2 . . . are associated with inherited forms of breast cancer.").

21. See Roger D. Klein & Maurice J. Mahoney, *LabCorp v. Metabolite Laboratories: The Supreme Court Listens, but Declines to Speak*, 36 J.L. MED. & ETHICS 141, 146 (2008).

22. See *id.*; Robertson, *supra* note 13, at 383.

23. See Lamis G. Eli, *Case Note, When Myriad Genetics Prohibited a Myriad of Options: Association for Molecular Pathology v. USPTO*, 21 DEPAUL J. ART TECH. & INTELL. PROP. L. 357, 382 (2011).

24. Andrew W. Torrance, *Open Source Human Evolution*, 30 WASH. U. J.L. & POL'Y 93, 129 (2009); Stone, *supra* note 13, at 224 ("[S]equencing DNA is time consuming and expensive . . .").

25. See David Galas, *Foreword to OFFICE OF HEALTH & ENVTL. RESEARCH, U.S. DEP'T OF ENERGY, HUMAN GENOME: 1991-92 PROGRAM REPORT*, at iv (1992); E. Donald Shapiro, Jennifer Long & Rebecca Gideon, *To Clone or Not to Clone*, 4 N.Y.U. J. LEGIS. & PUB. POL'Y 23, 28 (2000) (stating that the results of genetic research "have led to major advances in medicine, such as the development of insulin and anti-clotting medication").

26. See Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) ("[M]anifestations of laws of nature [are] free to all men and reserved exclusively to none."); Eli, *supra* note 23, at 382-86.

27. Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 311 (2007); Lauren M. Dunne, *Case Note, "Come, Let Us Return to Reason": Association of Molecular Pathology v. USPTO*, 20 DEPAUL J. ART TECH. & INTELL. PROP. L. 473, 501 (2010).

genetic material bearing the same informational content as the naturally occurring code.²⁸ These molecules, because they are a creation of human ingenuity, have been held by various patent offices around the globe (and recently by the courts) to be patent eligible. Nevertheless, patents on these molecules are subject to another problem. Given the advances in genetics, it does not take much (if any) creativity to make these molecules once the association and the native code are known.²⁹ Once that information is available, deriving the lab-created molecules is fairly straightforward, if occasionally laborious and expensive.³⁰ Patent laws, however, require that a patent seeker not only establish that the subject matter of his application is eligible for a patent as a general matter,³¹ but is also sufficiently innovative (“novel” and “non-obvious,” in patent terminology) to qualify for a patent once general eligibility has been established.³²

Explorers in this field are thus placed in a lose-lose situation. The true discoveries (of native code and its association with medical conditions) are not patent eligible. On the other hand, those genetic discoveries that *are* patent eligible (laboratory-created genetic material, for example) are often not sufficiently innovative to qualify for a patent. This inability to obtain patents because of either the subject matter eligibility bar or the novelty bar means that the incentive to innovate that is inherent in the patent system is absent (or at least diminished) in the field of genetics research. And given the fact that the search for the genes and their associations with specific diseases is costly and unpredictable, the inability to recoup investments through exclusive rights discourages investments in this area.

However, even if patents were available for genetic “discoveries” in some specific instances, such patents present a problem for the public. Since patents grant exclusive rights to *make* or *use* the patented invention,³³ one who holds a patent on a lab-created genetic sequence could prevent other scientists from making the same sequence in their laboratories to use in

28. See *Myriad I*, 702 F. Supp. 2d 181, 196–97 (S.D.N.Y. 2010) (discussing various uses for isolated and purified DNA), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012).

29. See John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 114–15 (2001) (discussing automation and routinization of DNA sequencing); Stone, *supra* note 13, at 224 (noting that though expensive, DNA sequencing is “routine”).

30. Timo Minssen, *Meanwhile on the Other Side of the Pond: Why Biopharmaceutical Inventions That Were “Obvious to Try” Still Might Be Non-Obvious—Part I*, 9 CHI.-KENT J. INTELL. PROP. 60, 126 (2010) (describing “sequencing and mere identification of genes” as “a routine process, which normally does not involve any particular difficulties”).

31. 35 U.S.C. § 101 (2006).

32. *Id.* §§ 102–103 (2006 & Supp. V 2011). Although the distinctions between novelty and obviousness are important ones, for the sake of brevity I refer to both requirements as the “novelty” requirement for the remainder of the Article.

33. *Id.* § 271 (2006 & Supp. V 2011).

further experiments.³⁴ This would be true even if no immediate economic benefit would accrue to those scientists and even if they were not selling (and competing) with the patentee.³⁵ If patents foreclose not just competitors' economic gains but further scientific exploration, they are detrimental rather than beneficial to the public.³⁶

This Article proposes a solution to the quandary. Innovation and research in genetics can be incentivized by providing innovators in this field with an alternate and more limited form of exclusivity than that bestowed by patents. Lawmakers can mold such a system on the exclusivity provisions of the Hatch-Waxman Act³⁷ and the new Biologics Price Competition and Innovation Act.³⁸ Under these Food and Drug Administration ("FDA") administered exclusivity regimes, no generic manufacturer can market a drug or biologic product similar to a protected one, *whether or not* the protected product is covered by a valid U.S. Patent. Unlike a patent, which grants exclusive rights to *make, use, or sell*, these types of statutory exclusivity provisions are limited to restrictions on competitors' marketing. In contrast, one need not satisfy the strict novelty requirements of the Patent Act in order to take advantage of the FDA exclusivity regime. These distinctions between patent protection and marketing exclusivity make the latter ideally suited to promoting research and innovation in genetics.

Under the proposed regime, parties who spend time, money, and energy looking for correlations between certain genetic sequences and medical conditions would be able to apply for market exclusivity for the tests and treatments they designed. As the sole providers of tests or treatments (or both), they would be able to recoup their investment and make a profit, even if their tests and treatments would not qualify for patent protection. Furthermore, by limiting the scope of exclusive rights only to the *sale* of tests or treatments, other researchers would not be constrained in making or using copies of the protected molecules for research purposes. In this way, the proposed marketing exclusivity regime reserves the chemical structure of the laboratory-created molecules for the innovator's exclusive commercial

34. See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) ("[T]ests, demonstrations, and experiments which are in keeping with the legitimate business of the alleged infringer are infringements for which experimental use is not a defense." (internal alterations omitted) (quoting *Pitcairn v. United States*, 547 F.2d 1106, 1125-26 (U.S. Ct. Cl. 1977)) (internal quotation marks omitted)), *superseded by statute in part*, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271(e) (2006 & Supp. V 2011)).

35. *Id.* at 861 ("[T]he patentee does not need to have *any* evidence of damage or lost sales to bring an infringement action.").

36. See *supra* note 17 and accompanying text.

37. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

38. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7002, 124 Stat. 804, 119 (2010) (codified as amended at 42 U.S.C. § 262(k)(7) (2006 & Supp. V 2011)).

exploitation (for a limited time), while leaving the information-carrying function of the gene for the public domain.

This Article begins in Part II by explaining the basics of molecular genetics. This primer is important in order to understand what it is that patents on genetic materials claim to be a protected invention. This Part will discuss the structure of genes, DNA, and the cellular mechanisms that control DNA's expression and functions. It will then explain the differences between naturally occurring and laboratory-made DNA molecules.

Part III lays out the architecture of patent law and applies it to the specific case of nucleic acids. It discusses the principles, history, and philosophical underpinnings of the patent system and why some kinds of matter are considered to be patent eligible while others are not. It also addresses the novelty requirements for a patent once the eligibility bar has been cleared. Part IV applies the principles from the preceding Part to argue that laboratory-created DNA molecules should be eligible for patent protection under current law. Part V demonstrates that, though isolated genes may be eligible for patent protection, they are ultimately not entitled to a patent for failure of the novelty requirements of the Patent Act.

Parts VI and VII detail this Article's proposal for a market exclusivity regime. Part VI discusses the current powers of the FDA to regulate drugs, biologics, and medical devices, as well as various statutory exclusivity provisions associated with these regulations. Part VII proposes expanding these provisions to cover novel genetic tests and treatments. This FDA-based protection would be in lieu of the protection offered by the patent system and would allow researchers whose patent applications might be rejected or invalidated on novelty grounds to obtain a return on their investment in developing new diagnostic and therapeutic modalities. Such a regime would provide proper incentives for the pioneers in the field of molecular genetics without limiting access to the newly discovered genes for purposes of further research.

The Article's concluding observations are offered in Part VIII.

II. THE SCIENCE AND USES OF GENE ISOLATION AND SEQUENCING

In the discussion of whether genes ought or ought not be patentable, the question of *what* innovators are seeking to patent is often lost. Instead, debates often degenerate into the somewhat strange discussion of whether a human being is patent eligible.³⁹ Such broadsides at the idea of patenting genes overlook the distinctions between naturally occurring DNA present in

39. See Lauren M. Nowierski, Note, *A Defense of Patenting Human Gene Sequences Under U.S. Law: Support for the Patenting of Isolated and Purified Substances*, 26 CARDOZO ARTS & ENT. L.J. 473, 505 (2008) (stating that patents on DNA "prompt[] the following question[]: . . . would a patent on a gene sequence confer ownership over a human being?"); cf. Ann Bartow, *Our Data, Ourselves: Privacy, Propertization, and Gender*, 34 U.S.F. L. REV. 633, 690 (2000) (describing attempts by a British woman to patent herself).

living human cells and the isolated and purified DNA synthesized in laboratories. Not only is synthesized DNA man-made, but it is structurally different from naturally occurring DNA.⁴⁰ At the same time, despite being chemically different, the man-made DNA codes for the same proteins as naturally occurring DNA.⁴¹ Understanding these distinctions is crucial to understanding the legal implications of gene patents.

A. DNA IN THE NATIVE STATE

The chemistry of a DNA molecule is surprisingly simple. A DNA molecule consists of two strands, each of which is simply "a long unbranched paired polymer chain[], formed always of the same four types of [subunits]."⁴² The subunits contain bases known as adenine, cytosine, guanine, and thymine ("A," "C," "G," and "T," respectively).⁴³ Each of these bases is attached to the repetitive sugar-phosphate chain "analogous to a necklace . . . strung with four types of beads."⁴⁴ The sugar unit in the DNA is called deoxyribose.⁴⁵ Each adenine base on one strand is paired to the thymine base on the other, and each cytosine base strand is paired to a guanine.⁴⁶ Thus, each strand of the DNA is "complementary" to the other.⁴⁷ The DNA molecule can be visualized as a zipper with each strand forming a backbone of the zipper and the A, C, T, G base pairs forming the "teeth."⁴⁸ Unlike a regular zipper, though, a molecule of DNA is neither straight nor flat.⁴⁹ Instead, in its native state the DNA molecule "is twisted in a spiral ladder shape."⁵⁰ Each strand forms a continuous helix giving rise to a "double-helix" model of the entire structure.⁵¹

The DNA double helix is but the beginning of the story of native DNA's physical structure. Each DNA molecule is packaged in a separate chromosome,⁵² and all of an organism's chromosomes taken together carry

40. See *supra* note 14 and accompanying text.

41. See *Myriad I*, 702 F. Supp. 2d 181, 222-32 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012).

42. BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 2 (5th ed. 2008).

43. *Id.* at 2-3.

44. *Id.* at 197.

45. *Id.*

46. *Id.* at 197-98.

47. *Id.* at 199.

48. Ryan McDonald, Note, *Juries and Crime Labs: Correcting the Weak Links in the DNA Chain*, 24 AM. J.L. & MED. 345, 348 (1998); see also ALBERTS ET AL., *supra* note 42, at 198 (illustrating DNA's structure schematically).

49. ALBERTS ET AL., *supra* note 42, at 199 (modeling and illustrating DNA's three-dimensional structure).

50. Melissa Kidder, Comment, *Human DNA v. Non-Human DNA: A Look at the General Admissibility of Non-Human DNA in the Courts*, 35 OHIO N.U. L. REV. 397, 398 (2009).

51. See ALBERTS ET AL., *supra* note 42, at 197-98.

52. *Id.* at 202.

the entirety of that organism's genetic information—the organism's genome.⁵³ The DNA is associated with chromosomal proteins (such as histones)⁵⁴ that pack the DNA molecule in an orderly way⁵⁵ and regulate gene expression.⁵⁶ Each chromosome then is not just a long, "twisted ladder" model consisting solely of a DNA molecule, but a much more complex structure where the DNA is coiled and packed in complex three-dimensional structures.

Each chromosome contains numerous genes.⁵⁷ The human genome contains upwards of 20,000 genes⁵⁸ that all have to fit on only twenty-three pairs of chromosomes. Each chromosome, therefore, contains hundreds or thousands of genes.⁵⁹ Although each cell contains its organism's entire genome, not all genes are expressed or "turned on" at all times.⁶⁰ This is rather self-evident. If all genes were turned on in all cells all of the time, cell differentiation would be impossible.⁶¹ In other words, cells would not be able to differentially develop into liver cells, brain cells, blood cells, skin cells, etc.⁶² That they actually do so is the result of certain genes being expressed in certain cells but not in others.⁶³ In order to allow for such differential gene expression, cells identify which genes to express through various cellular mechanisms, like chemical modification of the DNA molecule⁶⁴ or protein binding to relevant segments of DNA in order to turn them "on" or "off."⁶⁵

53. *Id.* at 7–8.

54. *Id.* at 211.

55. *See id.*

56. Rajesh C. Rao, *Alternatives to Embryonic Stem Cells and Cloning: A Brief Scientific Overview*, 9 YALE J. HEALTH POL'Y L. & ETHICS 603, 605 (2009) ("Gene expression is regulated by chemical modifications to DNA and DNA-associated proteins called histones, which are proteins around which DNA is 'wrapped.'").

57. A gene is a unit of DNA that produces a single functional RNA molecule. ALBERTS ET AL., *supra* note 42, at 204. RNA, in turn, codes for proteins and other materials necessary for operation of the cell. *See id.* at 5–7.

58. Erik Lillquist & Charles A. Sullivan, *The Law and Genetics of Racial Profiling in Medicine*, 39 HARV. C.R.-C.L. L. REV. 391, 410 (2004) ("Human beings, by current estimates, have between 26,000 and 40,000 separate genes, spread across twenty-three chromosomes" (footnote omitted)).

59. Mary Breen Smith, *An End to Gene Patents? The Human Genome Project Versus the United States Patent and Trademark Office's 1999 Utility Guidelines*, 73 U. COLO. L. REV. 747, 752 (2002).

60. *See* ALBERTS ET AL., *supra* note 42, at 432.

61. *See id.* at 411–12.

62. *See id.*

63. *See id.*

64. Katharine A. Van Tassel, *Genetically Modified Plants Used for Food, Risk Assessment and Uncertainty Principles: Does the Transition from Ignorance to Indeterminacy Trigger the Need for Post-Market Surveillance?*, 15 B.U. J. SCI. & TECH. L. 220, 236–37 (2009). Methylation is a "chemical modification of cytosine, one of the four chemical subunits of DNA. Without proper DNA methylation, higher organisms from plants to humans have a host of developmental problems, from dwarfing in plants to certain death in mice." *Does Environment Influence Genes? Researcher*

As complex as the DNA structure is, DNA itself serves no active function⁶⁶ other than providing a set of genetic instructions for the production of other molecules important in cellular function—proteins.⁶⁷ Proteins are made up of subunits called amino acids, of which there are twenty.⁶⁸ Each amino acid is coded for by DNA.⁶⁹ Since DNA is a linear polymer of four different nucleotides, one needs a sufficient combination of nucleotides to code for each amino acid. Mathematically, the smallest number of nucleotides needed to code for twenty amino acids, when selected from a total group of four nucleotides, is three.⁷⁰ Thus, each sequence of three nucleotides (also known as a “codon”)⁷¹ codes for a distinct amino acid.⁷² At first blush then, a gene could be described as a linear series of codons each coding for an amino acid of a resultant protein.⁷³ That description, however, would only be partially true. For reasons not wholly understood,⁷⁴ genes have non-coding regions (known as “introns”)⁷⁵ interspersed between coding regions (known as “exons”).⁷⁶

Gives Hard Thoughts on Soft Inheritance, SCIENCE DAILY (Aug. 8, 2006), <http://www.sciencedaily.com/releases/2006/08/060807154715.htm>.

65. See Rao, *supra* note 56, at 605.

66. See ALBERTS ET AL., *supra* note 42, at 4 (describing DNA as “information-bearing”).

67. See *id.*; Van Tassel, *supra* note 64, at 231 (“[A] gene provides the complete set of instructions on how to build a particular protein . . .”).

68. Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 832 (1999).

69. John Murray, Note, *Owning Genes: Disputes Involving DNA Sequence Patents*, 75 CHI.-KENT L. REV. 231, 246 n.110 (1999) (citing ROBERT SCHLEIF, GENETICS AND MOLECULAR BIOLOGY 188–90 (Johns Hopkins Univ. Press 1993) (1986)).

70. Mathematically, four letters each of which used alone would result in just four permutations. If four letters were used two at a time, sixteen permutations are possible. Only if four letters are used three at a time will the number of permutations (sixty-four) exceed twenty.

71. Eli A. Loots, Note, *The 2001 USPTO Written Description Guidelines and Gene Claims*, 17 BERKELEY TECH. L.J. 117, 120 n.23 (2002).

72. *Id.* Three codons are “stop codons,” i.e., instead of coding for an amino acid they send a signal that the protein chain is to terminate at that point. See ALBERTS ET AL., *supra* note 42, at 367 fig.6-50 (table of codons). However, because three codons taken from a set of four create sixty-four different coding permutations (i.e., significantly more than the twenty necessary ones), the code is said to be degenerate as more than one permutation can code for the same amino acid. *Id.*; Loots, *supra* note 71, at 120 n.23. For example, codons CGT, CGC, CGA, CCG, AGA, and AGG all code for the same amino acid—arginine. At the same time, only a single codon (ATG) codes for amino acid methionine. ALBERTS ET AL., *supra* note 42, at 367 fig.6-50 (table of codons).

73. In fact, that is precisely the structure of bacterial DNA. See ALBERTS ET AL., *supra* note 42, at 347.

74. ANTHONY J.F. GRIFFITHS ET AL., AN INTRODUCTION TO GENETIC ANALYSIS 8 (7th ed. 2000).

75. ALBERTS ET AL., *supra* note 42, at 206.

76. *Id.*

Indeed, the majority of the genetic material, contrary to intuition, consists of the non-coding regions.⁷⁷

A mutation in the codon sequence, whether by an inappropriate addition or deletion of a nucleotide or by changing one nucleotide to another, often results in coding for an incorrect amino acid,⁷⁸ which may result in the protein being defective⁷⁹ or completely nonfunctional.⁸⁰ Thus, when diagnosing genetic disorders, it is important to know both the normal sequence and the mutations so that either can be identified.⁸¹

As mentioned previously, the two DNA strands are complementary to each other,⁸² but they are not exact mirror images of each other. Thus if one strand, for example, has the sequence AAA, the complementary strand would have a sequence TTT.⁸³ Since each DNA sequence codes for a specific amino acid, it matters which strand is the “coding” strand, known as the “sense” strand, and which one is the “non-coding” strand, known as the “anti-sense” strand.⁸⁴ Identifying which strand is the “sense” strand for a particular protein is difficult because both strands can have both “sense” and “anti-sense” regions.⁸⁵ Cellular mechanisms have developed to differentiate between the two when the genetic code is converted into the final product,⁸⁶ but until such conversion happens, it is impossible to tell which strand at a given location is which.⁸⁷

77. *Id.*

78. Brian C. Cannon, Note, *Toward a Clear Standard of Obviousness for Biotechnology Patents*, 79 CORNELL L. REV. 735, 738 (1994) (“Genetic diseases arise from mutations in the code sequence of DNA. This gives rise to dysfunctional proteins. . . . [T]he mutation of just one base in a gene sequence can have disastrous consequences for the protein. . . . This results in the insertion of a wrong amino acid into the protein.” (footnote omitted)).

79. See, e.g., ALBERTS ET AL., *supra* note 42, at 17; Janet Brewer, “Diseases of Place”: *Legal and Ethical Implications of Surname and Ethnicity as Predictors of Disease Risk*, 9 QUINNIAC HEALTH L.J. 155, 157 (2006) (noting that a single amino acid change in a β unit of hemoglobin causes the protein not to function normally and is responsible for sickle cell anemia).

80. ALBERTS ET AL., *supra* note 42, at 558.

81. *Cf.* Dunne, *supra* note 27, at 479–80 (discussing how scientists diagnose genetic disease by linking mutations to specific conditions).

82. See *supra* note 47 and accompanying text.

83. See *supra* note 46 and accompanying text.

84. Matthew D. Kellam, Note, *Making Sense Out of Antisense: The Enablement Requirement in Biotechnology After Enzo Biochem v. Calgene*, 76 IND. L.J. 221, 233 (2001).

85. Sandra Schmieder, *Scope of Biotechnology Inventions in the United States and in Europe—Compulsory Licensing, Experimental Use and Arbitration: A Study of Patentability of DNA-Related Inventions with Special Emphasis on the Establishment of an Arbitration Based Compulsory Licensing System*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 163, 172 n.30 (2004) (“Genomic (or chromosomal) DNA is double-stranded and consists of interspersed coding and non-coding regions on both strands.”).

86. See ALBERTS ET AL., *supra* note 42, at 343 (discussing gene promoters and gene regulatory proteins).

87. *Cf. id.* (stating that neighboring genes can be located on opposing strands, and that many regulatory aspects of RNA synthesis have not been well defined).

It is from these complex chromosomal structures—portions of which are chemically modified in order to render them temporarily inactive, portions of which are tightly bound with complex proteins, portions of which are written upside down, and portions of which do not seem to serve any particular function at all—that proteins are made. It is that process to which I now turn.

B. FROM DNA TO RNA AND TO PROTEINS

As alluded to above, the DNA is just an instruction manual for the creation of the ultimate cellular product—the protein.⁸⁸ It is a rather complex manual, wrapped in a hard-to-break wrapper, with various pages being inaccessible, and interspersed with completely irrelevant and seemingly nonsensical information.⁸⁹ Yet somehow the cell follows this manual in two major steps: transcription and translation.⁹⁰

In the first step the DNA is “transcribed” into an RNA molecule. This molecule is an exact replica of the DNA’s own coding strand,⁹¹ but for two exceptions. In the RNA molecule, thymine nucleotides are replaced with uracil (“U”) nucleotides.⁹² Additionally, the “backbone” of the RNA molecule is somewhat different from that of the DNA. The sugar molecule in RNA is ribose,⁹³ whereas in DNA it is deoxyribose.⁹⁴

The initial RNA molecule has eliminated some of the “difficulties” of the DNA. The RNA’s nucleotides are not chemically modified,⁹⁵ it has only the sense strand rather than both the sense and anti-sense strands,⁹⁶ it contains only a single gene⁹⁷ rather than hundreds of genes found on any given chromosome, and it does not have histones bound to it.⁹⁸

Though the RNA is rid of some of the DNA’s chemical alterations, it has some new ones of its own. On one end of the RNA strand a special methylated guanine nucleotide is added which is known as a “5’ cap.”⁹⁹ On the other end, once the DNA to RNA copying is finished, a long tail

88. See *supra* notes 66–67 and accompanying text.

89. See *supra* Part II.A.

90. Stephen H. Schilling, Note, *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents*, 61 DUKE L.J. 731, 734 (2011).

91. ALBERTS ET AL., *supra* note 42, at 332–33 (noting that the non-template strand’s sequence corresponds to the synthesized RNA’s sequence).

92. *Id.* at 332.

93. *Id.*

94. *Id.* at 197.

95. See Van Tassel, *supra* note 64, at 236 n.106 (describing cytosine methylation as occurring in DNA).

96. See ALBERTS ET AL., *supra* note 42, at 333 (noting that RNA is a single-strand molecule and carries information for a single gene).

97. See *id.*

98. Histone, by definition, is a DNA-binding protein. *Id.* at 211.

99. *Id.* at 346.

consisting of 100 to 200 adenine nucleotides and known as a “poly-A tail” is added.¹⁰⁰ These structures, though they do not code for amino acids, promote the RNA’s stability and permit cellular mechanisms to verify that the strand is intact before beginning the process of producing proteins based on the RNA’s code.¹⁰¹

Additionally, at this stage the RNA still contains both introns and exons.¹⁰² If that was where the process stopped, the cellular mechanism would read non-coding regions, thus creating proteins with an incorrect structure.¹⁰³ Therefore, the RNA molecule is modified further through a process known as RNA splicing. Only once the RNA is properly spliced is it ready to be translated into a protein structure.¹⁰⁴ The spliced and modified RNA is known as messenger RNA, or mRNA.¹⁰⁵ With a majority of the genetic code spliced out back in the nucleus, the addition of the 5’ cap and a poly-A tail, the substitution of uracil for thymine, and a different sugar entity forming its “backbone,” the mRNA is a fundamentally different molecule from the DNA that formed the original template for the mRNA’s production.

C. DISCOVERING AND USING GENES

Though the actual molecule that serves as a template for protein synthesis is mRNA, scientists often have to work with DNA when they study genes. Since mRNA is produced only after the gene is turned on for transcription and translation, the mRNA is present only immediately before and during protein production.¹⁰⁶ In contrast, cellular DNA is always present and contains the code for all genes.¹⁰⁷ True, many of those genes are turned off, all have fairly randomly interspersed non-coding regions, and are otherwise difficult to access and assess; but nonetheless, because every cell in the organism contains that organism’s entire genome,¹⁰⁸ the DNA from any cell could in theory be used to find any gene of interest. To illustrate why working with DNA is necessary, consider a situation of a person who has a gene that codes for cancer. The gene may not yet be active and may not become active for several years. Since the gene is not presently active, it is not being used to produce proteins, so no mRNA is produced. However, the gene is present on the DNA molecule and will make itself known later. To the extent that one wishes to diagnose the unfortunate individual before the

100. *Id.*

101. *Id.*

102. *See id.* at 347.

103. *See id.* at 335–36 (describing how mRNA is “read” by the cellular mechanism).

104. *See id.* at 347–48.

105. *Id.* at 345.

106. *See id.* at 399 fig.6-97.

107. *See supra* notes 52–53 and accompanying text.

108. *See supra* note 60 and accompanying text.

onset of cancer, one must find a way to identify the gene on the DNA strand while it is quiescent. Thus, the ultimate target of genetic research is the molecule that carries all of the organism's genetic information—the DNA molecule.

In order to locate and identify the quiescent gene on a complex DNA molecule packed with thousands of other genes, scientists create a “probe” molecule designed to bind to the region of interest and alert the scientists to the targeted gene's location.¹⁰⁹ Such a probe is manufactured utilizing well-known processes in which scientists can “reverse transcribe” a strand of mRNA and create a DNA string that would be an identical copy of an *in vivo* anti-sense DNA strand's coding regions.¹¹⁰ This newly created DNA strand is referred to as complementary DNA or cDNA (because it is complementary to the mRNA strand that was used as a template).¹¹¹ The cDNA is a completely man-made molecule and does not duplicate anything that exists in nature.¹¹² It differs from the mRNA molecule in at least three ways. First, since the mRNA is used as a template, the cDNA is complementary to the mRNA rather than a copy of it.¹¹³ Second, since it is a DNA molecule, it again uses thymine nucleotides rather than uracil.¹¹⁴ Third, as described above, the sugar backbones of the RNA and DNA strands differ.¹¹⁵ Nor is the cDNA strand identical to the *in vivo* DNA. First, it is missing introns.¹¹⁶ Second, since the cDNA is a laboratory-produced molecule, it is not subjected to cellular regulation. Third, because cDNA is just a transcript of a single gene, it is not part of a larger structure such as a chromosome with additional nucleotides (and genes) on either end of the gene of interest. Finally, because cDNA is complementary to the mRNA, it has a region complementary to the poly-A tail—a region not present in the *in vivo* DNA.¹¹⁷ Nothing about cDNA then is “naturally occurring.” Rather, it is a completely artificial construct, though a useful one for studying naturally occurring DNA.

109. See ALBERTS ET AL., *supra* note 42, at 535–37.

110. *Id.*

111. *Myriad I*, 702 F. Supp. 2d 181, 198 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012); ALBERTS ET AL., *supra* note 42, at 535–37.

112. See Michael D. Davis, *The Patenting of Products of Nature*, 21 RUTGERS COMPUTER & TECH. L.J. 293, 315 (1995).

113. See ALBERTS ET AL., *supra* note 42, at 543 (discussing and illustrating the reverse transcription process); Douglas L. Rogers, *Coding for Life—Should Any Entity Have the Exclusive Right to Use and Sell Isolated DNA?*, PITT. J. TECH. L. & POL'Y, Fall 2011, at 1, 66–67.

114. Rogers, *supra* note 113, at 66–67.

115. See *supra* notes 93–94 and accompanying text.

116. Since the cDNA is complementary to the mRNA, and since mRNA is a genetic molecule from which introns have been spliced out, the cDNA does not have introns either.

117. A region complementary to the 5' cap is also initially present, but is usually cleaved off when the molecule is further processed in the laboratory.

Once a cDNA molecule is constructed, it can be used as a probe to identify genes *in vivo*. While the cDNA strand *as a whole* is not complementary to any *in vivo* DNA sequence because cDNA lacks introns,¹¹⁸ there is a sufficient amount of overlap to allow the cDNA to attach itself (or to “hybridize”) with the native DNA.¹¹⁹ Once the cDNA hybridizes with native DNA, the entire sequence of the native genes (including introns) can be identified by looking at the various points of hybridizations and finding the endpoints of each gene.¹²⁰ Then the entire gene of interest can be excised with the help of specific and well-known enzymes,¹²¹ and its entire sequence can be discovered through well-known (and mostly automated) methods.¹²²

The genetic sequence, once discovered, presents multiple opportunities for scientific advances. Researchers can construct probes to test for a mutated native DNA strand¹²³ and diagnose predisposition to cancer and other diseases.¹²⁴ They can also inject laboratory-created cDNA into bacteria, causing the modified bacteria to express proteins coded for by the injected sequence.¹²⁵ In one example, a DNA sequence coding for the human hormone insulin was injected into bacteria, which then caused the bacteria’s own cellular mechanism to express the new gene and produce the hormone it had not previously produced.¹²⁶ The protein thus produced could be used for the purposes of further research,¹²⁷ as well as treatment of human diseases caused by the deficiency of that protein (which, in the case of insulin, would be diabetes).

Isolated genes as a whole are also useful for both research and treatment. Though isolated “full” genes¹²⁸ contain non-coding regions, they are more useful in certain experiments. For instance, full genes are better suited for transgenic animals (i.e., animals with a foreign gene inserted into their native genome) studies because they somehow increase the odds that

118. Recall that cDNA is synthesized from mRNA from which introns have been excised. See *supra* note 116.

119. See ALBERTS ET AL., *supra* note 42, at 537.

120. *Id.* at 314.

121. Anne Lawton, *The Frankenstein Controversy: The Constitutionality of a Federal Ban on Cloning*, 87 KY. L.J. 277, 285 (1999).

122. Golden, *supra* note 29, at 114–15.

123. See *supra* note 109 and accompanying text.

124. See *Myriad I*, 702 F. Supp. 2d 181, 198 (S.D.N.Y. 2010), *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012).

125. ALBERTS ET AL., *supra* note 42, at 544.

126. Jake J. Allen, Note, *Conducting Embryonic Stem Cell Research on Native Lands in Michigan*, 11 MICH. ST. U. J. MED. & L. 395, 403 n.39 (2007).

127. See ALBERTS ET AL., *supra* note 42, at 544.

128. By “full” I mean code with introns present.

the inserted gene will remain stable and be transcribed into the host animal's RNA.¹²⁹

Furthermore, full genes (and occasionally cDNA) can be used in treatment of certain diseases, though such interventions are currently in their infancy and are experimental.¹³⁰ Laboratory-created "normal" genes can be inserted into the subject in order to counteract any genetic abnormality, thus treating the disease caused by the abnormal *in vivo* genes.¹³¹

Finally, as one might expect, the knowledge of the genetic sequence of one gene helps advance research into other genes and biological processes. All too often, diseases and other characteristics are controlled not by a single gene but by a combination of genes working together.¹³² In these situations, the expression of some genes is directly affected by expression of others.¹³³ Given the complex nature of genetic expression, scientists need to work with already discovered and described genes in order to continue their exploration.¹³⁴

D. SUMMARY

As can be seen from the foregoing discussion, genetic research is a complex endeavor that involves molecular manipulation, creation of new

129. Ralph L. Brinster et al., *Introns Increase Transcriptional Efficiency in Transgenic Mice*, 85 PROC. NAT'L ACAD. SCI. U.S. 836, 836-40 (1988).

130. Steven M. Silverberg, Note, *Safe at Home? Assessing U.S. Efforts to Protect Youths from the Effects of Performance Enhancing Drugs in Sports*, 35 BROOK. J. INT'L L. 271, 307 (2010); *Gene Therapy*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/therapy?show=all> (last updated Feb. 18, 2013).

131. Efthimios Parasidis, *A Uniform Framework for Patent Eligibility*, 85 TUL. L. REV. 323, 374 (2010); see also ALBERTS ET AL., *supra* note 42, at 566-69 (describing the process of creating transgenic mice and other organisms); Gerard Magill, *The Ethics Weave in Human Genomics, Embryonic Stem Cell Research, and Therapeutic Cloning: Promoting and Protecting Society's Interests*, 65 ALB. L. REV. 701, 716 (2002).

132. See, e.g., Michael Tomasson, *Legal, Ethical, and Conceptual Bottlenecks to the Development of Useful Genomic Tests*, 18 ANNALS HEALTH L. 231, 236 (2009); Courtney C. Scala, Note, *Making the Jump from Gene Pools to Patent Pools: How Patent Pools Can Facilitate the Development of Pharmacogenomics*, 41 CONN. L. REV. 1631, 1661 n.167 (2009).

133. See Jonathan Kaplan, *Misinformation, Misrepresentation, and Misuse of Human Behavioral Genetics Research*, 69 LAW & CONTEMP. PROBS. 47, 50 (2006); Wolf Reik, *Stability and Flexibility of Epigenetic Gene Regulation in Mammalian Development*, 447 NATURE 425, 425 (2007). This should not be surprising as, for example, some genes code for proteins that then themselves bind to other parts of the DNA and either facilitate or inhibit downstream gene expression. See Scott Dodson, *A Darwinist View of the Living Constitution*, 61 VAND. L. REV. 1319, 1337-38 (2008) (discussing the histone H4 gene); Rao, *supra* note 56, at 605; *supra* notes 56 and 65 and accompanying text (discussing the influence of binding proteins on gene expression). If the upstream gene undergoes mutations, then the expression of downstream genes would be affected.

134. See, e.g., *Myriad I*, 702 F. Supp. 2d 181, 187 (S.D.N.Y. 2010) (describing the work of one of the plaintiffs, Dr. Harry Ostrer), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012).

molecules unknown in nature, and even combining various pieces of DNA from unrelated organisms in order to produce the desired product. These manipulations are complex, involve the breaking of old and the creation of new chemical bonds, and require a significant amount of effort and skill. Viewed from a purely chemical and structural perspective, there is little doubt that molecules such as cDNA or pieces of “full” DNA isolated, purified, and extracted from a chromosome are radically different from what one could find in nature. However, viewed from a content- and information-based perspective, laboratory-created DNA molecules are identical to their naturally occurring chromosomal counterparts. Because DNA, whether naturally occurring or lab-created, codes for the same ultimate product of interest, its functionality and basic use is not altered by human intervention.

As a matter of scientific principle, both views are sound. However, the two viewpoints have very different implications for the question of whether a genetic innovation is patent eligible.

III. THE PRINCIPLES, PRECEDENTS, AND PURPOSES OF PATENT LAW

A. *THE BASIC DICHOTOMY BETWEEN DISCOVERY AND INVENTION IN AMERICAN PATENT LAW*

The U.S. Constitution, recognizing the need to “promote the Progress of Science and useful Arts,” bestows upon Congress the authority to grant “exclusive Right[s]” to inventors for their discoveries.¹³⁵ Congress has taken advantage of this grant of power throughout the nation’s history by passing various Patent Acts beginning as early as 1790.¹³⁶ Although both technology and the law changed and evolved from the late eighteenth century to the mid-twentieth century when Congress adopted the 1952 Patent Act¹³⁷ (currently in effect as amended),¹³⁸ at least one basic consideration of what is patent eligible¹³⁹ remained fairly constant. For instance, the 1790 Act provided that a patent shall issue to anyone who has “invented or discovered *any* useful art, manufacture, engine, machine, or device, or any

135. U.S. CONST. art. I, § 8, cl. 8.

136. Patent Act of 1790, ch. 7, 1 Stat. 109 (current version at 35 U.S.C. §§ 1–376 (2006)).

137. Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (codified as amended at 35 U.S.C. §§ 1–376).

138. Rebecca Greendyke, Comment, *No Patent for You!: How KSR v. Teleflex’s Nonobviousness Test Conflicts with the Scientific Method and Removes the Incentive to Innovate*, 35 U. DAYTON L. REV. 413, 420 (2010) (“The Patent Act of 1952 is the current patent statute.”).

139. I shall use the term “patent eligible” to refer to inventions that could obtain a patent if they satisfy other requirements such as novelty, non-obviousness, etc. I reserve the term “patentable” (which is often used to mean “patent eligible,” thus creating confusion) for description of inventions that are both patent eligible *and* are found to satisfy all additional requirements. Thus, an invention can be patent eligible but not patentable.

improvement therein not before known or used.”¹⁴⁰ The criteria remain basically unchanged,¹⁴¹ and the current Act requires an issuance of a patent to whoever “invents or discovers *any* new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”¹⁴²

As the legislative language shows, Congress has always been generous about the potential scope of patent eligibility.¹⁴³ In fact, Thomas Jefferson, who was (through his position as Secretary of State) the first de facto administrator of the Patent Office¹⁴⁴ and the author of the 1793 Patent Act,¹⁴⁵ wrote that “ingenuity should receive a liberal encouragement.”¹⁴⁶ This liberal approach persisted and was readopted in the 1952 Act.¹⁴⁷ The principal drafter of that Act testified that “anything under the sun that is made by man” is included within the scope of patent-eligible subject matter.¹⁴⁸ The committee reports accompanying the Act expressed the same view.¹⁴⁹ This broad view that almost all things are patent eligible has found

140. Patent Act of 1790 § 1 (emphasis added).

141. See *In re Bilski*, 545 F.3d 943, 977–78 (Fed. Cir. 2008) (Newman, J., dissenting), *aff'd*, 130 S. Ct. 3218 (2010).

142. 35 U.S.C. § 101 (2006) (emphasis added). The application is, of course, “subject to [all other] conditions and requirements of” the Patent Act. *Id.*

143. See *In re Bilski*, 545 F.3d at 977 (“From the first United States patent act in 1790, the subject matter of the ‘useful arts’ has been stated broadly, lest advance restraints inhibit the unknown future.”).

144. *Graham v. John Deere Co.*, 383 U.S. 1, 7 (1966) (“Thomas Jefferson, who as Secretary of State was a member of the group [of Commissioners for the Promotion of Useful Arts], was its moving spirit and might well be called the ‘first administrator of our patent system.’”); Keith Aoki, *Distributive and Syncretic Motives in Intellectual Property Law (with Special Reference to Coercion, Agency, and Development)*, 40 U.C. DAVIS L. REV. 717, 746 n.101 (2007).

145. *Graham*, 383 U.S. at 7.

146. Letter from Thomas Jefferson to Oliver Evans (May 2, 1807), in 5 THE WRITINGS OF THOMAS JEFFERSON 74, 76 (H.A. Washington ed., 1853). Jefferson expressed this view despite being generally opposed to monopolies. *Graham*, 383 U.S. at 7–8. Indeed, Jefferson was initially opposed to patents, but later came to view them as beneficial if limited in time. *Id.*

147. See *In re Bilski*, 545 F.3d at 978.

148. *Patent Law Codification and Revisions: Hearings on H.R. 3760 Before Subcomm. No. 3 of the H. Comm. on the Judiciary*, 82d Cong. 37 (1951) (statement of P.J. Federico, Examiner in Chief, U.S. Patent Office), cited in *Diamond v. Chakrabarty*, 447 U.S. 303, 309 & n.6 (1980).

149. See S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952). There has been some debate about the true meaning of the phrase which in full reads: “A person may have ‘invented’ a machine or a manufacture, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled.” S. REP. NO. 82-1979, at 5; H.R. REP. NO. 82-1923, at 6. In his concurrence in *In re Bilski*, Judge Dyk took the position that read in context, the phrase actually excludes certain man-made inventions from eligibility for patents. *In re Bilski*, 545 F.3d at 976 (Dyk, J., concurring); see also *Bilski v. Kappos*, 130 S. Ct. 3218, 3248 (2010) (Stevens, J., concurring in the judgment); *In re Bilski*, 545 F.3d at 1000, 1011 (Mayer, J., dissenting) (styling his opinion as a “dissent,” even though he actually agreed with the majority’s judgment, but feeling that the majority did not go far enough). *But see Chakrabarty*, 447 U.S. at 309 (“Congress intended

favorable reception in the courts going back to at least the middle of the nineteenth century.¹⁵⁰ Thus, in *O'Reilly v. Morse*, the Supreme Court opined that it makes no difference whether the invention “is produced by chemical agency or combination; or by the application of discoveries or principles in natural philosophy known or unknown before his invention; or by machinery acting altogether upon mechanical principles,”¹⁵¹ so long as the discovery is new and is described “in a manner so full and exact, that any one skilled in the science to which it appertains, can, by using the means he specifies, without any addition to, or subtraction from them, produce precisely the result he describes.”¹⁵² Throughout the twentieth century, the courts have generally adhered to this understanding of the breadth of patent-eligible subject matter. In the seminal *Diamond v. Chakrabarty* opinion, the Supreme Court stated that when an invention in question (whatever that invention happens to be) “is not nature’s handiwork, but [the inventor’s] own . . . it is patentable [i.e., patent-eligible] subject matter under § 101.”¹⁵³

Despite § 101’s breadth and the judicial opinions reaffirming that Congress intended it to be “merely a coarse filter,”¹⁵⁴ it has long been established that § 101 is not without limits.¹⁵⁵ Since at least 1852,¹⁵⁶ the courts have held that “[t]he laws of nature, physical phenomena, and abstract ideas” are not patent eligible.¹⁵⁷ Thus, though the Constitution speaks of exclusive rights for “[d]iscoveries,”¹⁵⁸ and the Patent Act declares both “invent[ions]” and “discover[ies]” to be patent eligible,¹⁵⁹ the courts

statutory subject matter to ‘include anything under the sun that is made by man.’” (quoting S. REP. NO. 82-1979, at 5 and H.R. REP. NO. 82-1923, at 6)).

150. See Thomas F. Cotter, *A Burkean Perspective on Patent Eligibility*, 22 BERKELEY TECH. L.J. 855, 859 (2007) (noting that by mid-nineteenth century courts began to uphold patents on methods, whereas prior to that “it was unclear whether processes were [patent eligible] to the extent they read on embodiments not disclosed within the patent description”).

151. *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 119 (1854).

152. *Id.*; see also *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931); *Shell Dev. Co. v. Watson*, 149 F. Supp. 279, 283 (D.D.C. 1957).

153. *Chakrabarty*, 447 U.S. at 310.

154. John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1059 (2011) (quoting Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*, 75 Fed. Reg. 43,922, 43,926 (July 27, 2010)) (internal quotation marks omitted).

155. See, e.g., *Chakrabarty*, 447 U.S. at 309.

156. See *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 174-75 (1853) (“It is admitted, that a principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known. . . . The same may be said of electricity, and of any other power in nature, which is alike open to all, and may be applied to useful purposes by the use of machinery.”).

157. *Chakrabarty*, 447 U.S. at 309 (citing *Le Roy*, 55 U.S. (14 How.) at 175).

158. U.S. CONST. art. 1, § 8, cl. 8.

159. 35 U.S.C. § 101 (2006).

have consistently construed that language to differentiate between patent-eligible *inventions* and non-patent-eligible *discoveries*. According to the Supreme Court, in order to become a patent-eligible “invention,” the non-patent-eligible “discovery . . . must come from the application of the law of nature to a new and useful end.”¹⁶⁰ In other words, only that which is “made by man” is patent eligible. And “[t]o be ‘made by man,’ something must not be pre-existing in nature; it must be, literally, an invention.”¹⁶¹ It follows, then, that a naturally occurring phenomenon, whether a physical entity such as a mineral or a scientific principle or formula, is not patent eligible.¹⁶²

This dividing line, though not explicit in either the constitutional or statutory text, is not arbitrary but rather stems directly from the underlying purposes of patent law. Scholars have advanced various philosophical and economic theories of why patent law should exist in the first place. Though these theories differ, they all in one way or another support the denial of exclusive rights for mere discoveries. The next Subpart briefly sketches out the chief arguments for the availability of patent protection because these arguments shed light on both empirical and normative claims that I will make later in the Article.

B. TRADITIONAL JUSTIFICATIONS FOR PATENT PROTECTION

On the most basic level, arguments in favor of exclusive patent rights are the same, or at least very similar to, the arguments for property rights generally.¹⁶³ These arguments can be roughly divided into two subsets: economic justifications¹⁶⁴ and moral justifications.¹⁶⁵

The utilitarian argument for patents is fairly straightforward and (as with most utilitarian arguments) reduces to an economic cost–benefit

160. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

161. *In re Nuijten*, 500 F.3d 1346, 1364 (Fed. Cir. 2007) (Linn, J., concurring in part and dissenting in part).

162. *Chakrabarty*, 447 U.S. at 309.

163. I. Trotter Hardy, *Not So Different: Tangible, Intangible, Digital, and Analog Works and Their Comparison for Copyright Purposes*, 26 U. DAYTON L. REV. 211, 221 (2001) (“[J]ustification for intellectual property laws is much the same as that for tangible real property laws.”); Joel Sage, Note, *Revenue Streams and Safe Harbors: How Water Law Suggests a Solution to Copyright’s Orphan Works Problem*, 16 B.U. J. SCI. & TECH. L. 294, 301 (2010) (“In order to understand the theoretical underpinnings of intellectual property law, it is helpful to first review the basis of property law generally.”).

164. William W. Fisher III, *Reconstructing the Fair Use Doctrine*, 101 HARV. L. REV. 1659, 1688 (1988) (“The utilitarian theory . . . is undoubtedly the most venerable and oft-recited of the justifications for the American law of intellectual property.”).

165. See Viva R. Moffat, *Mutant Copyrights and Backdoor Patents: The Problem of Overlapping Intellectual Property Protection*, 19 BERKELEY TECH. L.J. 1473, 1478 (2004) (“Justifications for protecting intellectual property abound: regulation of creative and inventive works may be based upon . . . natural rights, or personhood arguments.” (footnote omitted)).

analysis.¹⁶⁶ On one side of the scales is “the Progress of Science and useful Arts,”¹⁶⁷ and on the other side are the limitations on competition¹⁶⁸ and availability of whatever products and processes are subject to the patent’s monopoly power.¹⁶⁹ The problem, of course, is that exclusive rights that patents entail are not an unalloyed good.

On one hand, they may spur some innovation by serving as an economic incentive and reward to innovators.¹⁷⁰ In other words, people will innovate more if the reward for such innovation is higher.¹⁷¹ Additionally, patents are a quid pro quo transaction in which the inventor obtains exclusive rights in exchange for disclosing his invention to the public.¹⁷² Thus, patents build on the common wealth of mankind because they increase “the public stock of knowledge,”¹⁷³ allowing it to avoid having to reinvent the wheel every time.¹⁷⁴

On the other hand, because patents grant exclusive rights to make, sell, and use inventions,¹⁷⁵ they also tend to retard progress because they preclude others—absent permission from the patent-holder—from experimenting with and building upon whatever it is that is protected by

166. See Benjamin H. Barton, *Do Judges Systematically Favor the Interests of the Legal Profession?*, 59 ALA. L. REV. 453, 465–72 & n.104 (2008).

167. See Megan M. La Belle, *Patent Litigation, Personal Jurisdiction, and the Public Good*, 18 GEO. MASON L. REV. 43, 50 (2010) (quoting U.S. CONST. art. I, § 8, cl. 8) (internal quotation marks omitted); Kurt Van Thomme, Note, *Prosecution History Estoppel After Festo: Can an Equivalent Ever Break Through the File Wrapper?*, 53 DRAKE L. REV. 1099, 1124 (2005) (same).

168. See Andrew Beckerman-Rodau, *Patent Law—Balancing Profit Maximization and Public Access to Technology*, 4 COLUM. SCI. & TECH. L. REV. 1, 26 (2002), <http://www.stlr.org/html/volume4/beckerman.pdf>; Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. REV. 33, 33 (2004) (“Patents are intended to allow a patent holder to obtain monopoly profits. To have this effect, a patent must limit competition.”); Gregory N. Mandel, *The Generic Biologics Debate: Industry’s Unintended Admission that Biotech Patents Fail Enablement*, 11 VA. J.L. & TECH. 1, ¶ 20, at 7 (2006) (“Patent exclusivity rights limit competition . . .”).

169. See *Franklin Pierce Law Center’s Sixth Biennial Patent System Major Problems Conference*, 37 IDEA 623, 654 (1997) (“[P]atents inherently limit access to some degree The access issue is applicable to many types of technologies . . .”).

170. Some non-economic, reputational benefits may also be derived from patents. See generally William Hubbard, *Inventing Norms*, 44 CONN. L. REV. 369 (2011).

171. Kevin Arquit, Partner, Simpson Thacher & Bartlett LLP, Keynote Address at the International Law Journal 2009 Symposium: Comparative Antitrust Policies in Mergers and Acquisitions (Feb. 27, 2009), in 43 CORNELL INT’L L.J. 1, 17 (2010); see also Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 548 (2009).

172. See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002) (“[D]escription is the quid pro quo of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.”).

173. *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 513 (1917).

174. See Fromer, *supra* note 171, at 549–50.

175. 35 U.S.C. § 271(a) (2006).

patent exclusivity.¹⁷⁶ Ultimately, “[t]he economic significance of a patent depends on its scope: the broader the scope, the larger the number of competing products and processes that will infringe the patent,”¹⁷⁷ and therefore will be unavailable for public use during the lifetime of the patent.¹⁷⁸ In other words, “[t]he greater patent protection is, the smaller the benefit to competitors [and the public] from the information contained in the patent grant because the less they can do with it.”¹⁷⁹

In a utilitarian calculus then, both too much and too little patent protection is suboptimal.¹⁸⁰ Justice Breyer succinctly summed up the dilemma when he observed that

sometimes *too much* patent protection can impede rather than “promote the Progress of Science and useful Arts,” the constitutional objective of patent and copyright protection.

The problem arises from the fact that patents do not only encourage research by providing monetary incentives for invention. Sometimes their presence can discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing

176. *Special Equip. Co. v. Coe*, 324 U.S. 370, 382 (1945) (Douglas, J., dissenting) (“It is common practice to make an invention and to secure a patent to block off a competitor’s progress. By studying his ware and developing an improvement upon it, a concern may ‘fence in’ its rival; by a series of such moves, it may pin the trade enemy within a technology which rapidly becomes obsolete. As often as not such maneuvers retard, rather than promote, the progress of the useful arts.” (quoting WALTON HALE HAMILTON, *PATENTS AND FREE ENTERPRISE* 161 (1941)) (internal quotation marks omitted)); Nathan Machin, Comment, *Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act*, 87 CALIF. L. REV. 421, 438–39 (1999).

177. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 839 (1990).

178. 35 U.S.C. § 271(a) (“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”).

179. WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 298 (2003). The public may ultimately reap some benefit, for all patents eventually expire and the disclosures contained therein “become a part of the public stock of knowledge.” *Beidler v. United States*, 253 U.S. 447, 453 (1920). During the lifetime of the patent, however, the broader the scope of the patent and the lower the competition, the less benefit the public will receive (and the higher cost it will pay for that benefit). See LANDES & POSNER, *supra*, at 299–300.

180. Kevin Emerson Collins, *Constructive Nonvolition in Patent Law and the Problem of Insufficient Thought Control*, 2007 WIS. L. REV. 759, 767 (citing LANDES & POSNER, *supra* note 179, at 21–24).

arrangements, and by raising the costs of using the patented information, sometimes prohibitively so.¹⁸¹

Patent law, then, must always maintain the uneasy balance between providing sufficient incentives to invent and disclose, which in the aggregate, promote further innovation and the common good, and guarding against granting overly broad patents, which retard further research and thus are detrimental to the common good.¹⁸² It is hard to imagine a grant of exclusive rights broader than one on “the laws of nature and physical phenomena.” It is impossible to “invent around” an unalterable law of nature. The utilitarian balance then tips against granting such broad patents. Considering that utilitarian arguments were of some significance in the drafting of the Patent Clause and early Patent Acts,¹⁸³ the prohibition on patenting laws of nature or physical phenomena, though not explicitly written into the Constitution or the statutes, was understood to exist and was consistent with the statutory scheme.

In addition to utilitarian economic arguments, a number of moral justifications for patent law have been advanced. These justifications generally hold that it is just to reward one’s labor. For instance, John Locke argued that “[w]hatsoever [anyone] removes out of the State that Nature hath provided, and left it in, he hath mixed his Labour with it, and joined to it something that is his own, and thereby makes it his *Property*.”¹⁸⁴ Realizing that pure application of his theory could result in unjust over-appropriation of previously commonly held goods,¹⁸⁵ Locke maintained that such appropriation is permissible “*only* so long as there be ‘enough, and as good, left in common for others.’”¹⁸⁶

181. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126–27 (2006) (Breyer, J., dissenting) (citations omitted) (order dismissing certiorari as improvidently granted).

182. Clemens Kerle, *International IP Protection for GMO—A Biotech Odyssey*, 8 COLUM. SCI. & TECH. L. REV. 147, 173 (2007) (“Every IP regime, whether national or international, strives to establish a balance between providing sufficiently large incentives while not granting overly broad exclusive rights, which would result in supra-marginal deadweight costs without compensation through offsetting innovation.”).

183. See Adam Mossoff, *Rethinking the Development of Patents: An Intellectual History, 1550–1800*, 52 HASTINGS L.J. 1255, 1256 n.7 (2001).

184. See JOHN LOCKE, *TWO TREATISES OF GOVERNMENT* 306 (Peter Laslett ed., 2d ed. 1970) (1690).

185. See, e.g., David Friedman, *In Defense of Private Orderings: Comments on Julie Cohen’s “Copyright and the Jurisprudence of Self-Help,”* 13 BERKELEY TECH. L.J. 1151, 1160–61 (1998) (“If I acquire unrestricted control over the land, I am getting more than I have produced—which may be unjust and may also lead to inefficient rent-seeking as individuals clear land in part to appropriate its pre-existing value.”).

186. Peter B. Edelman, *The Next Century of Our Constitution: Rethinking Our Duty to the Poor*, 39 HASTINGS L.J. 1, 23 (1987) (quoting JOHN LOCKE, *CONCERNING CIVIL GOVERNMENT, SECOND ESSAY*, ch. V, § 26, in 35 *GREAT BOOKS OF THE WESTERN WORLD* 30 (R. Hutchins ed. 1952)). This is known as the “Lockean proviso.” *Id.*; see also David Elkins, *Responding to Rawls: Toward a*

Similarly, Wilhelm Hegel's argument has been characterized to mean that "to achieve proper self-development—to be a person—an individual needs some control over resources in the external environment."¹⁸⁷ According to Hegel, "[a]ttainments, erudition, talents, and so forth, are, of course, owned by free mind and are something internal and not external to it, but even so, by expressing them it may embody them in something external and alienate them . . ."¹⁸⁸ Thus, in order to "propertize" one's ideas, one needs to "embody them in something external,"¹⁸⁹ which in a patent context would be a requirement of describing the invention "in a manner so full and exact, that any one skilled in the science to which it appertains, can, by using the means [the patentee] specifies, without any addition to, or subtraction from them, *produce* precisely the result he describes."¹⁹⁰

Under the Locke–Hegel moral-justification approach, foreclosing patent eligibility for the "laws of nature, natural phenomena, and abstract ideas" is wholly appropriate.¹⁹¹ Not only are "laws of nature, natural phenomena, and abstract ideas" not the products of anyone's labors,¹⁹² but appropriating them for one's exclusive use (to the extent it is possible) necessarily leaves everyone else worse off. Whereas previously they had unlimited right to put laws of nature and natural phenomena to beneficial use, post exclusive appropriation of these things, they are no longer able to do so. Thus, it cannot be said that mere discovery and observation of the

Consistent and Supportable Theory of Distributive Justice, 21 BYU J. PUB. L. 267, 275 (2007) ("Where resources are limited and the appropriation by one would negatively impact the ability of others to act similarly, the Lockean proviso would act to deny the laborer's claim to exclusive rights in the product. Locke, therefore, limited the right to expropriate scarce natural resources for private use."); Jeremy Waldron, *Kant's Legal Positivism*, 109 HARV. L. REV. 1535, 1550 (1996) (noting that when one takes "more than his share," he is violating Lockean principles).

187. Margaret Jane Radin, *Property and Personhood*, 34 STAN. L. REV. 957, 957 (1982) (emphasis omitted).

188. HEGEL'S PHILOSOPHY OF RIGHT § 43, at 41 (T.M. Knox trans., Oxford Univ. Press 1965) (1821).

189. *Id.*

190. *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 119 (1854) (emphasis added).

191. Joan E. Schaffner, *Patent Preemption Unlocked*, 1995 WIS. L. REV. 1081, 1091 (quoting *In re Alappat*, 33 F.3d 1526, 1542 (Fed. Cir. 1994), *abrogated by In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)) (internal quotation marks omitted) ("Additionally, the federal patent statute, pursuant to the patentability criteria, defines and sets standards for the four Lockean conditions described above. First, the federal patent statute satisfies the 'labor' requirement of Locke by limiting the grant of property protection to enumerated eligible subject matter—manufacture, machine, process, and composition of matter. Thus, 'laws of nature, natural phenomena, and abstract ideas' are ineligible for patent protection." (footnotes omitted) (quoting *In re Alappat*, 33 F.3d at 1542)).

192. See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (stating that naturally occurring qualities of bacteria are not the result of the labor of the inventor, but rather "the work of nature").

“laws of nature, natural phenomena, and abstract ideas” is sufficient external embodiment to allow the discoverer exclusive property rights.

The moral philosophy of John Rawls lends further support to the idea that patent protection should not be available for discovering laws of nature or natural phenomena.¹⁹³ In a Rawlsian world, justice demands first that everyone has the same rights and access to basic liberties,¹⁹⁴ and second, that to the extent that there are economic inequalities, they be permitted to exist only if in the long run they benefit those least well-off.¹⁹⁵ Additionally, Rawls insists that decisions on the rules to govern society be made in the “original position” or “behind the veil of ignorance”—i.e., not knowing what our starting position in life will be.¹⁹⁶

What follows from the Rawlsian approach (as argued by Robert Merges in his book, *Justifying Intellectual Property*)¹⁹⁷ is that while some patent protection is permissible and perhaps even desirable,¹⁹⁸ overly broad patent protection that assigns too many resources to one individual (and therefore results in an unequal distribution) is not permissible.¹⁹⁹ In the Rawlsian paradigm, granting exclusive rights to a natural phenomenon or law of nature violates the second principle because the inequality created does not benefit the least well-off in society and perhaps even hurts them (by foreclosing the opportunity for others to provide competing products that would be governed by the patented law of nature).²⁰⁰

193. Of course, Rawls lived too late (1921–2002) to be of any influence on the Founding Fathers or the early judges and justices of the United States. Nonetheless, his approach is helpful in forming a solid basis for deciding whether intellectual property can be justified in today’s world, and if so, to what extent.

194. JOHN RAWLS, *A THEORY OF JUSTICE* § 46, at 266 (2d ed. 1999).

195. *Id.*

196. *Id.* § 24, at 118–23.

197. See generally ROBERT P. MERGES, *JUSTIFYING INTELLECTUAL PROPERTY* 102–35 (2011).

198. Of course, if Merges is wrong, then no IP protection ought to be available at all and the talk of *limiting* patent rights would become moot.

199. See MERGES, *supra* note 197, at 126–33.

200. See, e.g., Eli, *supra* note 23, at 372–73 (“[G]ranted patents on isolated DNA creates a potential for a lack of price competition on products controlled by few individuals. When a genetic testing company, such as Myriad Genetics, obtains exclusive control to a DNA sequence, the company consequently has the exclusive control over the use of the sequence necessary to develop the screening tests.” (footnote omitted)).

Narrow patents, on the other hand, strengthen the competition (and therefore benefit consumers) by encouraging competitors to design around the patent. See Michelle Armond, Comment, *Introducing the Defense of Independent Invention to Motions for Preliminary Injunctions in Patent Infringement Lawsuits*, 91 CALIF. L. REV. 117, 149 n.178 (2003) (“One of the benefits of a patent system is its so-called ‘negative incentive’ to ‘design around’ a competitor’s products, even when they are patented, thus bringing a steady flow of innovations to the marketplace.” (quoting *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235–36 (Fed. Cir. 1985))); Georgia E. Kralovic, Comment, *The Principle of Fair Notice: Is It Prudent Guidance for the Future of Patent Law?*, 26 PEPP. L. REV. 89, 93 (1998).

In summary, all theories, whether based on moral or economic arguments or both, converge on the fundamental point that the most basic knowledge and discoveries about laws of nature and physical phenomena ought not be eligible for patent protection even if the knowledge is new and useful. This convergence helps put the judicial decisions reading the “law of nature/natural phenomena” exception into the patent statutes in proper context.

C. RECONCILING THE BROAD LANGUAGE OF THE PATENT ACT AND THE NATURAL LAW EXCEPTION

In the previous Subparts I have described that the exclusion for laws of nature and natural phenomena from patent eligibility has a long legal and philosophical pedigree. At the same time, as Chief Judge Markey observed: “Only God works from nothing. Men must work with old elements.”²⁰¹ Thus, to some extent, all inventions utilize and apply laws of nature to solve problems at hand. If the “law of nature” bar were too broad, no invention would ever be patent eligible. After all, an antibiotic drug only works because it exploits a naturally occurring bacterial vulnerability to a particular chemical interaction,²⁰² and an airplane flies only because of Bernoulli’s forces—a natural phenomenon.²⁰³ Yet, an airplane is patent eligible,²⁰⁴ as are newly discovered antibiotics.²⁰⁵ So how do the courts draw the line between patent-ineligible “phenomena of nature [and] laws of nature” and patent-eligible “application of [that] law of nature to a new and useful end”?²⁰⁶

This differentiation is especially difficult in biological arts where the interaction of various chemical entities and organisms are governed by the immutable laws of nature,²⁰⁷ but where such interaction is only brought

201. *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 n.3 (Fed. Cir. 1985) (quoting Howard T. Markey, *Why Not the Statute?*, 65 J. PAT. OFF. SOC’Y 331, 334 (1983)) (internal quotation marks omitted).

202. See ALBERTS ET AL., *supra* note 42, at 1521–22.

203. See Andrew A. Schwartz, *The Patent Office Meets the Poison Pill: Why Legal Methods Cannot Be Patented*, 20 HARV. J.L. & TECH. 333, 336 (2007).

204. See, e.g., U.S. Patent No. 821,393 (filed Mar. 23, 1903) (patent by the Wright Brothers directed to a “Flying-Machine”).

205. See, e.g., U.S. Patent No. 4,670,444 (filed May 29, 1984) (patent directed to antibiotic Ciprofloxacin and held by Bayer A.G.); see also *Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377, 1378 (Fed. Cir. 2002) (“Bayer AG and Bayer Corporation (collectively Bayer) filed a patent application on May 29, 1984 that ultimately issued as the ‘444 patent on June 2, 1987. The subject matter of the ‘444 patent includes the antibiotic ciprofloxacin sold by Bayer under the brand name CIPRO®.”).

206. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

207. *Schering Corp. v. Gilbert*, 153 F.2d 428, 432 (2d Cir. 1946) (“[A] molecule is the inevitable result of the action of so-called laws of nature which are immutable . . .”); Jana R. McCreary, *This Is the Trap the Courts Built: Dealing with the Entanglement of Religion and the Origin of Life in American Public Schools*, 37 SW. U. L. REV. 1, 21 (2008) (“[A]ll biological elements and

about by human intervention.²⁰⁸ Courts have struggled (and muddled through) this distinction for decades without finding a clear-cut and bright-line resolution to the dispute.²⁰⁹ Though the decisions have not successfully delineated a legal bright line between “laws of nature” and “application of laws of nature,” some guideposts can be gleaned from a review of those decisions.

One early guidepost comes from Judge Learned Hand in *Parke-Davis & Co. v. H.K. Mulford Co.*²¹⁰ There, the patent was directed to highly purified and concentrated adrenaline²¹¹—a naturally occurring hormone.²¹² Despite the fact that adrenaline occurs naturally, had a generally known function and structure, and had been used therapeutically, Judge Hand upheld the patent.²¹³ He reasoned that the purified and concentrated form of adrenaline, separated as it was from the surrounding gland tissue, was different in kind from adrenaline naturally flowing through a person’s (or other mammal’s) body.²¹⁴ According to Judge Hand, the patentee in question

was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically.²¹⁵

processes are ultimately obedient to the laws of physics and chemistry.” (quoting Edward O. Wilson, *Let’s Accept the Fault Line Between Faith and Science*, USA TODAY, Jan. 15, 2006, available at 2006 WLNR 840576)).

208. See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (recognizing that the bacteria in question was man-made even though its behavior was governed by the laws of nature); *Schering Corp.*, 153 F.2d at 432 (recognizing that the molecule in question was man-made even though it obeyed the laws of nature).

209. Indeed, in a recent oral argument, Justice Breyer observed that “[i]f you look at the Court’s cases, they seem to say *Flook*, one thing, and *Diehr*, another thing.” Transcript of Oral Argument at 14, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (No. 10-1150).

210. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 98 (C.C.S.D.N.Y. 1911), *aff’d in part, rev’d in part*, 196 F. 496 (2d Cir. 1912).

211. *Id.* at 96.

212. Adrenaline is a hormone produced by the adrenal gland and is used in the “fight-or-flight” response (e.g., enhanced glucose mobilization, increased heart and breathing rates, differential distribution of blood flow to various body organs, etc.). See generally Daniel H. Funkenstein, *The Physiology of Fear and Anger*, in *PSYCHOPATHOLOGY* 223, 223–33 (Charles F. Reed et al. eds., 1958). Adrenaline may be administered to treat anaphylactic shock (i.e., a severe and life-threatening allergic reaction). See Marie Plicka, Note, *Mr. Peanut Goes to Court: Accommodating an Individual’s Peanut Allergy in Schools and Day Care Centers Under the Americans with Disabilities Act*, 14 J.L. & HEALTH 87, 90–91 (1999–2000).

213. *Parke-Davis*, 189 F. at 114–15.

214. *Id.* at 103.

215. *Id.*

There is certainly some truth to Judge Hand's observation that the discovery that gave rise to the patent in *Parke-Davis* dramatically broadened the therapeutic (and thus commercial) opportunities for adrenaline.²¹⁶ However, it is equally true that the extracting, purifying, and concentrating of adrenaline did not change its chemical compound or alter its function.²¹⁷ Nonetheless, the *Parke-Davis* opinion (though written by a single district judge) has been widely cited and relied on for the proposition that a "purified" form of a naturally occurring substance may be patent eligible.²¹⁸

Parke-Davis, although it provides one guidepost, certainly does not establish a clear and simple rule for determining patent eligibility, and the Supreme Court did little to clarify matters in later cases. In *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,²¹⁹ the patent claims were directed to a bacterial mixture.²²⁰ Each of the bacterial strains in the mixture was both naturally occurring and well known.²²¹ The mixture of the specific strains, however, was neither. The benefit of the mixture was its ability to promote growth in a wide variety of leguminous plants.²²² The Supreme Court, per Justice Douglas,²²³ held that the subject matter of the invention did not qualify for

216. Ashley McHugh, Note, *Invalidating Gene Patents*: Association for Molecular Pathology v. U.S. Patent & Trademark Office, 62 HASTINGS L.J. 185, 209 (2010) ("The prior art [to the *Parke-Davis* patent], powdered suprarenal glands, contained some desired therapeutic properties, but could not be safely administered in humans.").

217. *Parke-Davis*, 189 F. at 107 ("The chemical reactions of what now is ascertained to have been, and what was supposed to be, the active principle, had undoubtedly all been known just as they are set forth in the patent . . .").

218. See, e.g., *Myriad II*, 653 F.3d 1329, 1352, 1360, 1378 (Fed. Cir. 2011), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012); *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 162-63 (4th Cir. 1958); *In re Bergy*, 596 F.2d 952, 975 (C.C.P.A. 1979), *vacated as moot*, *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980); *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970); see also *In re Mays*, 175 F.2d 570, 573 (C.C.P.A. 1949). A quick LexisNexis search revealed that the case is also cited and discussed in over 175 law review articles.

219. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

220. U.S. Patent No. 2,200,532 (filed Aug. 24, 1938).

221. *Funk Bros.*, 333 U.S. at 129-30.

222. *Id.*

223. Justice Douglas generally took a dim view of patents and the exclusivity rights they granted. See, e.g., *Gottschalk v. Benson*, 409 U.S. 63 (1972) (Douglas, J., authoring the majority opinion declaring that an application for a patent covering a method for converting binary-coded decimal numerals into pure binary numerals on a general purpose digital computer must be denied as too abstract); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969) (Douglas, J., authoring the majority opinion finding patents invalid as obvious); *Graham v. John Deere Co.*, 383 U.S. 1 (1966) (Douglas, J., joining the judgment finding patents invalid for obviousness); *Wilbur-Ellis Co. v. Kuther*, 377 U.S. 422 (1964) (Douglas, J., authoring the majority opinion limiting the reach of the infringement cause of action when a patented product is repaired or replaced); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336 (1961) (Douglas, J., joining in a judgment limiting the reach of the infringement cause of action when a patented product is repaired or replaced); *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 612 (1950) (Douglas, J., dissenting from a judgment that upheld a finding of infringement under the doctrine of equivalents); *Mandel Bros. v. Wallace*, 335 U.S. 291, 296 (1948) (Douglas, J., concurring in a judgment invalidating a patent as

patent protection because, in the opinion of the Court, the useful qualities of the bacterial mixtures were “the work of nature . . . [and] of course not patentable[, for] patents cannot issue for the discovery of the phenomena of nature.”²²⁴ Though the patentee was the first one to discover that mixing certain strains of bacteria would result in a new, heretofore unknown product that was commercially useful,²²⁵ the Court opined:

Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. The aggregation of select strains of the several species into one product is an application of that newly-discovered natural principle. . . . No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility.²²⁶ Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning.²²⁷

The rule announced in *Funk Bros.*, if faithfully applied, would preclude patenting a vast amount of discoveries in biological sciences. After all, these discoveries all exploit the natural qualities of bacteria, viruses, proteins, nucleic acids, etc. Unlocking the secrets of these biological materials and putting them to use would be, if the *Funk Bros.* rule were followed, merely “an application of [a] newly-discovered natural principle.”²²⁸ At the same time, *Funk Bros.* at last announced a clear, if highly problematic, rule. Nonetheless, this state of affairs would not last. “Although the *Funk Brothers*

covering non-patent-eligible subject matter); *Funk Bros.*, 333 U.S. 127 (Douglas, J., authoring the majority opinion invalidating a patent); *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 335 (1945) (Douglas, J., concurring in a judgment that invalidated a patent); *Goodyear Tire & Rubber Co. v. Ray-O-Vac Co.*, 321 U.S. 275, 280 (1944) (Douglas, J., concurring in a judgment that invalidated a patent); *Williams Mfg. Co. v. United Shoe Mach. Corp.*, 316 U.S. 364, 371 (1942) (Douglas, J., dissenting from the judgment that upheld patent validity).

224. *Funk Bros.*, 333 U.S. at 130.

225. See *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F.3d 496 (2d Cir. 1912).

226. This, of course, is a questionable proposition. The very point of the mixture was that it could be used on a wider variety of leguminous plants, whereas each individual strain of bacteria is limited to a smaller range. Thus, the utility of the bacteria in mixture is much higher than the utility of it outside of mixture.

227. *Funk Bros.*, 333 U.S. at 131.

228. *Id.*

decision has never been overruled, in retrospect it seems to represent the high-water mark in the ‘products of nature’ doctrine.”²²⁹

In *Diamond v. Chakrabarty*, Dr. Ananda Chakrabarty developed and attempted to patent a genetically modified bacterium capable of breaking down crude oil.²³⁰ The USPTO rejected the application and Dr. Chakrabarty appealed.²³¹ In reversing the USPTO’s decision, the Supreme Court distinguished (without overruling) *Funk Bros.* by holding that Chakrabarty’s “claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’”²³² The Court went on to say that while in *Funk Bros.* each strain of the bacteria present in the mixture retained its original and nature-endowed qualities, the Chakrabarty bacterium had new qualities that were given to it by the inventor.²³³ Under this reasoning, though bacteria are naturally occurring organisms, *modified* bacteria with non-naturally occurring biological properties are patent eligible.²³⁴

In 2012, the Court added another guidepost when it decided *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*²³⁵ In *Prometheus*, the patent claim was directed to a method of adjusting medical treatment depending on the amount of active metabolite in the patient’s blood.²³⁶ The patented method involved just three steps: (1) administering a well-known drug, (2) measuring the level of the drug’s metabolite, and (3) considering changing the drug’s dose depending on the measurement results.²³⁷ The Court held this invention ineligible for a patent, concluding that the relationship between a metabolite’s concentration and a drug’s effect is a pure law of nature.²³⁸ The Court further concluded that the addition of the “administering” and “measuring” steps did not make the claim patent eligible because “simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.”²³⁹ In short, “[i]f a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical

229. Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 725 (1990).

230. *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

231. *Id.* at 306.

232. *Id.* at 309–10 (alteration in original) (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

233. *Id.* at 310.

234. *See id.* at 309–10.

235. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

236. *Id.* at 1295.

237. *Id.* at 1299.

238. *Id.* at 1302.

239. *Id.* at 1300.

assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.”²⁴⁰

This is where the law presently stands.²⁴¹ The Court has continued to adhere to the idea that “laws of nature” and “natural phenomena” are not patent-eligible subject matter.²⁴² Nevertheless, it has wavered on the corollary to that doctrine—patent eligibility of the “applications of the laws of nature.” It is not surprising, then, that in recent debates on the patent eligibility of genetic materials even the federal government, as a whole, could not agree on a uniform position.²⁴³ Nonetheless, as incoherent as the application of the current Supreme Court doctrine to real cases is, the doctrine itself can serve to separate the discoveries of “laws of nature, [which are] free to all men and reserved exclusively to none,”²⁴⁴ and inventions, which apply those laws of nature to create “for every practical purpose a new thing commercially and therapeutically.”²⁴⁵ This dichotomy legitimately finds its roots in the theory of patent law and can be applied, consistent with that theory, to questions of patent eligibility for genetic materials. This will be my task in Part IV. However, prior to embarking on that task, I will briefly elaborate on the additional requirement of novelty that the Patent Act imposes on applicants.

240. *Id.* at 1297.

241. For now I exclude from discussion the *Myriad I* and *Myriad II* cases that directly address gene patenting. I am doing so because instead of positing that case as the current legal standard, I wish to consider whether it was correctly decided in the next Part. I also omit discussion of *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), which is the most recent Supreme Court case on patent eligibility under § 101. I do so because *Bilski*'s patent was rejected on the grounds that it was an “abstract idea,” rather than on the grounds that it was a law of nature. *Id.* at 3230; *see also* *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

242. *See Bilski*, 130 S. Ct. at 3230 (“[W]hile an abstract idea, law of nature, or mathematical formula could not be patented, ‘an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.’” (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981) (emphasis omitted))).

243. The positions taken by the Solicitor General’s Office and the USPTO in the *Myriad* litigation were quite different. The USPTO (in its District Court brief) argued that isolated and purified genes are in fact patent eligible. Memorandum of Law in Support of Defendant United States Patent and Trademark Office’s Motion for Judgment on the Pleadings and in Opposition to Plaintiff’s Motion for Summary Judgment at 20–23, *Myriad I*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515 (RWS)), 2009 WL 5785024, *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012). The Solicitor General, however, argued that genes that are merely purified and isolated are not patent eligible. Brief for the United States as Amicus Curiae in Support of Neither Party at 17–36, *Myriad II*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 4853320, at *17–36, *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012). The Solicitor General’s Office did agree with the PTO that cDNA is patent eligible. *Id.* at 14–17.

244. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

245. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911), *aff’d in part, rev’d in part*, 196 F. 496 (2d Cir. 1912).

D. *BEYOND PATENT ELIGIBILITY—THE NOVELTY REQUIREMENT*

Until now, I have been focusing on the patent eligibility of an invention. Eligibility, though, is but an initial inquiry in determining whether the applicant is actually entitled to a patent and the exclusive rights associated with it. Section 101 of the Patent Act (which has been the focus of this Part thus far) reads: “Whoever 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 therefor, *subject to the conditions and requirements of this title.*”²⁴⁶ Only if the invention satisfies all other requirements of Title 35 is it patentable. Judge Rich²⁴⁷ described the system thus:

Achieving the ultimate goal of a patent under those statutory provisions involves, to use an analogy, having the separate keys to open in succession the three doors of sections 101, 102, and 103, the last two guarding the public interest by assuring that patents are not granted which would take from the public that which it already enjoys (matters already within its knowledge whether in actual use or not) or potentially enjoys by reason of obviousness from knowledge which it already has.

....

The first door which must be opened on the difficult path to patentability is § 101 (augmented by the § 100 definitions) . . . whether [the] invention is patentable or not. . . . If the invention, as the inventor defines it in his claims . . . falls into any one of the named categories, he is allowed to pass through to the second door, which is § 102; “novelty and loss of right to patent” is the sign on it.

....

The third door, under the 1952 Act, is § 103

....

Section 103 . . . refers to the difference between the subject matter sought to be patented and the prior art, meaning what was known before as described in section 102. If this difference is such that the subject matter as a whole would have been obvious at the time [the invention was made] to a person [ordinarily] skilled in the art, then the subject matter cannot be patented.

246. 35 U.S.C. § 101 (2006) (emphasis added).

247. Giles Rich was not only the preeminent expositor of patent law as a judge, he was also (prior to ascending to his seat on the bench) one of the primary authors of the 1952 Patent Act. See A. Samuel Oddi, *Regeneration in American Patent Law: Statutory Subject Matter*, 46 IDEA 491, 546 (2006).

If the inventor holds the three different keys to the three doors, his invention (here assumed to be “useful”) qualifies for a patent, otherwise not²⁴⁸

The mere fact that someone has worked with patent-eligible subject matter does not entitle him to a patent unless (1) the work resulted in something *new* (i.e., something not previously described or discovered)²⁴⁹ and (2) the result is a fairly significant improvement upon prior art (i.e., not an obvious, from the perspective of an ordinary skilled artisan, variation on the previous state of affairs).²⁵⁰ “To allow otherwise would not only add nothing to the sum of human knowledge, but ‘would in fact injure the public by removing existing knowledge from public use.’”²⁵¹

Under *KSR International Co. v. Teleflex Inc.*, whenever “there are a finite number of identified, predictable solutions . . . [that] lead[] to the anticipated success,” the invention is viewed as “obvious to try” and is not patentable.²⁵² Though progress in the chemical arts is held to be more unpredictable than in other fields,²⁵³ “[a] known [chemical] compound may suggest its homolog, analog, or isomer because such compounds ‘often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.’”²⁵⁴ This approach means that mere minor alterations in a known chemical compound would likely fail the post-*KSR* obviousness analysis.

248. *In re Bergy*, 596 F.2d 952, 960–62 (C.C.P.A. 1979) (alterations in original) (emphasis omitted), *vacated as moot*, *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980).

249. 35 U.S.C. § 102 (2006 & Supp. V 2011). I am not going to discuss this section because it is almost never an issue in chemical cases. In order for an application to fail the § 102 test, the prior art has to disclose the *exact same* invention. See *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985) (“[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed [W]here there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account.”). As a result, for any chemical entity (which a nucleic acid is) to escape rejection under § 102 all that is necessary is to show that neither an *identical* compound nor a generic species encompassing the compound has been previously disclosed. Cf. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007) (noting that even when a chemical compound is a “homolog, analog, or isomer,” the proper inquiry is its obviousness under § 103 rather than anticipation under § 102).

250. 35 U.S.C. § 103.

251. Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 931 (2011) (footnote omitted) (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989)).

252. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

253. See *Eisai Co. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008).

254. *Takeda*, 492 F.3d at 1356 (quoting *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995)).

IV. PATENT ELIGIBILITY OF GENETIC MATERIALS

Now that the science of DNA research and the legal framework for patentability have been discussed and clarified, we can apply the governing legal standards to this field of scientific endeavor. In this Part I will discuss how, in my view, the patent eligibility of genetic materials should be treated under the present law in light of the case law and the philosophical underpinnings of those decisions.

As noted above, there are four distinct possibilities when it comes to patenting DNA molecules. First, one could simply patent the natural sequence of a newly discovered gene as it appears on the chromosome in its native state. In other words, the only limitation of the claim would be the sequence of nucleotides. Second, one could patent a gene that is separated from the rest of the genetic code on the chromosome and associated protein structures. In this situation, in addition to being limited to the newly discovered sequence, the patent claim would also be limited to this sequence occurring in a "stand-alone" molecule. However, other than the requirement that this be a stand-alone molecule and thus free from all of the associated protein and nucleic acid structures, the claim would be directed to the same sequence that occurs *in vivo*. The third option would be to patent a genetic sequence containing protein coding regions only (i.e., cDNA). A claim of this type would be limited to a stand-alone molecule containing only the protein-encoding part of the gene. Importantly, whatever type of molecule is selected for patenting, each of the above three choices will carry the same coding information because each of these molecules (whether in the native state or stand-alone, and whether introns are present or absent) will code for the same target protein. Finally, the fourth option would be to patent a newly discovered association between a certain trait and a particular genetic sequence.

A. NATIVE IN SITU DNA

Turning to the first of the possibilities—attempting to patent a newly discovered genetic sequence *in situ*—the answer should be rather easy and apparent. Such sequences, regardless of how hard and expensive they are to find, how new they may be, and how much useful information they provide, are in no sense of the word "invented." They are mere products of nature, already present in a genetic sequence of an organism (human or otherwise). Their discovery, though useful, does not convert them into a new product, does not create for them a new function, and does not transform them into "a new thing commercially and therapeutically."²⁵⁵ Furthermore, granting exclusive rights on such discoveries would be inconsistent with the philosophical and economic underpinnings of patent law. Such patents

255. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912).

would fail under a Lockean labor theory because no labor was expended to create the genes. Not only that, granting patents on *in situ* DNA would fail the Lockean proviso because such exclusive rights would preclude all uses of those sequences and therefore would not leave “enough, and as good” for the rest of mankind.²⁵⁶

The same result obtains in a Hegelian approach because the person attempting to claim the gene *in situ* would not be producing or embodying his ideas in any external medium capable of alienation.²⁵⁷ Instead, such a discoverer would merely attempt to lay claim to something that has been “produced” and “embodied” long before he ever appeared. Exclusivity on the genes *in situ* also runs counter to the Rawlsian and utilitarian considerations, and largely for the same reasons. Granting a patent on a gene *in situ* results in a very broad grant of exclusive rights. It may be that such an exclusive right would prevent one from working not just on the newly discovered gene, but also on its neighbors and surrounding structures.²⁵⁸ Because the patented gene would be embedded in a chromosome and surrounded by other genes, as well as by structural proteins, it may well become impossible to conduct research on the neighboring regions without infringing the patent. At the very least, the cost of conducting such research would rise dramatically as scientists would have to take precautionary measures to avoid infringing on patents claiming genetic information located near their area of research.²⁵⁹ Thus, granting such patents would be economically inefficient and would slow down scientific progress, thus disadvantaging the least fortunate even further (as they would have to wait longer for medical and scientific breakthroughs). In short, both the case law and the fundamental principles underlying patent law support denying patent claims drawn to genetic sequences *in situ*.

B. ISOLATED AND PURIFIED DNA

The next possibility to consider is the patent eligibility of isolated and purified DNA whose sequence is identical to its native DNA counterpart. On one hand, these DNA molecules are not only mechanically separated from their associated protein structures, but they are also cleaved from the rest of

256. Edelman, *supra* note 186, at 23 (quoting LOCKE, *supra* note 186, ch. V, § 26 (internal quotation marks omitted)).

257. See *supra* notes 187–90 and accompanying text.

258. See *supra* notes 132–34 and accompanying text.

259. Wenrong Huang, *Enzo's Written Description Requirement: Can It Be an Effective Check Against Overly Broad Biotechnology Claims?*, 16 ALB. L.J. SCI. & TECH. 1, 24 (2006) (“[A]n ordinary competitor deciding which research and development project to pursue would have to make a difficult choice of either risking infringement of a broad patent or foregoing an otherwise valid project to avoid the claimed research area. Considering the high research and development costs associated with biotechnology products, a claim broad enough to cover a whole research area might well be enough to dissuade other people from engaging or investing in that area in the first place.”).

the chromosome. As a result, the isolated DNA is “a molecule with a different ionic charge, different chemical bonds, [different molecular weight], and a different chemical composition, as compared to the [native DNA].”²⁶⁰ This particular product does not occur in nature and appears only as a result of human activity—the *sine qua non* of patent eligibility.

Additionally, the three-dimensional structure of the DNA molecule depends on both the sequence of nucleotides and the binding of associated proteins. When the DNA of interest is cleaved from the neighboring DNA and is separated from the surrounding proteins, this three-dimensional structure changes. As a result, the function of isolated DNA differs somewhat from the native *in situ* DNA. Thus, isolating and purifying the gene of interest results in “a new thing commercially and therapeutically.”²⁶¹ Indeed, even the district court that found isolated DNA to be patent ineligible conceded the point.²⁶²

On this view, then, isolated DNA fits comfortably within the *Parke-Davis* and *Chakrabarty* line of cases. Because isolated DNA “control[s] the [nature] as to make it accomplish the purpose”²⁶³ of being a diagnostic or therapeutic tool, because it is “a new thing commercially and therapeutically,”²⁶⁴ and because it is “a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use,’”²⁶⁵ it constitutes patent-eligible subject matter.

On the other hand, despite being isolated and having different *chemical* structures and properties, these molecules have the same *biological* properties as the native DNA. The isolated DNA retains the same sequence of nucleotides as the native DNA, and therefore, when translated, codes for

260. *Myriad II*, 653 F.3d 1329, 1362 (Fed. Cir. 2011) (Moore, J., concurring in judgment), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012).

261. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912).

262. *Myriad I*, 702 F. Supp. 2d 181, 196–97 (S.D.N.Y. 2010) (“Purified or synthesized DNA may be used as tools for biotechnological applications for which native DNA cannot be used. For example, unlike native DNA, purified or synthesized DNA may be used as a ‘probe,’ which is a diagnostic tool that a molecular biologist uses to target and bind to a particular segment of DNA, thus allowing the target DNA sequence to be detectable using standard laboratory machinery. Purified or synthesized DNA can also be used as a ‘primer’ to sequence a target DNA, a process used by molecular biologists to determine the order of nucleotides in a DNA molecule, or to perform polymerase chain reaction (‘PCR’) amplification, a process which utilizes target-DNA specific primers to duplicate the quantity of target DNA exponentially.” (footnote omitted) (citation omitted)), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012).

263. *Dolbear v. Am. Bell Tel. Co. (The Telephone Case)*, 126 U.S. 1, 532 (1888).

264. *Parke-Davis*, 189 F. at 103.

265. *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980) (alteration in original) (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

the same sequence of amino acids.²⁶⁶ Though it is true that once a gene is cleaved from its larger surrounding structure (the chromosome) it acquires “a different ionic charge, different chemical bonds, [different molecular weight], and a different chemical composition,”²⁶⁷ it is equally true that no changes other than to terminal nucleotides of the gene are made.²⁶⁸ Thus, human creativity is arguably minimal and it can plausibly be argued that isolated DNA fits within the *Funk Bros.* and *Prometheus* framework.

Viewed from this perspective, it can be said that each isolated DNA molecule “has the same effect it always had. The [DNA] perform[s] in [its] natural way. [Its] use in [isolation] does not improve in any way [its] natural functioning.”²⁶⁹ It can be argued that the creation of these molecules is nothing more than “appending conventional steps . . . to laws of nature,”²⁷⁰ thus robbing these molecules of patent eligibility.

In short, on the question of whether isolated DNA is patent eligible, legal precedents provide support for either outcome depending on one’s view of whether the *chemical* or *biological* properties are important. The legal arguments for and against patent eligibility of isolated DNA, based on the case law as it currently stands, are at (or nearly at) equipoise. What, in my view, tips the balance of scales towards eligibility is congressional acquiescence in the practice of issuing patents on isolated DNA. The USPTO has been issuing patents on genetic materials since 1982.²⁷¹ Since 1982, Congress has had multiple opportunities to amend the Patent Act and exclude genetic materials from eligibility. In the same time period, Congress has enacted several statutes that amended the Patent Act. The Drug Price Competition and Patent Term Restoration Act of 1984 (popularly known as

266. Recall that the DNA code is conserved and that what matters in producing a proper protein sequence is not the “ionic charge,” or “chemical bonds,” or molecular weight, or “chemical composition,” *Myriad II*, 653 F.3d 1329, 1361 (Fed. Cir. 2011), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012), but the linear sequence of nucleotides. See *supra* notes 66–87 and accompanying text.

267. *Myriad II*, 653 F.3d at 1361.

268. Admittedly, some of the nucleotides may no longer be chemically modified, as they were in the native state. See *supra* note 64 and accompanying text.

269. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948).

270. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1300 (2012). In fact, following its decision in *Prometheus*, the Supreme Court vacated the Federal Circuit’s decision in *Myriad II* and sent the case back for further consideration in light of *Prometheus*. *Myriad III*, 132 S. Ct. 1794 (2012).

271. See U.S. Patent No. 4,447,538 (filed Feb. 5, 1982); *Gene Patents and Global Competition Issues: Protection of Biotechnology Under Patent Law*, LEGAL AFFAIRS (Jan. 1, 2006), <http://www.genengnews.com/gen-articles/gene-patents-and-global-competition-issues/1163/> (“In 1982, the United States Patent and Trademark Office (USPTO) issued the first gene patent to Regents of the University of California for work carried out on the construction of a plasmid contained in a bacterium and expression of genes for chorionic somatomammotropin.”).

the “Hatch-Waxman Act”²⁷² altered the legal landscape for patents on drugs and medical devices.²⁷³ In 1996, Congress amended the Patent Act to add § 287(c), which immunized physicians from liability for infringing patents directed to methods of treatment.²⁷⁴ The Consolidated Appropriations Act of 2004 prohibited the use of federal money “to issue patents on claims directed to or encompassing a human organism.”²⁷⁵ This prohibition continued from year to year in various appropriation bills,²⁷⁶ and was finally codified as a substantive exclusion from patent eligibility in the Leahy–Smith America Invents Act of 2011.²⁷⁷ Despite these (and other) amendments to the Patent Act, Congress never saw fit to exclude genetic materials from patent protection—and it is not for lack of notice that Congress did not act. Bills proposing a carve-out from § 101 for genetic materials were filed in Congress by members of both parties.²⁷⁸ Yet Congress failed to move these bills forward. Additionally, the Leahy–Smith America Invents Act was adopted after the Federal Circuit issued its decision in *Myriad II*, upholding patent eligibility for isolated DNA despite the Department of Justice’s position that isolated DNA is not patent eligible.²⁷⁹ The Department of Justice’s position, in turn, contravened the long standing practice and position of the USPTO, setting up a split in the executive branch²⁸⁰ and making the issue all the more acute. Still, Congress chose not to act, leaving the law as it has been for almost thirty years. Though *Prometheus* may cast doubt on this conclusion,²⁸¹ in my view the congressional decision to allow

272. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e) (2006 & Supp. V 2011)).

273. Under the Act, certain uses of patented products, while infringing activity, do not in and of themselves give rise to a cause of action for legal or equitable relief. See 35 U.S.C. § 271(e)(1).

274. Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3009-67 (codified as amended at 35 U.S.C. § 287(c)).

275. Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, § 634, 118 Stat. 3, 101.

276. O. Carter Snead, *Public Bioethics and the Bush Presidency*, 32 HARV. J.L. & PUB. POLY 867, 887 n.62 (2009) (“The Weldon Amendment has been reauthorized every year since its enactment.”).

277. Leahy–Smith America Invents Act, Pub. L. No. 112-29, § 33, 125 Stat. 284, 340 (2011) (to be codified at 35 U.S.C. § 101).

278. See, e.g., Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007) (showing a bill sponsored by one Republican and five Democratic Representatives); Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002) (showing a bill sponsored by one Republican and two Democratic Representatives).

279. The Federal Circuit decided *Myriad II* on July 29, 2011. The Leahy–Smith America Invents Act passed the House on June 23, 2011, the Senate on September 8, 2011, and was signed into law on September 16, 2011. Leahy–Smith America Invents Act, 125 Stat. 284.

280. See *supra* note 243 and accompanying text.

281. See *supra* note 270 and accompanying text.

the USPTO to continue issuing patents on DNA is indicative of a congressional view that genetic material is patent eligible.²⁸²

Whether the isolated DNA is patent eligible under the current law as a descriptive matter, though, does not resolve the question of whether it should be patent eligible as a normative matter. Unfortunately, the theoretical framework of patent law is also not of much help. On one hand, Locke's labor theory would suggest that because labor goes into sequencing and isolating the gene, that labor should be rewarded with a patent grant. On the other hand, the reward may very well exceed the labor invested, perhaps by orders of magnitude. Yet, Lockean theory suggests that the reward for labor should be commensurate with the labor itself, especially when one is permitted to withdraw matters from the commons.²⁸³

The other theories offer equally conflicting conclusions. A Hegelian approach suggests that isolated DNA is an external embodiment of the specific "[a]ttainments, erudition, [and] talents" of the scientists who sequenced, isolated, and purified the gene of interest, and is capable of being propertized and therefore patent eligible.²⁸⁴ However, what is being propertized is actually much greater than the mere external embodiment of the "[a]ttainments, erudition, [and] talents" of people who sequenced and isolated the gene. Instead, what is being propertized is the "[a]ttainments,

282. I recognize that "congressional acquiescence" is not the strongest of indications of congressional views on the subject. See, e.g., Marjorie A. Silver, *Evening the Odds: The Case for Attorneys' Fee Awards for Administrative Resolution of Title VI and Title VII Disputes*, 67 N.C. L. REV. 379, 403-04 (1989) ("[T]he doctrine of legislative acquiescence in judicial construction of congressional enactments generally supports only a weak inference of congressional intent . . ."); see also Patricia M. Wald, *Some Observations on the Use of Legislative History in the 1981 Supreme Court Term*, 68 IOWA L. REV. 195, 205 (1983); Richard J. Nelson, Note, *Regulation of Investigational New Drugs: "Giant Step for the Sick and Dying"?*, 77 GEO. L.J. 463, 482 (1988). Nonetheless, even if not a particularly strong indication of congressional intent, it is some indication of it.

283. I do not necessarily mean to suggest that Lockean theory requires that each individual invention has to be analyzed to determine whether the patent reward is commensurate with the labor invested. I make a more narrow claim that the labor theory requires the analysis of the general field of invention to make sure that rewards are parceled out in accordance with the nature of that field. If that is done, then the fact that occasionally a particular individual may be over- or under-rewarded is of little consequence. My point is that in the field of genetic research where a large (and perhaps overwhelming) amount of labor goes unrewarded (because it is directed at discovering fundamental truths), rewarding the last and perhaps least labor-intensive step with the entirety of the patent rights is asymmetrical and should be done cautiously, if at all. See Joshua D. Sarnoff, *Abolishing the Doctrine of Equivalents and Claiming the Future After Festo*, 19 BERKELEY TECH. L.J. 1157, 1159-60 (2004) ("For centuries, patent law has sought to reconcile a fair scope of protection for inventors with certainty for the public regarding the limits of patent rights and the consequent scope of the public domain. Protection must be commensurate with inventors' 'just merits,' but also must neither deprive the world of improvements nor retard the progress of the arts." (footnote omitted)).

284. See HEGEL'S PHILOSOPHY OF RIGHT, *supra* note 188 and accompanying text.

erudition, [and] talents” of others—those who actually discovered the locus and the function of the gene.²⁸⁵

Nor is it clear whether permitting patenting of isolated and purified DNA is, on balance, economically advantageous—i.e., utilitarian-consistent. Again, the research is costly and important for basic science, as well as for therapeutic and diagnostic advances. Furthermore, by applying for a patent on isolated DNA, the patentees are required to disclose the actual genetic sequence of that DNA.²⁸⁶ This disclosure benefits the scientific community and the public at large as it saves on the need for each subsequent researcher to spend time and resources on sequencing and isolating the same gene. At the same time, patents are an exclusive grant of right not just to sell, but to use.²⁸⁷ An exclusive right to *use* the entire isolated gene irrespective of the purposes of the use²⁸⁸ may preclude or at least slow down further genetic research. Such a preclusion or a slow-down would be tremendously detrimental to science and to the public. It goes without saying that all patents to some extent create roadblocks for others attempting to work in the same field,²⁸⁹ but although they may close one avenue, they encourage competitors to “design around” the patent.²⁹⁰ This “competition benefit” is beneficial because the substitutes thus produced

285. For example, the people who sequenced BRCA1 and BRCA2 were not the people who initially localized those genes. *Myriad II*, 653 F.3d 1329, 1373 (Fed. Cir. 2011) (Bryson, J., concurring in part and dissenting in part) (citing Jeff M. Hall et al., *Linkage of Early-Onset Familial Breast Cancer to Chromosome 17q21*, 250 SCIENCE 1684 (1990)), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012).

286. 35 U.S.C. § 112 (2006) (“The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.”); 37 C.F.R. §§ 1.801–.807 (2012) (requiring applicants for patents on biological materials to deposit such material in an acceptable public depository).

287. 35 U.S.C. § 271(a) (“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”).

288. Under the Patent Act it does not matter that the use is not the one for which a patented device was intended. Any use of a patented device is infringement, whether or not such use itself is novel or was contemplated by the patent holder. *See Paragon Solutions, LLC v. Timex Corp.*, 566 F.3d 1075, 1091 (Fed. Cir. 2009) (“Absent an express limitation to the contrary, any use of a device that meets all of the limitations of an apparatus claim written in structural terms infringes that apparatus claim.”).

289. Katherine J. Strandburg et al., *Law and the Science of Networks: An Overview and an Application to the “Patent Explosion,”* 21 BERKELEY TECH. L.J. 1293, 1321 (2006) (“[B]ecause a patent provides exclusive rights to practice the patented technology, patents impose costs on society that may include not only supra-competitive pricing of patented products but also increased barriers to building upon existing technology. These barriers arise because improving upon a patented technology may require either using the patented technology during development or incorporating it into the improved result.”).

290. *See generally* LANDES & POSNER, *supra* note 179.

ultimately provide a broader choice, and sometimes better goods, to the public.²⁹¹ In the field of genetics, however, the paradigm does not hold. One simply cannot “design around” a patent on isolated DNA.²⁹² The genetic sequence is what it is—it is conserved across individuals and species and cannot be improved upon. The code in the sequence is unique, and any attempts at a “design around” would produce a different protein, which would not be particularly useful in studying the target protein.²⁹³ In the area of genetics then, the public is not getting the competition benefit of the patent system.

The normative question is a close call. I tend to favor patent eligibility for the isolated DNA primarily because I believe that, on balance, the utilitarian considerations favor eligibility. Ultimately, even assuming that the patents on isolated DNA do serve to block some research, it is probably better to incentivize researchers to invest in and disclose the results of the research on genetic sequences. These incentives will result in broader (if not necessarily deeper)²⁹⁴ study of the human genome, helping unlock its secrets faster. Nonetheless, I admit that the matter is eminently debatable.

C. THE cDNA

In many ways, all of the arguments that apply to the isolated DNA apply to cDNA as well. However, cDNA has an even stronger (though again, by no means indisputable) claim for patent eligibility. Unlike the isolated and purified DNA, which has the same genetic sequence as native DNA, cDNA's sequence of nucleotides is different. Recall that cDNA is a DNA molecule that is transcribed from the mRNA and therefore contains only those pieces of the gene that actually code for the target protein. Because a given gene may be composed of over ninety percent non-coding regions, the chemical and structural differences between cDNA and native or isolated DNA are rather dramatic. Molecules of cDNA also have unique uses. For instance, cDNA can be inserted into bacterial DNA in order to cause the bacteria to

291. Miranda Jones, Case Note, *Permanent Injunction, a Remedy by Any Other Name Is Patently Not the Same: How eBay v. Mercexchange Affects the Patent Right of Non-Practicing Entities*, 14 GEO. MASON L. REV. 1035, 1044 (2007).

292. See Rochelle C. Dreyfuss & James P. Evans, *From Bilski Back to Benson: Preemption, Inventing Around, and the Case of Genetic Diagnostics*, 63 STAN. L. REV. 1349, 1371–72 (2011).

293. *Id.*

294. In other words, even assuming that these patents get asserted against scientists seeking to work on other issues associated with a patented sequence, researchers will simply move towards genes not yet discovered and therefore not subject to any patents. It is unclear, however, that this ever happens. See *Myriad II*, 653 F.3d 1329, 1347 (Fed. Cir. 2011) (stating that the patent holder does not enforce its patents against individuals merely conducting research and instead focuses enforcement only on those that offer commercial genetic testing), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012). This will likely result in discovering the function of genes sooner, which could in turn provide new and better diagnostic and therapeutic options.

produce the target protein.²⁹⁵ Native or isolated DNA cannot be used for that purpose because the bacterial cellular mechanism is incapable of differentiating between introns and exons, and therefore if the entire gene were inserted, the entire gene would be “read,” ultimately producing a wrong protein.²⁹⁶

That said, the objections to cDNA patent eligibility (both descriptive and normative) remain. If one were to consider only the ultimate function of nucleic acids, then the excision of non-coding regions would be irrelevant. What ultimately matters is the final product, and on that score the cDNA and native DNA are identical. Focusing on the information-carrying capacity of DNA would lead one to the conclusion that cDNA is not different from a product of nature and therefore not patent eligible.²⁹⁷ Similarly, all of the same philosophical objections to isolated DNA are equally applicable to cDNA. The ability to “design-around” is still absent, while the potential overcompensation of investment is still present.

Nonetheless, because cDNA has less in common with native DNA than isolated DNA, my arguments for patent eligibility of the latter apply a fortiori to the former.

D. ASSOCIATIONS BETWEEN DNA SEQUENCES AND CONDITIONS OF INTEREST

It is important to remember that inventors file patent applications on DNA not when they discover a sequence, but when they can point out what that sequence is responsible for. Utility is a fundamental requirement of the Patent Act.²⁹⁸ Individuals seeking patents on genetic sequences must, therefore, state why these sequences are useful—i.e., what they code for.²⁹⁹

Once a researcher understands what a particular genetic sequence does, he or she can screen people for the presence of the gene in question and predict the presence or absence of its associated medical or biological condition. The claims in these patents usually are directed to a method of diagnosing the relevant condition by comparing the tested individual's DNA

295. See *supra* notes 125–27 and accompanying text.

296. See ALBERTS ET AL., *supra* note 42, at 347.

297. See *Myriad I*, 702 F. Supp. 2d 181, 230 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012).

298. 35 U.S.C. § 101 (2006) (“Whoever 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 therefor, subject to the conditions and requirements of this title.” (emphasis added)).

299. Diana A. Villamil, Comment, *Redefining Utility in Determining the Patentability of DNA Sequences*, 5 J. MARSHALL REV. INTELL. PROP. L. 238, 255 (2006) (“The heightened utility standard in the 2001 Guidelines effectively prohibits the patenting of DNA sequences, even as research tools, because in order to satisfy the utility requirement, the claimed DNA sequence must correspond to a known gene.”).

to the sequenced gene.³⁰⁰ This comparison can be done by utilizing a variety of probes derived from either the isolated and purified DNA or cDNA.³⁰¹

The deleterious or health-enhancing quality of any genetic sequence (or mutation therein) is a natural phenomenon and is in no way man-made.³⁰² Consequently, the association between the presence or absence of a certain genetic sequence and any medical condition in and of itself is not patent eligible.³⁰³ Rather, the method of testing or treating such a condition utilizing man-made chemicals such as isolated DNA or cDNA is patent eligible.³⁰⁴ It matters, then, how the claim is drafted. As Judge Rich wrote more than thirty years ago, “the name of the game is the claim.”³⁰⁵ If the isolated DNA or cDNA (or its fragments) are patent eligible, then claims directed to the methods of their use are patent eligible as well. Unlike *Prometheus*, where the Court noted that the creation of metabolites was a naturally occurring, intra-corporeal process,³⁰⁶ neither the creation of isolated DNA or cDNA nor the hybridization of these molecules to *in situ* DNA is naturally occurring.

To be sure, some of the same objections that can be raised to patenting genetic material itself can be raised to patenting the use of that material. For instance, patents on diagnostic use of DNA (in whatever form) are still nearly impossible to design around.³⁰⁷ On the other hand, patents on the method of diagnosis or treatment reward the actual work of inventing such procedures and do not allow the inventor to propertize other people’s “[a]ttainments, eruditions, [and] talents.” From the § 101 perspective, then, patents drawn to diagnostic and therapeutic techniques utilizing man-made

300. See, e.g., U.S. Patent No. 5,710,001 (filed June 7, 1995); U.S. Patent No. 5,709,999 (filed June 7, 1995).

301. See ‘001 Patent; ‘999 Patent.

302. Eli, *supra* note 23, at 382 (“Genetic mutations associated with a particular condition, like a BRCA1 or BRCA2 mutation and its association to breast and ovarian cancer, are caused by nature. . . . [N]ature dictate[s] the significance of any person’s genetic sequence, whether wild type or mutated, and its relationship to any disease.”).

303. Such associations are “[a] principle, in the abstract, [which] is a fundamental truth; an original cause; a motive[, and] cannot be patented, as no one can claim in either of them an exclusive right.” *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853); see *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1302–05 (2012).

304. See James Bradshaw, Comment, *Gene Patent Policy: Does Issuing Gene Patents Accord with the Purposes of the U.S. Patent System?*, 37 WILLAMETTE L. REV. 637, 640 (2001) (“Gene patents may also be drawn to methods of treating diseases by using particular genes or proteins.”).

305. Giles S. Rich, *Extent of Protection and Interpretation of Claims—American Perspectives*, 21 INT’L REV. INDUS. PROP. & COPYRIGHT L. 497, 499 (1990) (emphasis omitted).

306. *Prometheus*, 132 S. Ct. at 1295.

307. If one only holds a patent on the isolated DNA, then a patent on cDNA may be a legitimate design-around (and vice versa). However, usually the same entity will hold a patent on both types of DNA. See, e.g., *Myriad II*, 653 F.3d 1329, 1334–35 (Fed. Cir. 2011) (quoting Myriad’s patents and noting that Myriad holds patents on both isolated BRCA1/2 genes and cDNA constructs for those genes), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012).

DNA molecules are the narrowest drawn and therefore have the highest claim for patent eligibility.³⁰⁸

V. PATENTABILITY OF GENETIC MATERIALS

Establishing patent eligibility for genetic materials is only half the battle. After all, § 101 is “merely a coarse filter,”³⁰⁹ and is just “[t]he first door which must be opened on the difficult path to patentability.”³¹⁰ My argument that man-made DNA is patent eligible does not mean that I believe that all such applications are patentable, i.e., entitled to receive a patent. Compliance with the novelty requirements must still be considered. In my view, most DNA inventions fail that requirement and are therefore not patentable.

To recapitulate, the genetic sequence itself is not patent eligible because the sequence (whether whole or limited to coding regions only) is a product of nature.³¹¹ Nor is the function of any sequence patent eligible as such. The only inventions on which patent applications could be filed are man-made chemical entities (either in the form of isolated DNA or cDNA), as well as methods of using these entities. Unfortunately, given the current state of knowledge in the field of molecular genetics, the creation of these man-made molecules is not sufficiently inventive to traverse the non-obviousness requirements of § 103.

The methods and techniques for sequencing genes are well known and have been so for quite some time.³¹² As Professor John Golden points out:

Historically, much of the difficulty in using recombinant DNA techniques has consisted in locating, isolating, and sequencing [of] . . . the genes associated with particular proteins. However, advances in technology and in laboratory techniques have eased and automated much of this process, substantially routinizing a

308. Of course, such claims cannot be directed at just abstract mental processes. See *Myriad II*, 653 F.3d at 1355-57 (concluding that claims drawn to merely “‘comparing’ or ‘analyzing’ two gene sequences fall outside the scope of § 101 because they claim only abstract mental processes”).

309. Golden, *supra* note 154, at 1059 (internal quotation marks omitted); see also *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1068 (Fed. Cir. 2011); *id.* at 1074 (Rader, J., providing additional views).

310. *In re Bergy*, 596 F.2d 952, 960-62 (C.C.P.A. 1979), *vacated as moot*, *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980).

311. Additionally, sequences themselves may not even be novel as of 2005 when the human genome project was completed and the results published.

312. See, e.g., Andrew B. Dzeguze, *The Devil in the Details: A Critique of KSR's Unwarranted Reinterpretation of "Person Having Ordinary Skill,"* 10 COLUM. SCI. & TECH. L. REV. 1, 52 (2009); Richard M. Mescher, Case Note, *Best Mode Disclosure—Genetic Engineers Get Their Trade Secret and Their Patent Too?—Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir.), cert. denied, 112 S. Ct. 169 (interim ed. 1991), 18 U. DAYTON L. REV. 177, 189 (1992).

variety of tasks that had previously required considerable effort and ingenuity.³¹³

It is worth noting that this observation was made over ten years ago. Needless to say, today the process is even easier and faster than it was in 2001, when Professor Golden was writing. Today, “the research community generally considers the sequencing and mere identification of genes in human and non-human organisms to be a routine process, which normally does not involve any particular difficulties or require innovative activity.”³¹⁴ Isolating the DNA of interest from the surrounding DNA and purifying it is also a routine procedure.³¹⁵

Admittedly, the Federal Circuit held in *In re Deuel* that “the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs.”³¹⁶ The *Deuel* case, however, is now eighteen years old.³¹⁷ The technology of 2013 is much more advanced than the technology of 1995, making the job of isolating, purifying, and synthesizing DNA not just routine but automated.³¹⁸ And since considerations of obviousness are based on the knowledge of a person of ordinary skill in the art at the time of the claimed invention,³¹⁹ it follows that in deciding the questions of obviousness the courts must consider the state of technology as it presently exists, not as it may have existed at the time the Federal Circuit decided *Deuel*. The technological advances combined with the completion of the human genome project (which now makes the “reference sequence” of an entire

313. Golden, *supra* note 29, at 114–15 (emphasis omitted).

314. Minssen, *supra* note 30, at 126.

315. See *Myriad I*, 702 F. Supp. 2d 181, 196 (S.D.N.Y. 2010) (“Native DNA may be extracted from its cellular environment, including the associated chromosomal proteins, using any number of well-established laboratory techniques.”), *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012); Lee Petherbridge, Comment, *Intelligent Trips Implementation: A Strategy for Countries on the Cusp of Development*, 25 U. PA. J. INT’L ECON. L. 1133, 1166 (2004) (noting that purification protocols are “well-known”).

316. *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995).

317. In fact, since the *Deuel* court had to consider the question of whether the claim invention was obvious at the time the patent application was filed (i.e., in 1993), the case is essentially twenty years old.

318. See Andrew Chin, *Artful Prior Art and the Quality of DNA Patents*, 57 ALA. L. REV. 975, 1037 (2006); Golden, *supra* note 29, at 114–15.

319. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1310 (Fed. Cir. 2009) (“The statutory standard requires us to decide whether the subject matter of the claimed invention ‘would have been obvious at the time the invention was made to a person of ordinary skill in the art to which [the subject matter of the invention] pertains.’” (alteration in original) (quoting 35 U.S.C. § 103(a) (2006))).

human DNA genome freely available)³²⁰ has seriously undermined the logic of *Deuel*.

Furthermore, *Deuel* was decided prior to *KSR*. The *KSR* Court reaffirmed that when “there are a finite number of identified, predictable solutions” that “lead[] to the anticipated success,”³²¹ the invention is obvious because it would be “obvious to try” those solutions.³²² For any particular sequence of DNA embedded in a larger unit of DNA (such as a chromosome), the application of “a finite number of identified, predictable solutions” (in the forms of certain chemical treatments) would lead to the “anticipated success” of isolating and purifying that sequence.³²³

A 2009 Federal Circuit case, *In re Kubin*,³²⁴ is a final nail in the *Deuel* coffin. In *Kubin*, the Federal Circuit opined that once the structure of a target protein is known, isolating and purifying the gene coding for the relevant protein is obvious.³²⁵ As the *Kubin* panel observed, “Insofar as *Deuel* implies the obviousness inquiry cannot consider that the combination of the claim’s constituent elements was ‘obvious to try,’ the Supreme Court in *KSR* unambiguously discredited that holding.”³²⁶ Even if the molecular structure of the target protein and the gene are both unknown, the structures themselves are not patent eligible. No matter how much effort is expended in identifying and sequencing these molecules, their native structure is a product of nature. Only isolated molecules are patent eligible. However, once the structure of a protein is known, the analysis of *Kubin* should apply. To the extent then that *Deuel* is inconsistent with *KSR* and *Kubin*, it is no longer good law.

The same general reasoning is applicable to cDNA. Although making cDNA molecules is harder than merely isolating and purifying DNA, it is likely obvious to a person skilled in the genetic arts, given the current state of knowledge and technology.³²⁷ The major problem in synthesizing cDNA is separating introns from exons and discarding the former while joining together the latter. Because there is no specific signal at the border between

320. Klein & Mahoney, *supra* note 21, at 141 (“The Human Genome Project has brought the free availability of reference sequences with which patients’ DNA can be compared.”).

321. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

322. *Id.*

323. *Id.*

324. *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009).

325. *Id.* at 1360–61.

326. *Id.* at 1358.

327. Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 408 (2002) (“[A] molecular biologist uses a well-known method of creating a cDNA replica of the gene, which contains only the expressed portions of the sequence (i.e., the exons).”); Amy Nelson, *Obviousness or Inventive Step as Applied to Nucleic Acid Molecules: A Global Perspective*, 6 N.C. J.L. & TECH. 1, 28 (2004) (“[I]t is well-known to prepare cDNA libraries from human organs and to randomly isolate and sequence DNAs therefrom.”).

the intron and exon regions, it is not immediately apparent where the excision should take place. Nonetheless, the problem is not as big as it may seem. Since the genetic code is conserved, once one knows the protein sequence,³²⁸ one can reverse engineer the DNA sequence that would code for that protein.³²⁹

None of this is to say that sequencing, isolating, and purifying DNA or creating cDNA molecules is easy or inexpensive, for it is neither. However, the expenditure of time or money on a particular effort does not necessarily make that effort inventive. For example, manufacturing hand-made precision Swiss watches may be costly and time consuming, but that does not make the known processes or mechanisms involved patentable. The test of obviousness is not the cost of coming up with the product, but whether, judged by the standards of a person with ordinary skills and knowledge in the relevant art, the product in question is merely an obvious improvement or variation on what is known.³³⁰

The bottom line then is that the results of the truly exploratory work—the discovery of a sequence of an existing but previously unknown gene, or the discovery of a gene's peculiar function—are not patent eligible, for these results simply uncover previously unknown but naturally occurring

328. The protein sequence and structure in and of themselves are not patent eligible for the same reason that DNA sequence in and of itself is not patent eligible.

329. See *In re Kubin*, 561 F.3d at 1354. To be sure, because the genetic code is degenerate, there will be several potential DNA sequences able to code for the protein that can be reverse engineered. Nonetheless, since the potential cDNA constructs can be compared to the naturally occurring DNA sequence (either through hybridization experiments or by comparing the cDNA sequences to the publicly available sequences), the most “correct” version of cDNA can be selected.

330. There is one caveat to the above discussion. Some DNA that is created in the laboratory may not have the same sequence as is present in native DNA (whether one counts introns or not). In other words, laboratory-created DNA may be such that it does not code for any naturally occurring protein and therefore does not replicate naturally occurring DNA in either sequence or structure. See Andrew W. Torrance, *Synthesizing Law for Synthetic Biology*, 11 MINN. J.L. SCI. & TECH. 629, 635 (2010); Dan Luo, *Creating Novel, DNA-Based Synthetic Materials*, VIVO, <http://vivo.cornell.edu/display/individual16724> (last visited Feb. 19, 2013).

These constructs may have a variety of uses, from creating new organisms, see, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), to “providing an efficient method for avoiding genetic diseases and optimizing desirable characteristics.” Andrew W. Torrance, *Family Law and the Genomic Revolution*, 79 UMKC L. REV. 271, 281 (2010). Engineering these synthetic DNA molecules involves significantly more creative work than merely isolating and purifying naturally occurring sequences out of a larger molecule. Nor is it simply reverse engineering DNA from a protein sequence utilizing known solutions to achieve a predictable result. Rather, synthetic DNA would involve creating a *new* gene, instead of replicating (and chemically modifying) an existing but previously *unknown* gene. This difference should result in a different outcome on the issue of obviousness. Whereas an existing but unknown gene can be sequenced and then purified, isolated, and modified using known methods and “predictable solutions,” creation of a synthetic gene has no template and, therefore, no solutions that are “predictable.” Indeed, these molecules are so without analogue in nature that some have suggested that they ought to be eligible for copyright protection. See *id.*

properties and phenomena. On the other hand, the work that artificially creates a gene and “control[s] the force [of nature] as to make it accomplish the [therapeutic and diagnostic] purpose[s]” and produces “new thing[s] commercially and therapeutically,” is not sufficiently inventive to be patentable.³³¹ Thus, patents and patent applications on genetic material (at least to the extent that they represent naturally occurring genes) should fail either under § 101 or § 103 of the Patent Act, leaving researchers and investors in this technology without any protection. Given the high cost of research and the comparatively low cost of copying in this area, a lack of patent protections would disincentivize further investments into genetic research. This, of course, would be detrimental to the public as a whole. Therefore, an alternative mechanism for incentivizing investment and spurring genetic research is needed. In the next Part I will discuss a currently existing system for non-patent-based exclusive rights that can serve as a model for non-patent-based protection for the fruits of genetic research.

VI. FDA-ADMINISTERED EXCLUSIVE REGIMES FOR PHARMACEUTICALS AND BIOLOGICS

In designing an alternative to the patent system for genetic materials, two things are important to bear in mind. First, a patent does not confer any right to use the patented technology.³³² The only right that a patent confers on the patentee is a right to *exclude others* from using (or selling) the patented technology.³³³ Thus, for instance, a pharmaceutical company may acquire a patent on a new drug but never be able to market it if the drug fails the Food and Drug Administration (“FDA”) approval process.³³⁴ Second (and directly related to the preceding point), patents themselves are worthless unless the patented technology can be practiced and is sufficiently profitable.³³⁵ In other words, “The present value of an invention without a current or foreseeable use is nothing.”³³⁶

331. See *supra* notes 263–65 and accompanying text.

332. See Jonah D. Jackson, Note, *Something Like the Sun: Why Even “Isolated and Purified” Genes Are Still Products of Nature*, 89 TEX. L. REV. 1453, 1487 (2011).

333. 35 U.S.C. § 271 (2006 & Supp. V 2011); see also Jackson, *supra* note 332, at 1487.

334. Katherine N. Addison, *The Impact of the Biosimilars Provision of the Health Care Reform Bill on Innovation Investments*, 10 J. MARSHALL REV. INTELL. PROP. L. 553, 571 (2011).

335. John F. Duffy, *The FCC and the Patent System: Progressive Ideals, Jacksonian Realism, and the Technology of Regulation*, 71 U. COLO. L. REV. 1071, 1141 (2000) (“If a patent is issued for a technological loser, the patent is worthless.”). In fact, most patents turn out to be worthless, because the patented technology is of no interest to the public or the competitors. See, e.g., Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1497 (2001); Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521 (2005); Glen O. Robinson, *Personal Property Servitudes*, 71 U. CHI. L. REV. 1449, 1495 (2004) (“It is regularly observed that most patents—the form of intellectual property most commonly associated with monopoly—are economically worthless . . .”).

336. Machin, *supra* note 176, at 438.

Patents on genetic materials are valuable because they read on approved and marketable therapeutic or diagnostic technologies. Thus, the greatest return on investment for genetic research comes at the market-entry stage and not at the patenting stage. If a certain technology requires permits or pre-approval to enter the market, the agency that controls the permitting process can also ensure necessary periods of exclusivity. With respect to DNA, such a system can be administered by an existing federal agency—the FDA.

Before any pharmaceutical manufacturer can sell its wares in the United States, it must obtain the FDA’s pre-market approval.³³⁷ In order to obtain such approval, the manufacturer must prove to the FDA that the drug in question is both safe for use and effective for the claimed purpose.³³⁸ The same requirement applies to medical devices.³³⁹ A similar, though not identical, process³⁴⁰ is followed by manufacturers seeking approval for “biological products” or “biologics.”³⁴¹ Thus, the FDA serves as a gatekeeper to the market for the manufacturers of pharmaceuticals and biologics. If the FDA could reject applications on economic or competition-promoting grounds, rather than only on safety and efficacy grounds, manufacturers of relevant products could seek protection under the FDA’s regime rather than (or in addition to) the patent regime.

As it happens, for most pharmaceuticals and some biologic products, such a regime is already in place. The FDA does indeed have authority to limit market entry by copyists, even if their products satisfy the “safe and

337. 21 U.S.C. § 355(a) (2006).

338. *Id.* § 355(d).

339. *Id.* § 360e (2006 & Supp. V 2011).

340. For a discussion of differences between the history, the governing law, and the approval processes, see generally John A. Vernon, Alan Bennett & Joseph H. Golec, *Exploration of Potential Economics of Follow-On Biologics and Implications for Data Exclusivity Periods for Biologics*, 16 B.U.J. SCI. & TECH. L. 55 (2010).

341. Biologics are defined as “any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.” 21 C.F.R. § 600.3(h) (2012); *see also* 42 U.S.C. § 262(i)(1) (2006 & Supp. V 2011) (defining biological products). As the FDA explains:

Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues.

Biologics are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.

Resources for You (Biologics), U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/default.htm> (last updated May 11, 2010).

efficacious” requirements. I will first describe the two systems and then explain how they could be expanded to cover genetic materials and what benefits would accrue from such an expansion.

A. *NEW CHEMICAL ENTITIES UNDER THE HATCH-WAXMAN ACT*

Several different types of market exclusivity are available to manufacturers of pharmaceutical products.³⁴² One such type of exclusivity protects “new chemical entities.”³⁴³ This provision was created in 1984 by the Drug Price Competition and Patent Term Restoration Act of 1984³⁴⁴ (commonly known as the Hatch-Waxman Act).³⁴⁵

The “new chemical entity” (“NCE”) exclusivity provision is aimed at protecting pioneering manufacturers from premature competition by generic (or copying) manufacturers.³⁴⁶ When a pioneering drug manufacturer seeks to market a new pharmaceutical, it must submit “‘full reports of investigations’ made ‘to show whether or not such drug is safe for use and whether such drug is effective in use.’”³⁴⁷ The clinical studies necessary to compile such reports are both long and expensive.³⁴⁸ Prior to 1984, any competitor that wished to enter the market, even if attempting to supply a generic (and therefore identical) version of a previously approved drug, needed to conduct its own “extensive (and expensive)”³⁴⁹ studies to prove something that was already known to the FDA.³⁵⁰ “Due to the lack of finances to undertake the expensive process of clinical studies to prove a

342. Alice O. Martin & Sendil K. Devadas, *Patents with an “I” = Patients*, 18 ANNALS HEALTH L. 261, 265 (2009).

343. 21 U.S.C. § 355(c)(3)(E)(ii) (creating exclusivity for drugs whose active ingredient has never been used in another drug previously submitted for approval).

344. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e) (2006 & Supp. V 2011)).

345. See Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL’Y L. & ETHICS 717, 727 (2005) (“In 1984, Congress added two more provisions for FDA-administered market exclusivity in the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the ‘Hatch-Waxman Act.’”).

346. See Kathleen R. Kelleher, Note, *FDA Approval of Generic Biologics: Finding a Regulatory Pathway*, 14 MICH. TELECOMM. & TECH. L. REV. 245, 255-56 (2007) (discussing how NCE exclusivity is meant to incentivize pioneering research in pharmaceuticals).

347. *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1316 (D.C. Cir. 1998) (quoting 21 U.S.C. § 355(b)(1) (1994)).

348. Jason Rantanen, *Slaying the Troll: Litigation as an Effective Strategy Against Patent Threats*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 159, 184 (2006) (“These clinical studies frequently involve hundreds of subjects, and may cost tens of millions of dollars (or more) each.”); Anne-Marie C. Yvon, *Settlements Between Brand and Generic Pharmaceutical Companies: A Reasonable Antitrust Analysis of Reverse Payments*, 75 FORDHAM L. REV. 1883, 1894 (2006) (recognizing that clinical studies are “extensive (and expensive)”).

349. Yvon, *supra* note 348, at 1894.

350. Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 287 (2011).

drug was safe and effective, few generic drugs entered the market”³⁵¹ The Hatch-Waxman Act solved the problem by creating

a new process called the Abbreviated New Drug Application (“ANDA”) whereby a manufacturer of a generic drug can certify that the drug it seeks to market is bioequivalent to a drug that has already been approved by the FDA. This process obviates the need for the manufacturer of the generic drugs to run duplicative tests to show, for the second time, that its drug is safe and efficacious.³⁵²

Instead of conducting its own clinical trials, an ANDA filer is permitted to rely on data gathered by the pioneer drug-maker.³⁵³

At the same time that the Hatch-Waxman Act was making life easier for generic manufacturers, it also sought to maintain the balance between competition and innovation.³⁵⁴ Specifically, it limited the FDA’s freedom to approve ANDA applications that relied on the pioneer drug manufacturer’s data. Under the Act, the FDA cannot approve an ANDA within five years of approving a pioneer application if the pioneer application involved a new active ingredient. This restriction is known as a “new chemical entity” exclusivity.³⁵⁵ Although usually a new active ingredient is also covered by a relevant patent,³⁵⁶ this statutory exclusivity provision is available “even if the underlying product was unpatented or off-patent,”³⁵⁷ and “even if the patent that protects an NCE is invalid.”³⁵⁸

Technically, the exclusivity provision only applies when the generic manufacturer wishes to rely on the pioneer’s data. Should the generic wish to conduct its own clinical trials, and submit its own new drug application, the Hatch-Waxman exclusivity provisions would not stand in the way of approval.³⁵⁹ However, conducting duplicative clinical studies is expensive,

351. Sarah M. Yoho, Note, *Reformation of the Hatch-Waxman Act, an Unnecessary Resolution*, 27 NOVA L. REV. 527, 531 (2003).

352. Dolin, *supra* note 350, at 288 (footnote omitted).

353. Sheila Kadura, Note, *Is an Absolute Ban on Reverse Payments the Appropriate Way to Prevent Anticompetitive Agreements Between Branded- and Generic-Pharmaceutical Companies?*, 86 TEX. L. REV. 647, 651 (2008).

354. Dolin, *supra* note 350, at 289 (“To counter-balance the benefit conferred on the generics, and to continue to promote the development of pioneer drugs, Congress enacted rules, as part of the Hatch-Waxman Act, that were meant to benefit brand-name manufacturers.”).

355. Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 592–93 (2003).

356. *Id.* at 593 (“NCE exclusivity usually overlaps with the patent term . . .”).

357. Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 306 (2008).

358. James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 465 (1986).

359. 21 U.S.C. § 355(c)(3)(E)(ii)–(iii) (2006 & Supp. V 2011). Of course, to the extent that the pioneer drug is covered by a patent, the generic would not be permitted to sell its own

and the return on such studies would be lower than the monopoly rents that a single provider could charge.³⁶⁰ Therefore, generic manufacturers do not undertake such studies, and data-based exclusivity is sufficient to protect the interests of the pioneering manufacturer.

B. BIOLOGICS UNDER THE AFFORDABLE CARE ACT

A similar exclusivity provision exists for biologic products. In 2010, as part of the Patient Protection and Affordable Care Act, Congress passed, and President Obama signed, the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”).³⁶¹ The BPCIA applies not to every biologic product, but only to those products that are classified as such under the Public Health Service Act of 1944 (“PHSA”).³⁶² Under that Act, “[t]he term ‘biological product’ means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product . . . or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.”³⁶³ By its terms the BPCIA does not include genetic materials—proteins, lipids, etc.—as such.³⁶⁴

Much like the Hatch-Waxman Act, the BPCIA seeks both to increase the availability of generic biologics and to protect pioneering manufacturers. The BPCIA opened up an avenue for the manufacturers of biological products to rely on pioneer manufacturers’ safety and efficacy studies in getting biosimilar³⁶⁵ products on the market. Under the BPCIA, however, the pioneering biologic gets not five, but twelve years³⁶⁶ of exclusivity.³⁶⁷

version. 35 U.S.C. § 271 (2006 & Supp. V 2011); *see also* Eisenberg, *supra* note 345, at 727–28 (“The five-year period of exclusivity for new chemical entities . . . does not prevent a competitor from obtaining approval of an unpatented product if it is willing to go to the trouble and expense of conducting its own clinical trials and to rely strictly on its own data for proof of safety and efficacy.”).

360. Rantanen, *supra* note 348, at 184.

361. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 7001–7002, 124 Stat. 119, 804–21 (codified as amended at 42 U.S.C. § 262 (2006 & Supp. V 2011)).

362. Public Health Service Act, Pub. L. No. 78-410, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. §§ 201–300).

363. 42 U.S.C. § 262(i)(1).

364. All of the above materials could be *part* of “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, . . . or analogous product,” *see What Are “Biologics” Questions and Answers*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm> (last updated Apr. 30, 2009), but they are not in and of themselves considered to be “biological products.”

365. “Biosimilar” is a generic version of a pioneering biologic. Under the BPCIA, a product is “biosimilar” if it is “(A) . . . [a] biological product [that] is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and (B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.” 42 U.S.C. § 262(i)(2)(A)–(B).

366. This can be extended by an additional six months if pediatric studies are conducted. *Id.* § 262(m)(2)(A).

Much like with Hatch-Waxman exclusivity, these provisions do not apply to the manufacturers of biosimilars that undertake their own studies and submit their own original application for approval.³⁶⁸

C. APPLYING THE CURRENT MARKET EXCLUSIVITY PROVISIONS TO
PHARMACEUTICALS

In determining whether the exclusivity provisions apply with respect to pharmaceuticals, the FDA follows a fairly straightforward rule. If the active ingredient³⁶⁹ in the drug has never been previously approved (whether as part of the same or other drug),³⁷⁰ the exclusivity provisions apply. The active ingredient is considered “new” even if the advance is minor and of the kind that would fail the non-obviousness requirement of the Patent Act.³⁷¹ With respect to biologics, the rules are very similar, except that the FDA is prohibited from approving not just identical copies of biologics but also molecules that are “biosimilar” to or “interchangeable”³⁷² with approved biologics.³⁷³ Unlike the patent examination process, in which the Patent Office examines the application for compliance with, *inter alia*, novelty requirements, the FDA does not engage in such an analysis. Instead, all the FDA determines is whether the pioneering biologic which is serving as a “reference product” for the generic application has been first approved for use within the last twelve years.³⁷⁴ If so, the FDA does not undertake any further evaluation and simply declines to act on the generic’s application.

In summary, the current FDA exclusivity process has two distinct features that make it easy to administer on one hand but easy (though incredibly expensive and therefore often financially infeasible) to circumvent on the other. It is easy to administer because the FDA does not engage in any significant novelty inquiry prior to conferring the relevant exclusivity benefit. It is easy to circumvent because the exclusivity is triggered

367. *Id.* § 262(k)(7)(A).

368. See Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 440 (2012).

369. An “active ingredient” is “any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals.” 21 C.F.R. § 210.3(b)(7) (2012).

370. It does not matter whether the chemical entity has been known or for how long. The question for the purposes of exclusivity is not whether the NCE is newly discovered but whether it has been previously approved for use. See 21 C.F.R. § 314.108(a).

371. See Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 39–40 (2009).

372. See 42 U.S.C. § 262(i)(3) (defining interchangeability as the ability of “the biological product [to] be substituted for the reference product without the intervention of the health care provider who prescribed the reference product”).

373. See *id.* § 262(k)(6).

374. *Id.* § 262(i)(4) (defining “reference product”).

only when the generic files an abbreviated application that relies on the pioneer's data. If the generic chooses to conduct its own safety and efficacy studies, then FDA's exclusivity provisions present no barriers to entry. The only barriers that would remain in that situation are patent protections and the cost of conducting independent studies.

This system serves as a useful but incomplete template for a system of FDA-based protections of inventions in the field of genetics that I propose below. My proposed system attempts to minimize the system's administrative burden while addressing the ease of evading the present FDA-based statutory exclusivity regime.

VII. FDA-ADMINISTERED EXCLUSIVE REGIME FOR GENETIC MATERIALS

As preceding sections show, a system for market exclusivity for the fruits of research in genetics has to satisfy several criteria. First, it has to provide sufficient protection to incentivize investment and innovation in the area. Second, the system ought not replicate all of the shortcomings of the patent system—it should not be a stumbling block for further research and inventing around the protected products. Nor should it overcompensate for the amount of labor invested by bestowing protections that go beyond rewarding the actual inventions (as opposed to discoveries) made. To say it another way, the non-patent-based system must accomplish its ends without withdrawing a significant amount of knowledge from the commons. Third, the system should be relatively easy to administer, permitting the relevant regulatory agency to approve or deny applications quickly and not replicate the interminable patent prosecution processes.³⁷⁵ Fourth, there must be no easy and inexpensive way to evade the non-patent-based exclusivity. With these requirements in mind, I will now turn to the proposal for an alternative, non-patent-based system of protecting genetic research.

A. THE SYSTEM DESIGN

As an initial matter, in order to create a system capable of protecting genetic inventions, the definition of a "biological product" or "biologic" in the PHSA must be expanded. Currently, biologics are only defined as any "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings."³⁷⁶ Although the FDA recognizes that nucleic acids can form a component of a biological

375. Enrique Seoane-Vazquez et al., *Analysis of the Impact of the Uruguay Round Agreements Act on Pharmaceutical Patents*, 64 FOOD & DRUG L.J. 171, 178 (2009) ("This study estimated that the average prosecution time of NME patents exceeded five years."). "NME" is a "new molecular entity," which the article defines as a "new drug containing an active substance that has never before been approved for marketing in the United States." *Id.* at 173.

376. 42 U.S.C. § 262(i)(1).

product,³⁷⁷ stand-alone nucleic acids are not considered to be “biologics” for the purposes of the PHSA.³⁷⁸

With respect to DNA-based treatments, if the definitions of the “biologic material” in the PHSA were broadened to include “nucleic acids” as such, then these treatments would come within the protections of the BPCIA. In order to get approval as a treatment, an individual seeking a biologic license on a DNA molecule would have to conduct clinical studies to show that that treatment is safe and effective for the relevant condition.³⁷⁹ The protections offered by the BPCIA’s data-exclusivity provisions would likely be enough for inventors seeking protection for DNA-based therapies.

Of course, nucleic acids can be used not only to treat disease, but also to diagnose various conditions as well.³⁸⁰ Indeed, diagnostics is the primary use of genetic materials today as gene therapy is still experimental and rare.³⁸¹ But currently, under BPCIA, unless a biological product is meant for the “prevention, treatment, or cure of a disease or condition,” it is not subject to the approval mechanism through the biologic license application. Thus, merely diagnostic tests do not fit within the PHSA/BPCIA framework. In order to provide a full measure of protection for genetic research, the biologic definition needs to be expanded to include not only biological products of which a nucleic acid is a component, but also nucleic acids themselves. Further, the statute must be expanded to cover products meant not only for “the prevention, treatment, or cure of a disease or condition,” but also ones meant for diagnosing such diseases or conditions. By so expanding the coverage of the PHSA, the FDA will be given authority to approve or disapprove applications for the use of genetic materials in the treatment, prevention, or the diagnosis of a disease.

Explicitly providing the FDA with authority to regulate genetic material meant to treat or diagnose any disease would be but a mild expansion of the

377. See *supra* note 341. This recognition is not surprising. For instance, a virus is an organism that consists of only a nucleic acid (either DNA or RNA) and a protein “housing” that envelops the genetic material. See *STEDMAN’S MEDICAL DICTIONARY* 1939 (Marjory Sprycar et al. eds., 26th ed. 1995). Some viruses also have a further lipid “envelope.” Thus, of necessity, a virus includes nucleic acids as a component.

378. 42 U.S.C. § 262(i)(1).

379. See Letter from Kathryn C. Zoon, Dir., Ctr. for Biologics Evaluation & Research, to Sponsors/Researchers, Human Cells Used in Therapy Involving the Transfer of Genetic Material by Means Other than the Union of Gamete Nuclei (July 6, 2001), available at <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm105852.htm>.

380. See *Myriad I*, 702 F. Supp. 2d 181, 196–97 (S.D.N.Y. 2010), *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom. Myriad III*, 132 S. Ct. 1794 (2012).

381. *Gene Therapy*, HUMAN GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml (last updated Aug. 24, 2011) (“The Food and Drug Administration (FDA) has not yet approved any human gene therapy product for sale. Current gene therapy is experimental and has not proven very successful in clinical trials. Little progress has been made since the first gene therapy clinical trial began in 1990.”).

FDA's regulatory authority. The Food, Drug, and Cosmetic Act already permits the FDA to regulate medical devices,³⁸² and defines a "device" as

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . and which does not achieve its primary intended purposes through chemical action within or on the body.³⁸³

All devices are classified as a Class I, II, or III device³⁸⁴ based on the level of danger they may present to a consumer,³⁸⁵ with Class I being the least and Class III the most potentially dangerous. Class III devices are subject to pre-market approval,³⁸⁶ whereas Class I devices are not.³⁸⁷ Class II devices are subject to "pre-market notification,"³⁸⁸ a process in which the FDA evaluates whether the device is similar to an already approved and safe device³⁸⁹ and, if not, whether it poses sufficient danger to be classified as Class III.³⁹⁰

Although Class I is exempt from pre-market approval or notification, only those devices that are shown to be safe and effective whenever not adulterated or misbranded qualify for this designation.³⁹¹ According to the testimony before the House Subcommittee on Oversight and Investigation by Dr. Jeffrey Shuren, most genetic tests are considered to be either a Class II or a Class III device.³⁹² Thus, the FDA already has the authority to regulate most genetic materials meant to test for a particular trait or disease.³⁹³ The FDA, however, has refrained from regulating "test[s] by a laboratory for use

382. 21 U.S.C. § 360c (2006).

383. *Id.* § 321(h).

384. *Id.* § 360c.

385. Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2131 (2000).

386. 21 U.S.C. § 360c(a)(1)(C).

387. *Id.* § 360c(a)(1)(A).

388. *Id.* § 360c(a)(1)(B).

389. Yann Joly et al., *Regulatory Approval for New Pharmacogenomic Tests: A Comparative Overview*, 66 FOOD & DRUG L.J. 1, 13 (2011); Annie Marie Murphy, Note, *The Biomaterials Access Assurance Act of 1998 and Supplier Liability: Who You Gonna Sue?*, 25 DEL. J. CORP. L. 715, 726-27 (2000).

390. See Joly et al., *supra* note 389, at 13.

391. 21 U.S.C. § 360c(a)(1)(A). A classic example of such a device is a home pregnancy test that does not present significant danger to human health and safety even if it "malfunctions." See *Direct-to-Consumer Genetic Testing and the Consequences to the Public: Hearing Before the Subcomm. on Oversight and Investigations*, 111th Cong. 4 (2010) [hereinafter Shuren] (statement of Jeffrey Shuren, Director, Center for Devices and Radiological Health, Food and Drug Administration) ("An example of a Class I test is a luteinizing hormone test that, if it gives a false result, may lead to delayed conception but is unlikely to directly harm the patient.").

392. Shuren, *supra* note 391, at 4, 7.

393. *Id.* at 7.

only by that laboratory,”³⁹⁴ which is how much genetic testing is done. In other words, if a sample of a patient’s DNA is sent to the laboratory for processing using the test developed by that very laboratory, the FDA is not involved in approving such tests.³⁹⁵ Nonetheless, the FDA is considering exercising its authority over these laboratory-developed tests as well³⁹⁶ because it has observed a number of problems with them, including “[f]aulty data analysis”; “[e]xaggerated clinical claims”; “[f]raudulent data”; “[l]ack of traceability/change control”; “[p]oor clinical study design”; and “[u]nacceptable clinical performance.”³⁹⁷

The only potential expansion of the FDA’s existing regulatory authority would thus come from requiring pre-market approval for those genetic materials that may now be classified as Class I devices. Most genetic tests do not fall into that category, however, making the expansion rather small.³⁹⁸ Further, I am not suggesting a more searching examination of the genetic materials currently classed as Class I or Class II devices. If the genetic material or test kit is not dangerous, or if a potential erroneous test result using that material “is unlikely to directly harm the patient,”³⁹⁹ there is no reason to require extensive and expensive studies to prove the obvious. Similarly, if the genetic material or test kit in its general (though not specific) function is similar to a previously approved test, or if it is not sufficiently dangerous to the patient to be classified as a Class III device, there is no reason to insist on complying with procedures established for Class III devices as such compliance would serve no useful purpose. Instead, all that I am suggesting is the requirement of obtaining an FDA license (like with every other biological product) prior to entering the market. The license itself, however, need not be predicated on clinical studies if such studies are not necessary to assure patients’ safety.

The authority to regulate genetic materials can be harnessed to create preferential market entry conditions for the first inventors, while restricting entry to the second-comers. Presently, the FDA approves genetic materials

394. *Id.*

395. *Id.*

396. *Id.* at 9 (“The Agency is now engaging in a public dialogue on how it should develop a consistent, reasonable, and fair approach to all genetic tests, whether packaged as kits or provided as [laboratory developed tests], to ensure safety and promote innovation.”).

397. *Id.* at 8.

398. See Shuren, *supra* note 391; Michael J. Malinowski & Maureen A. O’Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 YALE J. ON REG. 163, 206 (1996) (“Because of their complexity, genetics-based diagnostics generally are labelled Class III devices.”). But see Bruce Patsner, *New “Home Brew” Predictive Genetic Tests Present Significant Regulatory Problems*, 9 HOUS. J. HEALTH L. & POL’Y 237, 247 (2009) (“[B]y federal rule almost all such predictive genetic tests are not Class III devices but rather are classified as either Class I or Class II devices . . .”).

399. Shuren, *supra* note 391.

for market entry once they are shown to be safe and effective⁴⁰⁰ without regard to the novelty of the product. If, in addition, genetic materials were reclassified not just as “medical devices” but also as “biological products,” then the exclusivity provisions of BPCIA would come into play and preclude later filers (who choose to rely on the pioneer’s data) from obtaining approval. With this re-classification (or rather “double classification”) the amount of regulatory activity by the FDA would not increase, but the value of gaining the FDA approval for the first filer would.

To make the proposed exclusivity system for genetic materials effective, an additional change in the law would need to be made. That change stems from the recognition that current exclusivity provisions are triggered only when the subsequent filer attempts to rely on a pioneer’s data. To the extent that a new filer wishes to conduct his own safety and efficacy studies, the exclusivity provisions are not a barrier to market entry. Exclusivity provisions are effective because most safety and efficacy studies are costly and the return on investment in these studies diminishes with every subsequent market entrant. However, genetic materials or test kits that fall into the Class I or Class II device category do not have to go through extensive and costly clinical trials before gaining permission to enter the market. Thus, exclusivity provisions based on access to (or use of) the pioneer’s data would not serve as a sufficient barrier to entry for later filers. Consequently, a new type of provision that would provide sufficient protections for biological products of all classes (whether subject to extensive pre-approval clinical studies or not) must be designed. The exclusivity should be based not on the pioneer’s *data*, but on the pioneer’s *product*.

Recall that genetic tests are conducted by finding out whether the patient’s DNA hybridizes (i.e., “matches”) the test strand of DNA. This match can occur because of the complementary nature of DNA’s two strands. When researchers discover and sequence a new gene under the present regime, they can patent laboratory-produced, isolated, and purified complementary strands and then use these isolated strands to test patients for this newly discovered gene (and therefore any medical condition associated with that gene). Under my proposal, when a manufacturer of a new genetic test seeks FDA approval, the FDA would evaluate the application to see whether DNA with the same or similar sequence has been previously approved. The “similarity” would be judged not on the “obviousness” standard of the Patent Act’s § 103, but rather in a more straightforward way. If the later filer’s molecule has the same or highly similar (e.g., within ninety percent identical) hybridization properties as the pioneer’s molecule, then the later filer’s molecule would be deemed sufficiently “similar” and, therefore, subject to the exclusivity bar. This would be true *irrespective of*

400. The requirements for that showing may differ from Class I to Class III devices, but the standard of safety and efficacy is the same for all devices.

whether the later filer had (or even needed) his own data to support the safety and efficacy of the genetic material or test kit that he seeks to market. This approach would be similar to the exclusivity now available to the developers of “orphan drugs” (i.e., drugs developed to treat a rare disease).⁴⁰¹

Though under my proposal the exclusive rights would be broader than the current data-based provisions in the BPCIA, they would be, in several respects, more limited than patent-based rights to exclude. First, and most obvious, the exclusivity obtained through the FDA licensing scheme, unlike that obtained via a patent, would not apply to *every* “use” of the product. Instead, FDA-based exclusivity would apply only to products being (1) marketed to patients (either directly or through a healthcare provider) and (2) “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.”⁴⁰² Consequently, the gene itself, whether in native, isolated and purified, or cDNA form, would remain available for use in research and development of new treatments or diagnostics. Such use of a gene would not be subject to FDA regulation because it would not be marketed to patients and would not be used for “the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.”⁴⁰³

Second, unlike the Patent Act, my proposal would require that FDA-granted exclusivity include a “use it or lose it” provision similar to the one present in the amended Hatch-Waxman Act.⁴⁰⁴ Patent law permits a patentee not to practice the invention and instead merely to seek to license the patent to others who do practice it.⁴⁰⁵ There is, of course, nothing wrong with that practice in principle, as it allows inventors who are not necessarily able to manufacture the invention themselves to monetize their inventions. However, the FDA-based exclusivity provisions should serve as a spur not just to innovate and disclose information, but to bring products to market—products that may be costly and laborious to develop but that are not necessarily innovative because they are obvious to one of ordinary skill in the art of molecular genetics. It would make little sense then to allow the beneficiary of the provision intended to ensure availability of certain products on the market, to not actually bring the approved product to (or to prematurely withdraw from) the market.

401. See 21 U.S.C. § 360cc(a) (2006) (granting exclusivity to the first person to bring an orphan drug to market). For a full definition of “orphan drug,” see *id.* § 360bb(a).

402. *Id.* § 321(h)(2).

403. *Id.*

404. *Id.* § 355(j)(5)(D)(i)(I).

405. See *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995) (en banc) (“There is no requirement in this country that a patentee make, use, or sell its patented invention.”).

The third distinction from patent law that the system ought to have is varying lengths of exclusivity. Under the Patent Act (and pursuant to the international agreements) the length of patent terms on all inventions, irrespective of their field, must be twenty years from the date of filing the patent application.⁴⁰⁶ This approach has been criticized by a number of commentators as constricting the design of optimal innovation incentives.⁴⁰⁷ Nonetheless, if for no other reason than the obligation to adhere to our international agreements, the patent system cannot vary the patent term's length depending on the social utility of the innovation or the measure of its advance over the prior art. No such restrictions, however, apply to a non-patent-based grant of exclusive rights. As a result, in designing a system of FDA-based exclusive rights, different terms could be assigned to inventions depending on the value of each class of invention. Indeed, such differentiation is already present in the FDA's approval process. As I discussed in Part VII, the exclusivity period for new chemical entities is only 5 years, whereas the exclusivity periods on biologics is 12 years, and other provisions in the Food, Drug, & Cosmetic Act provide for exclusivity provisions of 180 days for the first generic drug on the market⁴⁰⁸ and 7 years for "orphan drugs."⁴⁰⁹ Thus, exclusivity provisions of different lengths are nothing new to the FDA.

A good departure point for genetic tests would be whether the particular application would seek approval as a Class I, II, or III device. The more complicated the test, or the more problematic an incorrect test result would present, the more likely that detailed studies proving safety and efficacy would be required and the more refined the ultimate product would have to be. These complex materials would be eligible for the longest exclusivity period. The easier the test, and the fewer problems an erroneous result would present, the more likely the product could be approved without extensive studies, and therefore the more likely it is that the product would not be as refined. These simpler products ought to receive the shortest exclusivity provisions. While I do not have particularly strong views on the length of each exclusivity provision, I would suggest taking the effective life of an average pharmaceutical patent⁴¹⁰ as a benchmark for the longest

406. See 35 U.S.C. § 154(a)(2) (2006); World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, 14 November 2001, 41 I.L.M. 755 (2002).

407. See, e.g., Eric E. Johnson, *Calibrating Patent Lifetimes*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 269, 292-93 (2006); Amir H. Khoury, *Differential Patent Terms and the Commercial Capacity of Innovation*, 18 TEX. INTELL. PROP. L.J. 373, 405-12 (2010); Frank Partnoy, *Finance and Patent Length* 27-38 (Univ. of San Diego, Law & Econ. Research Paper No. 19, 2001), available at <http://papers.ssrn.com/abstract=285144>.

408. 21 U.S.C. § 355(j)(5)(B)(iv) (2006 & Supp. V 2011).

409. *Id.* § 360cc(a) (2006).

410. Wheaton, *supra* note 358, at 451 ("In the context of the pharmaceutical industry, the term 'effective patent life' describes the period between FDA approval of a patented drug product and the expiration of that product's patent.")

exclusivity period. Under such a system, the maximal FDA-based market exclusivity provisions would last about 11.5 to 12 years.⁴¹¹ On the opposite end, the minimal exclusivity length would be about 3.5 to 4 years, which would correspond to the time frame when first patent maintenance fees would be due if the exclusivity were obtained under a patent-based system.⁴¹² The mid-level of protection would be set at about 7.5 to 8 years of exclusive rights, which would correspond to the due date for the second patent maintenance fee.⁴¹³ It makes sense to tie the exclusivity provisions to patent maintenance fee dates because patent maintenance fees serve as a mechanism to terminate patents without value.⁴¹⁴ It is true, of course, that a patent may present but a minor improvement and yet be very economically valuable, and vice versa. In that sense, the analogy of the exclusivity periods in my proposed system to the payment of maintenance fees in the patent system is not perfect. Nonetheless, setting periods at these lengths would provide a rough equivalence to the length of protections offered by the patent system. In any case, the *particular* length of the each exclusivity provision is not central to my proposal. To the extent that empirical data would show that any of these periods are suboptimal (as either too long or too short) to achieve the desired effect of incentivizing research in the area of molecular genetics, the length of each period ought to be adjusted. What is central to the proposal is the ability to differentiate between the genetic products seeking market entry and bestowing the longest exclusivity rights only on products of sufficient complexity and sufficient advancement over the prior art.

One final requirement necessary for the success of an FDA-based exclusivity system is a provision precluding applicants from taking advantage of both the patent system and the FDA system as they currently can with new pharmaceuticals and biologics. Criticism has been leveled at the current “double benefit” system (especially with respect to biologics) as being overprotective of inventors.⁴¹⁵ Whether or not that criticism is fully justified, at the very least the ability to reap both benefits could theoretically be justified on the grounds that FDA-based exclusivity as currently constituted only applies when the later filer seeks to use the pioneer’s data. Therefore, it

411. Richard A. Epstein & F. Scott Kieff, *Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents*, 78 U. CHI. L. REV. 71, 78 (2011) (“[T]he typical effective patent life for pharmaceuticals in the United States today is under twelve years for drugs with more than \$100 million in annual sales, which, not surprisingly, constituted 90 percent of the unit sales in the brand market in the United States during the period from 1995 to 2005. That effective period is even lower for some segments.”).

412. 35 U.S.C. § 41(b) (2006 & Supp. V 2011).

413. *Id.*

414. As Mark Lemley pointed out, “nearly two-thirds of all issued patents lapse for failure to pay maintenance fees before the end of their term: nearly half of all patents are abandoned in this way before their term is half over.” Lemley, *supra* note 335, at 1503.

415. See Heled, *supra* note 368, at 470–75.

could be argued, patent protections are necessary to prevent a copier from entering the market at all (even after conducting its own safety and efficacy studies). That argument would be unavailable in the system that I am proposing because exclusivity would be granted based on the DNA product itself and its hybridization properties, irrespective of who conducted the safety and efficacy studies and whether such studies were necessary in the first place. Consequently, additional patent protection would not be necessary. Indeed, patent protection would serve only to potentially extend the shorter of the exclusivity periods by allowing the patentee to tie up the generic in costly litigation for years. Furthermore, since it is likely, based on the analysis in Part V, that most of these patents would not survive an obviousness analysis, such litigation would only delay the inevitable to the detriment of consumers. As a result, my proposal would require every applicant seeking a license to market a new genetic test or treatment to choose between patent protection and FDA-based protection. If a patent has already been obtained, but the applicant thinks that FDA-based exclusivity rights would be more advantageous, the patentee would be required to disclaim any patent term extending beyond the term of FDA-based protection.

B. *THE JUSTIFICATION AND BENEFITS OF THE PROPOSED SYSTEM*

A system in which the FDA preferentially treats first market entrants and limits, for a certain amount of time, market access to later filers meets all the criteria identified in the beginning of this Part. First, if exclusivity is granted for a sufficient time period, the system provides adequate incentive to the inventors—much in the same way a patent system does. After all, because patent-based exclusivity becomes valuable only *after* market entry is made possible, the system that provides market exclusivity simultaneously with permission for market entry serves the same function as a patent: it permits the holder of the exclusive right to exclude others from the market and obtain monopoly rents on the product.⁴¹⁶ Second, the FDA-based system would not overcompensate the developers of new tests and treatment by granting them rights to more than they actually developed. Because the FDA-based exclusivity rights would apply only to products that are meant for diagnosis or treatment of diseases, the innovator would not be getting exclusive rights to all uses of a gene (in whatever form). This restriction

416. See, e.g., Daniel R. Cahoy, *An Incrementalist Approach to Patent Reform Policy*, 9 N.Y.U. J. LEGIS. & PUB. POL'Y 587, 600 (2006) ("A patent allows its owner to extract monopoly rents for the period of exclusivity."); Sean McElligott, *Addressing Supply Side Barriers to Introduction of New Vaccines to the Developing World*, 35 AM. J.L. & MED. 415, 426 (2009) ("[I]nnovator firms are granted periods of market exclusivity, through patents, in order to allow them to charge monopoly prices to recoup sunk R&D costs . . ."); David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1303, 1306 n.19 (2010) ("A brand company's patent allows it to set high monopoly prices . . .").

would allow others to continue working with that gene to develop new tests or extract new useful information from it. The limited rights available through the FDA would then address the fear of those concerned with the “anti-commons.”

Third, the proposal also satisfies the criterion of being easy to administer. The FDA already does (or is seriously contemplating doing) much of what I propose. It already reviews many genetic tests as medical devices and asserts the authority to regulate genetic therapies. The only additional burden on the applicant would be to seek a license, and the FDA would either issue or withhold one depending on the novelty of the test or treatment. Adjudicating novelty based on the hybridization properties of particular DNA molecules would also be easy. Complex legal analysis such as that conducted by the Patent Office in evaluating applications for compliance with the non-obviousness requirements would not be necessary. A simple experiment that would confirm whether or not the later filer’s product hybridizes to the same sequence as a pioneer’s product would suffice.

Finally, the requirement that exclusivity be product-based rather than data-based makes the regime nearly impossible to evade. Again, the test for approving or denying the later filer’s application would be simple. If its product hybridizes to the same DNA sequence as the pioneer’s product then no approval can be granted, and the later filer cannot enter the market until the pioneer’s exclusivity expires. This preclusion would be in place irrespective of whether the later filer conducted his own studies, has his own data, or any other factors.

The difficulty of evading the FDA-based exclusivity system that I propose has an additional salutary effect. Because this system will be rather straightforward and provide all applicants with an easy and inexpensive way to determine the likelihood that their application would be approved by the FDA, litigation costs would be reduced. Currently, the average cost of patent litigation exceeds \$3 million.⁴¹⁷ This money could be better spent on further research. After all, the parties to patent litigation on DNA are both likely to be invested in the market with neither being a “non-practicing entity.”⁴¹⁸ Given that pharmaceutical patents are among those most often subject to

417. See Christopher B. Seaman, *Reconsidering the Georgia-Pacific Standard for Reasonable Royalty Patent Damages*, 2010 BYU L. REV. 1661, 1725 (“[T]he average cost of patent litigation was approximately \$3.1 million.”).

418. Cf. Kyle Gross, Note, *Game On: The Rising Prevalence of Patent-Related Issues in the Video Game Industry*, 12 SMU SCI. & TECH. L. REV. 243, 243, 269 (2009) (noting that in pharmaceutical industries, entities that enforce their patents are the pharmaceutical companies who actually manufacture the drugs, whereas in high-tech industries, the manufacturers are often defendants in lawsuits brought by non-practicing entities).

litigation,⁴¹⁹ the certainty of the FDA-based rule and the litigation savings associated with that certainty would be very beneficial to all participants in the market.

In addition to meeting the above criteria, the system is consistent with the underlying philosophies of intellectual property discussed in Part III. Most obviously, the proposed system is justifiable on Benthamite utilitarian grounds. When properly administered, the system would permit the developer of a new product to recoup the investment in development and testing while also making a profit on the invention. The benefit will thus accrue directly to the inventors and indirectly to the public at large through the inventions. Though the public will pay monopoly rents for products subject to the FDA-based exclusivity provisions, this detriment would actually be narrower than in the patent system because the exclusivity provisions would apply to *specific* rather than *all* uses of the product in question. Therefore, the aggregate price the public will pay for the benefit obtained would actually be lower with the FDA-based exclusivity rights than with patent rights. Overall, then, the system is a better bargain for the public at large and, consequently, provides even greater utility than the patent system.

The grant of exclusive market rights to the pioneer genetic tests or treatments is also consistent with the Lockean approach to property rights as it rewards the innovator for his labor in devising, testing, and bringing a new product to market. Simultaneously, it does not over-reward him because it withholds the grant of exclusive rights on products of nature and the obvious inventions that follow from those naturally occurring products. In the same vein, my proposal fits within the Hegelian justification for intellectual property as it lets inventors properly and fully propertize (and monetize) their ideas. However, by limiting the rights granted only to the product that is actually developed rather than to a broader universe that would encompass all uses of an isolated gene, the proposed system does not permit one to propertize that which is not his idea and therefore should not rightly belong to him.

Finally, the proposed system satisfies Rawls' requirements for a just system of property. As discussed previously, the patent system can be justified on the Rawlsian view of a just society, despite the fact that it produces economic inequality. *A fortiori*, then, my proposed FDA-based system is justifiable because it is more beneficial to the least well-off than the patent system. By withdrawing a smaller set of knowledge from common property than the patent system does, the FDA-based system limits monopoly rents to a smaller class of products than the patent system would. Consequently, the least well-off would pay a lower price for some products in

419. John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B.U. L. REV. 77, 137 (2002) (“[B]iotechnology and pharmaceutical patents are more frequently litigated than patents in other industries . . .”).

the FDA-based system than they would in the patent-based system. With a greater ability to pay for products not subject to exclusivity provisions, the least well-off in society would have greater access to these goods and therefore be better off than they would be under the traditional patent system.

In summary, with respect to genetic material, the FDA-based exclusivity system can provide innovators with all of the benefits of the patent system while leaving more information in the public domain, and it can ensure that holders of exclusive rights actually practice their invention. Furthermore, these goals can be accomplished at a lower transactional cost than with the patent system as both the cost of obtaining valuable exclusive rights and defending them would be dramatically lowered.

VIII. CONCLUSION

The science of molecular genetics continues to challenge the long-accepted standards and rules of the patent law. The basic unit of molecular genetics—a molecule of DNA—is unlike any other chemical entity in that it has both chemical and informational properties. It is no surprise that determining how patent law should treat this molecule has been the subject of much debate.

Ultimately, though, with the scientific advancements of the last few decades, the patent-law question is resolving itself. Even if DNA is treated as a patent-eligible subject matter, it is unlikely to find much protection in the bosom of patent law because sequencing genes has become so routine as to no longer be inventive. In this sense, the patent system actually under-protects and therefore under-incentivizes investment and work in the field of molecular genetics. On the other hand, to the extent that some DNA sequencing may overcome the obviousness bar, the patent system over-protects and over-incentivizes the investment in this field as it allows the patentee to essentially limit access to that which is not truly his invention.

A new system is needed—one based on the desire to properly incentivize the work of pioneers in molecular genetics, while maintaining due regard for the need to permit access to genetic materials for further research. That system can be built by having the FDA regulate market entry for the makers of genetic diagnostic and therapeutic products. By allowing developers of new tests and treatments to enter the market on a preferential basis, as compared to later applicants, the system will permit innovators to enjoy monopoly rents much like they would under the patent system. At the same time, by limiting the monopoly to the *market* for diagnostics and therapeutics, the alternative FDA-based system would permit further research unfettered by the need to spend resources on licensing patents that encompass genetic materials. This new approach would finally resolve the debate on the patent eligibility of genetic materials and place all parties in a more advantageous position than they currently enjoy.

