EXCLUSIVITY WITHOUT PATENTS:
THE NEW FRONTIER OF FDA REGULATION FOR GENETIC MATERIALS

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Abstract

Over the last twenty years, the legal and scientific academic communities have been embroiled in a debate about patent eligibility of genetic materials. The stakes for both sides couldn't 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 the ability of scientists to continue and expand research into the human genome as well as patients' access to affordable diagnostic and therapeutic modalities. This debate is currently pending before the Supreme Court which has under consideration petition for *certiorari* in *Ass'n for Molecular Pathology v. USPTO*.

This paper recognizes that 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, the paper proposes a non-patent exclusivity system administered by the Food & Drug Administration. Under such a system, the innovators who bring new therapeutic or diagnostic products to market will receive exclusive rights to market their products for a limited time. This will provide sufficient market-based incentives to continue with the research and investment in this area. At the same time, because genetic sequences will no longer be broadly protected by patents, the public will be able to access these basic research tools without fear of infringement litigation. This approach addresses concerns of the 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 Regents of the University of California for work carried out in 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] The applications on genes have been filed in the United States, Canada, Japan, and the European Patent Office.[4] The number of patents granted on these applications number in the tens of thousands. As with other patents, the decision whether or not permit patenting of a certain category of inventions generally rests with the national patent authorities[5] and is based on consideration of public policy[6] and the answer to the question whether patents on genetic

[1] Edward Weck, *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); U.S. Patent No. 4,363,877 (filed Apr. 19, 1978) (issued Dec. 14, 1982).

[2] Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 MINN. J.L. SCI. & TECH. 157, 191 (2010); Larry I. Palmer, *Disease Management and Liability in the Human Genome Era*, 47 VILL. L. REV. 1, 20 (2002); Cara Koss, *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. LAW & TECH. ANN. 91, 102 (2009); Cydney A. Fowler, *Ending Genetic Monopolies: How the Trips Agreements 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, *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, 185-196 (2010) (discussing legal rules applicable to gene patents in Europe, Japan, Canada, Australia and China).

[5] Gretchen Ann Bender, *Clash of the Titans: The Territoriality of Patent Law vs. the European Union*, 40 IDEA 49, 51 (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.").

[6] *See* Marsha J. Ferziger, *Monopolies on Addiction: Should Recreational Drugs be Patentable?*, 1994 U. CHI. LEGAL F. 471, 483 (1994) ("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, *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.").

materials are beneficial or detrimental to the advance of science and human knowledge.[7] The debate on this topic raged on the pages of academic journals, in legislative committees, national patent offices, and the courts.[8] This is not surprising for several reasons.

First, unlike other chemical entities, genetic materials are carriers of information[9] and that information is the same whether the relevant molecule is created by nature or by human effort.[10] Second, this information is conserved not only as between "naturally-occurring" molecules and artificially engineered ones, but it is also conserved across essentially all biological entities.[11] 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 not just in humans, but in all future research.[12]

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[7] *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.").

[8] *See* Gaia Bernstein, *In the Shadow of Innovation*, 31 CARDOZO L. REV. 2257, 2293 (2010) (discussing the debate on the propriety of allowing gene patents); David C. Hoffman, *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 NIH's initial plans to file patent applications on genetic discoveries "spurred intense debate that has continued" to the present day).

[9] *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).

[10] Sean MacKenzie, *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).

[11] *See* Dr. Marshall Nirenberg, The Genetic Code, Nobel Lecture (Dec. 12, 1968), in NOBEL LECTURES, PHYSIOLOGY OR MEDICINE, 1963-1970, at 372, 390 (1972) ("[M]ost, perhaps all, forms of life on this planet use essentially the same genetic language, and that language is translated according to universal rules."); RICKI LEWIS, HUMAN GENETICS: CONCEPTS AND APPLICATIONS 316-17 (2nd ed. 1997); Mary B. Mahowald, *Genes, Clones, and Gender Equality*, 3 DEPAUL J. HEALTH CARE L. 495, 526 n.48 (2000) (noting that "all living species use the same genetic code."); William C. Mull, *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.").

[12] *See* Andrew S. Robertson, *The Role of DNA Patents in Genetic Test Innovation and Access*, 9 NW. J. TECH. & INTELL. PROP. 377, 383 (2011); Jennifer L. Davis, *The Test of Primary Cloning: A New Approach to the Written Description Requirement in Biotechnological Patents*, 20 SANTA CLARA COMPUTER & HIGH

At the same time, it cannot be gainsaid that laboratory-created genes are chemically and physically different from those that occur in nature even if both sets have the same informational content.[13] Focusing purely on the chemical structure then, these molecules should easily be eligible for patent protection as chemical entities.[14] The problem though is that these molecules' chemical structure and their informational content are inseparable and therefore, granting a patent to the innovators in this field may confer exclusive rights not just over the chemical structure, but over the informational content[15] – all to the detriment of future research in genetics and genetic diseases.[16]

Of course patent seekers in this area do not seek to patent random genetic sequences.[17] Instead, patent protection is sought on genes that are either known to

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TECH. L.J. 469, 480-481 (2004); Krista Stone, *Written Description After Ariad V. Eli Lilly: 35 USC §112's Third Wheel*, 11 J. HIGH TECH. L. 191, 193 (2010) .

[13] *See generally* Ass'n for Molecular Pathology v. U.S. PTO, 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) (hereinafter "Myriad II"). 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 (referring to decision as "*Myriad Genetics*."). *Myriad I* was the District Court's decision which the Federal Circuit reversed. *See* Ass'n for Molecular Pathology v. U.S. PTO, 702 F. Supp. 2d 181, 222-32 (S.D.N.Y. 2010), *rev'd*, 653 F.3d 1329 (hereinafter "Myriad I").

[14] *See id.* at 1349-55 (majority opinion) (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) (same with respect to some, though not all laboratory created DNA molecules).

[15] 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); *Myriad I*, *supra* note 13 (relying on the DNA's informational nature to conclude that patent claims on DNA cover the information contained therein and are therefore cannot be sustained under the Patent Act).

[16] *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.").

[17] *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*

produce certain proteins or the expression of which is found to be associated with a certain medical condition. Thus, for instance a patent on genes known as BRCA1/BRCA2 was sought[18] because these particular genetic sequences are associated with a higher incidence of breast cancer.[19] 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,[20] and for that matter in future genetic research about breast cancer or other disease.[21] The problem for the patentees that these associations between certain genetic sequences and corresponding conditions, are products of nature and are not an invention of anyone.[22] Though the search for these associations is laborious, expensive, painstaking,[23] and ultimately of significant importance to science and medicine,[24] the fruits of the search cannot be made exclusive to anyone.[25] Nor can the genetic sequence,

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Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and 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 ….").

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

[19] Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737, 814 n.186 (2004) (stating that genes "BRCA1 and BRCA2 [] are associated with inherited forms of breast cancer.").

[20] *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).

[21] *See id.*; Robertson, *supra* note 12, at 383.

[22] *See* Lamis G. Eli, *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).

[23] Stone, *supra* note 12, at 224 (noting that "sequencing DNA is time consuming and expensive."); Andrew W. Torrance, *Open Source Human Evolution*, 30 WASH. U. J.L. & POL'Y 93, 129 (2009).

[24] *See* E. Donald Shapiro, Jennifer Long & Rebecca Gideon, *To Clone or not to Clone*, 4 N.Y.U. J. LEGIS. & PUB. POL'Y 23, 28 (2000-2001) (stating that the results of genetic research "have led to major advances in medicine, such as the development of insulin and anti-clotting medication."); David Galas, Human Genome: 1991-1992 Program Report iv (1992).

[25] *See* Eli, *supra* note 22, at 382; Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (holding that "manifestations of laws of nature [are] free to all men and reserved exclusively to none.").

in and of itself, though it be newly found, be eligible for a patent; for that sequence is also a product of nature.[26]

On the other hand, once the association between certain genetic code and a condition is discovered, smaller laboratory-created versions of genetic material bearing the same informational content as the naturally occurring code can be created.[27] These molecules, because they are 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 and the current state of the art of genetics, it does not take much (if any) creativity to create these molecules once the association and the native code is known.[28] Once that information is available, the derivation of the lab-created molecules is fairly straight-forward, if occasionally laborious and expensive.[29] Patent laws, on the other hand, require that a patent seeker not only the establish that the subject matter of his application is eligible for patents as a general matter,[30] but is also sufficiently innovative ("non-obvious" in patent terminology) to qualify for a patent once general eligibility has been established.[31]

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[26] Lauren M. Dunne, *"Come, Let Us Return to Reason:" Association of Molecular Pathology v. USPTO*, 20 DEPAUL J. ART TECH. & INTELL. PROP. L. 473, 501 (2010); 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).
[27] *See Myriad I*, *supra* note 13, at 196 (discussing various uses for isolated and purified DNA).
[28] *See* Stone, *supra* note 12, at 224 (noting that though expensive, DNA sequencing is "routine."); 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 routinzation of DNA sequencing).
[29] 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 ….").
[30] 35 U.S.C. § 101 (2012).
[31] 35 U.S.C § 103 (2012).

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, and that which are patent-eligible are often not truly innovative and therefore though they clear the eligibility threshold, may fail to qualify for patent issuance. This inability to obtain patents because of either the subject matter eligibility bar or the obviousness bar means that the incentive to innovate that is inherent in the patent system is absent. And given the fact that the search for the genes and their associations with specific diseases is very costly and unpredictable, inability to recoup investments through exclusive rights presents a real problem and discourages investments in this area. On the other hand, even if in some specific instances patents were to be available, they present a problem for the public. Since patents grant exclusive rights to *make* or *use* the patented invention,[32] one who holds a patent on a lab-created genetic sequence could prevent other scientists from making the same sequence in their laboratories for the purposes of further experiments.[33] 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.[34] If patents foreclose not just competitors' economic gains but further scientific exploration, they are detrimental rather than beneficial to the public.[35]

This Article proposes a solution to the quandary. Innovation and research in genetics can be incentivized by providing innovators in this field with alternate and more

[32] 35 U.S.C. § 271 (2012).
[33] *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984), *superseded by statute in part*, Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Sept. 24, 1984) ("tests, 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, quotations, and citations omitted) .
[34] *Id.* at 861 ("[T]he patentee does not need to have any evidence of damage or lost sales to bring an infringement action.").
[35] *See supra* note 16 and accompanying text.

limited form of exclusivity than that bestowed by patents. The model for the system can be based on the exclusivity provisions of the Hatch-Waxman Act[36] that are applicable to some new drugs and the exclusivity provisions of the new Biologics Price Competition and Innovation Act.[37] Under these FDA administered exclusivity regimes, no generic manufacturer can gain approval to market a drug or biologic product similar to the 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. On the other hand, in order to take advantage of the statutory exclusivity provisions one need not satisfy the strict novelty[38] requirements of the Patent Act. It is these distinctions between patent protection and marketing exclusivity regime that make the latter ideally suited to promoting research and innovation in genetics.

Under the proposed regime, individuals 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 designed after the proper association has been found. By being the sole providers of either tests or treatments (or both), they would be able to recoup their investment and make a profit, and they would be able to do so even if these very same tests and treatments would not qualify for patent protection. On the other hand, by limiting the scope of exclusive rights only to the *sale* of tests or treatments, other researchers would not be constrained in

[36] Drug Price Competition and Patent Term Restoration Act of 1984, *supra* note 33 (codified in relevant parts at 21 U.S.C. § 355).
[37] Patient Protection and Affordable Care Act, Pub. L. No. 111-149, §§ 7001-7002, 124 Stat. 1025 (2010) (codified in 42 U.S.C. § 351(k)(7)).
[38] In this Article I will use the term "novelty" to refer both to the requirements of 35 U.S.C. § 102 (the "non-anticipation" requirement) and 35 U.S.C. § 103 (the "non-obviousness" requirement).

creating their own copies of molecules containing the newly discovered relevant genetic code so long as the purpose in such creation is future research rather than sale to the public. In this way, the information-carrying function of the gene would be preserved in the public domain, whereas the chemical structure of the laboratory-created molecules would be available for exclusive commercial exploitation (for limited time) to one who first discovered the correct genetic code and created said molecule.

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

The next section of the Article is dedicated to laying out the architecture of patent law and applying it to the specific case of nucleic acids. Part III will lay out the principles, history, and philosophical underpinnings of the patent system and discuss why some matter is considered to be patent eligible while other is not. It will also discuss the novelty requirements for a patent once the eligibility bar has been cleared. Next, in Part IV, I will apply the principles from the preceding section to argue that laboratory-created DNA molecules should be and eligible for patent protection under the current law and the philosophical principles underlying it. In Part V I will consider and reject calls for treating DNA as a *sui generis* entity that must be excluded from patent eligibility. Next, in Part VI I argue that given the advances in molecular genetics, though isolated genes may be eligible for patent protection, they are ultimately not entitled to a patent for

failure of the non-obviousness requirements of the Patent Act. I close this section of the Article with the observation that though the patent system is not closed to the innovators and researchers working in the field of molecular genetics, it offers precious little protection and reward for their efforts. Accordingly, I conclude that an alternative system for incentivizing research and innovation in this field is needed.

The final section of the paper consists of two parts. In Part VII, I discuss the current powers of the Food and Drug Administration to regulate drugs, biologics, and medical devices, as well as various statutory exclusivity provisions associated with these regulations. In Part VIII, I propose expanding these provisions to cover novel genetic tests and treatments. Under my proposal, this FDA-based protection would be in lieu to the protection offered by the patent system and allow researchers whose patent applications would be rejected on obviousness grounds to obtain a return on their investment in developing new diagnostic and therapeutic modalities. I close the section by arguing that these alternative, FDA-based exclusivity provisions 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 IX.

II. The Science of Gene Isolation, Sequencing and its Uses

In the discussion of whether genes ought or ought not be patentable, the question of *what* is sought to be patented is often lost. Instead, debates often degenerate into the somewhat strange discussion of whether a human being is patent-eligible.[39] Such

[39] *See* Lauren M. Nowierski, *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

broadsides at the idea of patenting genes overlooks the distinctions between naturally occurring DNA that is present in living human cells, and the isolated and purified DNA that is synthesized in laboratories. Not only is the DNA that is synthesize in laboratories man-made, it is structurally different from the naturally occurring DNA that is found in nature.[40] At the same time, and despite being chemically different, the man-made DNA codes for the same proteins as naturally occurring DNA.[41] The understanding of how and why that is so is crucial to the legal implication for 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 polymer composed of only four types of subunits."[42] The subunits contain bases known as adenine, cytosine, guanine, and thymine.[43] Each of these subunits is attached to the "repetitive sugar phosphate chain almost like four kinds of beads strung on a necklace."[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 stand forming a backbone of the zipper and the A, C, T,

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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.").

[40] *See supra* note 13 and accompanying text.

[41] *See Myriad I*, *supra* note 13, at 222-32.

[42] BRUCE ALBERTS ET. AL., MOLECULAR BIOLOGY OF THE CELL 98 (3rd ed. 1994).

[43] *Id.*

[44] *Id.* at 99.

[45] *Id.* at 60.

[46] *Id.* at 99.

[47] *Id.*

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 "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 into a separate chromosome,[52] and all of the organism's chromosomes taken together carry the entirety of that organism's genetic information – the organism's genome.[53] The DNA is associated with chromosomal proteins (such as histones)[54] which pack the DNA molecule in an orderly way,[55] as well as to 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 contains numerous genes. The human genome contains upwards of 20,000 genes[57] that all have to fit on only 23 pairs of chromosomes. Each chromosome, therefore, contains hundreds or thousands of genes.[58] Although each cell contains

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[48] Ryan McDonald, *Juries and Crime Labs: Correcting the Weak Links in the DNA Chain*, 24 AM. J. L. & MED. 345, 348 (1998); *see also* ALBERTS, *supra* note 42, at 101 (schematically illustrating DNA's structure).
[49] ALBERTS, *supra* note 42, at 101 (modeling and illustrating DNA's three-dimensional structure).
[50] Melissa Kidder, *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, *supra* note 42, at 99.
[52] *Id.* at 337.
[53] *Id.*
[54] *Id*.
[55] *See* ALBERTS, *supra* note 42, at 342.
[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] 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 . . . .").
[58] Smith, *supra* note 17, at 752.

organism's entire genome, not all genes are expressed or "turned on" at all times.[59] That this is so is rather self-evident. If all genes were turned on at all cells all of the times, cell differentiation would be impossible.[60] In other words, cells would not be able to differentially develop into liver cells, brain cells, blood cells, skin cells, etc.[61] That they actually do so is the result of certain genes being expressed in certain cells but not in others.[62] In order to allow for such differential gene expression, the cellular mechanism needs to identify genes which are to be expressed and which are not to be expressed.[63] One way that that is accomplished is through a chemical modification of the DNA molecule.[64] Gene expression may also be regulated by proteins binding to relevant segments of DNA in order to turn it "on" or "off."[65]

As complex as the DNA structure is, DNA itself serves no function[66] other than providing a set of genetic instructions for the production of other molecules important in cellular function – proteins.[67] For reasons not wholly understood,[68] genes have non-coding regions (known as "introns")[69] and interspersed between coding regions (known

[59] *See* ALBERTS, *supra* note 42, at 401.
[60] *Id.* at 401-02.
[61] *Id.*
[62] *Id.* at 402.
[63] *Id.* at 402-04.
[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 (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 Gives Hard Thoughts on Soft Inheritance*, SCIENCEDAILY, (Aug. 8, 2006), http://www.sciencedaily.com/releases/2006/08/060807154715.htm.
[65] *See* Rao, *supra* note 56, at 605.
[66] *Id.* at 104 ("DNA is relatively inert chemically. The information it contains is expressed indirectly via other molecules ….").
[67] *Id.*; Van Tassel, *supra* note 64, at 231. ("[A] gene provides the complete set of instructions on how to build a particular protein …."). DNA can also code for non-protein coding RNA molecules, but for ease of understanding I will focus just on protein coding function.
[68] ANTHONY J. F. GRIFFITHS ET AL., AN INTRODUCTION TO GENETIC ANALYSIS 8 (7th ed. 2000).
[69] ALBERTS, *supra* note 42, at 341.

as "exons").[70] Indeed, the majority of the genetic material, contrary to intuition, consists of the non-coding regions.[71]

A mutation in the codon sequence whether by an inappropriate addition or deletion of a nucleotide or by changing of one nucleotide to another often results in an incorrect amino acid being coded for,[72] which may result in the protein being defective[73] or completely non-functional.[74] Thus, in diagnosing the genetic disorders it is important to know both the normal sequence and the mutations so that either can be identified.[75]

As mentioned previously, the two DNA strands are complementary to each other,[76] but they are not exact mirror image of each other. Thus if one strand, for example, has the sequence AAA, the complementary strand would have a sequence TTT.[77] Since each DNA sequence codes for a specific amino acid, it matters which strand is the "coding" strand. What makes the problem harder is that each strand can have both coding and non-coding regions.[78] Cellular mechanisms have developed to

[70] *Id.*
[71] *Id.*
[72] Brian C. Cannon, *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.").
[73] *See, e.g.*, Janet Brewer, *"Diseases of Place": Legal and Ethical Implications of Surname and Ethnicity as Predictors of Disease Risk*, 9 QUINNIPIAC 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); ALBERTS, *supra* note 42, at 103.
[74] ALBERTS, *supra* note 42, at 103.
[75] *Cf.* Dunne, *supra* note 26, at 479-80 (discussing how scientists diagnose genetic disease by linking mutations to specific conditions).
[76] *See supra* note 47 and accompanying text.
[77] *See supra* note 46 and accompanying text.
[78] Dr. jur. Sandra Schmieder, *Cope 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, 234 n. 30 (2004) ("Genomic (or chromosomal) DNA is double-stranded and consists of interspersed coding and non-coding regions on both strands.").

differentiate between the two when the genetic code is converted into the final product,[79] but until such conversion happens, it is impossible to tell which strand at a given location is which.[80]

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.[81] Not only that, it is a rather complex manual, wrapped in hard to break wrapper, with various pages being inaccessible, and interspersed with completely irrelevant and seemingly gibberish information.[82] Yet, somehow this manual does ultimately get read and followed by the cell. This occurs through two major steps referred to as transcription and translation.[83]

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,[84] but for two exceptions. In the RNA molecule, instead of thymine nucleotides, are replaced with uracil ("U")

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[79] *See* ALBERTS, *supra* note 42, at 227 (discussing gene promoters and gene regulatory proteins).
[80] *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).
[81] *See supra* note 66 and accompanying text.
[82] *See supra* Part II. A.
[83] Stephen H. Schilling, *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).
[84] *Id.* at 225 (noting that the non-template strand's sequence corresponds to the synthesized RNA's sequence).

nucleotides.[85] Additionally, the "backbone" of the RNA molecule is somewhat different from that of the DNA. The sugar molecule in RNA is ribose,[86] whereas in DNA it is deoxyribose.[87]

The initial RNA molecule has eliminated some of the "difficulties" of the DNA. The RNA's nucleotides are not chemically modified,[88] it only has the coding strand rather than interspersed coding and non-coding regions,[89] it only contains a single gene rather than hundreds of genes found on any given chromosome,[90] and it does not have histones bound to it.[91] 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."[92] On the other end, once the DNA to RNA copying is finished a long tail consisting of 100 to 200 adenine nucleotides and known as "poly-A tail" is added.[93] These structures, though they are meant to code for no amino acids, promote both the RNA's stability and permit cellular mechanisms to verify that the strand is intact before beginning the process of producing proteins based on RNA's code.[94]

Additionally, at this stage the RNA (known as the primary transcript)[95] still contains both introns and exons.[96] If that was were the process stopped, the correct proteins would not be produced because the cellular mechanism would be forced to read

[85] *Id*. at 104.
[86] *Id.* at 60.
[87] *See supra* note 45 and accompanying text.
[88] *See supra* note 64 (describing cytosine methylation as occurring in DNA).
[89] *See* ALBERTS, *supra* note 42, at 340-41 (noting that RNA is a single-strand molecule and carries information for a single gene).
[90] *Id*. at 340.
[91] Histone, by definition, is a DNA-binding protein. *Id.* at 342.
[92] *Id.* at 369.
[93] *Id.* at 370.
[94] *Id.* at 369-70.
[95] ALBERTS, *supra* note 42, at 105.
[96] *Id.*

introns as codons coding for particular amino acids, thus creating proteins with an incorrect structure.[97] Therefore the RNA needs to be further modified before becoming a proper template for protein synthesis. This process is known as RNA splicing. Only once the RNA is properly spliced, is it ready to be translated into a protein structure.[98] At this point the spliced and modified RNA is known as messenger RNA or mRNA.[99] With majority of the genetic code being spliced out back in the nucleus, with the addition of the 5' cap and a poly-A tail, and with the substitution of uracil for thymine, and with 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 which serves as a template for protein synthesis is mRNA, when scientists study genes they often have to work with DNA. The reason for that is fairly straight-forward. Recall that not all genes are active all the time in all of the cells.[100] Some are quiescent, while others may be turned on almost permanently, and still others are turned on or off depending on the cell type, the point in organism's life-time and other factors.[101] Since mRNA is produced only after the gene is turned on for transcription and translation, the mRNA is present only when a particular protein is about to be or is in the process of being produced.[102] By contrast, the cellular DNA contains the code for all genes at all times.[103] True, many of those genes are turned off, all have

[97] *See id.* at 232-36 (describing how mRNA is "read" by the cellular mechanism).
[98] *See supra* note 97 and accompanying text.
[99] ALBERTS, *supra* note 42, at 105.
[100] *See supra* notes 59-63 and accompanying text.
[101] *Id.*
[102] *Id.*
[103] *See supra* note 53 and accompanying text.

fairly randomly interspersed non-coding regions, and otherwise difficult to access and assess, but nonetheless, because every cell in the organism contains that organism's entire genome,[104] 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, not yet active, but one which will become active in subsequent years, which codes for cancer. Since the gene is not presently active, it is not presently being transcribed, so no mRNA or relevant protein 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 onset of cancer then, one needs to 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 actually carries all of the organism's genetic information – the DNA molecule.

On the other hand, since any given DNA molecule contains simply too much information, beginning the research there would be looking for a needle in a hay stack. In order to locate and identify a gene, scientists create a molecule that would bind to the region of interest and when bound could be identified.[105] Such molecules are often known as probes and are targeted to the DNA region of interest.[106] Utilizing well-known processes, the scientists can "reverse transcribe" the mRNA and create a DNA string that would be an identical copy of *in vivo* anti-sense DNA strand's coding regions.[107] This newly created DNA strand is referred to as complementary DNA or cDNA (because it is

[104] *See supra* note 59 and accompanying text.
[105] *See* ALBERTS, *supra* note 42, at 300-03.
[106] *See generally* Andrew Chin, *Artful Prior Art and the Quality of DNA Patents*, 57 ALA. L. REV. 975, 1024-26 (2006) (describing hybridizing probes).
[107] *Id.*

complementary to the mRNA strand which was used as a template.[108] The cDNA is a completely man-made molecule and does not duplicate anything that exists in nature.[109] It also differs from the mRNA molecule. First, since the mRNA is used as a template, the cDNA is complementary to the mRNA rather than a copy of it.[110] Second, since it is a DNA molecule, it again uses thymine nucleotides rather than uracil.[111] Third, as described *ante*, the sugar backbone of the RNA and DNA strands differ.[112] Nor is the cDNA strand identical to the *in vivo* DNA. First, and most obviously, it is missing introns.[113] Second, since the cDNA is a laboratory produced molecule, it is not subjected to inter-cellular regulation discussed *ante*. 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.[114] Nothing about a cDNA then is "naturally occurring," rather it is a completely artificial construct, though a useful one for studying naturally occurring DNA.

Once a cDNA is constructed it can be used to identify genes *in vivo*. While the cDNA strand *as a whole* is not complementary to any *in vivo* DNA sequence because

[108] *Id.*; *Myriad I*, *supra* note 13, at 198.
[109] *See* Michael D. Davis, *The Patenting of Products of Nature*, 21 RUTGERS COMPUTER & TECH. L.J. 293, 316 (1995).
[110] *See* ALBERTS, *supra* note 42, at 282-83 (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?*, 12 U. PITT. J. TECH. L. & POL'Y 1, 66-67 (2011).
[111] Rogers, *supra* note 110, at 66-67.
[112] *See supra* notes 86-87 and accompanying text.
[113] Since the cDNA is complementary to the mRNA, and since mRNA is a genetic molecule from which introns have been spliced out, the cDNA doesn't have introns either.
[114] Region complementary to the 5' cap is also initially present, but is usually cleaved off when the molecule is further processed in the laboratory.

cDNA lacks introns,[115] there are sufficient amount of overlap to allow the cDNA to attach itself ("hybridize" with) the native DNA.[116] Once the cDNA hybridizes to native DNA, the entire sequence of the native genes (including introns) can be identified by looking at the various points of hybridizations, and figuring out where the end-points of each gene are.[117] Then the entire gene of interest can be excised with the help of specific and well-known enzymes[118] and its entire sequence can be discovered by well-known (and mostly automated) methods.[119]

The genetic sequence, once discovered, presents multiple opportunities for scientific advances. Probes may be constructed to test for mutated native DNA strand,[120] in order to diagnose predisposition to cancer and other diseases.[121] Laboratory created cDNA can also be injected into bacteria causing the modified bacteria to express proteins coded for by the injected sequence.[122] Thus, a DNA sequence coding for human hormone insulin was injected into bacteria which then caused bacteria's own cellular mechanism to express the new gene and produce the hormone it has not (obviously) previously produced.[123] The protein thus produced could be used for the purposes of further research,[124] as well as for treatment of human diseases caused by the deficiency of said protein (which in the case of insulin would be diabetes).

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[115] Recall that cDNA is synthesized from mRNA from which introns have been excised.
[116] *See* ALBERTS, *supra* note 42, at 305, 314.
[117] *Id.* at 314.
[118] Anne Lawton, *The Frankenstein Controversy: The Constitutionality of a Federal Ban on Cloning*, 87 KY. L.J. 277, 285 (1998-1999).
[119] Golden, *supra* note 28, at 114-15.
[120] *See supra* note 105-106 and accompanying text.
[121] *See Myriad I*, *supra* note 13, at 198; ALBERTS, *supra* note 42, at 300.
[122] ALBERTS, *supra* note 42, at 319-21.
[123] Jake J.Allen, *Conducting Embryonic Stem Cell Research on Native Lands in Michigan*, 11 MICH. ST. J. MED. & LAW 395, 445 n. 39 (2007).
[124] ALBERTS, supra note 42, at 320.

Isolated genes as a whole are also useful for both research and treatment. Though isolated "full" genes[125] contain non-coding regions, they are more useful in certain experiments. For instance, full genes are better suited for trans-genenic animals (*i.e.*, animals with a foreign gene inserted into their native genome) studies because they somehow increase the odds that the inserted gene will remain stable and be transcribed into the host animal's RNA.[126]

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.[127] 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.[128]

Finally, as to be expected, 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 combination of a number of genes working together.[129] In these situations, it is often the case that

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[125] By "full" I mean code with introns present.

[126] Ralph L. Brinster et al., *Introns Increase Transcriptional Efficiency in Transgenic Mice*, PROC. NATL. ACAD. SCI. USA (Feb. 1988), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC279650/pdf/pnas00255-0203.pdf.

[127] Steven M. Silverberg, *Safe at Home? Assessing U.S. Efforts to Protect Youths from the Effects of Performance Enhancing Drugs in Sports*, 35 BROOKLYN J. INT'L L. 271, 307 (2010); Genetics Home Reference, *Gene Therapy* (Mar. 5, 2012), *available at* http://ghr.nlm.nih.gov/handbook/therapy?show=all.

[128] Efthimios Parasidis, *A Uniform Framework for Patent Eligibility*, 85 TUL. L. REV. 323, 374 (2010); 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). *See also* ALBERTS, *supra* note 42, at 327-30 (describing the process of creating transgenic mice and other organisms).

[129] *See, e.g.*, Michael Tomasson, M.D., *Legal, Ethical, and Conceptual Bottlenecks to the Development of Useful Genomic Tests*, 18 ANN. HEALTH L. 231, 236 (2009); Courtney C. Scala, *Making the Jump From Gene Pools to Patent Pools: How Patent Pools Can Facilitate the Development of Pharmacogenomics*, 41 CONN. L. REV. 1631, 1667 n.167 (2009).

expression of some genes is directly affected by expression of others.[130] Because of the complex nature of genetic expression, scientists need to work with the already discovered and described genes in order to continue their exploration.[131]

D. Summary

As can be seen from the foregoing discussion, genetic research is a complex endeavor that involves molecular manipulation, creation of new molecules unknown in nature, and often, combining various pieces of DNA from various unrelated organisms with one another in order to produce the desired product. These manipulations are complex, involve breaking of old and creation of new chemical bonds, and require 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 the natural state of being. However, viewed from the content and informational perspective, DNA molecules created in the laboratory are identical to the 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.

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[130] *See* Wolf Reik, *Stability and Flexibility of Epigenetic Gene Regulation in Mammalian Development*, 447 NATURE 425, 425 (2007); Jonathan Kaplan, *The Impact of Behavioral Genetics on the Criminal Law: Misinformation, Misrepresentation, and Misuse of Human Behavioral Genetics Research,* 69 LAW & CONTEMP. PROB. 47, 50 (2006). 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, 1338 (2008) (discussing histone H4 gene); *supra* notes 56, 65 and accompanying text (discussing the influence of binding proteins on gene expression). If, then, the upstream gene undergoes mutations, then it is not surprising that the expression of downstream genes would be affected.

[131] *See, e.g.*, *Myriad I*, *supra* note 13, at 187 (describing the work of one of the plaintiff's, Dr. Harry Oster).

Both viewpoints are correct as a matter of scientific principles, yet leads to a distinctly different legal conclusion because the legal outcome largely depends on whether these laboratory-created molecules are viewed as "man-made" or "naturally occurring."

III. The Principles, Precedents, and Purposes of Patent Law

A. The Basic Dichtomy 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 rights" to "inventors" for their "discoveries."[132] Congress has taken advantage of this grant of power throughout the Nation's history by passing various Patent Acts beginning as early as 1790.[133] Although both technology and the law changed and evolved from the late 18th century to the mid-20th century when Congress adopted the 1952 Patent Act[134] (currently in effect as amended),[135] at least one basic consideration of what is patent-eligible[136] remained fairly constant.

[132] U.S. CONST. art. I, § 8, cl. 8.
[133] Patent Act of 1790, Ch. 7, 1 Stat. 109 (April 10, 1970).
[134] Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (July 19, 1952) (codified as amended at 35 U.S.C. §§1-376) (1994).
[135] Rebecca Greendyke, *No Patent for You!: How KSR v. Teleflex's Nonobviousness Test Conflicts with the Scientific Method and Removes the Incentive to Innovate*, 35 DAYTON L. REV. 413, 420 (2010) ("The Patent Act of 1952 is the current patent statute.").
[136] 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. The term "patenable" (that is often used to mean "patent-eligible" thus creating confusion) I reserve 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.

From the very first Patent Act, Congress has always been generous about the potential scope of patent eligibility.[137] In fact, Thomas Jefferson, who was (through his position as Secretary of State) the first *de facto* administrator of the Patent Office,[138] and the author of the 1793 Patent Act,[139] wrote that "ingenuity should receive a liberal encouragement."[140] This liberal approach persisted and was readopted in the 1952 Act.[141] The principal drafter of that Act testified that "anything under the sun made by man" is included within the scope of patent-eligible subject matter.[142] The Committee reports accompanying the Act expressed the same view.[143] This broad view that almost all things are patent-eligible has found favorable reception in the courts going back to at least the middle of the 19th century.[144] Thus, in *O'Reilly v. Morse*,[145] the Supreme Court

[137] *See In re* Bilski, 545 F.3d 943, 977 (Fed. Cir. 2008) (Newman, J., dissenting) ("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.").
[138] Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 7 (1966); Keith Aoki, *DISTRIBUTIVE JUSTICE AND INTELLECTUAL PROPERTY: Distributive and Syncretic Motives in Intellectual Property Law (with Special Reference to Coercion, Agency, and Development)*, 40 U.C. DAVIS L. REV. 717, 801 n. 101 (2007).
[139] *Graham*, *supra* note 138, at 7.
[140] Thomas Jefferson, *Letter from Thomas Jefferson to Oliver Evans*, *in* 5 WRITINGS OF THOMAS JEFFERSON 75-76 (Washington ed., 1895). Jefferson expressed this view despite being generally opposed to monopolies. Indeed, Jefferson was initially opposed to patents, but later came to view them as beneficial if limited in time.
[141] *See Bilski*, *supra* note 137, at 978.
[142] *Hearings on H. R. 3760 Before Subcomm. No. 3 of the H. Comm. on the Judiciary, 82d Cong., 1st Sess., 37 (1951)* (cited in Diamond v. Chakrabarty, 447 U.S. 303, 309 n.6 (1980)).
[143] *See* S. REP. NO. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. REP. NO. 1923, 82d Cong., 2d Sess., 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 made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled." H. R. REP. NO. 82-1923, at 7. In his concurrence in *Bilski*, Judges Dyk and Mayer took the position, that read in context, the phrase actually excludes certain man-made inventions from eligibility for patents. *Bilski*, *supra* note 137, at 976 (Dyk, J., concurring), 1000 (Mayer, J., dissenting), 1011 (though Judge Mayer styled his opinion as a "dissent," he actually agreed with the majority's judgment, but felt that the majority did not go far enough). *See also* Bilski v. Kappos, 130 S. Ct. 3218, 3248 (2010) (Stevens, J., concurring in the judgment). *But see* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) ("Congress intended statutory subject matter to 'include anything under the sun that is made by man.'") (citing to the Committee Reports).
[144] *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.").
[145] O'Reilly v. Morse, 56 U.S. 62 (1854).

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,"[146] 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."[147] Through the years, the Supreme Court (and lower courts) generally adhered to this understanding of the breadth of the patent-eligible subject matter. In the seminal *Diamond v. Chakrabarty*[148] opinion the Court stated that when the invention in question (whatever that invention happens to be) "is not nature's handiwork, but [inventor'] own [,] it is patentable [*i.e.*, patent-eligible] subject matter under § 101."[149]

Nonetheless, despite the very broad facial language of Section 101 (and its predecessors), and the judicial opinions re-affirming that Congress indeed always intended patent eligibility to be "merely a coarse filter,"[150] it has long been established that Section 101 is not without limits.[151] Since at least 1853[152] the courts have held that

[146] *Id.* at 119.
[147] *Id.*; *see also* American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11 (1931); Shell Development Co. v. Watson, 149 F. Supp. 279, 283 (D.D.C. 1957).
[148] *Chakrabarty*, *supra* note 143.
[149] *Id.* at 310.
[150] John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1059 (2011).
[151] *See e.g.*, *Chakrabarty*, *supra* note 143, at 309.
[152] *See* Le Roy v. Tatham, 55 U.S. 156, 174-175 (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.").

"[t]he laws of nature, physical phenomena, and abstract ideas" are not patent-eligible.[153] In order to be patent-eligible, an invention "must come from the application of the law of nature to a new and useful end."[154] 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…."[155] It follows then that that which is naturally occurring, whether a physical entity such as a mineral or a scientific principle or formula, is not patent-eligible.[156]

This dividing line, though provided for neither in the Constitutional nor statutory text, is not arbitrary, but rather stems directly from the underlying purposes of the patent law. Over the generations, various philosophical and economic theories of why patent law should exist in the first place have been advanced, and though these theories differ, they all in one way or another support the denial of exclusive rights for mere discoveries. Without getting into too detailed of a discussion on the justification for patent rights – after all this Article is not meant to be a philosophical exposition on the subject – I want to briefly sketch out chief arguments for the availability of patent protection, because these arguments shed light on both empirical and normative claims that I will make.

B. Traditional Justifications for Patent Protection

At its most basic levels, arguments in favor of exclusive patent rights are the same, or at least very similar to the arguments for property rights generally.[157] These

[153] *Chakrabarty*, *supra* note 143, at 309 (citing to, *inter alia Le Roy*, *supra* note 152).
[154] *Funk Bros.*, *supra* note 32, at 130.
[155] *In re* Nuijten, 500 F.3d 1346, 1364 (Fed. Cir. 2007).
[156] *Chakrabarty*, *supra* note 143, at 309.
[157] I. Trotter Hardy, *Not so Different: Tangible, Intangible, Digital, and Analog Works and Their Comparison for Copyright Purposes,* 26 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, *Revenue Streams and Safe Harbors: How Water Law Suggests a Solution to Copyright's Orphan Works Problem,* 16 B.U. J. SCI.

arguments can be roughly divided into two subsets: "moral justifications"[158] and "economic justifications."[159]

The utilitarian argument for patents is fairly straightforward and (as with most utilitarian arguments) reduces to an economic cost-benefit analysis.[160] On one side of the scales is the "progress of science and useful arts,"[161] and on the other side is the limitations on competition[162] and availability of whatever products and processes are subject to the patent's monopoly power.[163] 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.[164] In other words, people will innovate more if the reward for

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& 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.").

[158] *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.").

[159] William W. Fisher III, *Reconstructing the Fair Use Doctrine*, 101 HARV. L. REV. 1659, 1687-88 (1988) ("The utilitarian theory ... is undoubtedly the most venerable and oft-cited of the justifications for the American law of intellectual property.").

I readily admit that often these two subsets are overlapping and that the categorization is imprecise. However, this nomenclature is useful for the present purposes.

[160] Benjamin H. Barton, *Do Judges Systematically Favor the Interests of the Legal Profession?*, 59 ALA. L. REV. 453 (2008).

[161] *See* Megan M. La Belle, *Patent Litigation, Personal Jurisdiction, and the Public Good,* 18 GEO. MASON L. REV. 43, 50 (2010); Kurt Van Thomme, *Prosecution History Estoppel after Festo: Can an Equivalent ever Break Through the File Wrapper?,* 53 DRAKE L. REV. 1099, 1124 (2005).

[162] *See* Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. REV. 33 (2004) ("PATENTS ARE INTENDED to allow a patent holder to obtain monopoly profits. To have this effect, a patent must limit competition.") (capitalization in the original); Gregory N. Mandel, *The Generic Biologics Debate: Industry's Unintended Admission that Biotech Patents Fail Enablement*, 11 VA. J.L. & TECH. 8, 20 (2006) ("Patent exclusivity rights limit competition . . . ."); Andrew Beckerman-Rodau, *Patent Law - Balancing Profit Maximization and Public Access to Technology*, 4 COLUM. SCI. & TECH. L. REV. 1, 26 (2002-03).

[163] *Franklin Pierce Law Center's Sixth Biennial Patent System Major Problems Conference*, 37 IDEA 623, 654 ("[P]atents inherently limit access to some degree …. The access issue is applicable to many types of technologies ….").

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

such innovation is higher.[165] Additionally, patents are a *quid pro quo* transaction in which the inventor obtains exclusive rights in exchange for disclosing his invention to the public.[166] Thus, patents build on the common wealth of mankind because they increase "the public stock of knowledge,"[167] allowing it to avoid having to "reinvent the wheel" every time.[168]

On the other hand, because patents grant exclusive rights to make, sell, and use inventions,[169] 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 patent exclusivity.[170] 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,"[171] and therefore will be unavailable for public use during the lifetime of the patent.[172] In other words, "[t]he greater the

[165] Kevin Arquit, *Comparative Antitrust Policies in Mergers and Acquisitions: Keynote Address,* 43 CORNELL INT'L L.J. 1, 17 (2010); Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 548 (2009).
[166] *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.").
[167] Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 513 (1917).
[168] *See* Fromer, *supra* note 165 at 548-49.
[169] 35 U.S.C. § 271(a)(2012).
[170] Nathan Machin, *Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act*, 87 CALIF. L. REV. 421, 438 (1999); Special Equip. Co. v. Coe, 324 U.S. 370, 382-83 (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.") (internal quotations and citations omitted).
[171] Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 839 (1990).
[172] 35 U.S.C. § 271(a) (2012) ("[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.").

patent protection is, the smaller the benefit to the competitors [and the public] from the information contained in the patent grant because the less they can do with it."[173]

In a utilitarian calculus then, too much patent protection is as (or perhaps more) suboptimal as too little protection.[174] Justice Breyer succinctly summed up the dilemma when he observed that

> [S]ometimes *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 arrangements, and by raising the costs of using the patented information, sometimes prohibitively so.[175]

Patent law, then, must always maintain the uneasy balance between providing sufficient incentives to invent and disclose which would in the aggregate promote further innovation and common good on the one hand, and guarding against granting overly broad patents that would retard further research and thus be detrimental to the common good on the other hand.[176] It is hard to imagine a broader grant of exclusive rights than

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[173] 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." *See* 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.

[174] Kevin Emerson Collins, *Constructive Nonvolition in Patent Law and the Problem of Insufficient Thought Control,* 2007 WIS. L. REV. 759, 767 (2007).

[175] Lab Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 127 (2006) (order dismissing certiorari as improvidently granted) (Breyer, J., dissenting) (citations omitted).

[176] Clemens Kerle, *International IP Protection for MGO – 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.").

the grant of exclusivity on "[t]he 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,[177] 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 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 argue that it is just to reward one's labor. For instance, John Locke argued that "[w]hatever, [anyone] removes out of the state that Nature hath provided and left it in, he hath mixed his labor with it, and joined to it something that is his own, and thereby makes it his property."[178] Realizing that pure application of his theory could result in unjust over-appropriation of previously commonly held goods,[179] Locke maintained that such appropriation is permissible "only so long as there be 'enough, and as good, left in common for others.'"[180]

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

[178] *See* JOHN LOCKE, *The Second Treatise of Government*, in TWO TREATISES OF GOVERNMENT ch. v, § 27, at 288 (Peter Laslett ed., 1988).

[179] *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.").

[180] Peter B. Edelman, *The Next Century of Our Constitution: Rethinking Our Duty to the Poor*, 39 HASTINGS L.J. 1, 23 (1987) (quoting LOCKE, *supra* note 178, ch. v, § 26, at 288). This is known as "Lockean proviso." *See also* David Elkins, *Responding to Rawls: Toward a 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

Similarly, Wilhelm Hegel's argued that "to achieve proper self-development – to be a person – an individual needs some control over resources in the external environment."[181] According to Hegel "[a]ttainments, eruditions, 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."[182] Thus, in order to "propertize" one's ideas, one needs to "embody them in something external,"[183] 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."[184]

Under the Locke-Hegel approach foreclosing patent eligibility for "[t]he laws of nature, physical phenomena, and abstract ideas" is wholly appropriate.[185] Not only are "[t]he laws of nature, physical phenomena, and abstract ideas" not product of anyone's labors,[186] but appropriating them for one's exclusive use (to the extent that is possible) of necessity leaves other men 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. Nor can it be said that mere discovery and

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HARV. L. REV. 1535, 1550 (1996) (noting that when one takes "more than his share," he is violating Lockean principles).

[181] Margaret Jane Radin, *Property and Personhood*, 34 STAN. L. REV. 957, 957 (1982).

[182] Georg Friedrich HEGEL, PHILOSOPHY OF RIGHT § 43 (T.M. Knox trans. 1967) (1821).

[183] *Id.*

[184] O'Reilly, 56 U.S. at 119.

[185] Joan E. Schaffner, *Patent Preemption Unlocked,* 1995 WIS. L. REV. 1081, 1091(1995) ("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.").

[186] *See Funk Bros*., *supra* note 25, at 130 (stating that naturally occurring qualities of bacteria are not the result of the labor of the inventor, but rather "the work of nature").

observation of "[t]he laws of nature, physical phenomena, and abstract ideas" is sufficient external embodiment to allow the discoverer exclusive property rights.

The 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.[187] In Rawlsian world, justice demands first that everyone has same rights and access to basic liberties,[188] 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.[189] Additionally, Rawls insists decisions on the rules to govern society, be done in the "original position" or "behind the veil of ignorance" – *i.e.*, not knowing what our starting position in life will be.[190]

What follows from the Rawls' approach (as argued by Robert Merges in his book, *Justifying Intellectual Property*,[191]) is that while some patent protection is permissible and perhaps even desirable,[192] overly broad patent protection that assigns up too much of resources to one individual (and therefore results in an unequal distribution) is not permissible.[193] In the Rawlsian paradigm, exclusive rights to a natural phenomenon or the law of nature as such violate the second principle, because the inequality created does not benefit the least well off in the society and perhaps even hurts them (by foreclosing

[187] 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.
[188] JOHN RAWLS, A THEORY OF JUSTICE § 46, 266 (1999).
[189] *Id.*
[190] *Id.* at § 24, 118-23.
[191] *See generally* ROBERT MERGES, JUSTIFYING INTELLECTUAL PROPERTY 68-101 (2011).
[192] 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.
[193] MERGES, *supra* note 191, at 126-33.

the opportunity for others to provide competing products that would be governed by the patented law of nature).[194]

In summary, all theories, whether based in 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 Act and the Natural Law Exception

In the previous sections 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, "'[o]nly God works from nothing. Men must work with old elements.'"[195] 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 some sort of naturally-occurring bacterial vulnerability to a particular chemical

[194] *See, e.g.*, Eli, *supra* note 22, at 372-373 (2011) ("[G]ranting 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.").

Narrow patents, on the other hand, strengthen the competition (and therefore benefit the consumers) by encouraging competitors to design around the patent. *See* Michelle Armond, *Introducing the Defense of Independent Invention to Motions for Preliminary Injunctions in Patent Infringement Lawsuits*, 91 CALIF. L. REV. 117, 162 (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."); Georgia E. Kralovic, *The Principle of Fair Notice: Is it Prudent Guidance for the Future of Patent Law?*, 26 PEPP. L. REV. 89, 93 (1998).

[195] 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. & TRADEMARK OFF. SOC'Y 331 (1983)).

interaction,[196] and an airplane flies only because of Bernoulli's forces – a natural phenomenon.[197] Yet, an airplane is patent eligible,[198] as are newly discovered antibiotics.[199] So how do the courts draw the line between patent-ineligible "laws of nature [and] physical phenomena," and patent-eligible "application of [that] law of nature to a new and useful end."[200]

This differentiation is especially difficult in biological arts where the interrelation and interaction of various chemical entities and organisms are governed by the immutable laws of nature,[201] but where such interaction is only brought about by human intervention.[202] Courts have struggled (and muddled through) this distinction for decades without finding a clear-cut and bright line resolution to the dispute.[203] Though the decisions have not successfully delineated a legal bright line between "laws of nature" and "application of laws of nature," so guideposts can be gleaned from a review of those decisions. These guideposts, while not necessarily determinative (given the overall lack of clarity in this area), are, especially when viewed in light of the underlying theories justifying existence of patent law in the first place, quite helpful in determining what

[196] *See* ALBERTS, *supra* note 42, at 240-41.
[197] Andrew A. Schwartz, *The Patent Office Meets the Poison Pill: Why Legal Methods Cannot be Patented,* 20 HARV. J. L. & TECH. 333, 336 (2007).
[198] *See, e.g.*, U.S. Patent No. 821,393 (issued May 22, 1906) (Patent by the Wright Brothers directed to a "flying machine.")
[199] *See, e.g.*, U.S. Patent No. 4,670,444 (issued on June 2, 1987) (Patent directed to antibiotic Ciprofloxacin and held by Bayer A.G.).
[200] *Funk Bros.*, *supra* note 25, at 130.
[201] 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 processes are ultimately obedient to the laws of physics and chemistry.").
[202] *See, e.g.*, *Chakrabarty*, *supra* note 143 (recognizing that the bacteria in question was man-made though its behavior was governed by the laws of nature); *Gilbert*, *supra* note 201 (recognizing that the molecule in question was man-made, though it obeyed the laws of nature).
[203] Indeed, in a recent oral argument, Justice Breyer observed that "If you look at the Court's cases, they seem to say Flook, one thing, and Diehr another thing." Mayo Collaborative Services, et al. v. Prometheus Laboratories, Inc., No. 10-1150 U.S. Supreme Court, at 14 (2011), *available at* http://www.supremecourt.gov/oral_arguments/argument_transcripts/10-1150.pdf.

level of protection are available for discoveries and inventions in the area of genetics. To that end, I will briefly review the development and the current state of the law in this area.

One of the earliest cases dealing with biomedical patents was *Parke-Davis & Co. v. H. K. Mulford Co.*[204] authored by Judge Learned Hand. There, the patent was directed to highly purified and concentrated adrenaline – a naturally occurring hormone.[205] Despite the fact that adrenaline is naturally occurring, its function and structure has long been known, and it has been therapeutically used,[206] Judge Hand upheld the patent reasoning 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.[207] According to 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.[208]

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

[204] Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95, 98 (C.C.D.N.Y. 1911).
[205] Adrenaline is a hormone produced by the body's 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 223-233 (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, *Mr. Peanut Goes to Court: Accommodating an Individuals Peanut Allergy in Schools and Day Care Centers under the Americans with Disabilities Act,* 14 J.L. & HEALTH 87, 90-91 (1999-2000).
[206] *Parke-Davis*, *supra* note 204, at 114-15.
[207] *Id.* at 103
[208] *Id.*

commercial) opportunities for adrenaline.[209] However, it is equally true that the extracting, purifying, and concentrating adrenaline did not change its chemical compound or alter its function.[210] Nonetheless, the *Parke-Davis* opinion (though written by a single District Judge) has been widely cited and relied on.[211]

Though *Parke-Davis* does not necessarily leave one with a clear and simple rule (after all, how "new" and "purified" from the therapeutic and commercial perspective does a thing have to be before becoming patent-eligible?) it at the very least provided a guiding principle, however imperfect. The Supreme Court, however, muddied the waters further in subsequent decisions. In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*,[212] the claims were directed to a bacterial mixture.[213] Each of the bacterial strains in the mixture was both naturally occurring and well known.[214] 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.[215] The Supreme Court held the subject matter of the invention did not qualify for 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[, f]or patents cannot issue for the discovery of the phenomena of nature."[216]

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[209] Ashley McHugh, *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.").

[210] *Parke-Davis*, *supra* note 204, at 107 (noting that "[t]he 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" in suit).

[211] *See, e.g.*, *Myriad II*, *supra* note 13, at 1352, 1360, 1378 (Fed. Cir. 2011); *In re* Bergy, 596 F.2d 952, 975 (C.C.P.A. 1979); *In re* Fisher, 188 F.2d 509, 511 (C.C.P.A. 1962); Merck & Co. v. Olin Mathieson Chemical Corp., 253 F.2d 156, 162-63 (4th Cir. 1958); *In re* Mays, 175 F.2d 570, 573 (C.C.P.A. 1949). A quick Lexis search revealed that the case is also cited and discussed in over 175 law review articles.

[212] *Funk Bros.*, *supra* note 25.

[213] U.S. Patent No. 2,200,532 (filed Aug. 24, 1938)

[214] *Funk Bros.*, *supra* note 25, at 129.

[215] *Id.* at 129-30.

[216] *Funk Bros.*, *supra* note 25, at 130.

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,[217] the Court opined that

> 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.[[218]] 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.[219]

The rule announced in *Funk Brothers*, if faithfully applied, would preclude patenting vast amount of discoveries in biological sciences.[220] 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 Brothers* rule were followed, merely "an application of [a] newly-discovered natural principle."[221] At the same time, *Funk Brothers,* at last, announced a clear, if highly problematic, rule. Nonetheless, this state of affairs would not last. "Although the

[217] *See Parke-Davis*, *supra* note 204, at 103.
[218] 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, utility of the bacteria in mixture is much higher than the utility of it outside of mixture.
[219] *Funk Bros.*, *supra* note 25, at 131.
[220] *Cf.* Rebecca S. Eisenberg, *Genetics and the Law: Patenting the Human Genome*, 39 EMORY L.J. 721, 725 (1990) ("Although the Funk Brothers decision has never been overruled, in retrospect it seems to represent the high-water mark in the "products of nature" doctrine. Subsequent case law does not deny patent protection to all inventions composed of naturally occurring products or manifesting laws of nature.").
[221] *Funk Bros.*, *supra* note 25, at 131.

Funk Brothers decision has never been overruled, in retrospect it seems to represent the high-water mark in the 'products of nature' doctrine."[222]

In *Diamond v. Chakrabarty*,[223] Dr. Ananda Chakrabarty developed and attempted to patent a genetically modified bacterium capable of breaking down crude oil.[224] The PTO rejected the application and Dr. Chakrabarty appealed.[225] In reversing the PTO's decision, the Supreme Court distinguished (without overruling) *Funk Brothers* 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.'"[226] The Court went on to say that while in *Funk Brothers* each strain of the bacteria present in the mixture retained its original and nature-endowed qualities, the Chakrabarty bacterium had qualities that were new and given to it by the inventor.[227] Under this reasoning, though bacteria are naturally occurring organisms, *modified* bacteria with non-naturally occurring biological properties are patent eligible.[228]

In 2012, the Court only made the confusion worse when it decided *Mayo Collaborative Servs. v. Prometheus Labs.*[229] In *Prometheus*, the claim was directed to a method of adjusting medical treatment depending on the amount of active metabolite in the patient's blood.[230] The patented method involved just three steps: a) administering a well-known drug, b) measuring the level of the drug's metabolite, and c) considering

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[222] Eisenberg, *supra* note 220, at 725.
[223] *Chakrabarty*, *supra* note 143.
[224] *Id.* at 305.
[225] *Id.* at 306.
[226] *Id*. at 310 (quoting Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887) (alteration in original)).
[227] *Id.*
[228] *See id.* at 309-10.
[229] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S.___, 2012 U.S. LEXIS 2316 (Mar. 20, 2012).
[230] *Id.* at *12-13.

changing the drug's dose depending on the measurement results.[231] The Supreme Court held this invention to not be eligible for a patent concluding that the relationship between metabolite's concentration and drug's effect is a pure law of nature.[232] 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."[233] 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 assurance that the process is more than a drafting effort designed to monopolize the law of nature itself."[234]

This is where the law presently stands.[235] The Court has continued to adhere to the idea that "laws of nature" and "natural phenomena" are not patent eligible subject matter.[236] 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 the recent debate on the patent eligibility of genetic materials even the federal government as a whole could not agree on a uniform position.[237] Nonetheless, as incoherent as the

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[231] *Id.* at *14-15.
[232] *Id.* at *18.
[233] *Id.* at *27-28.
[234] *Id.* at *19.
[235] For now I exclude from discussion *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 section. 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 it was an "abstract idea," rather than on the grounds that it was a law of nature. *Chakrabarty*, *supra* note 143, at 3229-30.
[236] *See Bilski*, *supra* note 143, 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.") (internal citations and quotations omitted).
[237] The positions taken by the Solicitor General's office and the USPTO in the *Myriad* litigation were quite different. Whereas the USPTO (in its District Court brief) argued that isolated and purified genes are in fact patent eligible (Br. at 20-23; *available at* http://www.genomicslawreport.com/wp-

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,"[238] and inventions which apply those laws of nature to create "for every practical purpose a new thing commercially and therapeutically."[239] 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 talk about the additional requirement of novelty that the Patent Act imposes on applicants.

D. Beyond Patent Eligibility – The Novelty Requirement

Up until now, I have been focusing on patent eligibility of an invention. Eligibility, though, is but a first 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 Article 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*."[240] Only if the invention satisfies all other requirements of Title 35 is it patentable. Judge Rich[241] described the system thus:

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content/uploads/2010/01/USPTO-Memo.pdf), the Solicitor General argued that genes that are merely purified and isolated are not patent eligible (Br. at 17-36; *available at* http://www.aclu.org/files/assets/2010.10.29_-_United_States_Amicus_Brief.PDF). (The Solicitor General's office did agree with the PTO that cDNA is patent eligible. Br. At 14-17).

[238] *Funk Bros.*, *supra* note 25, at 130.

[239] *Parke-Davis*, *supra* note 204, at 103.

[240] 35 U.S.C. § 101 (2012) (emphasis added).

[241] Giles Rich was not only the pre-eminent 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 Act. *See* A. Samuel Oddi, *Regeneration in American Patent Law: Statutory Subject Matter*, 46 IDEA 491, 546 (2006).

> 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.
> If the inventor holds the three different keys to the three doors, his invention (here assumed to be "useful") qualifies for a patent, otherwise not . …[242]

The mere fact then that someone has worked with patent eligible subject matter does not entitle him to a patent (does not make that matter patentable) unless a) the work resulted in something *new* (*i.e.*, something not previously described or discovered)[243] and

[242] *Bergy*, *supra* note 211, at 960-62 (all alterations in the original).
[243] 35 U.S.C. § 102 (2012). 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 § 102 test, the prior art has to disclose the *exact same* invention. *See* Titanium Metals Corp. v. Banner, 778 F.2d 775, 780 (Fed. Cir. 1985) ("anticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where 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. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356 (Fed. Cir. 2007) (noting that even when chemical compounds

b) the result is a fairly significant improvement upon prior art (*i.e.*, not obvious, from the perspective of an ordinary skilled artisan, variation on the previous state of affairs).[244] "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.'"[245]

Under *KSR Int'l Co. v. Teleflex, Inc,*[246] 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.[247] Though progress in the chemical arts is held to be more unpredictable than in other fields,[248] "[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.'"[249] This approach means that mere minor alterations in a known chemical compound would likely fail the *post-KSR* obviousness analysis.

IV. Patent Eligibility of Genetic Materials

Now that the science of DNA research has been discussed and clarified, we can apply the legal governing standards to this field of scientific endeavor. In this part, I will discuss how, in my view, genetic materials should be treated under the present law. This discussion will focus both on the actual caselaw and the philosophical underpinnings of

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is a "homolog, analog, or isomer," the proper inquiry is obviousness under § 103 rather than anticipation under § 102).

[244] 35 U.S.C. § 103 (2012).

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

[246] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

[247] *Id.* at 422.

[248] *See* Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd, 533 F.3d 1353, 1359 (Fed. Cir. 2008).

[249] *Takeda Chem*., *supra* note 243, at 1356 (quoting *In re* Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995)).

these decisions, both of which were introduced in the preceding part. I will then turn to the various arguments that have been presented seeking to create a "special status" (in one form or another) for genetic materials and discuss why I find these arguments not particularly convincing.

As I have alluded previously, there are three distinct possibilities when it comes to patenting DNA molecules. First, one could attempt to patent simply the natural sequence of the 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 attempt to patent the gene that is separated from the rest of the genetic code on the chromosome and associated protein structures. In this situation, in addition to having 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*. Finally, the third option would be to attempt to patent a genetic sequence containing protein coding regions only (*i.e.*, cDNA). In that situation, the claim 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 with introns present or absent) will code for the same target protein. In addition, there is an issue of whether newly discovered associations between certain inherited traits and particular genetic sequences are in and of themselves patent eligible.

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, no matter how hard and expensive to find, no matter how new, and no matter 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 transform them into "a new thing commercially and therapeutically."[250] Furthermore, granting exclusive rights on such discoveries would be inconsistent with the philosophical and economic underpinnings of patent law. Such patents would fail under 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 exclusive rights on the DNA *in situ* would preclude all uses of that sequences, and therefore would not leave "enough, and as good" for the rest of mankind.[251]

Same result obtains on 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.[252] 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 reason. Granting a patent on a gene *in*

[250] *Parke-Davis*, *supra* note 204, at 103.
[251] *Id.*
[252] *Id.*

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.[253] 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 to their area of research.[254] Thus, granting such patents would be economically inefficient, and would slow down the 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 caselaw and the fundamental principles underlying patent law support denying patent claims drawn to genetic sequences *in situ*.

B. Isolated and Purified DNA

The next issue to consider is the patent eligibility of isolated and purified DNA, but one whose sequence is identical to the native DNA. On one hand, these DNA molecules are not only mechanically separated from the associated protein structures, but are also cleaved from the rest of the chromosome. As a result, the isolated DNA is "a molecule with a different ionic charge, different chemical bonds, [different molecular

[253] *See supra* note 130 and accompanying text.
[254] Wenrong Huang, *Enzo's Written Description Requirement: Can it be an Effective Check Against Overyl 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.").

weight], and a different chemical composition, as compared to the" native DNA.[255] 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."[256] Indeed, even the District Court that found isolated DNA to be patent ineligible, conceded the point.[257]

On this view, then, isolated DNA fits comfortably within the *Parke-Davis* and *Chakrabarty* line of cases. Because isolated DNA "so control[s] the [nature] as to make it accomplish the purpose"[258] of being a diagnostic or therapeutic tool, because it is "a new thing commercially and therapeutically,"[259] and because it is "a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use,'"[260] it constitutes patent eligible subject matter.

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[255] *Myriad II*, *supra* note 13, at 1362 (Moore, J., concurring in part and concurring in judgment).
[256] *Parke-Davis*, *supra* note 204, at 103.
[257] *Myriad I*, *supra* note 13, at 196-97 ("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.").
[258] Dolbear v. American Bell Tel. Co., 126 U.S. 1 (1888).
[259] *Parke-Davis*, *supra* note 204, at 103.
[260] *Chakrabarty*, *supra* note 143, at 310 (quoting Hartranft v. Wiegmann, 121 U. S. 609, 615 (1887) (alteration in original).

On the other hand, despite being isolated and having different *chemical* structure and properties, these molecules has the same *biological* properties as the native DNA. It must be remembered that the isolated DNA retains the same sequence of nucleotides as the native DNA, and therefore, when translated, codes for the same sequence of amino acids.[261] Though it is true that once the 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,"[262] it is equally true that no changes other than to terminal nucleotides of the gene are made.[263] Thus, human creativity is arguably minimal and it can plausibly be argued that isolated DNA fits within the *Funk Brothers 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."[264] It can be argued that the creation of these molecules nothing more than "appending conventional steps … to laws of nature,"[265] 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

[261] 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*, but the linear sequence of nucleotides. *See supra*, notes 66-80 and accompanying text.
[262] *Myriad II*, *supra* note 13, at 1362.
[263] 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.
[264] *Funk Bros*., *supra* note 25, at 131
[265] *Prometheus*, *supra* note 229, at *27. In fact, following its decision in *Prometheus*, the Supreme Court vacated Federal Circuit's decision in *Myriad II* and sent the case back for further consideration in light of *Prometheus*. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 566 U.S. ___, 2012 U.S. LEXIS 2356 (U.S. Mar. 26, 2012)

patent eligibility of isolated DNA, based on the caselaw 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.[266] Between 1982 and the present day 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 the "Hatch-Waxman Act")[267] altered the legal landscape for patents on drugs and medical devices.[268] In 1996, Congress amended the Patent Act to add § 287(c), which immunized physicians from liability for infringing patents directed to methods of treatment.[269] The Consolidated Appropriations Act of 2004 prohibited the use of federal money "to issue patents on claims directed to or encompassing a human organism."[270] This prohibition continued from year to year in various appropriation bills,[271] and was finally codified as a substantive exclusion from patent eligibility in the Leahy-Smith America Invents Act of 2011.[272] Despite these (and other) amendments to the Patent Act, Congress never saw fit to exclude genetic materials

[266] *See Gene Patents and Global Competition Issues: Protection of Biotechnology Under Patent Law, Genetic Engineering and Biotechnology News*, LEGAL AFFAIRS 26(1), Jan. 1, 2006, *available at* http://www.genengnews.com/articles/chitem.aspx?aid=1163&chid=0 ("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."); U.S. Patent No. 4,447,538 (issued May 8, 1984).
[267] Drug Price Competition and Patent Term Restoration Act of 1984, *supra* note 33.
[268] 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) (2012).
[269] Limitation on Patent Infringements Relating to a Medical Practitioner's Performance of a Medical Activity, Pub. L. No. 104-208, 110 Stat. 3009, § 616 (codified as amended at 35 U.S.C. § 287(c)).
[270] Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, § 634, 118 Stat 101 (2004).
[271] O. Carter Snead, *The George W. Bush Administration: A Retrospective: Public Bioethics and the Bush Presidency,* 32 HARV. J.L. & PUB. POL'Y 867, 913 n. 62 (2009) ("The Weldon Amendment has been reauthorized every year since its enactment.").
[272] Leahy-Smith America Invents Act, Pub. L. No: 112-29, § 33, 125 Stat. 284 (2011).

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.[273] 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.[274] The DOJ's position, in turn contravened long-standing practice and position of the USPTO, setting up a split in the Executive Branch[275] and making the issue all the more acute. Still, Congress chose not to act, leaving the law as it has been for almost 30 years. Though *Prometheus* may cast doubt on this conclusion,[276] in my view, Congressional decision to allow the PTO to continue issuing patents on DNA is indicative of Congressional view that genetic material is patent eligible.[277]

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

[273] *See*, *e.g.*, H.R. 977, 110th Cong. (2007) (sponsored by 5 Democratic and 1 Republican Representative); Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002) (sponsored by 2 Democratic and 1 Republican Representative).
[274] The Federal Circuit decided *Myriad* on July 22, 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.
[275] *See supra*, note 237 and accompanying text.
[276] *See supra*, note 265 and accompanying text.
[277] 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* Richard J. Nelson, *Regulation of Investigational New Drugs: "Giant Step for the Sick and Dying"?,* 77 GEO. L.J. 463, 482 (1988); Patricia M. Wald, *Some Observations on the Use of Legislative History in the 1981 Supreme Court Term*, 68 IOWA L. REV. 195, 205 (1983). Nonetheless, even if not a particularly strong indication of Congressional intent, it is some indication of it.

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 in reward for labor should be commensurate with the labor itself, especially when one is permitted to withdraw matters from the commons.[278]

The other theories offer equally conflicting conclusions. Hegelian approach suggests that isolated DNA is an external embodiment of the specific "[a]ttainments, erudtions, [and] talents" of the scientists who sequenced, isolated and purified the gene of interest, capable of being propertized and therefore patent eligible. On the other hand, what is being propertized is actually much greater than the mere external embodiment of the "[a]ttainments, erudtions, [and] talents" of people who sequenced and isolated the gene. Instead, what is being propertized is the "[a]ttainments, erudtions, [and] talents" of others – those who actually discovered the locus and the function of the gene.[279]

Nor is it clear whether permitting patenting of isolated and purified DNA, is no 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.

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[278] 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 to 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), caution in 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 ("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.").

[279] For example, people who sequenced BRCA1 and BRCA2 were not the people who initially localized those genes. *See Myriad II*, *supra* note 13, at 1373 (Bryson, J., dissenting in part) (citing Jeff M. Hall et al., *Linkage of Early-Onset Familial Breast Cancer to Chromosome,* 17q21, 250 Science 1684 (1990))

Furthermore, by applying for a patent on isolated DNA, the individuals are required to disclose the actual genetic sequence of that DNA.[280] 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.[281] An exclusive right to *use* the entire isolated gene irrespective of the purposes of the use[282] 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.[283] If that alone were reason enough to deny patent eligibility to inventions, we would have no patents at all. The reason we don't is that though patents may close one avenue, they encourage competitors to "design around" the patent.[284] This "competition benefit" is beneficial because the substitutes thus produced ultimately

[280] 35 U.S.C. § 112 (2012) ("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. §§ 1.801-1.807 (2012) (requiring applicants for patents on biological materials to deposit such material in an acceptable public depository).

[281] 35 U.S.C. § 271 (a) (2012) ("[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.").

[282] 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.") (emphasis in original).

[283] Katherine J. Strandburg, Gabor Csardi, Jan Tobochnik, Peter Erdi & Laszlo Zalanyi, *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.").

[284] *See generally* LANDES & POSNER, *supra* note 173.

provide a broader choice and sometimes better goods to the public.[285] In the field of genetics, however, the paradigm doesn't hold. One simply cannot "design around" a patent on isolated DNA.[286] 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.[287] 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, on balance, 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)[288] 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)

[285] Miranda Jones, *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).
[286] *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).
[287] *Id.*
[288] In other words, even assuming that these patents get asserted against scientists seeking to work on other issues associated with a patented sequence (and it is unclear that this ever happens, *see Myriad II*, *supra* note 13, at 1347 (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)) , researchers will simply move towards genes not yet discovered and therefore not subject to any patents. This will likely result in the learning the function of genes sooner, which could in turn provide new and better diagnostic and therapeutic options.

claim for patent eligibility. Unlike the isolated and purified DNA, which has the same genetic sequence as native DNA, cDNA's sequence of nucleotide 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 90% 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 produce the target protein.[289] Native or isolated DNA cannot be used for that purpose because 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.[290]

That said, the objections to cDNA (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.[291] 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.

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[289] See supra notes 122-124 and accompanying text.
[290] ALBERTS, *supra* note 42, at 105.
[291] *See Myraid I*, *supra* note 13, 230.

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. This utility requirement is a fundamental requirement of the Patent Act.[292] Individuals seeking patents on genetic sequences must, therefore state why these sequences are useful – *i.e.*, what they code for.[293]

These discovery allows the discoverer to screen other individuals for the presence or absence of the gene in question and predict presence or absence of a medical or biological condition that the gene codes for. The claims in these patents usually are directed to a method of diagnosing the relevant condition by comparing the tested individual's DNA to the sequenced gene.[294] This comparison can be done by utilizing variety of probes derived either from the isolated and purified DNA or cDNA.[295]

It should be self-evident that the deleterious (or for that matter health-enhancing) quality of any genetic sequence (or mutation therein) is a natural phenomenon and is in no way man-made.[296] Consequently, the association between the presence or absence of a certain genetic sequence and any medical condition in and of itself is not patent

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[292] 35 U.S.C. § 101(2012) ("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).

[293]Diana A. Villamil, *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.").

[294] *See, e.g.*, U.S. Patent No. 5,709,999 cl. 1 (issued Jan. 20, 1998); U.S. Patent No. 5,710,001 cl. 1(issued Jan. 20, 1998).

[295] *See id*.

[296] Eli, *supra* note 22, 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.").

eligible.[297] The method of testing (or treating) such a condition utilizing man-made chemicals such as isolated DNA or cDNA is patent eligible.[298] So it matters how the claim is drafted. As Judge Rich wrote more than thirty years ago, "the name of the game is the claim."[299] 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 concluded that the creation of metabolities was a naturally-occurring, intra-corporeal process,[300] 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.[301] On the other hand, patents on the method of diagnosing or treatment reward the actual work of inventing such procedures and do not allow the inventor to essentially propertize other people's "[a]ttainments, erudtions, [and] talents." From the section 101 perspective then, patents drawn to diagnostic and therapeutic techniques utilizing man-made DNA

[297] Such associations are "[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." *Le Roy*, *supra* note 152, at 175; *see Prometheus*, *supra* note 229, at *18-19.
[298] *See* James Bradshaw, *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.").
[299] Giles S. Rich, *Extent of Protection and Interpretation of Claims--American Perspectives*, 21 INT'L REV. INDUS. PROP. & COPYRIGHT L. 497, 499 (1990).
[300] *Prometheus*, *supra* note 229, at *18-19.
[301] 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*, *supra* note 13, at 1334-35 (quoting Myriad's patents and noting that Myriad holds patents on both isolated BRCA1/2 genes and cDNA constructs for those genes).

molecules, are the narrowest drawn and therefore have the highest claim for patent eligibility.[302]

V. Patentabilty of Genetic Materials

Establishing patent eligibility for genetic materials is only half the battle. After all, section 101 is "merely a coarse filter,"[303] and is just "[t]he first door which must be opened on the difficult path to patentability."[304] 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. In determining the answer to that question, compliance with the novelty requirements must 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 itself (whether whole or limited to just coding regions) is a product of nature.[305] Nor is the function of any sequence patent eligible as such. The only inventions on which patent applications could be filed are then 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 section 103.

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[302] Of course, such claims cannot be directed at just abstract mental processes. *See Myriad II*, *supra* note 13, 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.").
[303] John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1059 (2011); Classen Immunotherapies, Inc. v. Biogen Idec, 659 F.3d 1057, 1068 (Fed. Cir. 2011); *id.* at 1074 (Rader, J., concurring).
[304] *Bergy*, *supra* note 211, at 960-62 (all alterations in the original).
[305] Additionally, sequences themselves may not even be novel as of 2005 when the human genome project was completed and the results published.

The methods and techniques for sequencing genes are well known and have been so for quite some time.[306] As Professor John Golden points out,

> [h]istorically, 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 variety of tasks that had previously required considerable effort and ingenuity.[307]

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."[308] Isolating the DNA of interest from the surrounding DNA and purifying it is also a routine procedure.[309]

Admittedly, the Federal Circuit has 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."[310] The *Deuel* case, however,

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[306] *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; Richard M. Mescher, *Patent Law: Best Mode Disclosure – Genetic Engineers Get Their Trade Secret and Their Patent Too?,* 18 DAYTON L. REV. 177, 189 (1992).
[307] Golden, *supra* note 28, at 114-15.
[308] Minssen, *supra* note 29, at 126.
[309] *See Myriad I*, *supra* note 13, at 196 ("Native DNA may be extracted from its cellular environment, including the associated chromosomal proteins, using any number of well-established laboratory techniques."); Lee Petherbridge, *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).
[310] *In re* Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995).

is now 17 years old.[311] The technology of 2012 is much more advanced as compared to the technology of 1995, making the job of isolating, purifying and synthesizing DNA not just routine but automated.[312] 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,[313] 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 *In re Deuel*. The technological advances combined with the completion of the human genome project (which now makes the "reference sequence" of an entire human DNA genome freely available)[314] 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," the invention is obvious because it would be "obvious to try" those solutions.[315] For any particular sequence of DNA embedded in a larger unit of DNA (such a chromosome) the application of "a finite number of identified predictable solutions" (in the forms of certain chemical treatments) would lead to "anticipated success" of isolating and purifying that sequence.

A 2009 Federal Circuit case – *In re Kubin*,[316] is a final nail in the *Deuel* coffin. In *Kubin*, the Federal Circuit opined that once the structure of a target protein is known,

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[311] 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 19 years old.
[312] *See* Chin, *supra* note 106, 1037; Golden, *supra* note 28, at 114-15 (2006).
[313] 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.'") (quoting 35 U.S.C. § 103(a)) (alterations in original).
[314] Klein & Mahoney, *supra* note 20 ("The Human Genome Project has brought the free availability of reference sequences with which patients' DNA can be compared.").
[315] *KSR*, *supra* note 246, at 421.
[316] *In re* Kubin, 561 F.3d 1351 (Fed. Cir. 2009)..

isolating and purifying the gene coding for the relevant protein is obvious.[317] As the *Kubin* panel observed, "[i]nsofar 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."[318] 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 should no longer be viewed as good law.

The same general reasoning is applicable to cDNA. Although making cDNA molecules is harder than merely isolating and purifying DNA, given the current state of knowledge and technology it is likely obvious to a person skilled in the genetic arts.[319] The major problem in synthesizing cDNA is separating introns from exons and discarding the former while joining together the latter. Though there is no specific signal between at the border between 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

[317] *Id*.
[318] *Id.* at 1358.
[319] 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."); 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).").

seem. Because the genetic code is conserved, once one knows the protein sequence,[320] one can reverse engineered the DNA sequence that would code for that protein.[321]

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 known processes or mechanisms 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.

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 does not code for any naturally-occurring protein and therefore does not replicate naturally occurring DNA in either sequence or structure.[322] These constructs may have a variety of uses, from creating new organisms,[323] to "providing an efficient method for avoiding genetic diseases and optimizing desirable characteristics."[324] Engineering these synthetic DNA molecules involves significantly more creative work than merely isolating and

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[320] 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.

[321] *See Kubin*, *supra* note 316. To be sure, because the genetic code is degenerate, there will be several potential DNA sequences able to code for the protein 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.

[322] 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, *available at* http://vivo.cornell.edu/display/individual16724.

[323] *See, e.g.*, *Chakrabarty*, *supra* note 143.

[324] Andrew W. Torrance, *Family Law and the Genomic Revolution,* 79 UMKC L. REV. 271, 281(2010).

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 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 synthetic gene has no template and therefore, no solutions that are "predictable."[325]

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 gene's peculiar function – are not patent eligible for these results simply uncover previously unknown but naturally occurring properties and phenomena. On the other hand, the work that "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. Thus, patents and patent applications on genetic material (at least to the extent that they represent naturally occurring genes) should fail either under Section 101 or Section 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, lack of patent protections would disincetivize 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

[325] Indeed, these molecules are so without analogue in nature that some have suggested that they ought to be eligible for copyright protection. Torrance, *supra* note 322, at 635.

next section 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 & Biologics

In designing an alternative to the patent system for genetic materials two things are important to bear in mind. First, a patent, in and of itself does not confer any right to use the patented technology.[326] The only right that a patent confers on the patentee is a right to *exclude others* from using (or selling) the patented technology.[327] 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 FDA approval process.[328] Second, (and directly related to the preceding point), patents themselves are worthless unless the patented technology can be practiced and is sufficiently profitable.[329] In other words, "[t]he present value of an invention without a current or foreseeable use is nothing."[330]

The reason that patents on genetic material are valuable is because these patents read on approved and marketable therapeutic or diagnostic technologies. It follows then that (as with every other technology) the actual pressure point with respect to return on

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[326] Jonah D. Jackson, *Something Like the Sun: Why Even "Isolated and Purified" Genes are Still Products of Nature,* 89 TEX. L. REV. 1453, 1488 (2011).
[327] *Id.*; 35 U.S.C. § 271 (2012).
[328] Katherine N. Addison, *The Impact of the Biosimilars Provision of the Heath Care Reform Bill on Innovation Investments,* 10 J. MARSHALL REV. INTELL. PROP. L. 553, 571(2011).
[329] John F. Duffy, *A New Role for the FCC and State Agencies in a Competitive Environment?: 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.*, Kimberly A. Moore, *Worthless Patents*, 20 BERKLEY TECH. L.J. 1521 (2005); Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1497 (2001); 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….").
[330] Machin, *supra* note 170, at 438.

investment with genetic research is at the market-entry stage and not at the patenting stage. If 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 Food and Drug Administration ("FDA").

In order for any pharmaceutical manufacturer to be able to sell its wares in the United States, the manufacturer needs to obtain FDA's pre-market approval.[331] 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.[332] The same requirement applies to medical devices.[333] A similar, though not identical process[334] is followed by manufacturers seeking approval for "biological products" or "biologics."[335] Thus, FDA serves as a gate-keeper to the market for the manufacturers of pharmaceuticals and biologics. If FDA could reject applications on economic or competition-promoting grounds, rather than only on safety and efficacy grounds, that

[331] 21 U.S.C. § 355(a) (2012).
[332] *Id.* § 355(d).
[333] *Id.* § 360e.
[334] 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).
[335] 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) (2008); *see also* 42 U.S.C. § 262(i) (2012). As the FDA explains, biologics "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." U.S. Food and Drug Administration, *What is a Biological Product?* (Mar. 28, 2007), *available at* http://www.hhs.gov/fda/faq/faq/1612.html.

would allow the manufacturers of relevant products to 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 in place. The FDA does indeed have authority to limit market entry by copyists, even if their products satisfy the "safe and efficacious" requirements. I will first describe the two systems and then explain how they could be expanded to cover genetic materials and what benefits will accrue from such an expansion.

Several different types of market exclusivity are available to manufacturers of pharmaceutical products.[336] I will focus on just one such provision: the exclusivity for "new chemical entities."[337] This provision was created in 1984 by the Drug Price Competition and Patent Term Restoration Act of 1984[338] (commonly known as the Hatch-Waxman Act).[339]

The "new chemical entity" or "NCE" exclusivity provision is aimed at protecting pioneering manufacturers from premature competition by generic (or copying) manufacturers.[340] 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.'"[341] The clinical

[336] Alice O. Martin & Sendil K. Devadas, *Patents with an "I" = Patients,* 18 ANN. HEALTH L. 261, 265 (2009).
[337] 21 U.S.C. § 355(c)(3)(E)(ii) (2012).
[338] Drug Price Competition and Patent Term Restoration Act of 1984, *supra* note 33.
[339] *See, e.g.*, 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.'").
[340] *See* Kathleen R. Kelleher, *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).
[341] Serono Labs., Inc. v. Shalala, 158 F.3d 1313, 1316 (D.C. Cir. 1998) (quoting 21 U.S.C. § 355(b)(1)).

studies necessary to compile such reports are both long and expensive.[342] 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)"[343] studies to prove that which was already known by the FDA.[344] "Due to the lack of finances to undertake the expensive process of clinical studies to prove a drug was safe and effective, few generic drugs entered the market."[345] 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."[346] Instead of conducting its own clinical trials, an ANDA filer is permitted to rely on data gathered by the pioneer drug-maker.[347]

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

[342] 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).").
[343] Yvon, *supra* note 342, at 1894.
[344] Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals,* 24 HARV. J. L. & TEC 281, 287 (2011).
[345] Sarah M. Yoho, *Reformation of the Hatch-Waxman Act, an Unnecessary Resolution,* 27 NOVA L. REV. 527, 531 (2003).
[346] Dolin, *supra* note 344, at 288.
[347] Sheila Kadura, *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).

innovation.[348] Specifically, it limited FDA's freedom to approve ANDA applications which relied on 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 is known as a "new chemical entity" exclusivity. Although usually a new active ingredient is also covered by a relevant patent,[349] this statutory exclusivity provision is available "even if the underlying product was unpatented or off-patent,"[350] and "even if the patent that protects an NCE is invalid."[351]

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 NDA, the Hatch-Waxman exclusivity provisions would not stand in the way of approval.[352] However, because conducting duplicative clinical studies is expensive, while the return on such studies would be lower than the monopoly rents that a single provider could charge,[353] generic manufacturers don't undertake them and data-based exclusivity is sufficient to protect the interests of the pioneering manufacturer.

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[348] Dolin, *supra* note 344, 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.")

[349] Elizabeth Stotland Weiswasser, *The Hatch-Waxman Act: History, Structure, and Legacy,* 71 ANTITRUST L.J. 585 (2003) (noting that "NCE exclusivity usually overlaps with the patent term.").

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

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

[352] 21 U.S.C. § 355(c)(3)(E)(ii)-(iii) (2012). Of course, to the extent that the pioneer drug is covered by a patent, the generic would not be permitted to sell its own version. 35 U.S.C. § 271 (2012). *See also* Rebecca S. Eisenberg, *Pharmaceutical Innovation and Cost: An American Dilemma: The Problem of New Uses,* 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 727-28 (2005) ("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.").

[353] Rantanen, *supra* note 342, at 184.

A similar exclusivity provision exists for biologic products. In 2010, as part of the Patient Protection and Affordable Care Act,[354] Congress passed, and President Obama signed the Biologics Price Competition and Innovation Act (BPCIA).[355] 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").[356] Under that Act, "the 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."[357] By its terms the BPCIA does not include genetic materials, proteins, lipids, etc., as such.[358]

Much like the Hatch-Waxman Act, the BPCIA seeks to both increase the availability of generic biologics, while at the same time protecting 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 biosimilar[359] products on the market. Under the BPCIA, however, the pioneering biologic gets not five, but twelve years[360] of exclusivity.[361] Again, much like with Hatch-

[354] Patient Protection and Affordable Care Act, *supra* note 37.
[355] *Id.* at §§ 7001-7002 (codified in 42 U.S.C. § 351(k)(7)).
[356] Public Health Service Act, Pub. L. No. 78-410, 58 Stat. 682 (1944).
[357] 42 U.S.C. § 262(i)(1) (2012).
[358] 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* U.S. Food and Drug Administration, *What Are "Biologics" Questions and Answers*, *available at* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm, but they are not in and of themselves considered to be "biological products."
[359] "Biosimilar" is a generic version of a pioneering biologic. The BPCIA defines "biosimilar" as "(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. § 351(i)(2) (2012).
[360] This can be extended by additional six months if pediatric studies are conducted. *Id.* at § 351(m)(2).
[361] *Id.* at § 351(k)(7)(A).

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.[362]

In determining whether the exclusivity provisions apply with respect to pharmaceuticals, the FDA follows a fairly straightforward rule. If the active ingredient[363] in the drug has never been previously approved (whether as part of the same or other drug)[364] the exclusivity provisions apply.[365] 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.[366] 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"[367] with approved biologics.[368] Unlike the patent examination process which results in the Patent Office examining the application for compliance with *inter alia* novelty requirements, the FDA does not engage in such an analysis. Instead, all the FDA has to do is determine 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. If so, the FDA does not undertake any further evaluation and simply declines to act on generic's application.

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[362] Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*(2011), *available at* http://ssrn.com/abstract=1874130.

[363] 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 of animals." 21 U.S.C. § 348(e) (2012).

[364] It doesn't matter whether the chemical entity has been known or for how long. The question for the purposes of exclusivity is not whether the chemical entity is "newly discovered" but whether it has been previously approved for use. 21 C.F.R. § 314.108 (2012).

[365] *Id*. at § 314.108 (a).

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

[367] *See* BPCIA § 7002(b) (codified at 42 U.S.C. § 262(i)(3)) (defining interchangeability as 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.").

[368] *Id.* at § 7002(a) (codified at 42 U.S.C. § 262)

In summary, the current FDA exclusivity process has two distinct features which on one hand make it easy to administer, but on the other hand, easy (though incredibly expensive and therefore often financially not feasible) to circumvent. 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 only when the generic files an abbreviated application that relies on 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 own studies.

This system serves as a useful but incomplete template for a system of FDA-based protection of inventions in the field of genetics that I propose below. My proposed system will attempt 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 to 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 to be such that does 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 over-compensate 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 of protecting genetic research must accomplish its ends without withdrawing 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.[369] 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 the 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 Public Health Service Act must be expanded. Currently, only biologics are 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."[370] Although the FDA recognizes that nucleic acids can form a component of a biological product,[371] stand alone nucleic acids are not considered to be "biologics" for the purposes of the PHSA.[372]

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[369] Enrique Seoane-Vazquez, *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.

[370] 42 U.S.C. § 262(i) (2012).

[371] *See supra* note 358. 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.

With respect to DNA-based treatments, if the definitions of the "biologic material" in the Public Health Services Act 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.[373] 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 to diagnose various conditions as well.[374] Indeed, diagnostics is the primary use of genetic materials today as gene therapy is still experimental and rare.[375] In order to provide necessary protections for the inventors of new genetic tests further modifications to the law need to be made.

Currently, under BPCIA, unless the 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 definition needs to be expanded to include not only biological

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Some viruses also have a further lipid "envelope." *See* STEDMAN'S MEDICAL DICTIONARY 1939 (Williams & Wilkins, 26th ed. 1995). Thus, of necessity, a virus includes nucleic acids as a component.

[372] 42 U.S.C. § 262(i)(1) (2012).

[373] *See* U.S. Food and Drug Administration, *Letter 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

[374] *See Myriad I*, *supra* note 13, at 196-97.

[375] U.S. Department of Energy Office of Science, Office of Biological and Environmental Research, *Gene Therapy* (Aug. 24, 2011), *available at* http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml ("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.").

products of which a nucleic acid is a component, but 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 the 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 FDA's regulatory authority. The Food, Drug, and Cosmetic Act already permits the FDA to regulate medical devices,[376] 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.[377]

All devices are classified as Class I, II, or III device,[378] and are categorized by the level of dangers they may present to a consumer,[379] with Class I being the least and Class III the most potentially dangerous. Class III devices are subject to pre-market approval,[380] whereas Class I devices are not.[381] Class II devices are subject to "pre-market notification,"[382] a process in which the FDA evaluates whether the device is

[376] 21 U.S.C. § 360c (2012).
[377] *Id.* at § 321(h).
[378] *Id.* at § 360c.
[379] Michael D. Green & William B. Schultz, *Regulatory Compliance as a Defense to Products Liability: Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2131 (2000).
[380] 21 U.S.C. § 360c(a)(1)(C) (2012).
[381] *Id.* at § 360c(a)(1)(A).
[382] *Id.* at 360c(a)(1)(B).

similar to an already approved and safe device,[383] and if not, whether it poses sufficient danger to be classified as Category III.[384]

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.[385] 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.[386] Thus, FDA already has the authority to regulate most of genetic materials meant to test for a particular trait or disease.[387] The FDA, however, has refrained from regulating "test[s] by a laboratory for use only by that laboratory,"[388] which is how much of the genetic testing gets done. In other words, if a sample of 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.[389] Nonetheless, because in recent years the FDA has observed a number of problems with these laboratory-developed tests including "[f]aulty data analysis, [e]xaggerated clinical claims, [f]raudulent data, [l]ack of traceability/change control,

[383] Yann Joly et al., *Regulatory Approval for New Pharmacogenomic Tests: A Comparative Overview,* 66 FOOD DRUG L.J. 1, 13(2011); Annie Marie Murphy, *The Biomaterials Access Assurance Act of 1998 and Supplier Liability: Who You Gonna Sue?,* 25 DEL. J. CORP. L. 715, 726-727 (2000).
[384] Yann Joly et al., *supra* note 383, at 13.
[385] 21 U.S.C. § 360c(a)(1)(A) (2012). 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* Jeffrey Shuren, U.S. Food and Drug Administration, *Direct-to-Consumer Genetic Testing and the Consequences to the Public* (July 22, 2010), *available at* http://www.fda.gov/NewsEvents/Testimony/ucm219925.htm ("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.").
[386] Shuren, *supra* note 385.
[387] *Id.*
[388] *Id.*
[389] *Id.*

[p]oor clinical study design, [and] [u]nacceptable clinical performance,"[390] it is considering exercising its regulatory authority over these tests as well.[391]

The only potential expansion of 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. Though this would expand the regulatory reach of the agency, the expansion would be rather small, as most of the genetic tests do not fall into that category.[392] Further, I am not suggesting that a more searching examination of genetic materials currently classed as Class I or Class II devices take place. If the genetic material or test kit is not dangerous or if potential erroneous test result using that material "is unlikely to directly harm the patient,"[393] 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 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.

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[390] *Id.*

[391] *Id.* ("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.").

[392] *See* 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 labeled [sic] Class III devices."); Shuren, *supra* note 385. *But see* Bruce Patsner, *Predictive Health Technologies: 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….").

[393] Shuren, *supra* note 385.

This authority to regulate genetic materials can be harvested to create preferential market entry conditions for the first inventors, while restricting entry to the second-comers. Presently, the FDA approves genetic materials for market entry once they are shown to be safe and effective,[394] without regard to the novelty of the product. If, on the other hand, genetic materials were reclassified not just as a "medical device" but also as a "biological product" 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.

In order to make the 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 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. The reason that exclusivity provisions are as effective as they are is that most of safety and efficacy studies are costly, whereas the return on investment in these studies diminishes with every subsequent market entrant. However, genetic materials or test kits that fall into Class I or Class II device category do not have to go through extensive and costly clinical trial before gaining permission to enter the market. Thus exclusivity provisions based on access to (or use of) pioneer's data would not serve as a sufficient barrier to entry for later filers. Consequently, a new type of provision that would provide

[394] 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.

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 pioneer's *product*.

Recall, that genetic tests are conducted by seeing if the patient's DNA hybridizes (*i.e.*, "matches") the test strand of DNA. This is based on 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 stands and then use these isolated strands to test the 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 Patent Act's § 103, but rather in a more straight-forward way. If the later filer's molecule has the same or highly similar (*e.g.*, within 90% identical) hybridization properties as the pioneer's molecule, then the later filer's molecule would be viewed as sufficiently "similar" and have the exclusivity bar applied to it. This would be true *irrespective* of 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.*, or drug developed to treat a rare disease).[395]

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

[395] *See* 21 U.S.C. § 360cc(a) (2012) (granting exclusivity to the first person to bring an orphan drug to market). For a full definition of "orphan drug" *see id.* at § 360bb(a).

patent-based rights to exclude. First, and most obvious, the exclusivity obtained through FDA licensing scheme, unlike that obtained via a patent would not apply to any "use" of the product. Instead, FDA-based exclusivity would apply only to products being a) marketed to patients (either directly or through a healthcare provider) and b) "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."[396] 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."[397]

Second, I would require that the FDA-based exclusivity include (again unlike the Patent Act) a "use it or lose it" provision similar to the one present in the amended Hatch-Waxman Act.[398] Patent law permits a patentee to not practice the invention and instead merely seek to license the patent to others who do practice it.[399] 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, it must be remembered that the FDA-based exclusivity provisions would 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

[396] *Id.* at § 321(h).
[397] *Id.* at § 360c(a)(1)(C).
[398] *Id*. at § 355(j)(5)(D)(i)(I).
[399] *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.").

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) market.

The third distinction from patent law that the system ought to have is the variation in the length of exclusivity. Under the Patent Act (and pursuant to the international agreements) the length of patent terms on all inventions irrespective of the field must be 20 years from the date of filing the patent application.[400] This approach has been criticized by a number of commentators as too constricting in designing optimal innovation incentives.[401] Nonetheless, if for no other reason than the obligation to adhere to our international agreements, we are unable to 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, though apply to 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 have discussed in Part VII, *ante*, the exclusivity period for new chemical entities is only five years, whereas the exclusivity periods on biologics is 12 years, whereas other provisions in the Food, Drug, & Cosmetic Act provide for exclusivity provisions of 180 days for the first generic drug on the market[402] and seven years for an "orphan drugs."[403] Thus, exclusivity provisions of different lengths are nothing new to the FDA.

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[400] *See* 35 U.S.C. § 154(a)(2) (2012); Declaration on the Trips Agreement and Public Health § 33.
[401] *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. San Diego Sch. of Law, Law & Econ. Research Paper No. 19, 2001), *available at* http://papers.ssrn.com/abstract=285144.
[402] 21 U.S.C. § 355(j)(5)(B)(iv).

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 detailed studies proving safety and efficacy would be required and the more refined the ultimate product would have to be. These materials would be able to obtain the longest exclusivity period. The easier the test, and the fewer problems an erroneous result would present, the more likely the product to be approved without extensive studies, and therefore the more likely it is that the product would not be as refined. As a result these products ought to receive 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 patent[404] as a bench-mark for the longest exclusivity period. Under such system, the maximal FDA-based market exclusivity provisions would last about 11.5 to 12 years.[405] On the opposite end, I would set the minimal exclusivity length to 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.[406] The mid-level of protection would be set at about 7.5 to 8 years of exclusive rights which would correspond to the second patent

[403] *Id.* at § 360cc(a).
[404] Wheaton, *supra* note 351, 451 (1986) ("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.").
[405] Richard A. Epstein & F. Scott Kieff, *THE LICENSING OF INTELLECTUAL PROPERTY: 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.").
[406] 35 U.S.C. § 41(b).

maintenance fee being due.[407] The reason I believe it makes sense to tie the exclusivity provisions to patent maintenance fee dates is because patent maintenance fees in and of themselves serve as a mechanism to terminate not particularly valuable patents.[408] 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. I hasten to add that 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 sub-optimal (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 longest exclusivity rights only on products of sufficient complexity and sufficient advancement over the prior art.

One final requirement that I believe is necessary for the success of FDA-based exclusivity system is a provision precluding the applicants from taking advantage of both the patent system and the FDA system as they can currently do with new pharmaceuticals and biologics. Criticism has been leveled at the current "double benefit" system (especially with respect to biologics) as being over-protective of inventors.[409] Whether or not that criticism is fully justified, at the very least the ability to reap both benefits could

[407] *Id.*
[408] 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 329, 1503.
[409] *See generally* Heled, *supra* note 362, at 52-58.

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 could be argued, that in order to prevent a copier from entering the market at all (after conducting its own safety and efficacy studies) patent protections are necessary. 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 did 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 VI, *ante*, 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, I 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, he would be required to disclaim any patent term that would extend beyond the term of FDA-based protection.

B. The Justification and Benefits of the Proposed System

The system where the FDA preferentially treats first market entrants and limits, for certain amount of time, market access to later filers serves all of the criteria identified in the beginning of this section. First, if the exclusivity is granted for a sufficient time

period, it provides adequate incentive to the inventors – much 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 does a patent – it permits the holder of the exclusive right to exclude others from the market and obtain monopoly rents on the product subject to exclusive rights.[410] At the same time, the FDA-based system would not over-compensate 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 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." The two primary requirements of promoting innovation, while simultaneously, keeping maximum information in the commons.

In this sense the system is consistent with the underlying philosophies of intellectual property discussed in Part III, *ante*. 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

[410] 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, 1348 (2010) ("A brand company's patent allows it to set high monopoly prices."); Daniel R. Cahoy, *An Incrementalist Approach to Patent Reform Policy*, 9 N.Y.U. J. LEGIS. & PUB. POL'Y 587, 600 (2005-06) ("A patent allows its owner to extract monopoly rents for the period of exclusivity.").

directly to the inventors and indirectly to the public at large that will benefit from 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 overall 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 to 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 the 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 actually 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 the FDA-based system then 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 the society would have greater access to these goods and therefore be better off than they would be under the traditional patent system.

The proposal also satisfies the criteria of being easy to administer while hard to evade. With respect to the ease of administration, 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 for FDA to 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.

The requirement that exclusivity be product- 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 had, and the later filer cannot enter the

market until 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 straight-forward and provide all applicants with easy and inexpensive way to determine the likelihood that their application would be approved by the FDA, the litigation costs would be reduced. Currently, the average cost of patent litigation exceeds $3 million.[411] This is money that could be better spent on further research. After all, the companies that litigate patents on DNA are both likely to be invested in the market with neither being a "non-practicing entity."[412] Given that pharmaceutical patents are among those most often subject to litigation,[413] 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 summary, with respect to nucleic acids, the FDA-based exclusivity system can provide the innovators with all of the benefits of the patent system while leaving more information in the public domain, and ensuring that holders of exclusive rights actually practice their invention. Furthermore, this can be accomplished at a lower transaction cost than the patent system as both the cost of obtaining valuable exclusive rights and defending them would be dramatically lowered.

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[411] Christopher B. Seaman, *Reconsidering the Georgia-Pacific Standard for Reasonable Royalty Patent Damages,* 2010 B.Y.U.L. REV. 1661, 1725 (2010) ("[T]he average cost of patent litigation was approximately $ 3.1 million.").

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

[413] 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.").

VIII. Conclusion

The science of molecular genetics has challenged 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 then that determining how the patent law should treat this molecule has been subject of much debate.

Ultimately though, with the scientific advancement 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 of 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 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 is needed. That system can be built by having the Food and Drug Administration regulate market entry for the makers of genetic diagnostic and therapeutic modalities. By allowing developers of new tests and treatments to enter the market on preferential basis, as compared to later applicants, the system will permit innovators to enjoy monopoly rents much like they would under the patent system. On

the other hand, by limiting the monopoly only 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 that they currently enjoy.