PATENT POLICY, NATURAL PRODUCTS, AND THE GENE PATENT DEBATE: SEEKING THE PROPER JUDICIAL MODE OF ANALYSIS

*MATTHEW M. KARLAN**

INTRODUCTION

Since the early 1980s, the United States Patent and Trademark Office (USPTO) has issued patents claiming human genes.[1] By

* J.D. Candidate, May 2011, New York University School of Law; A.B. 2008, Bowdoin College. Development Editor for the *New York University Annual Survey of American Law* in 2010–11. I am grateful to Professor Frank Upham for his comments on earlier drafts of this Note. All errors are mine.

1. *See Gene Patents and Global Competition Issues: Protection of Biotechnology Under Patent Law*, GENETIC ENGINEERING AND BIOTECHNOLOGY NEWS, 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."); Microorganism Containing Gene for Human Chorionic Somatomammotropin, U.S. Patent No. 4,447,538 (filed Feb. 5, 1982) (issued May 8, 1984).

2005, approximately twenty percent of the human genome had been patented.[2] Unsurprisingly, the rise of human gene patents[3] has garnered significant attention from the public, with a number of critics denouncing the practice on various policy grounds.[4]

The policy critiques of gene patents break down into four general categories. The first and perhaps most basic criticism is that patenting human life violates a categorical moral rule, regardless of the consequences.[5] Second, some argue that gene patents contribute to a "patent thicket" that puts unreasonable costs on "downstream" research.[6] Third, others contend that gene patents have unreasonably restricted access to genetic screening and other

2. *See* Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCI. 239, 239 (2005).

3. The term "gene patent" is used throughout this Note to refer generically to patent claims covering sequences of nucleic acids derived from naturally occurring genetic material in humans, regardless of whether the patent claim only covers a version of the naturally occurring sequence that has been purified and isolated, i.e., separated from the other molecules with which it is found in nature. See discussion of biotechnology *infra* Part I.A.

4. *See, e.g.*, DAVID KOEPSELL, WHO OWNS YOU? THE CORPORATE GOLD-RUSH TO PATENT YOUR GENES (Michael Boylan ed., 2009).

5. One commentator summarized the common moral arguments against gene patents as follows:

> Essentially, opponents raise a plethora of moral arguments such as: it is morally wrong to allow the patenting of natural things that are created by God; it is repugnant and contrary to public policy to commodify the human body and nature; and DNA is humanity's common property and, as such, it should not be owned by private individuals.

Brian Zadorozny, Comment, *The Advent of Gene Patenting: Putting the Great Debate in Perspective*, 13 SMU SCI. & TECH. L. REV. 89, 110 (2009). *See also* Patricia A. Lacy, Comment, *Gene Patenting: Universal Heritage vs. Reward for Human Effort*, 77 OR. L. REV. 783, 783 (1998) ("Except for one's innermost thoughts, it is difficult to imagine what is closer to the core of our identity than our genes.").

6. *See* 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, 297–98 (2007) ("[S]ome have argued that the proliferation of gene patents threatens to create a patent thicket that will render it difficult to conduct biomedical research, or to pursue follow-on research subsequent to the initial discovery of a gene.") (citing Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCI. 239, 239–40 (2005); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 701 (1998)). *But see* 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, 182 (2010) ("[G]ene patents do not interfere with research on diagnoses and potential cures; in fact, they promote research and cures.").

healthcare benefits of genetic research.[7] Fourth, some argue that gene patents appropriate information that is either already in the public domain or would be brought to light without the incentive of patent protection.[8] A common thread through many of these policy concerns is the notion that genes, although molecules, are best thought of as units of information, and not as matter, because genes act as means of storing and transmitting the basic blueprints for life.[9]

Until recently, these policy critiques of gene patents had little impact on the state of the law. The USPTO and the courts had accepted that not only the processes[10] of biotechnology but also the "products" of biotechnology (in this case, genes artificially reproduced through the application of biotechnology) were patentable subject matter under the Patent Act.[11] The Supreme Court, how-

7. *See, e.g.*, Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL'Y L. & ETHICS 403, 408 (2005) ("Gene patents can interfere with clinical adoption of genetic tests, potentially compromising the quality of testing by limiting the development of higher quality and lower-cost alternative testing methods."); Michael Crichton, *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, at A23 ("You, or someone you love, may die because of a gene patent that should never have been granted in the first place.").

8. *See* Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L. J. 783, 795 (2000) ("Much DNA sequence information is freely disclosed in the public domain, both by publicly funded researches and by private firms. If a discovery is likely to be made and disclosed promptly even without patent incentives, there is little point in enduring the social costs of exclusionary rights.").

9. *See, e.g.*, *id.* at 797 ("DNA molecules may be thought of as a tangible storage medium for information about the structure of proteins."); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 836 (1999) ("Although DNA is, obviously enough, a chemical compound, it is more fundamentally a carrier of *information*.").

10. The Patent Act allows patents on both products and processes. *See* 35 U.S.C. § 101 (2006) (allowing patents on any "process, machine, manufacture, or composition of matter" when the other statutory requirements are met). The scope of this Note is restricted to product patents on DNA, due in large part to the fact that the processes behind gene discoveries have become standard lab procedures, largely ineligible for patent protection. *See, e.g.*, *In re* Kubin, 561 F.3d 1351, 1356 (Fed. Cir. 2009) (commenting on the standard nature of gene discovery procedures); Brief for the United States as Amicus Curiae in Support of Neither Party at 21, Ass'n for Molecular Pathology v. USPTO, No. 2010-1406 (Fed. Cir. Oct. 29, 2010), 2010 WL 4853320, at *21 ("The *process* of applying restriction enzymes to select and extract a naturally occurring segment of DNA in the human genome from its chromosomal environment (now well understood in the art) was undoubtedly patent-eligible when it was first conceived, and an improved process for doing so may be the subject of a patent in the future.").

11. 35 U.S.C. §§ 1–376 (2006).

ever, has never addressed this question.[12] In addition, the USPTO and the courts had accepted that gene patents do not violate the judge-made prohibition on patenting "laws of nature, natural phenomena, and abstract ideas,"[13] a prohibition referred to in this Note as the "natural products doctrine" because it is generally understood to prohibit patents on products of nature.[14] USPTO policy has been to allow gene patents as long as the sequences have been "isolated and purified" (separated from the other molecules with which they are found in nature),[15] and the courts have generally taken a similar view.[16]

Recent legal developments, however, threaten the patentability of genes in the future. The Supreme Court's 2007 decision in *KSR International Co. v. Teleflex Inc.*[17] called into question whether naturally occurring genes can meet the statutory non-obviousness requirement for patentability.[18] Although not directly concerned with gene patents, *KSR* altered the non-obviousness analysis by holding that an invention can be unpatentably obvious if it is "obvious to try" based on prior art.[19] In *In re Kubin*,[20] the Federal Circuit applied *KSR* to gene patents and held for the first time that a gene's sequence can be obvious if the prior art discloses the encoded protein and a method of identifying the corresponding gene.[21]

More recently, in a lengthy 2010 opinion by Judge Sweet, a federal district court invalidated patent claims on two human genes believed to be important to screening for and understanding breast

12. *See* Intervet Inc. v. Merial Ltd., 617 F.3d 1282, 1293 (Fed. Cir. 2010) (Dyk, J., concurring in part and dissenting in part) ("Neither the Supreme Court nor this court has directly decided the issue of the patentability of isolated DNA molecules.").

13. Diamond v. Diehr, 450 U.S. 175, 185 (1981).

14. *See infra* Part I.C; *see also* Richard Seth Gipstein, *The Isolation and Purification Exception to the General Unpatentability of Products of Nature*, 4 COLUM. SCI. & TECH. L. REV. 2, 2 (2003), http://www.stlr.org/cite.cgi?volume=4&article=2; Harold Thorne, *Relation of Patent Law to Natural Products*, 6 J. PAT. OFF. SOC'Y 23, 25 (1923).

15. *See* 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) ("Thus, an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.").

16. *See, e.g.*, Amgen, Inc. v. Chugai Pharm. Co., 13 U.S.P.Q.2d 1737 (D. Mass. 1989), *aff'd in part*, *vacated in part*, 927 F.2d 1200 (Fed. Cir. 1991), *cert. denied*, 502 U.S. 856 (1991).

17. 550 U.S. 398 (2007).

18. *See* 35 U.S.C. § 103 (2006).

19. *KSR*, 550 U.S. at 419.

20. 561 F.3d 1351 (Fed. Cir. 2009).

21. *See id.* at 1360.

and ovarian cancer.[22] The case, *Association for Molecular Pathology v. USPTO*[23] (hereinafter *Myriad*, after one of the patent holders, Myriad Genetics), broke with prior case law by holding that the gene patents at issue violated the natural products doctrine and were therefore not patentable subject matter under the Patent Act.[24]

This Note argues that neither *Kubin* nor *Myriad* represents the appropriate judicial approach to the gene patent debate. The analysis in *Kubin*, although it displays an admirable rejection of formalism, is simply inconsistent with the text of the Patent Act and is not fully supported by the Supreme Court's opinion in *KSR*. *Myriad*, though grounded in Supreme Court precedent, fails to provide a workable test for applying the natural products doctrine. Further, it reveals the extent to which that doctrine is untethered from any textual basis. These flaws suggest that neither case offers the proper analysis through which courts should engage the policy concerns pervading the gene patent debate. If the outcomes in *Myriad* and *Kubin* (the invalidation of gene patents) are to be defended as more than judicial overreaching in an effort to address underlying policy concerns, then they must be placed on more solid doctrinal footing. The scholarly literature on gene patents contains two modes of analysis that could serve this purpose: a novel interpretation of the Patent Act[25] and a constitutional approach under the Intellectual Property Clause[26] (IP Clause).[27] This Note examines these alternatives.

This analysis yields three conclusions. First, the natural products doctrine, which was applied explicitly in *Myriad*, and perhaps covertly in *Kubin*, has little basis in the text or history of the Patent Act. Second, no meaningful advantage is gained by grounding the doctrine in the Patent Act's text; such an artificial construction gives us no greater understanding of the policy issues driving the

22. *See* John Schwartz & Andrew Pollack, *Judge Invalidates Human Gene Patent*, N.Y. TIMES, Mar. 23, 2010, at B1, *available at* http://www.nytimes.com/2010/03/30/business/30gene.html.

23. 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

24. *See id.* at 232.

25. *See* Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobviousness Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303 (2002).

26. *See* Oskar Liivak, *Maintaining Competition in Copying: Narrowing the Scope of Gene Patents*, 41 U.C. DAVIS L. REV. 177 (2007) [hereinafter Liivak, *Maintaining Competition*]; Oskar Liivak, *The Forgotten Originality Requirement: A Constitutional Hurdle for Gene Patents*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 261 (2005) [hereinafter Liivak, *Forgotten Originality Requirement*].

27. U.S. CONST. art. I, § 8, cl. 8.

debate. Finally, if the natural products doctrine is to have legitimate application to gene patents, its force and scope should be derived from the constitutional mandate of the IP Clause, which instructs us that the purpose of the patent monopoly is "[t]o promote the Progress of . . . useful Arts,"[28] i.e., to advance technological progress. Only by grounding the natural products doctrine in the IP Clause can courts legitimately discriminate between policy concerns that are relevant to the judicial inquiry, such as encouraging research and maintaining the public domain, and those that must be left to the legislature, such as the morality of gene patents and their effect on access to healthcare and diagnostic screening.

Part I gives a basic overview of genetics. It then surveys some of the difficulties of applying the Patent Act to gene patents, focusing on the provisions at issue in *Kubin* and *Myriad*. Part II considers how *Kubin* and *Myriad* might fit within two alternative frameworks from the scholarly literature on gene patents, one advocating a ban on gene patents based in an alternative interpretation of the Patent Act[29] and the other proposing a limitation on the scope of gene patent protection based on the constitutional restraints of the IP Clause.[30] Although both approaches are defensible, the Conclusion suggests that greater clarity, coherence, and guidance would be offered by adopting an expressly constitutional approach to the gene patent debate and, more broadly, the natural products doctrine.

I.
PATENT LAW APPLIED TO GENES

A. Genetics Overview

All living things store their biological blueprints in molecules called polynucleotides.[31] Polynucleotides come in two types, deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). Genetic information is stored in these molecules based on the sequence of four different nucleotide bases (referred to in shorthand as A, T, C,

28. *Id.*

29. *See* Demaine & Fellmeth, *supra* note 25.

30. *See* Liivak, *Maintaining Competition*, *supra* note 26; Liivak, *Forgotten Originality Requirement*, *supra* note 26.

31. To supplement the overview provided in this section, see generally JAMES WATSON ET AL., MOLECULAR BIOLOGY OF THE GENE (6th ed. 2008); BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL (4th ed. 2002). Some court opinions may also be helpful. *See, e.g.*, *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 192–210; *In re* Fisher, 421 F.3d 1365, 1367–68 (Fed. Cir. 2005).

and G).[32] Nucleotide bases naturally bond together in pairs: A with T and C with G.[33] This complementary base paring is the foundation of crucial cellular processes, as well as the human imitations and modifications of these processes we call biotechnology.

Groups of three consecutive nucleotides form codons. Some codons code for one of twenty different amino acids that make up proteins. Other codons do not code for an amino acid but indicate the start or end of a coding sequence of DNA (i.e., a sequence that gives the instructions for the creation of a protein). Because there are only twenty amino acids but more than twenty possible codons, there is more than one codon coding for some amino acids. This redundancy is known as the degeneracy of the genetic code. While the code is redundant, it is not ambiguous, meaning that each codon codes for one and only one amino acid.[34]

Groups of consecutive codons make up genes. Each gene codes for a sequence of amino acids that, when strung together, form a protein. Not all of the codons in a gene, however, code for amino acids in the resulting protein. Some codons, called introns, do not correspond to an amino acid in the resulting protein, while others, known as exons, do code for amino acids in the resulting protein.

DNA is stored in a double helix, a double-stranded form in which two complimentary strands of DNA are intertwined. The entire human complement of genes (the human genome) is spread throughout forty-six separate strands of DNA known as chromosomes. During gene expression, enzymes open up the double helix and transcribe a single-stranded RNA copy (mRNA), which is later translated into a protein made of amino acids. During this process, the non-coding introns are removed and only the exons dictate the composition of the resulting protein.

Biotechnology capitalizes on base pairing to find, copy, isolate, reproduce, and modify nucleotide sequences.[35] Due to the degeneracy of the genetic code, a researcher cannot, in the abstract,

32. In the case of DNA, these bases are adenine (A), thymine (T), guanine (G), and cytosine (C). In RNA, thymine is replaced by uracil (U).

33. For example, the sequence ATCTG would bond with the sequence TAGAC.

34. By analogy, if nucleotides are the letters of the genetic language, then codons are the words. Just as the English language has multiple words with the same meaning, the genetic code has more than one codon with the same corresponding amino acid. Unlike the English language, however, each "word" in the genetic code (each codon) has only one meaning.

35. For a helpful summary of the biotechnologies discussed in this paragraph, see Figure 8-44 and the accompanying summary in WATSON, *supra* note 31, at 513.

know the sequence of a gene based on the amino acid sequence of the protein for which it codes. Using standard laboratory techniques, however, it is possible to find the corresponding gene when even a small portion of the genetic sequence can be determined or estimated from the amino acid sequence of the protein of interest. This is accomplished by synthesizing a small piece of DNA, known as a probe, that is likely (based on its sequence) to bind with the DNA sequence in the genome that codes for the protein of interest. After the gene of interest is located in the genome, its full sequence can be determined. Standard techniques also make it possible to create an isolated and purified copy of the gene of interest without the other molecules (e.g., proteins) with which DNA is normally associated in nature. A special copy of a gene, called a cDNA, can also be produced. A cDNA excludes the non-coding introns normally found in the naturally occurring DNA sequence. A key common feature among all of these techniques is that, while they modify the chemical structure of genetic material in some respects, they all seek to maintain the informational content of genes as it exists in nature.

These relatively new technologies, along with a host of other technologies falling under the broad umbrella of biotechnology, "hold the very real potential to have a substantial impact on the welfare of almost every human on the planet."[36] Potential benefits from biotechnology include diagnostic testing for hereditary diseases, more effective pharmaceuticals, and new heights in food production through genetically modified plants and animals.[37] At the same time, however, "[h]ow this genomic information is best harnessed for the greater good presents difficult questions touching upon innovation policy, social policy, medical ethics, economic policy, and the ownership of what some view as our common heritage."[38]

36. John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 102 (2001).

37. *See id.* at 102–03.

38. Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 193 (S.D.N.Y. 2010). The stakes of the gene patent debate in particular are well illustrated by the facts underlying the *Myriad* litigation. In a blog post following Judge Sweet's decision, the ACLU characterized the ramifications of the decision as follows:

> This is a huge victory for women's health and scientific freedom. . . . [I]t will mean that the thousands of researchers and clinicians who have the ability to conduct BRCA testing and provide results to women, will no longer be prohibited from doing so. This could well mean that the price of this test will come down, making it accessible to many women for whom the current cost (Myriad

B. Legal Overview

The basic requirements for patentability are found in sections 101, 102, and 103 of the Patent Act. The language of section 101 has been retained from the first American patent statute, authored by Thomas Jefferson,[39] while sections 102 and 103 were added in 1952 when the patent laws were added to the United State Code.[40] Section 101 ("[i]nventions patentable") indicates what subject matter is eligible for a patent (any "process, machine, manufacture, or composition of matter") and requires that patents only issue for inventions that are "new and useful."[41] Section 102 ("[c]onditions for patentability; novelty and loss of right to patent") stipulates, inter alia, that the invention sought to be patented must not have been previously known or practiced (i.e., it must be novel).[42] Finally, section 103 ("[c]onditions for patentability; non-obvious subject matter") requires that the claimed invention not be obvious to a person of "ordinary skill" in the relevant field in light of prior inventions and information available in the public domain.[43] Thus, there are four basic requirements for patentability: patentable subject matter, utility, novelty, and non-obviousness.

---

charges over $3,000) is prohibitive. It would also mean that our six individual women plaintiffs and the thousands of other women affected by hereditary breast and ovarian cancer can more freely access critical information about their own genetics, such as getting a second opinion before taking drastic preventative measures like mastectomy or having their ovaries removed.

Selene Kaye, *Who Owns Your Genes? You Do.*, BLOG OF RIGHTS (Mar. 30, 2010, 5:18 PM), http://www.aclu.org/blog/free-speech-womens-rights/who-owns-your-genes-you-do.

39. *See* Diamond v. Chakrabarty, 447 U.S. 303, 308–09 (1980) ("The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as 'any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof].' . . . Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language.").

40. *See* Patent Act of 1952, Pub. L. No. 82-593, §§ 102–03, 66 Stat. 792, 797–98 (1952).

41. *See* 35 U.S.C. § 101 (2006).

42. *Id.* § 102. There are a number of separate requirements in section 102, each of which acts as an independent bar to the granting of a patent. For example, subsection (a) states that a claimed invention is not patent-eligible if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent," while subsection (c) prohibits a patent if the inventor "has abandoned the invention." *Id.* § 102(a), (c).

43. *See id.* § 103.

The proper application of section 101's utility requirement to gene patents was once a source of controversy,[44] but following the USPTO's adoption of new utility guidelines in 2001[45] and subsequent Federal Circuit case law applying these guidelines,[46] this debate has largely subsided.[47] It has also been suggested that gene patents run afoul of the word "new" in section 101 or of section 102's novelty requirement, but this is not the prevailing view.[48]

The *Myriad* and *Kubin* decisions dealt with the application of section 101's subject matter requirement and section 103's non-obviousness requirement to gene patents. Therefore, these are the patentability requirements on which this Note will focus.

C. Myriad and the Subject Matter Requirement

Section 101 states in its entirety that "[w]hoever 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."[49] As discussed, the word "useful" imposes a utility requirement, while the word "new" is generally regarded as a

44. KALYAN C. KANKANALA, GENETIC PATENT LAW & STRATEGY 34 (2007) (commenting on the USPTO's "response to the huge volume of patent applications from the biotechnology industry for unknown DNA sequences that had no known biological function").

45. *See* 66 Fed. Reg. 1092 (Jan. 5, 2001) (giving notice of the adoption of Utility Examination Guidelines).

46. *See In re* Fisher, 421 F.3d 1365, 1373 (Fed. Cir. 2005) (applying the utility guidelines and holding that gene sequences that were mere "research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes," but which lacked a "specific and substantial" use on their own, were not patentable under section 101).

47. *See, e.g.*, Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 228 n.50 (S.D.N.Y. 2010) ("The parties do not appear to dispute that isolated DNA claimed in the patents-in-suit are 'useful' for purposes of § 101.").

48. According to the Senate report accompanying the bill, "[s]ection 102, in general may be said to describe the statutory novelty required for patentability, and include, in effect, an amplification and definition of 'new' in section 101," thereby foreclosing the argument that the word "new" in section 101 has meaning independent of section 102. S. REP. NO. 82-1979, at 6 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399. Nevertheless, Oskar Liivak, whose views are discussed at greater length *infra* Part II.B, argues that 35 U.S.C. § 102(f), which states that "[a] person shall be entitled to a patent unless . . . (f) he did not himself invent the subject matter sought to be patented," should be interpreted to bar patents on products of nature, including genes. *See* Liivak, *Forgotten Originality Requirement*, *supra* note 26, at 278–79.

49. 35 U.S.C. § 101 (2006).

prelude to section 102's novelty requirement. Less clear, however, is what limitation, if any, is imposed by the phrases "invents or discovers" and "process, machine, manufacture, or composition."[50] In other words, what limitations does section 101 put on the subject matter of a patent and the manner of its derivation?

The Supreme Court has established a limitation on the subject matter of patents that excludes "laws of nature, natural phenomena, and abstract ideas."[51] Neither the justification nor the statutory basis, if any, for this exclusion has been totally clear.[52] Justice Breyer and Justice Stevens have both suggested that the exclusion has a constitutional basis grounded in the IP Clause.[53] In contrast, Justice Kennedy has expressed the view that the excluded subject matter is now covered by statutory *stare decisis* based on the doctrine's 150-year history, regardless of whether the doctrine has a viable hook in the statutory language.[54]

As the following discussion will make clear, the constitutional origin of the prohibition on patenting laws of nature, natural phenomena, and abstract ideas is questionable as a historical matter. Whether the Court's prohibition on patenting nature can or should be grounded in the Constitution will be explored further in Part II.B.

---

50. *Id.*

51. Diamond v. Diehr, 450 U.S. 175, 185 (1981). *See, e.g.*, Bilski v. Kappos, 130 S. Ct. 3218, 3226–30 (2010) (holding that a business method for hedging risk could not be patented because it was not a "process" within meaning of section 101 but instead covered "abstract ideas").

52. The notion that the natural products doctrine is grounded in the Patent Act's text is doubtful given that commentators cannot agree on which provisions are implicated. *Compare* John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part I)*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 301, 307 (2003) (proposing section 101's patentable subject matter requirement as "a legal hook on which to hang the varied, often inchoate concerns about the rapid monopolization of the biological public domain"), *with* Michael A. Sanzo, *Patenting Biotherapeutics*, 20 HOFSTRA L. REV. 387, 391–92 (1991) (arguing that "[t]here is, in fact, nothing in the patent statute precluding the patenting of products of nature" and that "[t]o the extent that such statements have a statutory basis, they are really contentions that inventions are unpatentable because they lack novelty or are obvious"). Others have looked to the Constitution's IP Clause for guidance. *See* Gipstein, *supra* note 14, at ¶ 6 ("[I]t may be preferable to disregard the statutory provisions altogether, and determine whether an invention is a product of nature by conducting a constitutional analysis.").

53. *See infra* Part II.B.

54. *See infra* Part II.A.

1. Precedent for Patenting Nature

The debate regarding the application of the subject matter requirement to biotechnology is often traced to the 1948 case, *Funk Brothers Seed Co. v. Kalo Inoculant Co.*,[55] in which the Supreme Court rejected a patent on a combination of naturally occurring bacteria. Although *Funk Brothers* was decided before the addition of sections 102 and 103 to the Patent Act in 1952, the tension between the majority opinion and Justice Frankfurter's concurrence encapsulates much of the doctrinal debate surrounding gene patents today under section 101.

The patent at issue in *Funk Brothers* claimed, *inter alia*, a useful combination of bacteria,[56] the unique composition of which allowed growers to use a single mixture of inoculants for a variety of crops.[57] In rejecting the claim to the bacterial combination, the Court emphasized that the patentee had not invented anything new, but had merely repackaged nature's handiwork. As the Court explained:

> [The patentee] does not create state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. . . . The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.[58]

Although the patentee's combination was new as a practical matter and useful for growing plants, the Court considered the patentee's contribution to be a mere advance in the packaging of na-

55. 333 U.S. 127 (1948).

56. *Id.* at 128 n.1 (The patent claimed "[a]n inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus Rhizobium, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.").

57. *Id.* at 131 ("There is, of course, an advantage in the combination. The farmer need not buy six different packages for six different crops. He can buy one package and use it for any or all of his crops of leguminous plants. And, as respondent says, the packages of mixed inoculants also hold advantages for the dealers and manufacturers by reducing inventory problems and the like.").

58. *Id.* at 130 (internal citations omitted).

ture, which failed to "satisfy the requirements of invention or discovery"[59]—language that remains in the statute today.[60]

Justice Frankfurter's concurrence, in contrast, would have steered clear of the majority's broad language and decided the case on narrower grounds. Although agreeing that the patent was invalid due to its failure to specify the precise combination of bacteria claimed, Frankfurter objected that "[i]t only confuses the issue . . . to introduce such terms as 'the work of nature' and the 'laws of nature,'" reasoning that "[e]verything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.'"[61] Frankfurter pointed out that the majority's requirement that "[i]f there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end"[62] was easily satisfied by the combination of bacteria at issue. Despite Frankfurter's objections, however, the decision continues to stand for the proposition that nature is not patentable.

The Supreme Court's next significant foray into the field was the 1980 case *Diamond v. Chakrabarty*,[63] which was also the first time this issue was dealt with under the 1952 Patent Act. In *Chakrabarty*, the Supreme Court considered whether "a live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101."[64] At issue was a "human-made, genetically engineered bacterium . . . capable of breaking down multiple components of crude oil."[65] One of Chakrabarty's patent claims covered the bacterium itself, as contrasted with the process of creating the organism.[66] The Court treated the question presented as "a narrow one of statutory interpretation," thus requiring that the Court "determine whether respondent's micro-organism constitutes a 'manufacture' or 'composition of matter' within the meaning of the statute."[67]

59. *Id.* at 131–32.

60. Although *Funk Bros.* was decided before the 1952 Patent Act, the statutory language applicable at the time was the same as that presently found in section 101. *See* Diamond v. Chakrabarty, 447 U.S. 303, 308–09 (1980) ("The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as 'any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof].' . . . Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language.").

61. *Funk Bros.*, 333 U.S. at 135–36 (Frankfurter, J., concurring).

62. *Id.* at 130.

63. 447 U.S. 303 (1980).

64. *Id.* at 305.

65. *Id.*

66. *Id.* at 306.

67. *Id.* at 307 (quoting 35 U.S.C. § 101).

In affirming the validity of the patent claim, the Court highlighted both the broad scope embraced by the 1952 Patent Act and its relevant limits. As evidence of the Act's broad scope, the Court quoted both Committee Reports, which stated that the statutory subject matter requirement encompasses "anything under the sun that is made by man."[68] The Court reaffirmed, however, that "laws of nature, physical phenomena, and abstract ideas have been held not patentable."[69] To preserve this distinction, the Court distinguished *Funk Brothers*: "the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101."[70]

As one article noted, "[p]erhaps the most surprising aspect of *Chakrabarty*, and the one with the most profound implications, is that the Supreme Court construed section 101 of the 1952 Patent Act to encompass living organisms."[71] As exemplified by *Funk Brothers*, the doctrine prior to the adoption of the 1952 Patent Act had been that life was not patentable.[72] The change of course in *Chakrabarty* cannot be attributed to the adoption of new statutory language, as the text of section 101 in the 1952 Patent Act dates back to the first American patent statute.[73] Thus, given that the Court chose to preserve the prohibition against patents on natural phenomena, *Chakrabarty* is probably best understood as the application of old doctrine to new facts.

The Court has never ruled on gene patents specifically, although it has denied *certiorari* on at least one occasion.[74] In the absence of a case refining the distinction between *Funk Brothers* and

68. *Id.* at 309 (quoting S. REP. NO. 82-1979, at 5 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399; H.R. REP. NO. 82-1923, at 6 (1952)).

69. *Id.* (collecting cases).

70. *Id.* at 310.

71. Demaine & Fellmeth, *supra* note 25, at 317.

72. The only exception to this rule was the limited protection Congress extended to unique asexually reproducing plants under the Plant Patent Act of 1930. *See* 35 U.S.C. §§ 161–164 (2006).

73. *See* Diamond v. Chakrabarty, 447 U.S. 303, 308–09 (1980) ("The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as 'any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof].' . . . Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language.").

74. Genetics Inst. v. Amgen, Inc., 502 U.S. 856 (1991), *denying cert.* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991).

Chakrabarty, the USPTO and lower courts have been left to determine on which side of the divide gene patents fall.[75]

2. The Purification Exception to the Natural Products Doctrine

An additional question central to the gene patent debate is whether the act of purifying a natural substance, not patentable in its natural form, renders the resulting substance patentable. There is an abundance of case law holding that purified natural substances are not patentable, but there are also cases indicating that purification can render a substance not only different in concentration but also different in kind from the natural form, at which point it becomes patentable.[76]

Opponents of gene patentability often cite the 1874 case *American Wood Paper Co. v. Fibre Disintegrating Co.*,[77] in which the Supreme Court held that purified wood and vegetable pulp was not patentable because it was "an extract obtained by the decomposition or disintegration of material substance" found in nature.[78] The Court reasoned that, although the inventor may have devised a new and useful method of obtaining the substance, the substance itself had not changed. Thus, "[a] process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture."[79] This distinction between a natural substance and the man-made process used to extract or purify it was maintained in several other cases dealing with, for example, a purified natural dye, the removal of a natural fiber from a species of tree, and a purified form of tungsten; the Supreme Court has not since ruled to the contrary.[80]

75. The Court revisited the patentability of life in a case concerning whether plants could be patented under the 1952 Patent Act in light of the more specific provisions of the Plant Patent Act of 1930, 35 U.S.C. §§ 161–164, and the Plant Variety Protection Act, 7 U.S.C. §§ 2321–31, 2351–57, 2371–72, 2401–04, 2421–27, 2441–43, 2461–63, 2481–86, 2501–04, 2531–32, 2541–45, 2561–70, 2581–83 (2006). *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001). The analysis in *J.E.M.* reaffirmed the line drawn by *Chakrabarty*, holding that the more specific provisions of the Plant Patent Act did not restrict the scope of patentable subject matter under section 101 of the 1952 Patent Act. *See id.* at 129–30.

76. *See generally* Gipstein, *supra* note 14.

77. 90 U.S. 566 (1874).

78. *Id.* at 570.

79. *Id.* at 593–94.

80. *See* Gen. Electric Co. v. De Forest Radio Co., 28 F.2d 641, 643 (3d Cir. 1928) (holding purified tungsten not patentable because "[i]t existed in nature and doubtless has existed there for centuries. The fact that no one before [appli-

In response, defenders of gene patentability point to instances in which purified natural substances were granted patent protection. This exception to the natural products doctrine can be traced back to Learned Hand's 1911 decision in *Parke-Davis & Co. v. Fibre Disintegrating Co.*,[81] upholding a product patent on human adrenaline purified from the suprarenal glands. Prior to the advent of the patentee's claimed invention, it had been common to inject or consume a solution made from the dried and powdered glands, which, although therapeutic, had dangerous side effects stemming from the solution's impurity.[82] Through a process (for which he also was issued a patent), the patentee had purified the active ingredient, allowing him to sell a purer, and therefore safer, form of adrenaline.[83] In evaluating the validity of the patent claims covering the product, Judge Hand stated that "even if it were merely an extracted product without change, there is no rule that such products are not patentable" and that "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."[84]

In what might be considered the leading case for the proposition that purification renders a natural product patentable subject matter, *Merck & Co. v. Olin Mathieson Chemical Corp.*,[85] decided in 1958, the Fourth Circuit upheld a patent on a purified form of vitamin B_{12}. Although the vitamin is found "in minute quantities in the bodies of cattle,"[86] the patentee claimed the B_{12} resulting from the fermentation of Fungi, which he had discovered yielded a more

cant] found it there does not negative its origin or existence"); *Ex parte* Latimer, 1889 Dec. Comm'r Pat. 123, 125 (1889) (rejecting a patent on fiber removed from a species of pine tree); Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293 (1884) (holding a man-made dye not patentable because of similarity to a naturally occurring version, despite being brighter).

81. 189 F. 95 (C.C.S.D.N.Y. 1911).

82. *Id.* at 106.

83. *Id.*

84. *Id.* at 103. Hand elaborated as follows:

> Everyone not already saturated with scholastic distinctions, would recognize that [the patentee's] crystals were not merely the old dried glands in a purer state, nor would his opinion change if he learned that the crystals were obtained from the glands by a process of eliminating the inactive organic substances. The line between different substances and degrees of the same substance is to be drawn rather from the common usages of men than from nice considerations of dialectic.

Id.

85. 253 F.2d 156 (4th Cir. 1958).

86. *Id.* at 161.

therapeutically useful composition.[87] The district court had held that the product claims were invalid "upon the grounds that they covered a 'product of nature.'"[88] The Fourth Circuit reversed, holding that the product claims did not cover pure vitamin B_{12} but only the specific B_{12}-active composition derived from the claimant's fermentation process, thereby excluding "B_{12} compositions derived from liver or any source other than the specified fermentates."[89] According to the court, the key difference between the two was that the claimed product was "of very great therapeutic and commercial importance," as it could be "cheaply and abundantly produced and all toxic and harmful substances eliminated."[90] In a manner reminiscent of Justice Frankfurter's concurrence in *Funk Brothers*, the *Merck* court reasoned that "[a]ll of the tangible things with which man deals and for which patent protection is granted are products of nature in the sense that nature provides the basic source materials"[91] and denied that this created any barrier to patentability.[92] In other words, *Merck* held that the claimed vitamin composition, although similar to a version found in nature, was different in commercially significant ways and was therefore patentable.

While *Parke-Davis* and *Merck* remain influential, two things should be kept in mind. First, these cases were decided neither by the Supreme Court nor by the Federal Circuit, which has become largely responsible for the development of patent law. Second, the reasoning in both cases relied heavily on the enhanced utility of the claimed product, without regard to whether it was also "new" pat-

87. *Id.* at 157–58.

88. *Id.* at 157 (citation omitted).

89. *Id.* at 160.

90. *Id.*

91. *Id.* at 161–62.

92. More specifically, the *Merck* opinion maintained that the natural products doctrine was really nothing more than shorthand for the conclusion that a particular product was not patentable under the requirements of the Patent Act. *Id.* The court broke down the natural products doctrine into two distinct propositions, each of which it considered independently valid. First, the court stated that "a patent may not be granted upon an old product though it be derived from a new source by a new and patentable process." *Id.* at 162. Second, "every step in the purification of a product is not a patentable advance . . . if the new product differs from the old 'merely in degree, and not in kind.'" *Id.* Applying the first principle, the *Merck* court distinguished *American Wood Paper* on the grounds that the B_{12} composition was not an old product produced by a new method, but in fact a "new product" with "advantageous characteristics as to replace" the older form of treatment, which was to consume large amounts of liver in order to ingest the required B_{12}. *Id.* at 163. Applying the second principle, the court found that the B_{12} composition was not only more pure than the natural liver product, but it was in fact different in kind because of its far superior practical application. *Id.* at 163–64.

entable subject matter as required by section 101 or novel under section 102. The *Parke-Davis* and *Merck* courts concluded that a natural substance that is purified to the point that it achieves a new utility is *ipso facto* new, an interpretation that tends to erode the independent meaning of the subject matter and novelty requirements.

3. The Purification Exception Applied to Gene Patents

Until recently, it was generally understood that patents on purified and isolated genes fit within the exception to the natural products doctrine put forward in *Parke-Davis* and *Merck*. This, at least, was the position of the USPTO as expressed in 2001,[93] as well as the conclusion of the District Court for the District of Massachusetts in the 1989 case *Amgen, Inc. v. Chugai Pharmaceutical Co.*,[94] which was affirmed by the Federal Circuit without discussion of the section 101 issue. The 2010 *Myriad* decision, however, broke this pattern by holding that patents on naturally occurring genes, even if the patents only claim isolated and purified sequences, are invalid under section 101.[95]

In *Amgen*, the district court found that the purification exception to the natural products doctrine applied to gene patents.[96] The case concerned the validity of a claim for the "purified and isolated" DNA sequence encoding the human protein erythropoietin (EPO).[97] The district court indicated that a patent on a human gene as it exists in nature would be invalid, stating, "[t]he invention claimed . . . is *not* as plaintiff argues the DNA sequence encoding human EPO since that is a nonpatentable natural phenomenon 'free to all men and reserved exclusively to none.'"[98] The court found that the claim was valid because it covered only the "'purified and isolated' DNA sequence encoding erythropoietin."[99] The Federal Circuit affirmed the district court's decision on this issue without further discussion.[100]

93. *See* 66 Fed. Reg. 1092 (Jan. 5, 2001).

94. 13 U.S.P.Q.2d 1737 (D. Mass. 1989), *aff'd in part*, *vacated in part*, 927 F.2d 1200 (Fed. Cir. 1991), *cert. denied*, 502 U.S. 856 (1991).

95. Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 232 (S.D.N.Y. 2010).

96. *Amgen*, 13 U.S.P.Q.2d at 1759.

97. *Id.* at 1738, 1759.

98. *Id.* at 1759 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

99. *Id.*

100. *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1203 (Fed. Cir. 1991) ("We affirm the district court's holding in all respects, except that we reverse the court's ruling that claims 1 and 3 of the '195 patent are enabled.").

The Notice accompanying the USPTO's 2001 utility guidelines (the Notice) contains reasoning similar to *Amgen*.[101] In responding to public comments on the guidelines, the USPTO explained why it considered isolated and purified gene sequences patentable subject matter. "Patent law," the Notice stated, "provides no basis for treating DNA differently from other chemical compounds that are compositions of matter,"[102] stressing that the hands of the USPTO were tied by the statutory requirements of the Patent Act.[103]

The Notice outlined a fairly formalistic interpretation of section 101, under which purified and isolated gene sequences are treated as "compositions of matter," and flatly rejected the notion that the patentability inquiry should focus on the informational content of genes (i.e., their role as the basic unit of inheritance). The Notice stated that, "[l]ike other chemical compounds, DNA molecules are eligible for patents when isolated from their natural state and purified or when synthesized in a laboratory from chemical starting materials."[104] The Notice drew a distinction between the informational content of a gene, as represented by the sequence of nucleotides, and the actual molecule itself, explaining that a DNA sequence in the abstract "is not patentable because a sequence is merely descriptive information about a molecule," while "[a]n isolated and purified DNA molecule may be patentable because a molecule is a 'composition of matter,' one of the four classes of invention authorized by 35 U.S.C. 101."[105]

In 2010, Judge Sweet of the Southern District of New York broke with precedent in holding that patent claims on two purified and isolated genes were invalid under section 101.[106] The plaintiffs challenged the validity of patent claims covering two genes, BRCA1 and BRCA2, mutations in which had been found to correlate with increased risk of breast and ovarian cancer. Although the plaintiffs challenged the patents on both statutory and constitutional grounds,[107] Judge Sweet decided the case solely under the natural

101. 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

102. *Id.* at 1095.

103. *Id.* ("The scope of subject matter that is eligible for a patent, the requirements that must be met in order to be granted a patent, and the legal rights that are conveyed by an issued patent, are all controlled by statutes which the USPTO must administer.").

104. *Id.* at 1093.

105. *Id.* at 1095.

106. *See* Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

107. *Id.* at 184. The plaintiffs challenged the patents under the following bases:

products doctrine, construing the doctrine as a judicial gloss on section 101.

The court's analysis treated *Chakrabarty* as the controlling Supreme Court precedent. Judge Sweet noted that the Court in that case contrasted "the *Chakrabarty* bacterium with the bacterial mixture at issue in *Funk Brothers*, stating that in Chakrabarty's case, 'the patentee has produced a new bacterium with markedly different characteristics from any found in nature.'"[108] Seizing upon this language,[109] Sweet elucidated the requirement that an invention possess "markedly different characteristics" from a naturally occurring substance in order to qualify as patentable subject matter.[110]

Using this test, Sweet determined that the isolated DNA sequences claimed by the defendants were not "markedly different" from naturally occurring DNA sequences and therefore found the patent claims invalid under section 101.[111] The court's reasoning evaded the isolation and purification exception by focusing on the informational content of the genetic sequences instead of their chemical composition: "In light of DNA's unique qualities as a physical embodiment of information," Sweet explained, "none of the structural and functional differences cited by Myriad between native BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed in the patents-in-suit render the claimed DNA 'markedly different.'"[112] The perseveration of DNA's "defining characteristic"—the fact that it coded for proteins—thus rendered the isolated sequences not "markedly different" from the natural sequences, and therefore the purification exception to the natural products doctrine did not apply.[113]

---

(1) the Patent Act, 35 U.S.C. § 101 (1952), (2) Article I, Section 8, Clause 8 of the United States Constitution, and (3) the First and Fourteenth Amendments of the Constitution because the patent claims covered products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought.

Id.

108. *Id.* at 223 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980)).

109. It was by no means clear that the phrase "markedly different" best captured the holding in *Chakrabarty*, as others have focused on the requirement that a proposed invention be a "nonnaturally occurring manufacture or composition of matter—a product of human ingenuity." Conley & Makowski, *supra* note 52, at 303 (quoting *Chakrabarty*, 447 U.S. at 308–09); Golden, *supra* note 36, at 124 & n.118 (same).

110. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 223.

111. *Id.* at 227–32.

112. *Id.* at 229.

113. *Id.* Judge Sweet distinguished *Parke-Davis* as a case about "novelty (a modern-day § 102 question), and not of patentable subject matter" under modern-

It appears that Judge Sweet's position might have at least one vote among the judges on the Federal Circuit. Judge Dyk, concurring in part and dissenting in part from an unrelated gene patent dispute before the Federal Circuit on issues unrelated to patentable subject matter, expressed skepticism that purified and isolated genes are patentable subject matter.[114] "It is far from clear," Dyk stated, "that an 'isolated' DNA sequence is qualitatively different from the product occurring in nature such that it would pass the test laid out in *Funk Brothers* and *Chakrabarty*."[115] Judge Dyk also hinted at the policy concerns that might justify a prohibition on gene patents: "[A]llowing the patenting of naturally occurring substances," Dyk explained, might "preempt the use by others of substances that should be freely available to the public."[116]

In contrast, Chief Judge Rader of the Federal Circuit has criticized Judge Sweet's reasoning. In a statement that sparked a motion for his recusal in the ensuing appeal from Judge Sweet's decision,[117] Rader said the following at an academic conference following the *Myriad* decision:

> A troublesome question for me is the lack of legal standard for making this decision. In an obviousness analysis, there are some neutral steps that I can apply. But using Section 101 to say that the subject matter is unpatentable is so blunt a tool that there is no neutral step to allow me to say that there is a line here that must be crossed and that this particular patent claim crosses it or does not. . . . This approach is subjective, and, to be frank, it's politics. It's what you believe in your soul, but it isn't the law.[118]

---

day section 101, and noted that the statement relied upon by Myriad was dicta. *Id.* at 225. To distinguish *Merck*, the court noted that the *Merck* court found that "the purified B_{12} was more than a 'mere advance in the degree of purity of a known product,'" such that the *Merck* court presumably would have found that the purified product was not just more pure, but in fact qualitatively different under Sweet's "markedly different" test. *Id.* at 227 (quoting Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 164 (4th Cir. 1958)).

114. *See* Intervet Inc. v. Merial Ltd., 617 F.3d 1282, 1293–94 (Fed. Cir. 2010) (Dyk, J., concurring in part and dissenting in part).

115. *Id.* at 1295.

116. *Id.* at 1294.

117. *See* Motion by Plaintiffs-Appellees for Recusal of Chief Judge Randall R. Rader, Ass'n For Molecular Pathology v. USPTO, No. 2010-1406 (Fed. Cir. June 29, 2010), *available at* http://patentdocs.typepad.com/files/motion-for-recusal-of-chief-judge-rader.pdf.

118. *Id.* at 5 (quoting John T. Aquino, *Finding Gene Patents Unpatentable Too Blunt an Approach, Panelists Say*, BNA's PAT., TRADEMARK & COPYRIGHT J., May 14,

Rader's comments are noteworthy for two reasons. First, he raised an important criticism of Sweet's approach in *Myriad*. Although Sweet treated the "markedly different" language from *Chakrabarty* as the section 101 test for patenting natural products, the test doesn't offer much guidance—how different is "markedly different"?[119] Second, Rader (who wrote for the Federal Circuit in *Kubin*, in which the Federal Circuit found a gene patent obvious under section 103[120]) drew a stark contrast between the section 103 obviousness limitation imposed on gene patents in that case and the "blunt," politically motivated section 101 subject matter approach in *Myriad*.

The following discussion of *Kubin*, however, gives reason to doubt that the section 103 approach to the gene patent problem is truly more objective and faithful to the statutory text and controlling precedents than the reasoning in *Myriad*.

D. Kubin and the Non-Obviousness Requirement

Besides *Myriad*, the most recent judicial event in the gene patent debate was the Federal Circuit's 2009 decision in *In re Kubin*.[121] The *Kubin* decision, written by Judge Rader, has also received criticism for stretching the meaning of the non-obviousness requirement found in section 103.

Section 103 promotes the aims of the patent system by prohibiting the patenting of inventions too obvious to warrant patent protection.[122] Subsection (a) states:

2010, at 47). See discussion of *In re Kubin* and the non-obviousness requirement, *infra* Part I.D.

119. The United States, in its amicus brief in Myriad's appeal to the Federal Circuit, took the intermediate position that while purified genomic DNA is not patentable under *Chakrabarty*, Judge Sweet's opinion "erroneously cast doubt on the patent-eligibility of a broad range of man-made compositions of matter whose value derives from the information-encoding capacity of DNA" such as "cDNAs, vectors, recombinant plasmids, and chimeric proteins." Brief for the United States as Amicus Curiae in Support of Neither Party at 9, Ass'n for Molecular Pathology v. USPTO, No. 2010-1406 (Fed. Cir. Oct. 29, 2010), 2010 WL 4853320. Whether the distinction between purified genomic DNA and cDNA should be legally significant is questionable, given that cDNA is created through standard laboratory procedures and serves the same protein-encoding function as genomic DNA. *See* Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 198 (S.D.N.Y. 2010) ("Because it is derived from mRNA, a cDNA molecule represents an exact copy of one of the protein coding sequences encoded by the original genomic DNA.").

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

121. *Id.*

122. *See* 35 U.S.C. § 103(a) (2006).

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.[123]

It also states that "[p]atentability shall not be negatived by the manner in which the invention was made."[124]

Prior to *Kubin*, the Federal Circuit applied a non-obviousness standard to gene patents that focused on the structure of the claimed sequence.[125] In order for a claimed chemical, including DNA, to be obvious, it had to be structurally similar in its chemical composition to another chemical found in the prior art.[126] Despite the increasing availability of methods allowing researchers to use the structure of a protein to locate the coding DNA sequence in the genome,[127] the Federal Circuit had held that the structure of a pu-

123. *Id.*

124. *Id.* Section 103(a) was added in 1952 in recognition of the reality that both patent examiners and the courts had been rejecting patent claims "on the ground of lack of invention or lack of patentable novelty . . . since at least as early as 1850," and in the hope that "an explicit statement in the statute may have some stabilizing effect, and also to serve as a basis for the addition at a later time of some criteria which may be worked out." 35 U.S.C.A. § 103 (1952 Notes). The second sentence of section 103 was included in order to clarify that "it is immaterial whether [an invention] resulted from long toil and experimentation or from a flash of genius." *Id.* In other words, the test for inventiveness (i.e., non-obviousness) is not the proverbial "sweat of the brow." The anticipated "criteria" for non-obviousness were apparently never "worked out" by Congress.

Subsection (b), which was added in 1995, deals specifically with claims to a "biotechnology process." 35 U.S.C. § 103(b); Pub. L. No. 104-41, § 1(3) (1995) (adding subsection (b) to section 103). The legislative history for this section evidences a concern with foreign competition and the ability of U.S. patent holders to protect the processes by which useful therapeutics are produced. *See* 141 Cong. Rec. S11201-03, S11207 (daily ed. Aug. 2, 1995) (statement by Sen. Hatch). Although interesting in its own right, subsection (b) does not bear directly on the subject of this Note because it concerns the patentability of biotechnology processes, and not the patentability of products such as purified and isolated gene sequences.

125. *See In re* Deuel, 51 F.3d 1552 (Fed. Cir. 1995); *In re* Bell, 991 F.2d 781 (Fed. Cir. 1993).

126. *See Deuel*, 41 F.3d at 1558; Bell 991 F.2d at 781.

127. *See* Rebecca S. Eisenberg, *Pharma's Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375, 403 (2008) ("In the early years of the biotechnology industry, isolating a DNA sequence that encodes a known protein was a significant technological challenge . . . . But over time, this became a routine step using familiar techniques that scientists of ordinary skill would deploy with a reasonable expectation of success."); Rai, *supra* note 9, at 834 ("[M]any biotechnology companies are seeking patents on hundreds of thousands of DNA sequence fragments that they have been able to isolate quickly through routine, automated methods.").

rified and isolated gene was not obvious simply because the structure of the encoded protein was known in the prior art. The reasoning behind this approach was that the degeneracy of the code meant that one could not be derived from the other without conducting an experiment.[128] Thus, prior to *Kubin*, "a DNA molecule [would] be determined to be obvious only if it [was] structurally similar to prior art products, even if one of skill in the art would consider it obvious to obtain the DNA molecule using familiar prior art methods."[129] The Supreme Court's decision in *KSR*, however, substantially undermined the Federal Circuit's structural non-obviousness analysis, and *KSR*'s application to gene patents in *Kubin* marks a significant shift in the Federal Circuit's treatment of gene patents,[130] potentially opening the door for other challengers to contest the validity of gene patents on similar facts.[131]

1. *KSR* Clarifies the Non-Obviousness Requirement

KSR International Co. v. Teleflex Inc.[132] arose out of Teleflex's claim that KSR had infringed Teleflex's patent on an adjustable

128. *See Deuel*, 51 F.3d at 1558–59. The *Deuel* court reasoned as follows:

> A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein . . . [and t]he PTO's focus on known methods for potentially isolating the claimed DNA molecules is also misplaced because the claims at issue define compounds, not methods.

Id. Thus, in the court's view, "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." *Id.* at 1559.

129. Amy Nelson, *Obviousness or Inventive Step as Applied to Nucleic Acid Molecules: A Global Perspective*, 6 N.C. J. L. & TECH. 1, 6 (2004); *see also* Michael J. Stimson, *Is the Gene Patenting Party Over? Biotechnology Patents After* In re Kubin, 28 BIOTECHNOLOGY L. REP. 329, 329 (2009) ("But even when the sequence of the protein was known, as was the case in Bell and Deuel, the court held that the structure of the nucleic acid was not obvious because it could not be derived from the protein sequence.").

130. While *Kubin* marks a significant shift in the Federal Circuit's analysis, the standard employed in *Kubin* was actually used in an earlier Federal Circuit case. *See In re* O'Farrell, 853 F.2d 894, 903–04 (Fed. Cir. 1988).

131. *Cf.* Conley and Makowski, *supra* note 52, at 307 (writing before *KSR* that, "[w]ith obviousness being an issue only in occasional contexts, and with patent lawyers having adroitly solved problems of utility and the written description requirement, there is little basis in the text of the statute other than subject matter for denying patents to cell lines, gene sequences, and the like").

132. 550 U.S. 398 (2007).

pedal assembly.[133] KSR's defense was that Teleflex's patent was invalid for obviousness because it merely combined elements already disclosed in the prior art.[134] Applying the teaching, suggestion, or motivation (TSM) test, the Federal Circuit held that the patent claim was not obvious under section 103.[135]

The Supreme Court reversed, rejecting the TSM test, at least as applied by the Federal Circuit,[136] and gave an explanation of the history and proper application of section 103 grounded in the Court's holding in the 1966 case *Graham v. John Deere Co. of Kansas City*.[137] Writing for the Court, Justice Kennedy noted that the analysis found in *Graham* originated with the nineteenth-century case *Hotchkiss v. Greenwood*,[138] which advocated a "functional approach" to patentability and "invited courts, where appropriate, to look at any secondary considerations that would prove instructive."[139] In contrast, Kennedy characterized the TSM test employed by the Federal Circuit as "rigid."[140] In rejecting the TSM test, at least as applied below, Kennedy emphasized that the proper analysis under section 103 predates the 1952 Act. "Neither the enactment of § 103 nor the analysis in *Graham*," Kennedy explained, "disturbed this Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in

133. *Id.* at 406 (The patent claimed "a mechanism for combining an electronic sensor with an adjustable automobile pedal so the pedal's position can be transmitted to a computer that controls the throttle in the vehicle's engine.").

134. *Id.*

135. *Id.* at 407. Under the TSM test, a claim is "only proved obvious if 'some motivation or suggestion to combine the prior art teachings can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art.'" *Id.* (quoting Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1323–24 (Fed. Cir. 1999)).

136. *Id.*

137. Graham v. John Deere Co. of Kan. City, 383 U.S. 1 (1966). In *Graham*, the Court laid out the following section 103 framework:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Id. at 17–18.

138. 52 U.S. (11 How.) 248 (1851).

139. *KSR*, 550 U.S. at 415.

140. *Id.*

the prior art."[141] Thus, Kennedy reaffirmed that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."[142]

KSR not only rejected the rigid application of the TSM test, but also explicitly endorsed the "obvious to try" standard previously rejected by the Federal Circuit in favor of an approach based on structural similarity.[143] Kennedy explained that a claimed invention could be "obvious to try" and hence invalid under section 103 "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions," such that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp."[144] In such cases, the claimed invention is "likely the product not of innovation but of ordinary skill and common sense."[145]

The situation Kennedy described is arguably a close fit with many gene discoveries today and commentators anticipated that *KSR* would have great significance for gene patents.[146] These predictions were vindicated by the Federal Circuit's decision in *In re Kubin*.[147]

2. *Kubin* Applies *KSR* to Gene Patents

In re Kubin[148] involved an appeal from the rejection of appellants' claim to the nucleotide sequence encoding a protein called Natural Killer Cell Activation Inducing Ligand (NAIL) on section 103 grounds. NAIL is a protein that may be important to regulating tumor- and virus-fighting functions.[149]

Writing for the court, Chief Judge Rader found the claim in *Kubin* obvious in light of an earlier patent (Valiante) disclosing the existence of NAIL and a standard laboratory manual (Sambrook) detailing a method of gene discovery when the encoded protein is

141. *Id.*

142. *Id.* at 416 (citing Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152 (1950)).

143. *See In re* Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995) ("'Obvious to try' has long been held not to constitute obviousness.").

144. *KSR*, 550 U.S. at 421.

145. *Id.*

146. *See* Kate M. Lesciotto, Note, KSR*: Have Gene Patents Been KO'd? The Non-Obviousness Determination of Patents Claiming Nucleotide Sequences When the Prior Art Has Already Disclosed The Amino Acid Sequence*, 86 WASH. U. L. REV. 209, 213 (2008); Eisenberg, *supra* note 127, at 379.

147. 561 F.3d 1351 (Fed. Cir. 2009).

148. *Id.*

149. *Id.* at 1352.

known.[150] While the court recognized that Valiante disclosed "neither the amino acid sequence [of NAIL] nor the polynucleotide sequence" encoding NAIL, the court nevertheless concluded that the standard techniques described in Sambrook allowed a person of ordinary skill in the field to discover the nucleotide sequence for the protein described in Valiante.[151]

Rader did not purport to rest this conclusion, however, on the fact that standard laboratory techniques were in fact used by appellants. The court stated that "any putative difference in Valiante's/Sambrook's and appellants' *processes* does not directly address the obviousness of [the claim], which claims a genus of *polynucleotides*."[152] Thus, it was the nucleotide sequence itself that was claimed and was found to be obvious, not the method employed to discover it.

Relying on the Supreme Court's decision in *KSR*, the court held that, in certain situations, a skilled artisan's ability to combine elements of prior art renders the discovery obvious.[153] Thus, Rader stated that "[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."[154]

150. *Id.* at 1354. The Valiante patent was U.S. Patent No. 5,688-690, and the laboratory manual was 2 JOSEPH SAMBROOK ET AL., MOLECULAR CLONING: A LABORATORY MANUAL, 43–48 (2d ed. 1989).

151. *Kubin*, 561 F.3d at 1360 ("The record shows that the prior art teaches a protein of interest, a motivation to isolate the gene coding for that protein, and illustrative instructions to use a monoclonal antibody specific to the protein to for cloning this gene.").

152. *Kubin*, 561 F.3d at 1356 (emphasis in original).

153. *Id.* at 1359.

154. *Id.* at 1358. The court was careful to lay out the proper application of the "obvious to try" standard. Relying on distinctions originally set out by the Federal Circuit in *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988), the court delineated two impermissible applications of "obvious to try." In the first situation, "where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness." *Kubin*, 561 F.3d at 1359. In other words, luck in the face of great uncertainty should not be confused with obviousness. In the second situation, "what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Id.* at 1359 (quoting *O'Farrell*, 853 F.2d at 903). Here, too, the court urged caution, lest hindsight bias be confused with obviousness.

Kubin has received considerable critical attention.[155] A Note by Rebecca Hays questioned "to what extent the holding of *KSR* translates to biotechnology" and argued that the Federal Circuit should have applied "industry-tolerant obviousness standards" custom-tailored for biotechnology.[156] Central to Hays' argument is that *Kubin* got the science wrong: "Due to degeneracy of the code the amino acid sequence of a protein does not give a read of the parent gene sequence."[157] Hays also argues that *Kubin* is in conflict with the text of section 103, which states that "[p]atentability shall not be negatived by the manner in which the invention was made."[158] Thus, Hays argues, "the focus of an obviousness inquiry should be the product of the inventive effort, not the means employed by the inventor"[159]—essentially, the structural approach employed prior to *Kubin*.[160]

Another criticism of *Kubin* is that *O'Farrell*, on which the *Kubin* court in part relied, is inapposite because *O'Farrell* involved process claims, not product claims.[161] It would have made sense to consider the method used to obtain the sequence at issue in *Kubin* if the claim had been for the process, and not for the isolated and purified gene itself, but this was not the case. The *Kubin* court purported to find the sequence itself obvious, but what it really found was that the method for obtaining the sequence was obvious.

Finally, the result in *Kubin* is not clearly supported by *KSR*. In *KSR*, two mechanical elements found in the prior art were literally

155. *See, e.g.*, Stimson, *supra* note 129; Rebecca Hays, Note, *Biotechnology Obviousness in the Post-Genomic Era:* KSR v. Teleflex *and* In re Kubin, 10 MINN. J. L. SCI. & TECH. 801 (2009); Warren D. Woessner & Tania A. Shapiro-Barr, In re Kubin: *Federal Circuit Ignores Principles of Structural Obviousness in Applying "Obvious to Try" Test*, PAT. STRATEGY & MGMT., July 2009, at 1.

156. Hays, *supra* note 155, at 803, 824, 833. The court in fact rejected the suggestion that biotechnology should categorically be treated differently from other fields. *Kubin*, 561 F.3d at 1360 ("This court cannot, in the face of *KSR*, cling to formalistic rules for obviousness, customize its legal test for specific scientific fields in ways that deem entire classes of prior are teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area of art.").

157. Hays, *supra* note 155, at 813. To drive the point home, Hays notes that in *Bell* "the claimant calculated 10^{36} potential coding sequences" for the protein at issue. *Id.* at 813 n.63. Others disagree with the relative scientific merits of the structural approach to obviousness. *See* Rai, *supra* note 9, at 836 (arguing that while structural similarity is a good measure of obviousness for other chemicals, DNA should be treated differently because of its function as "a carrier of *information*").

158. Hays, *supra* note 155, at 828 (quoting 35 U.S.C. § 103(a) (2006)).

159. *Id.* at 829.

160. *See In re* Deuel, 51 F.3d 1552 (Fed. Cir. 1995); *In re* Bell, 991 F.2d 781 (Fed. Cir. 1993).

161. *See* Woessner & Shapiro-Barr, *supra* note 155, at 2.

joined together to create a new, but obvious, mechanical device.[162] *Kubin*, in contrast, involved a combination of a known fact (a protein of interest) and a known technique (a method to locate the gene corresponding to a known protein).[163] The two situations are not truly analogous, and as a result the analysis in *Kubin* focused on the mode of invention (despite the court's statement to the contrary) while the analysis in *KSR* focused on the constituent parts of the resulting invention.

What are we to make of *Kubin* if it is inconsistent with the text of section 103 and not clearly supported by either *O'Farrell* or *KSR*? Similarly, what should we make of Judge Sweet's decision in *Myriad*, which takes certain liberties with both the text of section 101 and the Supreme Court's decision in *Chakrabarty*

II.
ALTERNATIVE FRAMEWORKS

If the outcomes in *Kubin* and *Myriad* are not clearly supported by the Patent Act's text, how, if at all, can these opinions be defended as legally sound? The following sections approach the question through two different lenses. The first section considers whether the decisions can be supported by a reinterpretation of the Patent Act, an approach to the gene patent problem advanced by professors Linda J. Demaine and Aaron Xavier Fellmeth.[164] The second section asks whether increased attention to the constitutional limits imposed by the IP Clause, as advocated by professor Oskar Liivak,[165] would better justify the outcomes in *Kubin* and *Myriad*.[166] While either approach offers a plausible justification for the outcomes in these cases, the constitutional analysis offers a clearer guiding principle.

A. A Statutory Approach

Both *Kubin* and *Myriad* are ostensibly based on provisions of the Patent Act. Although the statutory analysis in these cases is a stretch, the outcome in both cases might be justified by the judge-made natural products doctrine. Despite the absence of any explicit

162. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 409–10 (2007).

163. *In re* Kubin, 561 F.3d 1351, 1360 (Fed. Cir. 2009).

164. Demaine & Fellmeth, *supra* note 25.

165. *See* Liivak, *Forgotten Originality Requirement*, *supra* note 26; Liivak, *Maintaining Competition*, *supra* note 26.

166. The articles setting forth these alternative approaches predated the decisions in *Kubin* and *Myraid*; the goal here is to see to what degree their theories are helpful in understanding and rationalizing subsequent developments in the field.

authorization for such a doctrine in the text of the Patent Act, Justice Kennedy has suggested that the prohibition is now protected by statutory *stare decisis*: "While these exceptions are not required by the statutory text, they are consistent with the notion that a patentable process [or product] must be 'new and useful.' And, in any case, these exceptions have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years."[167] Thus, Kennedy admits that the natural products doctrine is not mandated by the Patent Act's text, but argues that the doctrine should be couched in section 101 terms, as was done in *Myriad*.[168]

Professors Demaine and Fellmeth take this statutory approach a step further by arguing that Congress actually intended to exclude products of nature when passing the 1952 Patent Act. The authors argue that the prevailing application of the Patent Act erroneously disregards the "invention requirement" that existed in case law prior to the Act's adoption in 1952 and that Congress intended to codify in the Act, thereby allowing patents on genes and other natural products in contravention of the legislative intent.[169] This effort by Demaine and Fellmeth to reinterpret the Patent Act's application to genes is relevant here not only in light of the possibility

167. Bilski v. Kappos, 130 S. Ct. 3218, 3221 (2010) (Kennedy, J.) (citing Le Roy v. Tatham, 14 How. 156, 174–75 (1853)). Although *Bilski* dealt with the patentability of a process, and not a composition of matter, the Court quoted a product case for its statement of the doctrine, which applies in both contexts. *See id.* (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

168. Ass'n For Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 222–322 (S.D.N.Y. 2010).

169. Demaine & Fellmeth, *supra* note 25, at 384–85. Confusingly, Demaine and Fellmeth use the word "invention" as shorthand for the line of cases, including *Funk Bros.* and *Chakrabarty*, generally associated with the subject matter requirement under section 101, while others use "invention" as shorthand for the cases leading to the modern-day nonobviousness requirement under section 103. Demaine and Fellmeth outline the doctrine as follows:

> Beginning with the founding of the U.S. patent system in 1790, it has been a homily of patent law that naturally occurring phenomena are not patentable subject matter, both for reasons of policy and because such discoveries fail to fulfill the essential requirement of a creative or ingenious mental step. This requirement of ingenuity became manifest in a judicially crafted requirement of 'invention,' which crystallized early in the nineteenth century.

Id. at 330 (collecting cases). Other commentators draw the divisional boundaries between patent doctrines differently, causing confusion over the proper label for a given principle. *See* Liivak, *Forgotten Originality Requirement*, *supra* note 26, at 266–72 (breaking down prohibitions discussed in this Note into three distinct doctrines: the doctrine of scientific principles, the natural products doctrine, and the invention doctrine). Liivak places *Chakrabarty* in the scientific principles line of cases, *Funk Bros.* under the natural products line, and *Hotchkiss* in the invention requirement line. *Id.*

that their hypothesis is correct (in which case it may offer validation for *Kubin* and *Myriad*, albeit on different reasoning), but also because it illustrates the lengths to which one must go in order to find gene patents invalid under the Patent Act.

Demaine and Fellmeth contend that "[t]here was no congressional intent to change the standard of invention" when enacting the 1952 Patent Act.[170] Instead, Congress intended to codify the invention requirement through sections 102 and 103.[171] Demaine and Fellmeth argue, however, that the intended codification was imperfectly executed.[172] Congress's mistake, the argument goes, was to phrase the Act in terms of "nonobviousness in light of *prior art*, which is to say, available 'prior human knowledge,'" by which Congress "unwittingly undermined the prohibition on patenting naturally occurring phenomena."[173] Indeed, when interpreting section 103 the Supreme Court has treated it as a codification of the invention doctrine but has only considered that doctrine as covering improvements over prior art, not the question of patentable subject matter.[174]

Congress's mistake is not without remedy, however, in that Demaine and Fellmeth locate the missing prohibition in sections 101 and 102, requiring that patented subject matter be "new" and "novel," respectively. In their view:

> Although Congress's purported motivation for drafting section 103 was to codify the invention standard in clearer terms, in that section Congress in fact codified only one part of the test for invention—nonobviousness. The second and simplest part

170. Demaine & Fellmeth, *supra* note 25, at 382.

171. *Id.* at 381–82. *But see* Liivak, *Forgotten Originality Requirement*, *supra* note 26, at 271 ("Congress' principal aim was to remove the 'requirement of invention.' Congress did remove it and Congress explicitly replaced it with the statutory requirement of nonobviousness.").

172. Demaine & Fellmeth, *supra* note 25, at 382–83.

173. *Id.* at 383.

174. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 427 (2007) (discussing that the "bar on patents claiming obvious subject matter [was] established in *Hotchkiss* and codified in § 103"). *Hotchkiss* concerned what would today be considered a question of obviousness, not natural products or patentable subject matter. *See* Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248, 266 (1851) (holding that substitution of materials in a doorknob design did not warrant a patent because the substitution was "destitute of ingenuity or invention"); Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 3–4 (1966) ("We have concluded that the 1952 Act was intended to codify judicial precedents embracing the principle long ago announced in Hotchkiss v. Greenwood, and that while the clear language of § 103 places emphasis on an inquiry into obviousness, the general level of innovation necessary to sustain patentability remains the same.") (internal citation omitted).

> is found in section 102, dealing with novelty, while the requirement for newness (i.e., 'new and useful') remained explicit but unelaborated in section 101 and is missing entirely from section 103.[175]

Thus, in the absence of what they would consider a proper codification of the invention doctrine in section 103, Demaine and Fellmeth are content to look to sections 101 and 102 for the prohibition on patenting nature.

Demaine and Fellmeth also contend that the argument for gene patents gains nothing by referencing the word "discovers" in the Patent Act. "When the Patent Act speaks of discoveries," the authors explain, "it follows the historical usage of the term 'discoveries,' meaning 'inventions,' because only inventions can be 'new,'" as is required by section 101.[176] The authors argue that discovery "was intended to denote a fortuitous creation of the inventor and not merely something found by him or her," and therefore, "an 'invention' and a 'discovery' share the requirement that the inventor create something original; the difference between the two is that an 'invention' is consciously sought, while a 'discovery' is created unexpectedly."[177]

We can infer how Demaine and Fellmeth would apply the invention doctrine to *Kubin* and *Myriad* because claims on isolated and purified genes are the central focus of their paper. The authors contend that a claimed invention runs afoul of the invention requirement due to its similarity to something found in nature "where their differences are pro forma or technically inconsequential," i.e., "when the two products are equivalent in each important characteristic."[178] "[M]erely isolating and purifying a DNA molecule," Demaine and Fellmeth argue, "does not result in an invention because nothing 'new' is created; the claimed biochemical previously existed in nature, albeit in a slightly different form."[179] This reasoning relies heavily on the informational aspect of DNA: because isolated and purified DNA serves the same function as nat-

175. Demaine & Fellmeth, *supra* note 25, at 382.

176. *Id.* at 370.

177. *Id.*

178. *Id.* at 393.

179. *Id.* at 380. This assumes, of course, that *American Wood-Paper*, and not *Merck* or *Parke-Davis*, contains the correct approach to purified natural substances. *See* discussion *supra* Part I.C.2.

urally occurring DNA (coding for proteins), the differences between the two are pro forma.[180]

This reasoning, which relies heavily on DNA's function as an informational molecule, is very close to the reasoning employed in *Myriad*.[181] It would therefore be but a small adjustment to put *Myriad* into the invention doctrine paradigm outlined by Demaine and Fellmeth. In fact, there is no real textual constraint on *Myriad*'s reasoning. Although Judge Sweet cited section 101, that section makes no explicit mention of products of nature. Given the lack of textual support in the Patent Act for the natural products doctrine, it makes little difference which statutory provision is cited in support of the outcome in *Myriad*.[182] The outcome in *Myriad* would be the same accepting Demaine and Fellmeth's contention that the Patent Act was intended to prohibit patents on natural products, either through section 101 or section 103.

Kubin was decided on section 103 grounds, notwithstanding the criticism that the decision was inconsistent with that section's text.[183] But, accepting *arguendo* Demaine and Fellmeth's contention that section 103 was intended to codify the invention doctrine writ large (i.e., encompassing the natural products doctrine as well as the non-obviousness requirement), this difference between *Kubin* and *Myriad* is irrelevant. If the proper interpretation of the Patent Act includes the invention doctrine as understood by Demaine and Fellmeth, the possibility emerges that *Kubin* was wrongly decided under the prevailing interpretation of section 103, yet correctly decided as an application of the invention doctrine that was the impetus for section 103.

When it comes to justifying the outcomes in *Kubin* and *Myriad*, Demaine and Fellmeth offer a credible argument that Congress intended to exclude natural products, including genes, from patent

180. *See* Demaine & Fellmeth, *supra* note 25, at 400 ("If a naturally occurring DNA molecule has the useful function of coding for Protein X, then no purified or otherwise altered version of the DNA molecule can be 'new' unless its claimed function is fundamentally different than coding for Protein X. . . . [W]ithout a change in biological function, the DNA molecule lacks adequate creative input to qualify as an invention; it is little more than a molecule found in nature with superficial modifications.").

181. *See* Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 229 (S.D.N.Y. 2010) ("In light of DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad between native *BRCA1/2* DNA and the isolated *BRCA1/2* DNA claimed in the patents-in-suit render the claimed DNA 'markedly different.'").

182. *See supra* note 52.

183. *See* discussion *supra* Part I.D.2.

protection. Beyond this, however, the statutory proposal doesn't offer much guidance in interpreting the scope of the ban on patents covering products of nature. Although couched in terms of statutory interpretation, their proposal is grounded in the invention doctrine, which even the authors acknowledge is a murky concept.[184] This is not to say that Demaine and Fellmeth's "pro forma" test is any vaguer than the "markedly different" test employed in *Myriad*, but certainly it is not any clearer. In this sense, Demaine and Fellmeth's proposal does not offer better guidance for the application of the natural products doctrine to gene patents; mostly, what it offers is a way to ground the doctrine in the statute's legislative history.

The next section considers whether the Constitution's IP Clause offers greater justification for the prohibition on patenting nature or greater guidance in applying the prohibition to gene patents.

B. A Constitutional Approach

The IP Clause authorizes Congress "[t]o Promote the progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[185] The Court has stressed that this language imposes limits on the patent power:

> The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. Moreover, Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.[186]

184. Conscious that invention can be a murky concept, but unsatisfied with the codification of invention in the non-obviousness requirement, Demaine and Fellmet suggest that the "substantial transformation test" be adopted from international trade law, under which two items are considered the same "where their differences are pro forma or technically inconsequential." Demaine & Fellmeth, *supra* note 25, at 393. The Supreme Court has also noted that the word invention "cannot be defined in such manner as to afford any substantial aid in determining whether a particular device involves an exercise of the inventive faculty or not." Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 11–12 (1966) (quoting McClain v. Ortmayer, 141 U.S. 419, 427 (1891)).

185. U.S. CONST. art. I, § 8, cl. 8.

186. *Graham*, 383 U.S. at 5–6.

Justice Breyer has argued that the IP Clause thus offers an alternative to the (somewhat tortured) statutory analysis necessary to justify the judge-made exceptions to patentable subject matter:

> The justification for the principle does not lie in any claim that "laws of nature" are obvious, or that their discovery is easy, or that they are not useful. . . . Rather, the reason for the exclusion is that sometimes *too much* patent protection can impede rather than "promote the Progress of Science and useful Arts," the constitutional objective of patent and copyright protection.[187]

Similarly, Justice Stevens stated that "no one can patent laws of nature, natural phenomena, and abstract ideas" because "[t]hese are the basic tools of scientific and technological work, and therefore, if patented, would stifle the very progress that Congress is authorized to promote."[188] As the discussion of Demaine and Fellmeth's proposal demonstrates, the statutory gymnastics necessary to fit concerns about the public domain and the promotion of progress into the Patent Act can be cumbersome.[189] It therefore behooves us to ask, does the IP Clause offer a more attractive analysis?

One objection to using the IP Clause to guide the application of the natural products doctrine is that the IP Clause's mandate—to promote progress—is itself quite vague. Undeterred, Professor Liivak has attempted to give the IP Clause a more concrete application to patent law through an analogy to copyright law, arguing that courts should apply the same "originality" requirement in patent law that the Supreme Court has required in the copyright context.[190] The thrust of Liivak's argument is that "patents claiming isolated and purified naturally-occurring gene sequences" represent mere copying of nature and therefore cannot pass the constitutional originality test imposed by the IP Clause,[191] at least not without limiting their scope considerably.[192]

Liivak relies on the *Trade-Mark Cases*,[193] in which the Supreme Court held that the Trademark Act could not be founded on the IP

187. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 126–27 (2006) (Breyer, J., dissenting) (quoting U.S. CONST., art. 1, § 1, cl. 8).

188. Bilski v. Kappos, 130 S. Ct. 3218, 3253 (2010) (Stevens, J., concurring) (internal quotation marks and citation omitted).

189. *See supra* Part II.A.

190. *See* Liivak, *Forgotten Originality Requirement*, *supra* note 26; Liivak, *Maintaining Competition*, *supra* note 26, at 183.

191. Liivak, *Forgotten Originality Requirement*, *supra* note 26, at 261.

192. Liivak, *Maintaining Competition*, *supra* note 26, at 184–85.

193. 100 U.S. 82 (1879).

Clause because under that clause "originality is required."[194] While the *Trade-Mark Cases* are more than 130 years old, the Court reaffirmed the importance of originality in the copyright context in the 1991 case *Feist Publications Inc. v. Rural Telephone Services*.[195] In *Feist*, the Court held that "[t]he originality requirement articulated in the *Trade-Mark Cases* . . . remains the touchstone of copyright protection today," and that originality "is constitutionally mandated for all works."[196] There is also evidence in the Congressional Record that "Congress intended the patent act to be interpreted to stay within the limits of the Patent and Copyright Clause," as opposed to being grounded in, for example, the Commerce Clause, as is federal trademark law.[197] Even if this were not the legislative intent, however, there is reason to believe that the Court would construe the IP Clause as erecting an "absolute" limit on the patent power such that the Patent Act could not be supported by other constitutional provisions.[198]

Liivak does not argue for a *per se* rule that purification of a natural substance cannot yield a patentable invention, but instead focuses on limiting the scope of the patent monopoly for purified natural substances.[199] Liivak argues that "[t]o be consistent with the requirement of originality, patent claims should cover no more than the specific copy of the gene sequence created by the paten-

194. *Id.* at 94.

195. 499 U.S. 340 (1991).

196. *Id.* at 347 (citations and internal quotation marks omitted).

197. Liivak, *Forgotten Originality Requirement*, *supra* note 26, at 277. Liivak quotes the Senate Report issued with the 1952 Act, which stated that "[t]he patent laws are enacted by Congress in accordance with the power granted by article I, section 8, of the Constitution." S. REP. NO. 82-1979, at 3 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2396.

198. *See* Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 5 (1966) ("At the outset it must be remembered that the federal patent power stems from a specific constitutional provision . . . . The clause is both a grant of power and a limitation. This qualified authority, unlike the power often exercised in the sixteenth and seventeenth centuries by the English Crown, is limited to the promotion of advances in the 'useful arts.'"); Paul J. Heald & Suzanna Sherry, *Implied Limits on the Legislative Power: The Intellectual Property Clause as an Absolute Constraint on Congress*, 2000 U. ILL. L. REV. 1119 (2000); Rochelle Cooper Dreyfuss, *A* Wiseguy*'s Approach to Information Products: Muscling Copyright and Patent into a Unitary Theory of Intellectual Property*, 1992 SUP. CT. REV. 195, 230 (1992) ("Restrictions on constitutional grants of legislative power, such as the Copyright Clause, would be meaningless if Congress could evade them simply by announcing that it was acting under some broader authority.").

199. Liivak, *Maintaining Competition*, *supra* note 26, at 187.

tee."[200] This would mean that a patent could issue for the discovery of a naturally occurring gene sequence, once purified and isolated, but that an independent discovery of the gene by another person would not infringe on this patent.[201] Although it presents practical difficulties,[202] Liivak's proposal offers a middle road that might address some of the policy concerns with respect to the granting of gene patents, such as inhibiting research and diminishing the public domain, while giving an economic incentive to biotech firms to invest in gene discovery.[203]

On the facts in *Kubin*, Liivak would presumably allow a patent on the gene encoding the NAIL protein but limit the scope of the patent monopoly to protection from direct copying of the isolated sequence. The patentee in *Kubin* would be given some economic incentive to identify the DNA sequence encoding NAIL but would not be permitted to stop others from doing the same independently.

While Liivak's proposal would allow a gene patent found invalid under *Kubin*'s obviousness analysis, it would be less subject to evasion on differing facts. The gene discovery in *Kubin* was obvious because the prior art disclosed both a protein of interest and a standard laboratory technique for locating the corresponding gene. Thus, other cases may be distinguishable where the prior art does not disclose the protein of interest or where nonconventional

200. *Id.* at 199. This limitation in claim scope is derived through analogy to copyright law, which includes a distinction between high and low authorship. Works of high authorship, such as plays or novels, are accorded a high level of protection against unauthorized appropriation of their content, while low inventorship works, such as cartography, are only accorded protection against explicit copying of the protected work, which is itself little more than a copy of nature. *See id.* at 184.

201. This section outlines the constitutional dimension of Liivak's proposal, but Liivak also fits this proposal into the text of the Patent Act, contending that section 102(f) should be interpreted "to bar not only copying from another person but also copying from any other source." *Id.* at 197.

202. Liivak acknowledges that in practice it would be difficult to know whether a second-arriving inventor had derived a given gene sequence independently (and thus had not infringed the patent held by the first-arriving patent holder) or whether the second inventor had merely copied the patented sequence (and had therefore infringed the patent). To address this concern, Liivak suggests that "patents will only issue for a later arriving gene sequence if the later discovered sequence is sufficiently different from the initial sequence," a compromise he deems reasonable given that "recent scientific results suggest that gene sequences may show more variation than previously thought, and thus each differing version of the gene could be patentable." *Id.* at 232–33.

203. For an overview of the policy issues with respect to the granting of gene patents, see *supra* notes 5–9, 36–38, and accompanying text.

methods are required to sequence the gene.[204] According to Liivak's originality argument, however, these differences should not alter the conclusion that an isolated and purified gene is a copy of nature entitled to a lesser degree of protection.

Myriad's reasoning applies by its terms to all gene patents so long as the claimed sequence conveys the same genetic information as a naturally occurring sequence. Judge Sweet chose not to rest this categorical distinction on the Constitution, citing the doctrine of constitutional avoidance and the availability of the Supreme Court's decision in *Chakrabarty* under section 101 as an alternative basis for resolving the case.[205] Sweet's hesitancy to invoke the Constitution when determining the validity of a patent may have been misplaced given the Supreme Court's instruction that "patent validity 'requires reference to a standard written into the Constitution.'"[206] Beyond this, the statutory basis for the distinction in *Chakrabarty* is not clear, and it certainly is not based on the text of section 101.[207] The language of *Funk Brothers* is instructive: "the heat of the sun, electricity, or the qualities of metals, are part of the

204. *See* Stimson, *supra* note 129, at 331 ("One approach to overcoming Kubin would be to describe all the failed attempts and all the adjustments needed to achieve success. The more modifications to the standard methods required to achieve a result, the less obvious the invention will appear.").

205. *See* Ass'n for Molecular Biology v. USPTO, 702 F. Supp. 2d 181, 237 (S.D.N.Y. 2010) ("As determined above, the patents issued by the USPTO are directed to a law of nature and were therefore improperly granted. The doctrine of constitutional avoidance, which states that courts should not reach unnecessary constitutional questions, thereby becomes applicable.").

206. Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 6 (1966) (quoting Great A. & P. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 154 (1950)). Justice Stevens expressed a similar view in a case concerning the patentability of a business method for hedging risk:

> Thus, although it is for Congress to implement the stated purpose of the Framers by selecting the policy which in its judgment best effectuates the constitutional aim, we interpret ambiguous patent laws as a set of rules that weed out those inventions which would not be disclosed or devised but for the inducement of a patent, and that embody the careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy. And absent a discernable signal from Congress, we proceed cautiously when dealing with patents that press on the limits of the standard written into the constitution, for at the fringes of congressional power, more is required of legislatures than a vague delegation to be filled in later.

Bilski v. Kappos, 130 S. Ct. 3218, 3252–53 (2010) (Stevens, J., concurring) (internal quotation marks and citations omitted).

207. Although the *Chakrabarty* Court purported to address the patentability of the microorganism at issue as "a narrow one of statutory interpretation requiring

storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none."[208] Surely this is not the language of statutory interpretation; it is a policy argument based on the proper balance between the public and private domains. The majority in *Funk Brothers* was expressing an anti-enclosure sentiment, but neither *Funk Brothers* nor *Chakrabarty* gives adequate justification for that sentiment. The high rhetoric, as with the statutory analysis considered above, brings us no closer to an understanding of the policy considerations that underlie the gene patent debate. A constitutional paradigm at least offers the possibility of a principled approach to that issue by confining the judicial debate to a single patent philosophy: that the patent system should promote technological advancement.

III.
CONCLUSION

This Note attempts to refine the intuition in both *Kubin* and *Myriad* that there is something "wrong" with gene patents. In examining the doctrinal complexities plaguing the legal debate over gene patents, none of the statutory candidates for a ban on patenting products of nature offers a clear advantage above the others, as none is grounded strongly in the policy concerns driving the debate about gene patents. The more attractive analysis lies in the constitutional mandate of the IP Clause, which requires that patent protection be aligned with the patent system's goal of advancing technological progress.

It would not be difficult, doctrinally at least, to hold that gene patents lacking in originality fail "[t]o promote the Progress of . . . useful Arts"[209] and are therefore invalid, or at least entitled to a narrower patent monopoly. This is not to say that a constitutional approach to the gene patent problem requires adopting Liivak's specific proposal,[210] which is built on an analogy to copyright law and policy that some may find untenable. Once it is clear that the

us to construe 35 U.S.C. § 101," the Court's reasoning has little to do with the text of that section. 447 U.S. 303, 307 (1980); *see supra* note 52.

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

209. U.S. CONST. art 1, § 8, cl. 8.

210. Exactly what it means to promote progress is by no means obvious, and Liivak's proposed originality standard is but one plausible suggestion. *Compare* Liivak, *Forgotten Originality Requirement*, *supra* note 26 (arguing that the constitutional test of the validity of patents on nucleotide sequences under the IP Clause is originality), *with* Heald & Sherry, *supra* note 198, at 1165 (putting forward a quid pro quo principle as the constitutional test, under which, for example, "if isolating and purifying adrenaline is expensive and difficult, then providing incentives to do

prohibition on gene patents is constitutional in nature, however, the label given to the doctrine is of less importance; the constitutional grounding would allow for greater clarity in interpreting the scope of the prohibition, as only those patents that fail to advance technological progress would be prohibited.

Although it is somewhat ambiguous, the constitutional mandate does offer a guiding principle. Basing the natural products doctrine in the IP Clause and addressing concerns over gene patents through that doctrine would limit the extent to which certain policy concerns are relevant. Concerns over the morality[211] of gene patents or the extent to which they restrict access to healthcare,[212] while perhaps relevant to defining societal "progress" in a in broader sense, are not, strictly speaking, relevant under the IP Clause because they are not concerned with technological advancement. To the extent that these policy concerns are to be vindicated, it must be through legislation,[213] as the courts presently have no legitimate basis for taking such policy concerns into account. On the other hand, concerns relating to restrictions on future research[214] and on the public domain[215] do properly fit under the IP Clause's rubric because these policy issues concern the ability of the patent system to give the "liberal encouragement"[216] to innovation that is its purpose.

The ultimate determination of whether gene patents pass the constitutional test may be a close call, and it is not a call that this Note endeavors to make. Any inquiry into whether gene patents generally, or a specific gene patent in particular, promote progress

so seems to be fully consistent with the underlying principles of the Intellectual Property Clause").

211. For a discussion of the concern that gene patents are immoral, see *supra* note 5 and accompanying text.

212. For a discussion of the concern that gene patents restrict access to healthcare, see *supra* note 7 and accompanying text.

213. For example, Representatives Becerra (D-CA) and Weldon (R-FL) introduced legislation, the Genomic Research and Accessibility Act, that if passed would exclude genes from patentable subject matter under the Patent Act. *See* H.R. 977, 110th Cong. (2007) (proposing addition of 35 U.S.C. § 106, under which "[n]otwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies").

214. For a discussion of the concern that gene patents can restrict future research, see *supra* note 6 and accompanying text.

215. For a discussion of the concern that gene patents can restrict the public domain, see *supra* note 8 and accompanying text.

216. Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 8 (1966) (quoting Letter from Thomas Jefferson to Oliver Evans (May 1807)).

in the useful arts is highly fact-intensive and requires deep insight into both molecular genetics and the biotechnology industry.[217] Indeed, these considerations suggest that the policy concerns presented by gene patents may not be appropriate matters for judicial resolution, as they require the fact-finding and deliberative functions of Congress. To the extent that the courts do engage in the gene patent policy debate, however, their approach should focus exclusively on the express provisions of the Patent Act as it is currently written and on the constitutional mandate of the IP Clause.

217. *See* Golden, *supra* note 36, at 109–10 (examining "the roles of each of the major players in American biotechnology: the federal government, private investors and industry, the university, and scientific researches themselves," and concluding that "current concerns about the possible overextension of American patent law are justified"). "Study that confines itself to formal legal materials," Golden posits, "cannot answer whether patent monopolies, on balance, promote or impede innovation, for such study ignores an institutional and social context that provides independent spurs to innovation, spurs that may already suffice to inspire potentially patentable inventions." *Id.* at 102.