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GENE PATENTS: BALANCING THE *MYRIAD* ISSUES CONCERNING THE PATENTING OF NATURAL PRODUCTS

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Thomas Jefferson wrote about “the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.”¹ The controversy over gene patents is a case in point. As a widely publicized case on gene patents makes its way up the courts, it has exposed the difficulty courts are having in determining the patentability of genes.² So far, two judges have found genes to be patentable and two have found them patent-ineligible.³ This is not surprising given that the doctrine on the patentability of products of nature is far from coherent. Indeed, some have described the doctrine as “a source of confusion rather than a pillar of instruction.”⁴ However, even apart from the legal issues, gene patents are controversial because genes embody our hereditary material.

The patentability of genes cannot be resolved in isolation from the patentability of other products of nature. The Federal Circuit recently attempted to extricate the doctrine from its incoherency in *Association for Molecular Pathology v. United States Patent & Trademark Office* (“AMP”), but without much success.⁵ The divided court found genes patentable with the judges diverging significantly on the patentability standards for natural

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1. *Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813)*, in 6 WRITINGS OF THOMAS JEFFERSON 181 (H. Washington ed. 1854), available at http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html.

2. *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office (AMP)*, 653 F.3d 1329 (Fed. Cir. 2011).

3. Judge Sweet of the Southern District of New York and Judge Bryson of the Federal Circuit are opposed to the idea of patenting genes while the AMP majority, Judge Lourie and Judge Moore support gene patents.

4. Richard Gipstein, *The Isolation and Purification Exception to the General Unpatentability of Products of Nature*, 4 COLUM. SCI. & TECH. L. REV. 2 (2003) (quoting Matthew Erramouspe, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipation Races*, 43 UCLA L. REV. 961, 985 (1996)).

5. *See AMP*, 653 F.3d 1329.

products.⁶ Writing for the majority, Judge Lourie emphasized the structural difference, while Judge Moore (concurring), and Judge Bryson (dissenting), required a claimed product to have a different structure and new utility compared to its native form to be patent-eligible.⁷ This Note agrees that mere structural difference, regardless of its triviality, is not sufficient to establish patentability. But, even the dissent's and concurrence's articulation of the test fails to capture the essence of transformation in a product because it confuses the function of a molecule with its utility. The distinction between function and utility is important and might explain some of the analytical inconsistencies plaguing this doctrine. It also explains why despite adopting the same test, Judge Moore and Judge Bryson come to different conclusions.⁸

While function and properties are inherent characteristics of a molecule, utility is the exploitation of these characteristics by man to serve his purpose. Man may find a new use of an old article. However, the new utility need not reflect a change in the product. On the other hand, at the molecular level, there is, in general, a stronger correlation between the structure and function of a molecule. Rather than utility, molecular properties (including function) are a better indicator of the transformation of natural products to artificial products. The relationship between structure and properties is, however, not always linear. Sometimes small structural changes can profoundly affect the properties of a product while at other times structurally different products may have similar properties. In order to accommodate this complex interrelationship, this Note proposes using a sliding scale of structure and properties to discern the patentability of a product derived from nature.⁹ Applying this test to genes, leads to the conclusion that genes should not be patented.

Part I explains the relevant science and technology behind gene patents, and Part II reviews the case law on the patentability of products of nature. Part III discusses the Federal Circuit's opinion in *AMP* and demonstrates the shortcomings of the standard adopted by the court.¹⁰ Finally, this Note argues that although product patents should not be granted on genes,

6. *Id.* It was a two-one decision in favor of patent-eligibility of genes. *Id.* at 1333.

7. *Id.* at 1351; *id.* at 1367 (Moore J., concurring); *id.* at 1378 (Bryson J., dissenting).

8. *Id.* at 1366 (Moore J., concurring); *id.* at 1371 (Bryson J., dissenting).

9. Because this test prevents a patentee from getting patents by making insignificant changes to the natural product, it aligns well with the principles outlined by the recent Supreme Court ruling in *Mayo Collaborative Services v. Prometheus Laboratories*. In *Mayo*, the Court required some inventive contribution from the patentee claiming an application of a natural phenomenon. *See Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1289 (2012).

10. *AMP*, 653 F.3d at 1329.

method patents covering the new utility of isolated gene sequences could serve the goal of promoting the innovation and commercialization of these inventions.

I. CHEMISTRY AND BIOLOGY OF DNA

Confronted with the complicated issue of patentability of purified adrenaline in *Parke-Davis & Co. v. H.K. Mulford Co.*, Judge Learned Hand made the following observation: “I cannot stop without calling attention to the extraordinary condition of the law which makes it possible for a man without a knowledge of even the rudiments of chemistry to pass upon such questions as these.”¹¹ Just as Judge Hand had to learn the chemistry of adrenaline to determine the patentability of purified adrenaline, an understanding of the basic molecular biology of DNA is crucial to appreciating the issues presented in the debate over gene patents. Hence, a discussion of the relevant science, however “rudimentary” it may be, precedes the legal analysis.

DNA, or deoxyribonucleic acid, is the hereditary material in most organisms.¹² Proteins wrap around the DNA to form a compact structure called chromosomes.¹³ The building blocks of the polymeric DNA are four molecules, called nucleotides, which are made of nucleobases: adenine(A), thymine(T), guanine(G), and cytosine(C).¹⁴ These nucleotides are strung together using covalent bonds called phosphodiester bonds to form the polymer (polynucleotide) DNA.¹⁵ There are two strands of these DNA polymers intertwined in a helical manner in each chromosome.¹⁶ This is achieved by the nucleotides of each strand pairing with a complementary nucleotide of the other strand through weak hydrogen bonds, which are non-covalent forces of attraction.¹⁷ In the DNA, adenine(A) always pairs with thymine(T), and guanine(G) pairs with cytosine(C).¹⁸

11. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 115 (S.D.N.Y. 1911).

12. *What is DNA?*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/basics/dna> (last visited Feb. 7, 2012).

13. *What is a Chromosome?*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/basics/chromosome> (last visited Feb. 7, 2012).

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. *A Brief Guide to Genomics*, NAT'L HUMAN GENOME RES. INST., <http://www.genome.gov/18016863> (last updated Oct. 19, 2011).

A gene is a sequence of these nucleotides, which directs the synthesis of proteins.¹⁹ This involves a number of steps. First, the DNA sequence is replicated into the form of another polymeric molecule called RNA (also called pre-mRNA).²⁰ This is done by unwinding the DNA strands, followed by pairing of the DNA nucleobases with complementary RNA nucleotides.²¹ The RNA nucleotides have some variation in structure. For instance, while the sugar sub-unit of the nucleotides in DNA consists of deoxy-ribose, those in the RNA contain ribose sugars.²² Also, instead of the thymine(T) nucleobases, RNAs contain uracil(U), which pairs with adenine(A).²³ These monomeric units called ribonucleosides polymerize to form the RNA.²⁴ Once this RNA is formed, enzymes chop off certain portions (introns) of this molecule and combine the remaining portions (exons) into a molecule called messenger RNA (“mRNA”).²⁵ Because of this process, called splicing, the mRNA no longer contains the entire nucleotide sequence of the gene.²⁶ This mRNA then directs the synthesis of proteins with each sequence of three nucleotides (triplet code) coding for one amino acid.²⁷ The amino acids are strung together into the polymeric structure called proteins.²⁸

The nucleotide sequence in a gene—the genetic sequence—is important for a number of reasons. Sometimes, due to alterations in these sequences (mutations), there is a change in the corresponding mRNA and hence, a change in the protein produced by the cell. This change may manifest itself in many ways including diseases such as cancer.²⁹ As a result, finding a correlation between mutations and diseases could have significant diagnostic and therapeutic value. One of the ways scientists achieve this correlation is through association studies, which identify the sequence of DNA in genes of

19. *How Do Genes Direct the Production of Proteins?*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/basics/howgeneswork/makingprotein> (last visited Feb. 20, 2012).

20. *Id.*

21. *Id.*

22. RNA, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/glossary=rna> (last visited Feb. 20, 2012).

23. *Id.*

24. *Id.*

25. *Splicing*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/glossary=splicing> (last visited Feb. 20, 2012).

26. *Id.*

27. *How Do Genes Direct the Production of Proteins?*, *supra* note 19.

28. Suzanne Clancy & William Brown, *Translation: DNA to mRNA to Protein*, SCITABLE, <http://www.nature.com/scitable/topicpage/translation-dna-to-mrna-to-protein-393> (last visited Feb. 7, 2012).

29. *See A Brief Guide to Genomics*, *supra* note 18.

a healthy person and compare it to those of diseased patients.³⁰ Scientists can also try to determine the sequence of the mRNA and identify the mutations in it. This can be done by artificially copying the mRNA into complementary DNA sequences called cDNA.³¹ These cDNA sequences can then be potentially used to screen mRNAs or DNAs in other patients for potential mutations.³² They may also be inserted into the chromosomes of bacteria to drive the synthesis of proteins in these organisms, a process called molecular cloning.³³

Gene patents typically claim the original DNA sequence that initiates the production of pre-mRNA. These patents prevent someone from extracting that particular DNA sequence from the cell.³⁴ Thus, gene patents effectively exclude others from further investigating the gene, whether it is for detecting more disease-correlating mutations or for developing therapeutics. In fact, any application that involves isolating the genes from the cells would be preempted.

II. THE PATENTABILITY REQUIREMENTS AND THE “PRODUCT OF NATURE” DOCTRINE

The Constitution 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.”³⁵ In authoring the first Patent Act, Thomas Jefferson defined the subject matter for patents as “any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof].”³⁶ Subsequent patent statutes passed in 1836, 1870, and 1874, maintained this

30. See *Genome-wide Association Studies*, NAT’L HUMAN GENOME RES. INST., <http://www.genome.gov/20019523> (last updated Sept. 16, 2011).

31. See *Complementary DNA*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/glossary=complementarydna> (last visited Feb. 6, 2012).

32. See Joseph DeRisi et al., *Use of a cDNA Microarray to Analyse Gene Expression Patterns in Human Cancer*, 14 NATURE GENETICS 457 (1996).

33. See S.B. PRIMROSE & R.M. TWYMAN, PRINCIPLES OF GENETIC MANIPULATION AND GENOMICS 1 (7th ed. 2006).

34. Gene patents, however, do not protect the underlying sequence information in the sense that they do not prevent someone from analyzing the sequence of the isolated DNA (i.e., the biological information that the DNA represents) as it is represented on a piece of paper or a computer screen. U.S. PATENT & TRADEMARK OFFICE, DEP’T OF COMMERCE, UTILITY EXAMINATION GUIDELINES 1093 (2001).

35. U.S. CONST. art. I, § 8, cl. 8.

36. See *Diamond v. Chakrabarty*, 447 U.S. 303, 308–09 (1980) (quoting Patent Act of Feb. 21, 1793, § 1, 1 Stat. 319).

language.³⁷ In 1952, when Congress recodified the Patent Act, it chose to retain this language in § 101 and added §§ 102 and 103, which essentially codified the existing common law requirements of novelty and nonobviousness.³⁸

Section 101 of the 1952 Patent Act states: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent therefor.”³⁹ Thus, the statute explicitly requires the patented invention be “new” and “useful.” However, it is unclear, what limitations, if any, are imposed on the phrase “invents or discovers” or on the categories of patentable subject matter—“process, machine, manufacture, or composition.”⁴⁰ Courts have nevertheless placed certain limitations on patentable subject matter, which have evolved in common law over the last 150 years.⁴¹ Courts have declared “laws of nature, physical phenomena, and abstract ideas” unpatentable.⁴²

The “product of nature” doctrine evolved from the early common law rule against patenting natural phenomena.⁴³ According to this doctrine, a naturally occurring product cannot be patented.⁴⁴ As with any common law doctrine, establishing the doctrine is only a first step. The difficulty is in working out the details of the doctrine and its scope, without legislative guidance. Unfortunately, as the following line of cases demonstrates, the application of the judicial doctrine has been inconsistent and unclear. As a result, the main debate surrounding gene patents is whether they are excluded from patent-eligibility based on this doctrine.

One of the earliest cases restricting the patentability of natural products was *Ex parte Latimer*.⁴⁵ In this case, the patent applicant had developed a method for extracting long fibers from the needles of Australian pine and claimed a patent for both the product and the process of obtaining it.⁴⁶ Commissioner Hall pointed out that plant fiber was a well-known material and whether obtained from leaves, stalks, or wood, was “essentially the same

37. *See id.*

38. *See id.*; John M. Webb, *The Changing Standard of Patentable Invention: Confusion Compounded*, 55 MICH. L. REV. 985, 990–91 (1957).

39. 35 U.S.C. § 101 (2006).

40. *Id.*

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

42. *Id.*

43. *See id.* at 308–10.

44. *See id.*

45. *Ex parte Latimer*, 1889 Dec. Comm’r Pat. 123.

46. *Id.* at 125.

thing, and possesse[d] the same construction.”⁴⁷ The difference in length, strength, and fineness of the fiber was not due to the removal process but due to the processes of nature.⁴⁸ Thus, Commissioner Hall found that the fiber was “a natural product and can no more be the subject of a patent in its natural state when freed from its surroundings than wheat which has been cut by a reaper.”⁴⁹

Although Commissioner Hall’s opinion in *Ex parte Latimer* had some effect on the practices of the patent office, it took some time before any higher court explicitly adopted the “product of nature” doctrine.⁵⁰ In fact, Judge Learned Hand dealt a serious blow to the doctrine when he held purified adrenaline patentable in *Parke-Davis & Co. v. H.K. Mulford Co.*⁵¹ In doing so, he asserted that even if the claimed products were “merely an extracted product without change, there is no rule that such products were not patentable.”⁵² He found the applicant’s adrenaline “a new thing commercially and therapeutically.”⁵³ Referring to the commercial and therapeutic success of the product, Judge Hand said, “[t]he line between different substances and degrees of the same substance is to be drawn from the common usages of men [rather] than from nice considerations of dialectic.”⁵⁴ In this case, Judge Hand found that there “was a distinction not in degree, but in kind.”⁵⁵

However, Judge Hand’s “purification” doctrine did not survive unscathed for too long. In 1928, the Third Circuit in *General Electric Co. v. De Forest Radio Co.*, deemed purified tungsten unpatentable.⁵⁶ The court noted that pure tungsten was chemically and physically different from native

47. *Id.*

48. *Id.*

49. *Id.* at 127.

50. See K.P. McElroy, *Notes and Correspondence: Elements in Patent Law*, 21 J. INDUS. & ENGINEERING CHEMISTRY 6, 608–09 (1929). Although *Ex parte Latimer* had an impact on the USPTO’s practices, none of the major late nineteenth century and early twentieth century cases that dealt with the issue of natural products mentioned it. *Diamond v. Chakrabarty*, decided in 1980, was one of the first major cases that cited *Ex parte Latimer*.

51. See *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 115 (S.D.N.Y. 1911).

52. *Id.* Interestingly, the cases that Judge Hand cited to, in holding that purification of the product was valid ground for granting the patent, both involved purification of synthetic substance not natural products. Judge Hand cited *Kuehnmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701 (7th Cir. 1910), and *Union Carbide Co. v. American Carbide Co.*, 181 F. 106 (2d Cir. 1910). While the former involved a patent on purified aspirin, the latter validated the patent for crystalline calcium carbide over the amorphous form mentioned in the prior art.

53. *Parke-Davis*, 189 F. at 115.

54. *Id.*

55. *Id.* at 103.

56. See *General Electric Co. v. De Forest Radio Co.*, 28 F.2d 641, 648 (3d Cir. 1928).

tungsten ore.⁵⁷ Tungsten existed in nature as brittle tungsten oxide while pure tungsten derived from the oxide was ductile and had enhanced utility.⁵⁸ However, the court asserted that the patentee merely discovered “the natural qualities of pure tungsten”; he neither created pure tungsten nor did he create its characteristics.⁵⁹

Similarly, in *In re Merz*, the Court of Customs and Patent Appeals denied patents for ultramarine and went on to outline the contours of the purification doctrine as follows:

We are in agreement with the tribunals below in their holdings that while appellant may be entitled to a patent on a method for purifying an ultramarine either artificial or natural, he is not entitled to a patent on the article which after being produced has a greater degree of purity than the product produced by former methods. This general rule is a well-settled one, but like all other rules it has an exception. The exception is that if the process produces an article of such purity that it differs not only in degree but in kind it may be patentable.⁶⁰

As subsequent cases have revealed, it is not always easy to determine whether the purification is a matter of degree or kind. In the years following *Merz*, courts have upheld the patentability of Vitamin K₁⁶¹ but denied patents on extracts containing chlorophyll,⁶² extracts from muskrat glands,⁶³ Vitamin C,⁶⁴ and glucoside isolated from red quill.⁶⁵

The Supreme Court revisited the issue in *Funk Brothers Seed Co. v. Kalo Inoculant Co.* and found a combination of naturally occurring non-inhibitive bacteria to be patent-ineligible.⁶⁶ The Court pointed out that the patentee did not “create a state of inhibition or of non-inhibition in the bacteria.”⁶⁷ These qualities were natural.⁶⁸ The Court accepted that there were advantages to the

57. *See id.* at 642–43.

58. *See id.*

59. *Id.* at 643.

60. *In re Merz*, 97 F.2d 599, 600–01 (C.C.P.A. 1938).

61. Ruloff F. Kip, Jr., *The Patentability of Natural Phenomena*, 20 GEO. WASH. L. REV. 371, 378 n.24 (1951) (citing *Ex parte* Thayer, file wrapper of U.S. Patent No. 2,348,037 (filed Sept. 11, 1939)).

62. *Ex parte* Berkman & Berkman, 90 U.S.P.Q. 398 (1951).

63. *Ex parte* Sparhawk, 64 U.S.P.Q. 339 (1945).

64. *See In re King*, 107 F.2d 618, 619–20 (C.C.P.A. 1939).

65. *Berkman*, 90 U.S.P.Q. at 400 (citing *Ex parte* Stoll, file wrapper of U.S. Patent No. 2,294,811 (filed July 17, 1939)).

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

67. *Id.*

68. *Id.*

new combination and that it might “well have been an important commercial advance.”⁶⁹ But “[t]he qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men . . . free to all men.”⁷⁰ Hence, the aggregation of these bacteria fell short of patentable invention.

However, in one of the first major cases dealing with natural products after the enactment of the 1952 Patent Act, *Merck & Co. v. Olin Mathieson Chemical Corp.*, the Fourth Circuit rejected a categorical exception to the products of nature doctrine.⁷¹ It held that “[t]here is nothing in the language of the Act which precludes the issuance of a patent upon a ‘product of nature’ when it is a ‘new and useful composition of matter’ and there is compliance with the specified conditions for patentability.”⁷² The Fourth Circuit upheld the patent on a purified form of Vitamin B₁₂ obtained from the fermentation of fungi.⁷³ The court clarified that this was not merely an advance in the degree of purification.⁷⁴ Until the patentee had produced it, Vitamin B₁₂ was “unidentified and unknown.”⁷⁵ “From the natural fermentates, which . . . were not known to contain the desired activity in even the slightest degree, products of great therapeutic and commercial worth have been developed.”⁷⁶ Thus, the court held that “[t]he new products [were] not the same as the old, but new and useful compositions.”⁷⁷

In 1980, *Diamond v. Chakrabarty* provided the Supreme Court an opportunity to weigh in on this issue under the 1952 Act.⁷⁸ In *Chakrabarty*, the patentee was claiming “a genetically engineered bacterium capable of breaking down multiple components of crude oil.”⁷⁹ While reaffirming the limitations on patenting natural phenomenon, the Court held that a live, human-made microorganism was patentable as a “manufacture” or “composition of matter.”⁸⁰ The Court observed that the patentee’s claim was “not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human

69. *Id.* at 131–32.

70. *Id.* at 130.

71. *See Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156 (4th Cir. 1958).

72. *Id.* at 161.

73. *See id.* at 160.

74. *Id.* at 164.

75. *Id.* at 163.

76. *Id.* at 164.

77. *Id.*

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

79. *Id.* at 305.

80. *Id.* at 309–10.

ingenuity 'having a distinctive name, character [and] use.'"⁸¹ Distinguishing *Funk Brothers*, the Court noted, "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."⁸² It is this "markedly different" language that was later adopted as a standard by the Federal Circuit for assessing patent-eligibility of genes in *AMP*.⁸³

Chakrabarty opened the door for biotechnology patents. Not long after the Supreme Court decided *Chakrabarty*, the U.S. Patent and Trademark Office ("USPTO") started granting gene patents.⁸⁴ "Isolated and purified" naturally occurring substances like DNA and protein biomolecules were patented on the premise that they were substantially separated from other cellular components, which accompanied the native products. In 1991, the validity of a claim for "purified and isolated DNA sequence encoding EPO" was upheld in *Amgen, Inc. v. Chugai Pharmaceuticals Co.*⁸⁵ The district court in *Amgen* explained that unlike the erythropoietin ("EPO") gene found in nature, which would not have been patentable because it was a natural product, the "purified and isolated" DNA sequence encoding EPO was patentable.⁸⁶

It has been estimated that the USPTO has issued more than 2,000 patents on "isolated DNA" and more than 40,000 related patents.⁸⁷ In fact, one study indicates that one-fifth of human genes have been covered by patents.⁸⁸ However, the patenting of DNA has not been without controversy. In the 1990s, an attempt by the National Institute of Health ("NIH") to patent Expressed Sequence Tags ("ESTs"), which are DNA sequences useful for screening cells for complementary RNA sequences, faced stiff

81. *Id.*

82. *Id.* at 310 (emphasis added).

83. See discussion *infra* Section III.A & III.B.

84. See *AMP*, 653 F.3d 1329, 1355 (Fed. Cir. 2011) (citing Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PATENT & TRADEMARK OFFICE SOC'Y 19, 40 (2010)).

85. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1219 (Fed. Cir. 1991).

86. See *Amgen, Inc. v. Chugai Pharm. Co.*, 808 F. Supp. 894, 896–97 (D. Mass. 1992), *aff'd*, 927 F.2d 1200, 1219 (Fed. Cir. 1991).

87. See *AMP*, 653 F.3d at 1355 (citing Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PATENT & TRADEMARK OFFICE SOC'Y 19, 40 (2010)).

88. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCI. 239, 239 (2005); cf. David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1694 n.80 (2007) (urging a more careful interpretation of this figure because nearly all the patents cited in the study were directed to diagnostic applications and a vast majority were narrow patents covering short sections of the genome).

opposition.⁸⁹ It eventually resulted in raising the utility bar for such products.⁹⁰ However, the USPTO continued granting gene patents and in 2001, issued the *Utility Examination Guideline*, which maintained the agency's position that isolated DNA molecules are patent-eligible.⁹¹

III. ISOLATED GENES: PRODUCTS OF NATURE OR MAN-MADE PRODUCTS?

A. *AMP V. MYRLAD*: THE LATEST BATTLE OVER GENE PATENTS

Given the importance of DNA as a fundamental molecule in human beings, the intense public attention and the passionate debate surrounding DNA patents are unsurprising. This debate finally made its way to the courtroom in 2009, when a lawsuit, *Association for Molecular Pathology v. U.S. Patent & Trademark Office* (“AMP”), was filed against Myriad Genetics, seeking to invalidate their claims on isolated DNA on grounds that the claims covered unpatentable subject matter.⁹² The challenged composition claims covered two “isolated” human genes, *BRCA1* and *BRCA2*.⁹³ Alterations or mutations in these genes were found to be associated with a predisposition for breast and ovarian cancers.⁹⁴ The plaintiffs argued that isolated DNA retaining the same nucleotide sequence as native DNA was unpatentable because it was a product of nature.⁹⁵ Also challenged were process claims covering methods of “analyzing” or “comparing” a patient's *BRCA* sequence with the normal, or wild-type sequence, to identify the presence of cancer-predisposing mutations.⁹⁶ The plaintiffs further sought to invalidate some method claims directed at a method of screening potential cancer therapeutics by comparing the growth rates of cells transformed with mutated *BRCA* genes in the presence of potential therapeutics.⁹⁷ They

89. See Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 323–25 (2002).

90. See *id.*

91. See Utility Examination Guidelines, 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.”).

92. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (“AMP II”), 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1334 (Fed. Cir. 2011).

93. See *id.* at 184.

94. See *id.* at 181.

95. See *id.* at 221.

96. See *id.* at 233–37.

97. *Id.*

contended that these claims were directed to patent-ineligible, abstract mental processes.⁹⁸

Judge Robert Sweet of the U.S. District Court of the Southern District of New York ruled that the *BRC A* genes were not patentable because they were “not markedly different from native DNA.”⁹⁹ This conclusion was “driven by the overriding importance of DNA’s sequence to both its natural biological function as well as the utility associated with DNA in its isolated form.”¹⁰⁰ Purification alone, he held, did not change the essential characteristic of DNA—its nucleotide sequence.¹⁰¹ Indeed, the ability to reliably detect mutations depended on this essential characteristic remaining unchanged.¹⁰² Because its coding arrangement was “the result of the natural phenomena of RNA splicing,” even cDNA was found unpatentable.¹⁰³ Judge Sweet interpreted the claim language of the method claims to include comparing not only DNA molecules, but DNA sequence information as well.¹⁰⁴ As a result, he also invalidated Myriad’s method claims because they were directed at “abstract mental processes.”¹⁰⁵

On appeal, the Federal Circuit reversed the holding regarding the patentability of isolated DNA and the method claims covering the screening of cancer therapeutics.¹⁰⁶ However, all three judges agreed with the district court that method claims directed to “comparing” or “analyzing” sequences of gene for diagnostic purposes were invalid.¹⁰⁷ They “fail[ed] to satisfy the machine-or-transformation test and [were] instead directed to the abstract mental process of comparing two nucleotide sequences.”¹⁰⁸ The court stated that gene sequences could be compared by “mere inspection alone.”¹⁰⁹ In order to make the claims eligible, the court suggested including some limitations like extraction of metabolites from bodily samples.¹¹⁰ In contrast to the diagnostic claims, the court upheld the method claims directed at the screening of potential cancer therapeutics by comparing the growth rates of cells transformed with mutated *BRC A* genes. The court found that the steps

98. *Id.* at 233–34.

99. *Id.* at 232.

100. *Id.* at 229.

101. *Id.* at 231.

102. *See id.* at 231–32.

103. *Id.* at 230.

104. *Id.*

105. *Id.* at 234.

106. *AMP*, 653 F.3d 1329, 1334 (Fed. Cir. 2011).

107. *Id.*

108. *Id.* at 1356–57.

109. *Id.*

110. *Id.*

involving “growing” host cells and “determining” their growth rate were transformative steps involving manipulation of cells.¹¹¹

On the issue of patenting DNA sequences, the judges disagreed. Judge Lourie found that isolated DNA was patentable subject matter regardless of whether it was claimed as cDNA, or DNA claiming the entire gene or gene fragments.¹¹² He reasoned that isolated DNA is “markedly different” because it is not covalently bonded to other genetic material found in native DNA.¹¹³ He noted that isolated DNA has been chemically “cleaved” from native DNA or “synthesized to consist of just a small fraction of a naturally occurring DNA molecule.”¹¹⁴ Besides, isolated DNA is free from proteins, unlike the native DNA molecule, which is “packaged around histone proteins into a structure called chromatin.”¹¹⁵ Distinguishing this case from *Parke-Davis*, Judge Lourie clarified that “isolated DNA is not purified DNA” because purification makes pure what was the same material.¹¹⁶ He explained that “[i]n this case, the claimed isolated DNA molecules do not exist as in nature within a physical mixture to be purified.”¹¹⁷

In her concurring opinion, Judge Moore agreed that isolated cDNA sequences were “markedly different” from native DNA.¹¹⁸ Based on *Funk Brothers*, she posited that “an invention which ‘serve[s] the ends nature originally provided’ is likely unpatentable subject matter, but an invention that is an ‘enlargement of the range of . . . utility’” may be patentable.¹¹⁹ Since cDNA sequences did not exist in nature and had the additional utility of acting as tools for mutation detection, she found them falling squarely on the side of patent-eligible subject matter.¹²⁰

Judge Moore admitted that DNA sequences claiming either whole genes or gene fragments presented “a more difficult case.”¹²¹ She was not convinced that the “different chemical structure” alone was sufficient to make “isolated DNA ‘markedly different.’”¹²² However, given the differences, she felt that precedent required investigating whether the

111. *Id.* at 1357–58.

112. *See id.* at 1350–51.

113. *See id.* at 1351–52.

114. *Id.*

115. *Id.*

116. *Id.*

117. *Id.* at 1350–51.

118. *Id.* at 1358 (Moore, J., concurring).

119. *Id.* at 1359–60 (Moore, J., concurring).

120. *Id.* at 1363–64 (Moore, J., concurring).

121. *Id.* at 1364 (Moore, J., concurring).

122. *Id.*

differences “impart[ed] a new utility.”¹²³ She found the shorter gene fragments patentable because their application as probes and primers was “clearly an ‘enlargement of the range of . . . utility.’”¹²⁴ On the other hand, “[d]espite the literal chemical difference, the isolated full length gene does not clearly have a new utility and appears to simply serve the same ends devised by nature, namely to act as a gene encoding a protein sequence.”¹²⁵ However, she felt that in light of settled expectation of the industry and the USPTO’s policy to grant gene patents, any “recalibration of the standard of patentability” should come from Congress.¹²⁶

In his dissent, Judge Bryson agreed that cDNA was patentable but differed with the majority on the issue of claims to genes and gene fragments.¹²⁷ In his view, *Chakrabarty* required an analysis of the difference in both structure and utility between what is claimed and what is found in nature.¹²⁸ He asserted that in the case of isolated genes, the structural changes were merely “incidental to the extraction of the genes” from nature.¹²⁹ He considered it similar to the extraction of new minerals from the earth.¹³⁰ Furthermore, unlike cDNA, which “can be attached to a promoter and inserted into a non-human cell to drive protein expression,” the isolated *BRCA* genes and gene fragments had no other use than their native counterpart.¹³¹ He concluded that the use of genetic sequences in a clinical setting “is not a new use; it is only a consequence of possession.”¹³² Hence, he found that isolated *BRCA* genes and gene fragments were patent-ineligible.¹³³

B. APPLYING THE STANDARD IN A “MARKEDLY DIFFERENT” MANNER

If there is one thing that all three judges in the *AMP* panel agreed upon, it is that a product “markedly different” from its natural form is patentable. Where they diverged was on the application of this standard to gene patents. Judge Lourie focused on the “distinctive chemical identity” of isolated DNA compared to the naturally occurring chromosome.¹³⁴ Judge Moore, on the

123. *Id.*

124. *Id.*

125. *Id.* at 1367 (Moore, J., concurring).

126. *Id.* at 1371–72 (Moore, J., concurring).

127. *Id.* at 1373 (Bryson, J., dissenting).

128. *Id.* at 1350–51.

129. *Id.* at 1375 (Bryson, J., dissenting).

130. *Id.*

131. *Id.* at 1379 (Bryson, J., dissenting).

132. *Id.* at 1378 (Bryson, J., dissenting).

133. *Id.*

134. *Id.* at 1351.

other hand, required a new utility compared to the natural molecule and not just “literal chemical difference.”¹³⁵ In his dissent, Judge Bryson agreed that the test required comparing the structure and utility of the claimed product to what is found in nature.¹³⁶ But in the case of isolated DNA, he found that the structural changes were superficial and “irrelevant” to “the functioning of the gene, and to their utility in their isolated form.”¹³⁷

This Note illustrates that a better way to determine whether a product is “markedly different” from another product is by comparing their structures *and* molecular properties. As Judge Moore and Judge Bryson stated, although structural difference is important, it is not dispositive. However, the Federal Circuit’s analysis was muddled by the court’s conflation of the utility of a product with its function. While a new utility of a natural product may be the basis for a claim to that utility, it does not necessarily make the product different enough to be patent-eligible. Utility is the exploitation of a product’s property by man towards a particular end, while function is the way the product behaves naturally. The following Sections explain why molecular properties (including function) are a better marker of patentable difference, rather than utility. Section III.F then offers a test for patent eligibility, which compares the structure and properties of the claimed products compared with their native form.

C. STRUCTURAL DIFFERENCE CANNOT BE THE SOLE BASIS OF PATENTABILITY

The *AMP* majority attempted to distinguish isolated DNA from the inconsistent line of cases on purified natural products by focusing on the cleavage of covalent bonds involved in isolating DNA. Judge Lourie explained that isolated DNA is more than just a purified form of the natural product.¹³⁸ It is a structurally distinct chemical identity, which was obtained by cleaving covalent bonds in natural DNA.¹³⁹ However, this emphasis on the structural difference is not supported by case law. Structural difference has neither been the necessary nor sufficient criteria for patentability of a product derived from nature. If it were a sufficient characteristic, then elements like lithium, which exist as distinct molecular species in nature, would have been patentable.¹⁴⁰ On the other hand, if structural dissimilarity

135. *Id.* at 1367 (Moore, J., concurring).

136. *Id.* at 1378 (Bryson, J., dissenting).

137. *Id.*

138. *Id.* at 1351.

139. *Id.*

140. *Id.* at 1354. Both the dissent and the majority agree that lithium is unpatentable. *Id.* at 1376 (Bryson, J., dissenting).

was essential, then purified natural proteins and vitamins could not have been patented in chemically unaltered form. Indeed, proteins like human Blood Clotting Factors VIII and IX, insulin, human growth hormone, erythropoietin, tissue plasminogen activator, and all monoclonal antibodies were found patentable in a form structurally unaltered from their natural sources.¹⁴¹

While structural differences may be an important consideration, making them the sole basis of patentability risks elevating form over substance. It is true that technically the isolated genes are different molecules than genes in the chromosome. But, as Judge Bryson correctly noted, the structural differences are irrelevant to their function in the isolated form.¹⁴² The majority emphasized the cleavage of the phosphodiester bond into terminal hydroxyl and phosphate groups in these isolated genes.¹⁴³ However, even if the terminal hydroxyl and phosphate groups were modified, the DNA sequences would still be useful for hybridizing with complementary sequences.¹⁴⁴ In fact, these modifications, called 3' and 5'-modifications, are very common and well-known molecular biology techniques.¹⁴⁵ Thus, these structural changes are not necessary to the functioning of the isolated DNA sequences but rather attendant to the process of isolation.

Besides, it is unclear from the majority's analysis what kind of structural changes merit a patent grant. For instance, instead of cleaving a bond as the majority suggests happened here, would adding a bond be sufficient? Even

141. See Brief of Intellectual Property Owners Ass'n in Support of Neither Party, *AMP*, 653 F.3d 1329 (No. 2010-1406), 2010 WL 4853326, at *22-23; see also, Robert Cook-Degan, *Gene Patents*, THE HASTINGS CENTER, <http://www.thehastingscenter.org/Publications/BriefingBook/Detail.aspx?id=2174> (last visited March 10, 2012) ("Well before the Supreme Court decision, in 1977, the University of California had applied for patents on genes for insulin and growth hormone; the patent for insulin was granted in 1982 and the one for growth hormone in 1987.").

142. *AMP*, 653 F.3d at 1378 (Bryson, J., dissenting).

143. *Id.* at 1352.

144. Sandeep Verma & Fritz Eckstein, *Modified Oligonucleotides: Synthesis and Strategy for Uses*, 67 ANN. REV. BIOCHEMISTRY 99, 104 (1998) ("The modification of either the 3'- or the 5'-terminus is a convenient method for equipping an oligonucleotide with a reactive aminoalkyl or a mercaptoalkyl group. . . . Such oligonucleotide conjugates have been used extensively for a number of applications, which include cellular delivery of antisense oligonucleotides, synthesis of artificial nucleases, and hybridization probes for biological detection.").

145. *Modifications*, INTEGRATED DNA TECHS., <http://www.idtdna.com/catalog/Modifications/ModificationHome.aspx> (last visited Feb. 25, 2012) ("A wide variety of modifications can be incorporated into an oligonucleotide at the time of synthesis. When possible, this is done using a modified solid support (CPG) for 3'-modifications or a specialized phosphoramidite reagent for internal and 5'-modifications.").

adding a hydrogen atom to the molecule would technically make it a new molecule. Would that be adequate to procure a patent? Granting patents based on any structural difference regardless of the triviality of such changes may lead to patentability hinging on inconsequential structural changes. Thus, mere structural difference should not be the sole criteria in determining the patentability of natural products. As discussed later, it could be one of the factors that tilts the scale in favor of patentability and would become a particularly strong factor if the structural change is significant or adds some value to the natural product.¹⁴⁶

D. CONFLATING UTILITY WITH FUNCTION

Aside from examining structural changes, the concurrence and dissent in *AMP* also seemed attracted to a doctrine that requires the claimed product to have a “new utility” compared to the natural product.¹⁴⁷ Relying on *Funk Brothers*, Judge Moore explained that “new utility” involves an “enlargement of the range of utility’ as compared to nature.”¹⁴⁸ Thus, she found that small gene fragments, which could be used as probes and primers, had a new utility, but the full-length sequence did not.¹⁴⁹ This is because the full-length DNA “serve[s] the same ends devised by nature, namely to act as a gene encoding a protein sequence.”¹⁵⁰ Judge Bryson, on the other hand, found that both full-length genes and gene fragments lacked new utility. In his opinion, the use of gene fragments as probes in determining genetic sequence in a clinical setting was not a new use but merely “a consequence of possession.”¹⁵¹ He explained that “each gene must function in the same manner in the laboratory as it does in the human body.”¹⁵²

In other words, despite articulating the same standard, the dissent and the concurrence in *AMP* reached different conclusions on the patent eligibility of gene fragments.¹⁵³ Judges disagreeing over the application of a test is nothing unusual, particularly in cases like these, which involve some degree of value judgment. However, in this case, one of the main reasons for the disagreement is the court’s conflation of the utility of a molecule with its function. In fact, both the concurrence and the dissent repeatedly

146. For a discussion on using the sliding scale of molecular structure and property to distinguish artificial products from products of nature, see Section III.F, *infra*.

147. *AMP*, 653 F.3d at 1361 (Moore, J., concurring); *id.* at 1378 (Bryson, J., dissenting).

148. *Id.* at 1361 (Moore, J., concurring).

149. *Id.* at 1366 (Moore, J., concurring).

150. *Id.* at 1367 (Moore, J., concurring).

151. *Id.* at 1378 (Bryson, J., dissenting).

152. *Id.* at 1329; *id.* at 1378 (Bryson, J., dissenting).

153. *Id.* at 1366 (Moore, J., concurring); *id.* at 1371 (Bryson, J., dissenting).

interchanged utility and function in the opinion. But utility is not the same as function. Utility is defined as “fitness for some purpose or worth to some end,” while function is “any of a group of related actions contributing to a larger action.”¹⁵⁴ In the context of molecules, function is often the “characteristic behavior of a chemical compound due to a particular reactive unit.”¹⁵⁵ Utility is an exploitation of the function and properties of a molecule by man. In other words, a molecule is useful for particular purposes because it has particular properties. Also, a molecule may have multiple uses based on the same function or property. For example, the use of gene fragments as primers and as probes involves the same basic mechanism or function of hybridization between complementary nucleobases.¹⁵⁶ In this case, the utility is man’s application of a gene’s natural properties to serve diagnostic or therapeutic purposes.

Some examples explain the difference between utility and function better. A piece of wood chopped from a tree could have many uses. It may be used for making fire or as a weapon or floatation device. In all these different instances of utility, the wood remains the same; the function of the wood is still determined by its inherent properties or structure. On the other hand, no one would claim that a wooden boat is the same as a block of wood just because both can keep us afloat. By starting with pieces of wood, man has made something that has both a new utility *and* a new function. It is useful because people can use it to traverse water. Its function is also new because by constructing the boat in a particular shape, man has increased its stability, buoyancy, and load-carrying capacity far beyond that of a wooden block. No doubt, some of the natural properties of wood make it particularly suitable for making a boat but the function of a piece of wood is not the same as that of a wooden boat.

Similarly, adrenaline (found patentable in *Parke-Davis*), is released in the body in response to threat or excitement, and it increases heart rate.¹⁵⁷ But, the same adrenaline can be used therapeutically to treat cardiac arrest by

154. *Definition of Utility*, MERRIAM-WEBSTER ONLINE DICTIONARY, <http://www.merriam-webster.com/dictionary/utility> (last visited Apr. 4, 2012); *Definition of Function*, MERRIAM-WEBSTER ONLINE DICTIONARY, <http://www.merriam-webster.com/dictionary/function> (last visited Apr. 4, 2012).

155. *Definition of Function*, *supra* note 154.

156. *See AMP*, 653 F.3d at 1378 (Bryson, J., dissenting) (“In order to sequence an isolated gene, each gene must function in the same manner in the laboratory as it does in the human body.”).

157. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 115 (S.D.N.Y. 1911).

exploiting its capacity to increase the cardiac output.¹⁵⁸ Here, treating cardiac arrest is the utility of adrenaline but the function of purified adrenaline is the same as that of adrenaline in human body, i.e., increasing the heart rate. The only difference is the human control in harnessing the function of adrenaline.

Thus, when Judge Moore discussed the utility of gene fragments as “primers in diagnostic screening,” she was indeed discussing how the gene fragments could be *used* in a different manner when they are isolated.¹⁵⁹ By contrast, Judge Bryson’s argument that the genes “must *function* in the same manner in the laboratory as [they do] in the human body” is actually an argument about the lack of their functional difference.¹⁶⁰ Both are correct. Isolated gene fragments (and even full-length genes) do have a new utility, but they behave in the same way as in their natural form.¹⁶¹ Thus, the key difference between the concurrence and the dissent is that one is looking for new utility while the other is looking for new function. So, the question becomes, which is the more appropriate inquiry: utility or function?

E. DIFFERENCE IN FUNCTION AND PROPERTY ARE BETTER MARKERS OF ARTIFICIAL PRODUCTS

It is important to understand the role that the requirement of “new utility” is playing here before deciding whether the dissent’s or the concurrence’s approach is correct. This requirement of “new utility” is distinct from the § 101 utility doctrine.¹⁶² Utility and subject matter-eligibility are two different inquiries of patentability. The § 101 utility requirement does not need the utility to be new. As long as a claimed invention has specific, substantial, and credible utility, it satisfies the § 101 utility requirement.¹⁶³ A

158. See T.H. Rainer & C. E. Robertson, *Adrenaline, Cardiac Arrest, and Evidence Based Medicine*, 13 J. ACCIDENT & EMERGENCY MED. 234 (1996).

159. *AMP*, 653 F.3d at 1365 (Moore, J., concurring).

160. *Id.* at 1378 (Bryson, J., dissenting) (emphasis added).

161. Judge Moore’s conclusion of inadequate utility of full-length gene sequences fails to capture the full range of application of DNA sequences. DNA sequences are not only useful in diagnostic screening but can also be inserted into bacteria and model animals. “The ability to introduce DNA into the germline of mice is one of the greatest achievements of the twentieth century and has paved the way for the transformation of other mammals.” PRIMROSE & TWYMAN, *supra* note 33, at 251. Apart from aiding in basic scientific research on gene function and regulation, these transgenic animals have been used as models for human diseases and in producing valuable recombinant proteins. In fact, it has been established that full-length genes are better suited for this purpose than cDNA. They also have potential medical use in gene therapy. See *id.* at 251, 259, 261.

162. 35 U.S.C. § 101 (2006).

163. *Revised Interim Utility Guidelines Training Materials*, U.S. PATENT & TRADEMARK OFFICE 3 (1999), <http://www.uspto.gov/web/menu/utility.pdf>.

new invention with an *old use* may still be patentable.¹⁶⁴ No one doubts that the claimed gene sequences have a specific utility that would satisfy the § 101 utility requirement.

Likewise, it does not appear that the “new utility” requirement is driven by a policy goal of encouraging socially beneficial inventions that have a new use over prior art. That goal can be served by granting process patents on the new utility. Newly discovered utility of an old or natural product may be the basis for patenting *that utility* but not the product.¹⁶⁵ For instance, in *Funk Brothers*, the Supreme Court had found the mixture of bacteria patent-ineligible despite recognizing that “there was ‘an advantage in the combination,’ and it was ‘new and useful.’”¹⁶⁶ Similarly, a wide range of plant extracts have been found to have therapeutic effects.¹⁶⁷ Their medicinal use is indeed a “new utility” compared to their utility in nature. However, this new utility cannot be sufficient ground for granting patent on the *product* unless they are structurally and functionally different. Instead, such discoveries should be incentivized by allowing *process* patents claiming the newly discovered utility.¹⁶⁸

Rather, the underlying goal of this inquiry is to determine whether the natural product has been sufficiently changed so that it would be considered a man-made product. Both the dissent and the concurrence agreed with Judge Lourie that cDNAs were structurally different enough from natural DNA to be considered artificial products.¹⁶⁹ cDNAs “differ from the natural gene sequence in that the introns are removed, and are the opposite (complementary) sequence of the naturally occurring RNA.”¹⁷⁰ However, for full-length genes and gene fragments, they found that the structural difference was not substantial enough to weigh in favor of patentability. According to Judge Moore, “although the different chemical structure does suggest that claimed DNA is not a product of nature,” this difference alone

164. *See id.* (“In determining credibility the examiner should consider whether or not there currently are similar or equivalent materials and/or procedures available for achieving that utility. If there are, the utility is credible and no rejection under 35 U.S.C. § 101 should be made.”).

165. Paul G. Alloway, *Inherently Difficult Analysis for Inherent and Accidental Biotechnology Inventions*, 38 SUFFOLK U. L. REV. 73, 79 (2004) (“[S]ection 101 precludes the patenting of a known product based on the discovery of a new use of the product.”).

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

167. *See* Liz Hanellin, *Protecting Plant-Derived Drugs: Patents And Beyond*, 10 CARDOZO ARTS & ENT. L.J. 169 (1991).

168. *See* discussion *infra* Section III.G.

169. *AMP*, 653 F.3d 1329, 1358 (Fed. Cir. 2011) (Moore, J., concurring); *id.* at 1373 (Bryson, J., dissenting).

170. *Id.* at 1364 (Moore, J., concurring).

did not make isolated DNA “markedly different from chromosomal DNA to be per se patentable subject matter.”¹⁷¹ In other words, they are different from the natural products but not different enough to be considered “markedly different.”

If the aim is to distinguish artificial products from natural products, function rather than utility, is a better marker of the transformation of a product. For instance, both Judge Moore and Judge Bryson agreed that a baseball bat is a man-made manufacture rather than a product of nature because it is “a product with a *function* that is entirely different from that of the raw material from which it was obtained.”¹⁷² A baseball bat may also be *used* as a weapon but it still remains a baseball bat. In other words, a new and different utility may be discovered in an old and known product, but that does not necessarily indicate a transformation of the product. Compared to utility, there is a closer correlation between function and structure.¹⁷³ In fact, properties of a product are a more comprehensive marker of transformation. At the molecular level, different physicochemical or biological properties are generally associated with different molecules. Broadly speaking, properties of a product also include its functions.¹⁷⁴ “[P]roperty is . . . to the passive coordination of the internal physical relations, as the function is to the operative co-action of these same internal physical relations.”¹⁷⁵ Hence, an inquiry into a product’s properties necessarily includes looking into its function as well. In other words, probing the properties of the product, rather than utility, can help in determining whether it has sufficiently changed to be considered “markedly different” from the natural product.

The emphasis on property and function of the claimed invention also explains the outcome of some of the Supreme Court cases on products of nature. In *Funk Brothers*, the Court found the inoculant mixture of non-

171. *Id.* at 1365.

172. *Id.* at 1366, 1377 (emphasis added).

173. See Torgeir R. Hvidsten et al., *A Comprehensive Analysis of the Structure-Function Relationship in Proteins Based on Local Structure Similarity*, PLOS ONE, (2009), available at <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0006266>.

174. This Note is not claiming that function and property are exactly the same aspect of a product. Purists may quibble over such characterizations. This Note is merely defining molecular property broadly to encompass its function such that an investigation of the properties of a molecule includes investigating its function as well. See Bernard Testa & Lemont B. Kier, *The Concept of Molecular Structure in Structure-Activity Relationship Studies And Drug Design*, 11 MED. CARE RES. REV. 35, 36 (1991) (discussing the correlation between structure and property). According to Testa and Kier, “a general definition of structure must begin with the differentiation between *the form* (i.e., *the structure, or substructural elements*) and *the functions* (i.e., *the properties*) of the entities recognized as molecules.” *Id.* (emphasis added).

175. Kip, *supra* note 61, at 399.

inhibiting bacteria unpatentable because “[t]he combination of species produce[d] no new bacteria, no change in the six species of bacteria, and . . . each species ha[d] the same *effect* it [has] always had.”¹⁷⁶ The Court accepted that the mixture had some use and there was “an advantage in the combination.”¹⁷⁷ However, the Court did not find a patentable difference over the natural bacteria because the “use in combination” of the bacteria did “not improve in any way their natural *functioning*.”¹⁷⁸ Similarly, the *Chakrabarty* Court showed an understanding of the difference between function and use of the invention when it noted that Chakrabarty’s bacterium was “*capable of breaking down multiple components of crude oil*.”¹⁷⁹ “*Because of this property*, which [was] possessed by no naturally occurring bacteria, Chakrabarty’s invention [was] believed to have significant value for the treatment of oil spills.”¹⁸⁰ In other words, the “markedly different characteristics” of the claimed bacterium over naturally occurring bacteria was its capacity to down oil. Cleaning up an oil spill was merely an application of that property.

F. THE SLIDING SCALE OF MOLECULAR STRUCTURE AND PROPERTY

Since a molecule’s structure and properties give us a good measure of any change in the molecule, courts should analyze the molecular structure and properties to assess whether a product is “markedly different” from its natural counterpart. At the molecular level, the structure describes both the arrangements of atoms within a molecule as well as the overall shape of the molecule. Properties include all physicochemical and biological properties including function.

Although it is generally recognized that structure influences property, this correlation is not always very linear.¹⁸¹ Sometimes, small structural changes can significantly impact the properties, while at other times significant structural changes have little effect. For instance, it is well-known that the replacement of a critical amino acid in a protein can drastically affect its function, while removing an entire sub-section containing multiple amino acids may have little effect.¹⁸² On the other hand, two molecules with very

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

177. *Id.*

178. *Id.* (emphasis added).

179. *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980) (emphasis added).

180. *Id.* (emphasis added).

181. See Hedi Hegyi & Mark Gerstein, *The Relationship Between Protein Structure and Function: A Comprehensive Survey with Application to the Yeast Genome*, 288 J. MOLECULAR BIOLOGY 147, 147 (1999).

182. See H. Eldon Sutton & Robert P. Wagner, *Mutation and Enzyme Functions in Humans*, 9 ANN. REV. GENETICS 187 (1975).

different chemical formulae may behave in a similar manner.¹⁸³ In fact, investigating the structure-function relationship of macromolecules is an intensely pursued field of study in biology and chemistry.¹⁸⁴

In order to accommodate this complex interrelationship, a sliding scale of structure and properties would be an appropriate way to distinguish a natural product from a synthetic one. Although the *AMP* court did not explicitly describe it, Judge Moore likely envisioned a similar test when she stated, “Whether an isolated gene is patentable subject matter depends on how much weight is allocated to the different structure as compared to the similarity of the function to nature.”¹⁸⁵

Let us see how such a test would work. The easy case would be a product that is both structurally different from the native form and has different properties. Such a product is more likely to be artificial. A product, whose structure is substantially different from the natural product, but functions in a similar manner, may still be considered artificial. For instance, different drugs treating a particular disease often function in the same way, such as by inhibiting a particular protein. The fact that two structurally different molecules have similar or even the same function does not make them the same. At the other end of the scale are molecules with slight structural difference but profoundly different properties. Such products should also be patentable over their natural form. As discussed already, some subtle variations in molecules can have very significant effect on their function. For instance, some molecules, called stereoisomers, have the same molecular formulae and sequence of bonded atoms and differ only in the three-dimensional orientations of their atoms in space.¹⁸⁶ If these molecules have very different biological activities, they should be considered distinct from an old or natural product.

This analysis of structural and functional difference is not new to the courts. Courts have looked into structural and functional difference in distinguishing claims on chemicals from prior art for the § 103 nonobviousness analysis.¹⁸⁷ In *Application of Papesch*, the court stated that

183. Biomimetic or bio-inspired molecules, for example, are molecules synthesized by chemists that can have very different chemical composition but function like the natural molecules.

184. See P. Güntert, *Structure Calculation of Biological Macromolecules from NMR Data*, 31 Q. REV. BIOPHYSICS, 145–237 (1998).

185. *AMP*, 653 F.3d 1329, 1366 (Fed. Cir. 2011) (Moore, J., concurring).

186. See *Stereoisomers*, VIRTUAL TEXTBOOK OF ORGANIC CHEMISTRY, MICHIGAN STATE U. DEPARTMENT OF CHEMISTRY, <http://www2.chemistry.msu.edu/faculty/reusch/VirtTxtJml/sterisom.htm> (last visited Feb. 25, 2012).

187. 35 U.S.C. § 103 (2006); see also *In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963).

“[p]atentability cannot be determined on the basis of obviousness of the structure alone.”¹⁸⁸ Compounds structurally similar to those in prior art could be nonobvious if they possess a new and unexpected property.¹⁸⁹ For example, structurally similar isomers and homologues of prior art molecules have been found nonobvious based on their unexpected therapeutic properties.¹⁹⁰ It is not surprising that the nature of inquiry in nonobviousness determinations for chemical patents is similar to the approach adopted in distinguishing natural products and artificial products. Natural products are, after all, chemical entities. Besides, both the nonobviousness bar and the proposed test aim to prevent trivial improvements from being patented. But there is a difference between the analysis under § 103 and the one undertaken here. Nonobviousness is based on the knowledge of a person of ordinary skill in the art; previously unknown products or phenomena of nature cannot be part of that knowledge.¹⁹¹ While the nonobviousness inquiry compares the claimed invention with the prior art, this test compares the claimed invention with the natural product.

This nonobviousness-type inquiry is also consistent with the Supreme Court’s latest pronouncements on the patent eligibility of natural phenomena in *Mayo Collaborative Services v. Prometheus Laboratories*.¹⁹² The Court insisted that a claim based on a natural phenomenon should contain an “‘inventive concept,’ sufficient to ensure that the patent in practice amount[ed] to significantly more than a patent on the natural [phenomenon] itself.”¹⁹³ Although *Mayo* concerned a natural process, the same considerations of preempting a natural phenomenon are at issue when patenting natural products and hence the same principles should apply.¹⁹⁴

Courts also undertake a similar analysis under § 271(g), which prohibits importation of products made by using patented processes abroad.¹⁹⁵ Products “materially changed” by subsequent processes are exempted from infringement liability.¹⁹⁶ Courts utilize a “two-phased test” to determine whether a product has been “materially changed.”¹⁹⁷ Expositing one part of

188. *Papesch*, 315 F.2d at 391.

189. *Id.* at 389–90.

190. *Id.* at 388–89.

191. *See* 35 U.S.C. §§ 102, 103.

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

193. *Id.* at 1294.

194. *See id.* at 1294–95.

195. *See* 35 U.S.C. § 271(g).

196. *Id.*

197. *See Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1576–77 (1996), for an elaboration of this two-part test. The first part considers a product materially unchanged if it

that test, the Federal Circuit has observed that “[i]n the chemical context, a ‘material’ change in a compound is most naturally viewed as a significant change in the compound’s *structure and properties*.”¹⁹⁸ “[M]inor chemical conversion, (e.g., conversion to a salt, base, acid, hydrate, or addition or removal of a protecting group) would not be a ‘material’ change.”¹⁹⁹ For instance, in *Amgen Inc. v. F. Hoffmann-La Roche, Ltd.*, although the accused product was structurally different the court found no “material change” because “the *structural and functional differences*” were not “significant enough.”²⁰⁰ Similarly, courts have held that mere alkylation of the claimed product, “a common reaction well known to organic chemists,” without changing “the basic structure . . . of [the] compound” does not alter it materially.²⁰¹ However, even a minor change can sometimes be important and may change a product materially if it relates to “an important feature.”²⁰²

The nonobviousness test for chemical patents and the “materially changed” test for § 271(g) demonstrate the judicial and statutory appreciation of the importance of changes in structure and properties as indicators of transformation of chemical entities. They are very similar to the sliding-scale analysis suggested by this Note, in that they recognize fact situations where

would not have been commercially viable to produce it without using the patented process. *See id.* at 1576. The second part is guided by the Senate Judiciary Report’s explanation:

A product will be considered to have been made by a patented process if the additional processing steps which are not covered by the patent do not change the physical or chemical properties of the product in a manner which changes the basic utility of the product [produced] by the patented process. However, a change in the physical or chemical properties of a product, even though minor, may be “material” if the change relates to a physical or chemical property which is an important feature of the product produced by the patented process. Usually a change in the physical form of a product (e.g., the granules to powder, solid to liquid) or minor chemical conversion, (e.g., conversion to a salt, base, acid, hydrate, ester, or addition or removal of a protection group) would not be a “material” change.

Id. at 1577 (quoting S. REP. NO. 100-83, at 49 (1987)).

It is to be noted that the Report requires changes to “basic utility of the product.” This appears to be different from *any new utility* and is more akin to requiring a change in the basic use or function of the molecule. However, courts have not elaborated on this distinction, and this Note is not undertaking the effort of interpreting § 271(g). At least for the purpose of distinguishing products of nature from artificial products, the author maintains that function and properties of a molecule are more useful indicators than utility.

198. *Id.* at 1573 (emphasis added).

199. *See id.* at 1577.

200. *See Amgen Inc. v. F. Hoffmann-La Roche, Ltd.*, 580 F.3d 1340, 1378–79 (2009) (emphasis added).

201. *Pfizer Inc. v. F & S Minerals Corp.*, 856 F. Supp. 808, 816 (S.D.N.Y. 1994).

202. *See Eli Lilly*, 82 F.3d at 1577.

significant variations in one aspect of a product may outweigh minor variations in other aspects. They provide a rich source of case law which could guide courts in their assessment of patent-worthy changes to natural products. Of course, as always, the distinctions would be fact-specific and a matter of degree. It is neither wise, nor possible, to draw a bright-line rule.

Applying the sliding-scale test to isolated gene sequences leads to the inescapable conclusion that they are *not* “markedly different” from their natural counterparts. The structural difference mainly involves the cleavage of two phosphodiester bonds into terminal hydroxyl and phosphate bonds. One could arguably compare the DNA of the entire chromosome with the isolated gene sequence and claim significant structural difference. But since the claimed product is an isolated gene sequence, rather than an isolated chromosome, such a comparison is not logical. Comparing the claimed isolated gene sequence with the gene sequence in nature, one finds insignificant structural difference because the nucleotide sequence is exactly the same. Since the same nucleotide sequence interacts with other DNA sequences using the same phenomenon of base-pairing between complementary nucleobases, an isolated gene sequence also functions in the same manner. The same reasoning is applicable to smaller gene fragments. In other words, isolated gene sequences and gene fragments are products of nature.

The cDNA sequences, on the other hand, are structurally very different from the mRNA, from which they were derived. Although the nucleotide sequence is replicated in cDNA, the ribose sugars of RNA have been replaced by the deoxyribose sugars in the entire molecule, along with the nucleobase change from thymine(T) to uracil(U). They are structurally so different from RNA that they are called DNA. Unlike mRNA, cDNAs cannot directly synthesize proteins. On the other hand, cDNAs function in a similar manner as the RNA molecules, mainly by base-pairing with complementary sequences. Comparing the structure and properties of cDNA against its closest natural counterpart, mRNA, leads to the conclusion that it is “markedly different” from mRNA. cDNA is also structurally very different from the genomic DNA because it does not contain the nucleotides in the intron regions of genomic DNA. Hence, it is distinguishable from the genomic DNA as well.

G. UNNECESSARY PRODUCT PATENTS

Several commentators have already undertaken extensive analysis of the policy ramifications of granting gene patents.²⁰³ Instead of rehashing the well-known arguments, this Note intends to dispel one policy argument traditionally forwarded in support of gene patents: they are necessary to incentivize the discovery of genes. The persistent (and often tenuous) effort by the courts to distinguish isolated genes from their natural state in order to establish their patentability is driven by this unsupported presumption. However, empirical studies indicate that we may not even need product patents to induce the discovery of genes.²⁰⁴ If that is the case, then granting exclusive rights on genes imposes a loss on society since they would have been isolated regardless of patent protection. Studies show that a significant portion of the research involved in isolating gene sequences are done in academic and non-profit research institutes. For instance, a study conducted by the National Academy of Sciences found that as of 2005, University of California was the owner of the largest number of DNA-based U.S. patents.²⁰⁵ Among the top thirty owners of DNA-based patents, almost half were public or academic research institutes.²⁰⁶ Another study found that “63% of the patents on gene sequences resulted from federally funded research.”²⁰⁷ While some may infer from this data that patents are necessary to incentivize such research, studies show that the prospect of patent protection on genetic research “does not play a significant role in motivating scientists to conduct genetic research.”²⁰⁸ “Only 7 percent [of the researchers] consider [patents] more than moderately important—but it pales in comparison to scientific importance (97 percent), personal interest (95

203. See Wesley M. Cohen & John P. Walsh, *Real Impediments to Academic Biomedical Research*, in INNOVATION POLICY AND THE ECONOMY 1, 13 (Adam B. Jaffe et al. eds. 2008), available at <http://www.nber.org/~marschke/mice/Papers/cohenwalsh.pdf>; NAT'L RES. COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 28 (2006), available at <http://www.nap.edu/catalog/11487.html>; SECRETARY'S ADVISORY COMM. ON GENETICS, HEALTH & SOC'Y, GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS (2010) [hereinafter SACGHS REPORT]; Rebecca S. Eisenberg, *A Technology Policy Perspective on The NIH Gene Patenting Controversy*, 55 U. PITT. L. REV. 633, 648–49 (1993); Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 720 (2004); Tina Saladino, Note, *Seeing the Forest Through the Trees: Gene Patents and the Reality of the Commons*, 26 BERKELEY TECH. L.J. 301 (2011).

204. See SACGHS REPORT, *supra* note 203, at 1.

205. NAT'L RES. COUNCIL, *supra* note 203, at 104.

206. *Id.*

207. *AMP II*, 702 F. Supp. 2d 181, 210 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1334 (Fed. Cir. 2011).

208. SACGHS REPORT, *supra* note 203, at 1.

percent), feasibility (88 percent), and access to funding (80 percent) as reasons to do the work.²⁰⁹ Academic researchers are generally driven by other factors such as the desire to advance scientific understanding, prestige, publication, ability to secure funding for additional research, and concerns for their own career development.²¹⁰

The fact that scientists are not motivated by patents might indicate that the number of gene-related patents secured by the academic research institutes may be an underestimation of the amount of genetic research done in academia. These statistics on gene patents do not take into account those researchers who did not seek patent rights for isolated DNA sequences. More importantly, the fact that academic researchers conduct a substantial portion of research aimed at isolating genes shows that public institutes are capable of successfully undertaking such research. For instance, it was the King laboratory at University of California, Berkeley that published the landmark paper showing that a gene related to breast cancer (*BRC A*), whose sequence was then unknown, was located in a region of chromosome 17.²¹¹ In fact, one day after Myriad filed its patent application for *BRC A2* genes, the Stratton group in the United Kingdom published the sequence of the gene in an article in *Nature*.²¹² Thus, “the technical question presented by the genome project was not whether the human genome could be sequenced, but which group would finish first.”²¹³

Moreover, patenting of DNA sequences by public institutions may not effectively serve the purpose of commercializing such inventions. Public institutes are incapable of undertaking product development because of their limited resources and limited experience in the fast-paced, market-oriented development of products.²¹⁴ The only way patents may secure revenues for a university is through licensing.²¹⁵ It is thought that this revenue may then be reinvested in research, thereby spurring further innovation.²¹⁶ So far, this has been wishful thinking. Studies have shown that most technology transaction offices either break even or lose money.²¹⁷ Also, since the federal government

209. NAT'L RES. COUNCIL, *supra* note 203, at 122.

210. *Id.*; see also Cohen & Walsh, *supra* note 203, at 1, 13.

211. Ass'n for Molecular Pathology, 702 F. Supp. 2d at 201.

212. *Id.* at 202.

213. STEPHEN A. MERRILL, RICHARD C. LEVIN & MARK B. MYERS, A PATENT SYSTEM FOR THE 21ST CENTURY 91 (2004), available at <http://www.nap.edu/catalog/10976.html>.

214. SACGHS REPORT, *supra* note 203, at 23.

215. Eisenberg, *supra* note 203, at 648–49 (1993).

216. *Id.*

217. See Donald Siegel & Mike Wright, *Intellectual property: The Assessment*, 23 OXFORD REV. OF ECON. POL'Y 529, 534 (2007).

is the major funder of basic science research, it seems unfair that taxpayers—who fund the research in the first place—would also have to pay high premiums for using the subsequent products, which absorb the costs of licensing patents.²¹⁸ Then again, it is contended that securing patent rights may enable public agencies to control prices charged for subsequent products emanating from these patents.²¹⁹ However, it is doubtful whether such price-regulation is possible in a free-market system because any price control clauses in licensing agreements would make them less attractive to private firms and thereby reduce the bargaining power of the university.²²⁰

Besides, even in the absence of product patents, incentives for the discovery of genes would be maintained through process patents because patent applicants can still patent processes covering new uses of the genetic sequences. Identifying genetic sequences is the first step towards developing their potential applications. Thus, even if the academic institutes are incapable of, or uninterested in, isolating certain genes, process patents would maintain the incentive for the industry to step in and isolate the genes themselves. Moreover, contrary to industry belief, process patents would not be difficult to enforce. Traditionally, companies have preferred to obtain product patents over process patents because of the difficulty in enforcing the latter. However, the difficulty in enforcing a process patent is a greater concern when the process claims *making* a product than when it claims *using* a product. This is because inspecting a product sold in the market does not enable one to ascertain whether the product has been secretly made by the claimed process. But, in case of process patents, such as those covering genetic diagnosis, the processes cannot be accomplished without using the gene sequences. Thus, any competitor offering the same genetic screening test to the public, would necessarily have to use the same isolated genetic sequence information in standard biological assays. Since the claimed process essentially covers the consumer good or service offered, any infringement would be readily detectable. In other words, even in the absence of product patents on genes, the efforts to isolate genes would continue by virtue of the incentive provided by process patents.

The policy of granting patents on the applications of a natural phenomenon, rather than the phenomena itself, is also in accord with Supreme Court precedent. The Supreme Court has consistently recognized that applications of natural phenomena are patentable. For example, the Court in *O'Reilly v. Morse* held:

218. Eisenberg, *supra* note 203, at 648.

219. *Id.* at 649–50.

220. *Id.*

When a new and hitherto unknown product or result, beneficial to mankind, is effected by a new application of any element of nature, and by means of machines and devices, whether new or old, it cannot be denied that such invention or discovery is entitled to the denomination of a “new and useful art.”²²¹

Similarly, *Funk Brothers* held that “[h]e 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.”²²²

This Note suggests that all “products of nature” can be distinguished from artificial products using the sliding-scale analysis described in Section III.F, *supra*. It recommends withholding product patents whenever it is clear that the products do not meet the prescribed threshold of artificiality, but granting process patents on any new uses discovered. Under this analysis, purified but unaltered natural products (previously found patent-eligible) would not be granted product patents.²²³ For example, “[o]ne fourth of all currently dispensed prescriptions in the United States contain at least one drug that is extracted from higher plants.”²²⁴ While the natural extracts may not be patented, the discovery of their therapeutic application should be rewarded. In order to discover the therapeutic properties of these natural extracts, firms have to invest huge amounts of resources in exploration, collection, and analysis of samples.²²⁵ Subsequent product development, FDA approval, and marketing make it possible for these substances to be finally available to the consumer.²²⁶ Without some form of patent protection, private investors would not be willing to undertake such expensive and time-consuming endeavors, and the society would not benefit from such inventions. Hence, the appeal of this policy lies in the fact that it provides enough incentive to the biotechnology companies to invest in the development of socially useful application of natural products, without giving them a complete monopoly over such products.

221. *O'Reilly v. Morse*, 56 U.S. 62, 133 (1853).

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

223. *See, e.g., Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 160 (4th Cir. 1958) (finding purified Vitamin B12 patentable); *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 115 (S.D.N.Y. 1911), *rev'd on other grounds*, 196 F. 496 (2d Cir. 1912). (holding purified adrenaline patentable).

224. *See Liz Hanellin, Protecting Plant-Derived Drugs: Patents and Beyond*, 10 CARDOZO ARTS & ENT. L.J. 169, 170 (1991).

225. *See id.* at 169, 173 n.21.

226. *See id.* at 169 n.3.

IV. CONCLUSION

We cannot realize the aim of “promot[ing] science and useful arts”²²⁷ if we fail to properly distinguish patent-worthy inventions from unworthy ones because of a lack of nuanced understanding of the science behind the inventions. As this Note demonstrated, the distinction between function and utility of products is critical to our appreciation of their patent-worthiness. Taking that into consideration, this Note provides a comprehensive test under which claims to natural products can be analyzed. It posits that in the absence of significant structural or functional changes, isolated or purified natural products like genes should not be patented. However, process patents on novel applications of natural products should be granted. Such an approach would balance the needs of incentivizing these discoveries against the broad preclusive effects of a product patent. After all, the goals of patent law can be accomplished by neither leaving all discoveries in the public domain, nor by assigning exclusive rights to all discoveries to private entities.

227. U.S. CONST. art. I, § 1, cl. 8.

