The Patentability of Isolated DNA Sequences Deoxyribonucleic Acid (DNA)

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I. WHAT IS DNA?

Genes dictate the physical characteristics of a person. Each gene codes for a protein that corresponds to a physical trait. Two copies of each gene are present in every individual. One copy is inherited from each parent. Genes are made up of deoxyribonucleic acid (DNA). The DNA that makes up the individual genes is a template used to create proteins.[1]

DNA typically exists in the familiar double-helix form. That is, two strands of DNA are bound to one another. DNA is made up of four nucleotides: adenine, thymine, cytosine, and guanine. These nucleotides

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1. Information for this Part was gathered from conferences with Kelsey Beno, a Ph.D. candidate in Molecular Biology at the University of Memphis.

are referred to as "bases." Each base is typically referred to by the first letter of its name—A for adenine, G for guanine, etc. Each DNA base binds with only its complementary base: adenine (A) binds only to thymine (T) and cytosine (C) binds only to guanine (G).[2] Because each base binds exclusively with its complementary base, for two DNA strands to combine to form a double helix, each strand must be entirely complementary.[3]

The vast majority of genes are identical among people. However, a small fraction of nucleotides within the genes—less than one percent—vary slightly between individuals. These slightly distinct genes are known as alleles. These minimal differences are what make each person unique. Some variations dictate skin or eye color and have no adverse effect, however, other variations can present significant consequences to a person's health. For example, variations in certain DNA nucleotide sequences can be indicative of a predisposition to certain forms of cancer.

A. What Is the Importance of Genetic Research?

Research in genetics can provide information pertinent to several areas of study. Two important fields of study are evolution and the relationship between different populations, and medical science. In the field of medical science, conditions such as sickle cell anemia, Tay-Sachs disease, and certain cancers have been linked to mutations in the nucleotide sequence of genes. The ultimate goal of genetic research in the field of medical science is to predict predispositions to certain disorders and minimize their resulting harm to patients or potentially prevent their occurrence altogether.

B. How Is Research Conducted with DNA?

To determine a specific nucleotide sequence, the relevant DNA must be extracted from the patient. Once extracted, the patient's DNA is

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2. In actuality, the four nucleotide bases can also bind to nucleo*sides*. This however is of little significance to the current discussion, and simply complicates things beyond what is necessary. Both nucleo*tides* and nucleo*sides* contain a nitrogen base and a pentose sugar. Additionally however, nucleo*tides* also contain a phosphate group, whereas nucleo*sides* do not contain a phosphate group. In essence, nucleo*sides* are to ribonucleic acid (RNA) as nucleo*tides* are to deoxyribonucleic acid (DNA).

3. Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 194 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, No. 2010-1406, 2011 WL 3211513, at *1 (Fed. Cir. July 29, 2011) ("For example, if one strand of DNA has the nucleotide sequence ACTCGT, the corresponding section of DNA on the complementary strand will have the nucleotide sequence TGAGCA.").

compared to "normal" DNA—DNA that does not exhibit any mutations.[4] The sequence of the nucleotides can be analogized to the combination of individual letters to form a word. The normal DNA would exhibit a nucleotide sequence that would spell the word correctly. The patient's DNA, if mutated, would exhibit a nucleotide sequence that would misspell the word.

As previously stated, DNA in its natural state exists in the double-helix form where one strand of DNA is bound to its complementary pair. In its natural state, the nucleotides sequence—the spelling of the word—cannot be determined. To determine the individual nucleotide sequence of a gene, the complementary pairs must be severed, because analysis can only be done with a single strand of DNA. This lone strand is referred to as an "isolated DNA sequence." For example, if the complementary pairs have the nucleotide sequences ACTCGT and TGAGCA, the pairs must be separated leaving only the ACTCGT sequence or the TGAGCA sequence. Once isolated, the specific nucleotide sequence of the lone strand of DNA can be analyzed.[5]

When the strands are separated, a mutation is observable because the normal nucleotide sequence fails to bind with that of the mutated DNA sequence. This inability to bind evidences the incorrect spelling of the word—the incorrect nucleotide sequence. For example, if a patient's mutated DNA has the nucleotide sequence ACTCGA, it will not bind with the complementary pair of normal DNA exhibiting the nucleotide sequence TGACGA.[6] These strands will not bind because they are not complementary; the mutated strand substitutes an A for a T as the final nucleotide in the sequence.

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4. The word "normal" is used simply to refer to the standard or most common nucleotide sequence of the subject DNA.

5. At this point, a primer is bound to the isolated DNA sequence. Research is rarely done with only a single strand. Rather, a single strand is necessary to allow the synthetic primer to bind, which provides the relevant information pertaining to the nucleotide sequence of the relevant DNA strand. However, for purposes of simplification, I will refer to an isolated DNA sequence as a single strand of DNA as opposed to a single strand of DNA bound to a human-made primer. This difference is of no significance to the ultimate conversation because the primer is human-made and the DNA is isolated by human intervention.

6. In actuality, the variation of a single base is unlikely to prevent the *almost* complementary pairs from binding. Although the pairs may still bind, they may not produce a functional protein if transcribed to mRNA. This simplified example is used, although not completely accurate, because in theory these pairs should not bind as they are not truly complementary. Actual DNA sequences can contain thousands of nucleotides. Typically a variation will be more significant than a single divergent nucleotide. For instance, many nucleotides may be missing or the order of a portion of the nucleotide sequence may be reversed. This example is an illustrative simplification to aid in the understanding of the background science.

C. History of Challenges to Patenting Isolated DNA Sequences

The patentability of isolated DNA sequences has been challenged in the past on two grounds.[7] First, the patentability of isolated DNA sequences has been challenged on the grounds of nonobviousness.[8] In *In re Deuel*, the Patent and Trademark Office Board of Patent Appeals rejected the patentee's claim to an isolated DNA sequence of heparin-binding growth factors (HBGFs).[9] The prior art against which obviousness was considered was the well-known method of extracting and isolating DNA, and a reference involving heparin-binding brain mitogens (HBBMs).[10] The Board of Patent Appeals rejected the composition claims to the isolated DNA sequence because the process used to extract and isolate the DNA was obvious, and as the Board seemed to imply, the patentee's HBGFs were identical to the HBBMs of the prior art reference.[11] The United States Court of Appeals for the Federal Circuit, in reversing the Board's finding of nonpatentability based on obviousness, emphasized the fact that although "[the] general chemical nature [of the HBGFs] may have been obvious from [the HBBM prior art reference], and the knowledge that some gene existed may have been clear, the precise . . . molecule . . . claims[, the nucleotide sequence of the DNA,] would not have been obvious."[12] In other words, the Federal Circuit held that although it was known that the gene existed, the actual nucleotide sequence was not obvious; there are seemingly infinite possibilities for any one nucleotide sequence containing hundreds, if not thousands, of nucleotide bases.[13] The court concluded, "A general motivation to search for some gene that exists does not necessarily make obvious a specifically-defined gene that is subsequently obtained as a result of that search."[14]

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7. *See In re* Deuel, 51 F.3d 1552 (Fed. Cir. 1995) (challenging patentability on § 103 grounds); *see also* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997) (challenging patentability on § 103 grounds (2010)); *Ass'n for Molecular Pathology*, 702 F. Supp. 2d 181 (challenging patentability on § 101 grounds).

8. *See In re Deuel*, 51 F.3d at 1555-56.

9. *Id.*

10. *Id.* at 1556.

11. *Id.* at 1557.

12. *Id.* at 1558.

13. *See id.*

14. *Id.* For a more comprehensive discussion of the history of litigation involving human genes and DNA sequences, see Christopher Holman, *Trends in Human Gene Patent Litigation*, SCIENCE, Oct. 10, 2008, at 198-99, *available at* http://www.sciencemag.org/content/322/5899/198.full.

Second, patentability of isolated DNA sequences is currently being attacked on grounds that DNA sequences are a product of nature.[15] The argument against patentability is that isolated DNA sequences are simply a purification of a product of nature, and as such, should not be patentable.[16] This argument follows a relatively straightforward path: (1) DNA is a naturally occurring chemical, (2) isolated DNA is simply DNA in a purified form, and (3) the mere purification of a natural product does not render the purified product patentable.[17] To analyze this argument completely, the product of nature doctrine specifically pertaining to purified substances and the article of manufacture doctrine must be carefully scrutinized. As will be discussed, the patentability of isolated DNA sequences rests on whether the purified DNA differs in kind, as opposed to simply differing in degree of purity from the naturally occurring DNA.[18] In addition, to be patentable subject matter under 35 U.S.C. § 101, the utility of the purified DNA must be the result of the handiwork of man, as opposed to the handiwork of nature, making the purified DNA an article of manufacture.[19]

This Comment will focus on the different bars to patentability that stem from § 101. It will then address the question of whether isolated DNA sequences fall under the product of nature doctrine bar to patentability. Finally, this Comment will address the economic and public policy issues surrounding the patentability of isolated DNA sequences. In sum, this Comment will discuss whether patents on isolated DNA sequences should continue to be upheld, as they traditionally have been, under the new product of nature line of attack.[20]

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15. *See* Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, No. 2010-1406, 2011 WL 3211513, at *1 (Fed. Cir. July 29, 2011).

16. *See id.* at 230.

17. *See* Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 162 (4th Cir. 1958); *see also Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 230.

18. *See* 253 F.2d at 162. Throughout this Comment, "isolated DNA sequences" and "purified DNA" will be used interchangeably to promote the ease of readability. It should be noted that isolated DNA sequences are not simply "purified DNA." Using these terms interchangeably suggests that isolated DNA sequences should not be patentable. This is of no consequence, however, as this Comment will show that even considered simply as "purified DNA," isolated DNA sequences are indeed patentable subject matter under § 101.

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

20. Stating that the isolated DNA patents have traditionally been upheld is a misstatement. To this author's knowledge, until the United States District Court for the Southern District of New York considered the patentability of isolated DNA sequences under § 101, no case had specifically addressed this issue. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d 181. However, the validity of many patents covering isolated DNA sequences have been litigated on grounds other than § 101. In many of these cases, the patents were held valid under different challenges. A more accurate statement may be that isolated DNA sequences have not traditionally been held invalid on § 101 grounds. This minor difference in terminology is of no

II. PATENTABLE SUBJECT MATTER

The purpose of the patent system in the United States is plainly stated in the United States Constitution—"To promote the Progress of Science and useful Arts."[21] This goal of advancing scientific knowledge is achieved by granting inventors the exclusive right to exploit their inventions. The balance has long been recognized between encouraging inventors to invent, and allowing unrestricted access to the fruits of the inventor's labor.[22] This balance is enumerated in the second portion or Article I, Section VIII—"by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[23] Granting to the inventor exclusive rights for a period of time provides the inventor with an incentive to invent. The limited duration of the exclusive rights means that the invention will eventually be free for all to exploit.

The Patent Act is codified in 35 U.S.C. § 1.[24] Many of the provisions, specifically § 101, remain substantially unchanged since the first U.S. Patent Act—the Patent Act of 1790.[25] The Patent Act of 1790 defined eligible subject matter as "any useful art, manufacture, engine, machine, or device."[26] In 1793, Thomas Jefferson drafted a new Patent Act which modified the 1790 Act and enumerated four categories of patent-eligible inventions: "art, machine, manufacture[, and] composition of matter."[27] These four categories have persisted into the present day.[28] The only change since 1793 was the exchange of the word "process" for the word "art."[29] However, this revision does not change the scope of patentable subject matter; the Patent Act defines "process" as a "process, *art* or method."[30] Accordingly, what would have been

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significance as long as the reader has a rudimentary background knowledge of litigation pertaining to patents covering isolated DNA sequences. A thorough analysis has been omitted from this Comment because its inclusion would be outside the scope of the Comment. The focus rather is that isolated DNA sequences fall under the statutorily enumerated categories of patentable subject matter.

21. U.S. CONST. art. I, § 8, cl. 8.

22. *See* Viktor Mayer-Schönberger, *The Law as Stimulus: The Role of Law in Fostering Innovative Entrepreneurship*, 6 ISJLP 153, 165 (2010) (discussing utilitarian aspects of patent law).

23. U.S. CONST. art. I, § 8, cl. 8.

24. 35 U.S.C. §§ 1-2 (2006).

25. Patent Act of 1790, ch. 7, § 1, 1 Stat. 109, 110 (repealed 1793).

26. *Id.*

27. Patent Act of 1793, ch. 11, § 1, 1 Stat. 318, 318-19 (repealed 1836); Graham v. John Deere, 383 U.S. 1, 7 (1966).

28. *See* 35 U.S.C. § 101.

29. Diamond v. Diehr, 450 U.S. 175, 182 (1981).

30. 35 U.S.C. § 100 (emphasis added).

patentable subject matter in 1793 would still be patentable subject matter in 2011.[31]

One large category of "inventions" excluded from § 101 patentable subject matter is "products of nature."[32] If something is a product of nature, it is not made by man; rather, it is the handiwork of nature.[33] When an invention is not the handiwork of nature, it is an article of manufacture.[34] Thus, the product of nature doctrine and the article of manufacture doctrine are opposite sides of the same coin.[35] Essentially, the analysis of the two doctrines is the same: is an "invention" a product of nature, or is it the handiwork of man, and accordingly, an article of manufacture?[36] The two categories are mutually exclusive and can be loosely considered a determinative test for § 101 patentability.[37]

III. PRODUCT OF NATURE DOCTRINE

A. Basics of the Doctrine

Frequently, inventions that are not captured in the field of patentable subject matter do not advance the goals of the patent system. For example, in *Le Roy v. Tatham*, the patentee developed an improvement in machinery for making pipes.[38] The improvement that the patentee "invented" was merely an exploitation of a newly discovered property of lead.[39] The newly discovered property itself was held unpatentable by the United States Supreme Court.[40] The Court found that the newly discovered property was outside the scope of patentable subject matter because a patent on certain properties of lead would actually remove

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31. *See In re* Nuijten, 500 F.3d 1346, 1352 (Fed. Cir. 2007).

32. *See* Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 162 (4th Cir. 1958). The word "inventions" is placed in quotations here because if a patentee seeks to patent something which is indeed a product of nature, the product is not an invention. Simply put, products of nature are not inventions. Likewise, throughout this Comment, if the word "invention" is used to describe something that is not patentable subject matter, it will be placed in quotations.

33. *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 132 (1948).

34. *See id.*

35. *See Merck*, 253 F.2d at 162. I will use the term "article of manufacture doctrine" to refer to the principle that inventions that are the handiwork of man are articles of manufacture.

36. *See* Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 10-11 (1931); *see also Funk Bros. Seed Co.*, 333 U.S. at 130.

37. If an "invention" is a product of nature, it is by definition not the handiwork of man and is thus unpatentable. If an invention is the handiwork of man, it is by definition not the handiwork of nature, and therefore not a product of nature. Accordingly, inventions that are the handiwork of man are patentable subject matter.

38. Le Roy v. Tatham, 55 U.S. 172, 172-73 (1852).

39. *Id.*

40. *Id.* at 176.

information from public knowledge rather than enhance the public knowledge.[41] This result directly contradicts the constitutionally stated purpose of the patent system—"To promote the Progress of . . . useful Arts."[42] The Court noted however that even though the newly discovered property could not itself be patented, a process utilizing the newly discovered property could be patentable as long as the process used the property to some specific end.[43]

Essentially the Court in *Le Roy* held that a product of nature in and of itself is not patentable subject matter.[44] However, the Court recognized that processes employing such products of nature could potentially be patentable.[45] Both of these principles were reiterated by the Court shortly after *Le Roy*, in *O'Reilly v. Morse*.[46] In *O'Reilly*, the patentee sought a patent for harnessing electromagnetism as a means of communicating over distances—more commonly known as a telegraph.[47] The patentee had invented a means of achieving this. However, one of the claims of the patent was overly broad and covered any invention utilizing electromagnetism to communicate over distance.[48] The Court held this claim invalid because it attempted to claim an abstract idea—the use of electromagnetism to communicate over distances—as opposed to a specific embodiment of that abstract idea.[49]

The claim in *O'Reilly*[50] was invalidated for the same reason that the patent in *Le Roy* was invalidated.[51] The patent in *Le Roy* utilized a newly discovered property of a naturally occurring material.[52] The Court in *Le Roy* stated however, that although this newly discovered property could not be patented itself, the principle could be used to some specific end to create a patentable invention.[53] Likewise, in *O'Reilly*, an invention that used the natural principle to a specific end—the telegraph—was patentable subject matter.[54] On the other hand, a claim covering all inventions utilizing electromagnetism for communication purposes was

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41. *Id.*
42. U.S. CONST. art. I, § 8, cl. 8.
43. *Le Roy*, 55 U.S. at 175.
44. *Id.* at 174-75.
45. *Id.* at 175.
46. *See* O'Reilly v. Morse, 56 U.S. 62, 132-33 (1853).
47. *Id.* at 112.
48. *Id.* at 119-20.
49. *See id.*
50. *Id.*
51. Le Roy v. Tatham, 55 U.S. 172, 176 (1852).
52. *Id.* at 172-73.
53. *Id.* at 175.
54. *Morse*, 56 U.S. at 132-33.

an attempt to patent a newly discovered property of electromagnetism itself, and was thus outside the scope of patentable subject matter.[55]

In both *Le Roy* and *O'Reilly*,[56] the Court held that claims to properties of naturally occurring "discoveries" were invalid.[57] These claims were unpatentable because they were an attempt to patent a product of nature.[58] Although attempts to patent a product of nature are invalid, inventions utilizing properties of a product of nature to a specific end can be patentable.[59]

B. Purification

Purified substances are a subcategory of the product of nature doctrine.[60] As a basic example, consider salt dissolved in water. To purify the salt, the water must be removed. The simplest way to do this is to boil the water. Once the water has evaporated, only the salt remains—the salt is in its "purified" form. This is where the product of nature doctrine comes into play. The purified salt that is present after boiling the water was the same salt that was present in the saltwater mixture. Thus, by purifying the salt, a new product is not obtained.

Courts have consistently struggled with the purification concept.[61] As early as the nineteenth century, the Supreme Court had to determine whether a purified substance was patentable subject matter.[62] In *American Wood Paper Co. v. Fibre Disintegrating Co.*, the patentee received a patent for both a process for purifying fibers used to make paper and for the actual fibers as a product.[63] At the time of the patent, there were already processes in place for extracting certain fibers.[64] The new process however produced fibers that were more pure than the fibers extracted through the previous processes.[65] Although the Court upheld the process claims for the chemical process for purifying the fibers, the Court rejected the product claims to the actual purified fiber.[66] The Court

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55. *Id.* at 119-20.
56. *Id.*
57. *Id.*; *Le Roy*, 55 U.S. at 176.
58. *See Le Roy*, 55 U.S. at 174-75; *Morse*, 56 U.S. at 119-20.
59. *Le Roy*, 55 U.S. at 175.
60. *See In re* Marden, 47 F.2d 958, 959 (C.C.P.A. 1931).
61. *See* Am. Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. 566 (1874); Am. Fruit Growers, Inc. v. Bregdex Co., 283 U.S. 1 (1930); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).
62. *See Am. Wood-Paper*, 90 U.S. 566.
63. *Id.* at 593.
64. *Id.* at 595-96.
65. *Id.*
66. *Id.* at 596.

reasoned that the minimal difference in purity of the fibers was insufficient to permit patent protection for the claimed product.[67] Essentially, the purified fibers were not substantially different from the unpurified fibers, which were a product of nature. Therefore, the purified fibers fell within the product of nature doctrine.[68] The purified fibers differed from previously purified fibers and from naturally occurring fibers only in degree of purity, not in kind.[69]

Although a purified substance may be deemed unpatentable, purification is not necessarily a sufficient condition to preclude patentability.[70] A substance that is purified may still be patentable.[71] For a purified substance to be patentable, the resulting product must differ not simply in degree of purity, but in kind.[72] In the saltwater mixture example, the purified salt would likely be unpatentable because the salt in solution differs only in degree of purity from the "purified" salt. If the utility of the salt is its ability to lower the freezing temperature of water, as used in the northern states to prevent the formation of ice on roadways, the salt in solution produces the same effect as the "purified" salt. If the saltwater mixture is poured on a road, the freezing temperature of water on the road is lowered. Similarly, if the "purified" salt is poured on a road, the freezing temperature of water on the road would decrease an equal amount. The benefit of "purifying" the salt is that a smaller amount is sufficient to achieve the desired result. The saltwater mixture may contain only fifty percent salt, requiring twice as much solution as the "purified" salt to achieve the same result. This difference would be in the degree of purity. This difference would not be a difference in kind because the saltwater mixture achieves the same result as the "purified" salt. Essentially, the question of whether a product in its purified form is patentable rests on how different the purified product is from its naturally occurring counterpart.[73]

The United States Court of Appeals for the Third Circuit followed this principle in *General Electric Co. v. De Forest Radio Co.*[74] In that case, the court held the patent for purified tungsten invalid.[75] The purified tungsten was significant because it was more ductile and

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67. *See id.* at 594.
68. *Id.* at 595-96.
69. *See id.* at 594.
70. Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 162-65 (4th Cir. 1958).
71. *See id.* at 164.
72. *See id.* at 162.
73. Gen. Elec. Co. v. De Forest Radio Co., 28 F.2d 641, 642-43 (3d Cir. 1928).
74. *See id.*
75. *Id.* at 641-42.

stronger than other available tungsten.[76] The court stated that while these differences were due to the purification process, they were not substantial enough to warrant patent protection.[77] Additionally, the court opined that the patentee had simply "discovered" pure tungsten and likewise had "discovered" the properties of pure tungsten.[78] Accordingly, the court found the desirable qualities of pure tungsten to be the handiwork of nature and not of the inventor himself.[79] Because the inventor did not invent the pure tungsten himself, and the qualities of the pure tungsten were not substantially different from those of impure tungsten, the pure tungsten was a product of nature.[80] In sum, the pure tungsten differed only in degree of purity, not in kind, from the impure tungsten.[81]

In contrast to the Third Circuit's decision in *General Electric Co.*, the United States Court of Appeals for the Second Circuit ruled in favor of the patentee's patent covering purified Adrenalin in *Parke-Davis & Co. v. H.K. Mulford & Co.*[82] In holding the patent valid, the court referred to district court Judge Learned Hand's explanation of the facts.[83] As Judge Hand explained, the Adrenalin was created through isolation from the suprarenal gland, and then subjected to a purification process.[84] Unpurified Adrenalin does not produce any of the therapeutic effects that purified Adrenalin creates.[85] In upholding the validity of the patent, Judge Hand emphasized the utility of the patent.[86] Because the purified Adrenalin could be used in a therapeutically valuable way in which the impure substance could not, the purified Adrenalin differed substantially from the impure substance such that it was outside the scope of the product of nature doctrine.[87] This difference was a difference in kind, rather than simply a difference in degree of purity.[88] The Second Circuit

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76. *Id.*
77. *Id.*
78. *Id.*
79. *Id.* The "handiwork of nature" distinction will be discussed at greater length in the following Part.
80. *Id.*
81. *Id.*
82. *See* Parke-Davis & Co. v. H.K. Mulford & Co., 196 F. 496, 500 (2d Cir. 1912).
83. *Id.* at 497.
84. *See* Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 102 (S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912).
85. *Id.* at 103.
86. *See id.*
87. *See id.*
88. *Id.*

later upheld Judge Hand's reasoning in affirming the validity of the patent.[89]

The United States Court of Appeals for the Fourth Circuit came to a result similar to that of Judge Hand in *Merck & Co. v. Olin Mathieson Chemical Corp.*[90] At issue in this case was the purification of Vitamin B(12) from cattle liver.[91] The trial court held the composition patents invalid.[92] The trial court stated that the product claims "covered a 'product of nature' and that there was [a] lack of invention."[93] The appellate court however, upheld the validity of the patent, focusing both on the historical context of the purification of Vitamin B(12), as well as on the principle that a purification, as long as it varies in kind, not just in degree, is patentable.[94]

In focusing on the history of Vitamin B(12), the court emphasized the substantial difficulties faced by scientists throughout the discovery and purification process.[95] The court first explained, "In 1926 it was found that pernicious anemia patients were benefited by the addition to their diets of substantial amounts of the liver of cattle."[96] The court further explained that "by 1947 a number of liver extracts and concentrates were available."[97] The court noted, however, that although these extracts and concentrates were available, and "not ineffectual in the treatment of pernicious anemia . . . they were expensive and some patients were unable to tolerate them."[98] The court culminated this discussion by emphasizing that the patentee was the first to successfully determine what the beneficial factor was in the cattle liver and isolate it.[99]

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89. *See Parke-Davis*, 196 F. at 500. Of note is the fact the Judge Hand made a clearly erroneous statement of law in his opinion: "But, even if it were merely an extracted product without change, there is no rule that such products are not patentable." *Parke-Davis*, 189 F. at 103. Although this statement is an erroneous statement of the law, the circuit court upheld the validity of the patent because the purified substance differed not in degree, but in kind. *See Parke-Davis*, 196 F. at 497; *Parke-Davis*, 189 F. at 103.

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

91. *Id.* at 157.

92. *Id.*

93. *Id.* (quoting Merck & Co. v. Olin Mathieson Chem. Corp., 152 F. Supp. 690 (W.D. Va. 1954)).

94. *See id.* at 157-65. The word "discovery" is used here because it was not immediately apparent what compound within the animal liver was producing the beneficial effects. The word "discovery" was not used to imply that the compound was a product of nature. *See id.* at 158.

95. *See id.* at 157-60.

96. *Id.*

97. *Id.*

98. *Id.*

99. *See id.* at 160.

The court focused on the history of this invention to bolster its conclusion that the Vitamin B(12) was both new and useful.[100]

The second emphasis of the court's discussion was that the purified Vitamin B(12) was not merely an "advance in the degree of purity of a known product," but rather was an entirely new product.[101] The court relied on multiple decisions, including *Parke-Davis*, all of which held the inventions at issue to be something new, not just a more pure substance.[102] Because the product that was created, Vitamin B(12), was new, it differed in kind and not simply in degree of purity.[103] During this analysis, the court stated that "where the requirements of the [Patent] Act are met, patents upon products of nature are granted and their validity sustained."[104]

In sum, the court in *Merck* held the patents on the purified Vitamin B(12) valid because the patents satisfied the requirements of the Patent Act.[105] However, this determination focused on § 102 of the Patent Act, requiring novelty,[106] and to a lesser extent, on § 103's nonobviousness requirement.[107] Under the court's analysis a patent will be held valid as long as it meets the requirements of §§ 102 and 103 and the purification creates a product differing not simply in degree of purity, but in kind.[108]

IV. ARTICLE OF MANUFACTURE

As discussed previously, on the opposite side of the product of nature doctrine coin is the article of manufacture consideration.[109] Under the article of manufacture analysis, the test is similar to the product of nature doctrine test, with some slight variations.[110] When considering whether an "invention" is a product of nature, the court examines whether the "invention" is something that is naturally occurring.[111] Under the article of manufacture analysis, the court considers whether the utility of the invention is due to the handiwork of man, and thus patentable, or to the handiwork of nature, and thus unpatentable.[112] In other words, if

100. *See id.* at 158-60.
101. *Id.* at 164.
102. *See id.* at 163.
103. *See id.* at 164.
104. *Id.* at 162.
105. *Id.* at 164.
106. 35 U.S.C. §§ 102-103 (2006); *see Merck*, 253 F.2d at 161.
107. *See Merck*, 253 F.2d at 161.
108. *See id.* at 161-62.
109. *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 132 (1948).
110. *See id.*
111. *See Merck*, 253 F.2d at 162.
112. *See Funk Bros. Seed Co.*, 333 U.S. at 131.

the utility of the "invention" is simply a characteristic of the natural product, the "invention" does not fall within the § 101 enumerated categories of patentable subject matter.[113] Conversely, if the utility of the invention is due to the handiwork of man, the invention is an article of manufacture and thus falls within the § 101 enumerated categories of patentable subject matter.[114]

In *American Fruit Growers, Inc. v. Brogdex Co.*, the patent-in-suit was for a treatment for fresh produce that would inhibit degradation of the produce by blue mold.[115] The treatment at issue consisted of "washing [the fruit] with a solution of boric acid and then applying a coating of gelatin."[116] In upholding the validity of the patents, the Third Circuit stated, "The product claims define an article of manufacture, since the fruit is the result of a process which is defined and described and not a natural product."[117] The court heavily emphasized that treating the fruit in boric acid created an article that was not naturally occurring and was therefore "an article of manufacture."[118] The Supreme Court however, disagreed with the appellate court's determination.[119] The Supreme Court defined "manufacture" as "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations."[120] Ultimately, the Supreme Court concluded that the treatment did not produce an "article of manufacture" because "[t]here [was] no change in the name, appearance, or general character of the fruit."[121] Because treating the fruit in a boric acid wash did not create an "article of manufacture," the Supreme Court held the patent invalid.[122]

The Supreme Court came to a similar result in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*[123] In *Funk Bros. Seed Co.*, the patentee sought to patent a combination of bacteria that was beneficial in the cultivation of certain crops.[124] The benefits of certain bacteria of the genus *Rhizobium* in the cultivation of leguminous plants had long been known.[125] Each

113. *See id.*
114. 35 U.S.C. § 101 (2006); *see Funk Bros Seed Co.*, 333 U.S. at 131.
115. *See* Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 8 (1931).
116. *Id.* at 13.
117. *Id.* at 11.
118. *Id.*
119. *Id.*
120. *Id.*
121. *Id.* at 12.
122. *Id.* at 14.
123. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 132 (1948).
124. *Id.* at 130.
125. *Id.* at 129.

species of *Rhizobium* bacterium provided benefits only to specific plants.[126] To complicate things further, in all attempts to create mixtures of bacteria to benefit a greater number of crops, the bacteria would inhibit the benefits conferred to the plants by the other bacteria.[127] The patent-in-suit in this case was for a combination of bacteria that did not inhibit the others, thus allowing one combination of bacteria to be used on the majority of leguminous crops.[128] In considering only the product claims (as opposed to the process claims) the Court reasoned that the patent-holder did not "create [the] state of inhibition or of non-inhibition in the bacteria."[129] Because this characteristic was not created by the patent-holder, the Court found it was "the work of nature."[130] In holding the subject matter unpatentable, the Court stated that the bacteria in the patented combination "serve[d] the ends nature originally provided and act[ed] quite independently of any effort of the patentee."[131]

In *American Fruit Growers*, the boric acid treatment for produce was not patentable because the treatment did not alter the produce and therefore was not a manufacture.[132] In *Funk Bros. Seed Co.*, the bacteria combination was also not patentable because the bacteria combination did not alter the natural qualities of the bacteria.[133] Additionally in *Funk Bros. Seed Co.*, the Court found that the utility of the bacteria combination was "the handiwork of nature."[134] These cases stand in opposition to the Court's subsequent holding in *Diamond v. Chakrabarty*.[135]

In *Chakrabarty*, the subject matter of the patent-in-suit was a bacterium, similar to the subject matter of the patent-in-suit in *Funk Bros. Seed Co.*[136] In *Chakrabarty*, the patent-holder created a bacterium with the ability to break down crude oil, an ability possessed by no other bacterium.[137] In upholding the validity of the patent, the Supreme Court distinguished the bacterium in *Chakrabarty* from both the bacterium combination in *Funk Bros. Seed Co.* and the boric acid wash in

126. *Id.*
127. *Id.*
128. *Id.* at 130.
129. *Id.*
130. *Id.*
131. *Id.* at 131.
132. *See* Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11-12 (1931).
133. *See Funk Bros. Seed Co.*, 333 U.S. at 131.
134. *Id.*
135. *See* Diamond v. Chakrabarty, 447 U.S. 303, 318 (1980).
136. *Id.* at 308.
137. *Id.* at 305.

American Fruit Growers, Inc..[138] In distinguishing the bacterium in *Chakrabarty* from the bacterium combination in *Funk Bros. Seed Co.*, the Court focused on utility of the bacterium.[139] Whereas the utility of the bacterium combination in *Funk Bros. Seed Co.* was a product of nature, the utility of the bacterium in *Chakrabarty* was "not nature's handiwork, but [the inventor's] own."[140] The Court determined that the bacterium in *Chakrabarty* was unlike the bacteria combination in *American Fruit Growers, Inc.* because the bacterium created in *Chakrabarty* had "markedly different characteristics from any found in nature."[141] Because the utility of the bacterium in question was not a product of nature's handiwork and constituted a manufacture, the Court held that the bacterium at issue was patentable subject matter under § 101.[142]

V. DNA AND PATENTABLE SUBJECT MATTER

As stated previously, composition patents on isolated DNA sequences are currently being attacked on § 101 grounds.[143] The attack relies on the proposition that isolated DNA sequences fall under the product of nature doctrine, and thus are not articles of manufacture.[144] At first glance this argument appears to have some merit. An isolated DNA sequence is essentially a purification.[145] Just like the salt in the saltwater solution, the single strand of DNA exists before the purification. As the salt is mixed with water in the saltwater solution, the single strand of DNA can be considered to be "mixed" with its complementary strand forming a double helix. Following this path of reasoning, the single strand of DNA appears to simply be a purification of naturally occurring DNA, and accordingly, unpatentable.

Although it initially appears that isolating DNA sequences is a simple purification, this is not entirely accurate. While the saltwater solution and the "purified" salt perform the same function—lowering the freezing point of water—the naturally occurring DNA is unable to perform the same function as the isolated DNA sequence. Native DNA performs the function of coding for characteristic traits. Isolated DNA

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138. *Id.* at 308-10.
139. *Id.* at 310.
140. *Id.*; *see also* Funk Bros. Seed Co. v. Kali Inoculant Co., 333 U.S. 127, 131 (1948).
141. *Chakrabarty*, 447 U.S. at 310.
142. *Id.* at 309.
143. *See* Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 181 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, No. 2010-1406, 2011 WL 3211513, at *1 (Fed. Cir. July 29, 2011).
144. *See id.* at 223.
145. *Id.* at 231.

sequences however do not code for characteristic traits. Rather, isolated DNA sequences are used for research.[146] As a result, native DNA cannot be used for research in the same manner in which isolated DNA sequences are used.[147] Accordingly, isolated DNA sequences do not differ simply in degree of purity from their native DNA counterparts. Rather, isolated DNA sequences differ in kind from their native DNA counterparts because of the dramatically different utility of isolated DNA.

In *Parke-Davis*, the patentee purified animal adrenal glands to create purified Adrenalin.[148] The raw product did not have the same therapeutic values as the purified Adrenalin.[149] Because of this therapeutically valuable use for purified Adrenalin, the purified Adrenalin was substantially different than the raw product.[150] As a result, the purified Adrenalin differed in kind, not simply in degree of purity, from the raw product.[151] The court in *Parke-Davis* held, following previous case law, that a purified substance which varied in kind, as opposed to simply in degree of purity, from its raw product was patentable subject matter.[152]

In *Merck*, the court took the purification process one step further.[153] Whereas in *Parke-Davis* the purified substance was the only product of its type, in *Merck*, there were extracts made from animal livers, aside from the Vitamin B(12), that provided therapeutic effects.[154] The court stated that although there were previous extracts available that were "not ineffectual in the treatment of pernicious anemia[,] they were expensive and some patients were unable to tolerate them."[155] The invention, Vitamin B(12), eliminated some of these problems because the Vitamin B(12) was pure and did not contain the superfluous material that the previous extracts contained.[156] Like the Adrenalin in *Parke-Davis*,[157] the Vitamin B(12) had a substantially higher therapeutic value than the

146. *Id.*
147. *Id.*
148. *See* Parke-Davis Co. v. H.K. Mulford Co., 196 F. 496, 500 (2d Cir. 1912).
149. Parke-Davis Co. v. H.K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911).
150. *Id.*
151. *Id.*
152. *Id.*
153. *See* Merck Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 158 (4th Cir. 1958).
154. *See id.* at 158; *Parke-Davis*, 189 F. at 102.
155. *Merck*, 253 F.2d at 158.
156. *Id.* at 160. The word "invention" is used here to emphasize that the Vitamin B(12) was not simply a discovery, but rather a patentable invention.
157. *Park-Davis*, 189 F. at 103.

previous extracts.[158] This difference indicated a difference in kind, rather than simply a difference in degree of purity.[159] Accordingly, the Vitamin B(12) was patentable subject matter.[160]

Isolated DNA sequences are most similar to the Adrenalin in *Parke-Davis* and the Vitamin B(12) in *Merck*. Like both the Adrenalin and the Vitamin B(12), isolated DNA sequences provide therapeutic qualities that their naturally occurring native DNA counterparts do not. This difference is the ability to use isolated DNA sequences to test for genetic mutations. The ability of isolated DNA to do what native DNA cannot, test for genetic mutations, is a difference in kind, rather than simply a difference in degree of purity. Accordingly, isolated DNA sequences hold the requisite difference in kind to remove them from the product of nature doctrine and meet the § 101 requirement of patentable subject matter.

VI. ARTICLE OF MANUFACTURE

Because the product of nature and the article of manufacture categories are mutually exclusive, it stands to reason that since the isolated DNA sequences are not products of nature, they are an article of manufacture.[161] However, it is not enough to merely say that because something is not heads, it is necessarily tails. Indeed, isolated DNA sequences not only escape the product of nature doctrine, but also fit within the previous case law defining articles of manufacture.

As in the product of nature doctrine, isolated DNA sequences initially seem to fail the requirements of an article of manufacture. Certainly, isolated DNA sequences bind to complementary DNA sequences just as they bind to their complementary nucleotide sequence in native form. Because of this, isolated DNA sequences seem to be similar to the bacterium combination in *Funk Bros. Seed Co.*[162] In *Funk Bros. Seed Co.*, each bacterium in the combination was naturally occurring.[163] Additionally, each bacterium functioned in the combination the same as they would separately.[164] As a result of these two factors, the utility of the bacterium combination was the handiwork of nature rather than the handiwork of man.[165] Similarly, because the isolated DNA

158. *Merck*, 253 F.2d at 161.
159. *See id.*
160. *See id.* at 165.
161. *See id.* at 162.
162. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 107, 131 (1948).
163. *Id.* at 130.
164. *Id.*
165. *Id.* at 131.

sequences bind in the same manner as native DNA, it seems that their utility would likewise be the handiwork of nature as opposed to the handiwork of man. However this is where the similarities end.

In *Funk Bros. Seed Co.*, each bacterium was naturally occurring.[166] In contrast, although the isolated DNA seems to be naturally occurring, isolated DNA sequences are created by man. DNA does not exist in nature in its isolated form.[167] Whereas the utility of the bacterium combination comes from the utility of each bacterium in the mixture, the utility of the isolated DNA sequences is not present in the naturally occurring native DNA.[168] The utility of the isolated DNA sequence is present solely because of human intervention.[169]

In *Chakrabarty*, the patentee took a naturally occurring bacterium and inserted certain "energy-generating plasmids" which enabled the bacterium to break down crude oil.[170] With the addition of the plasmids, the patentee created something new that was not naturally occurring.[171] Similarly, in the case of isolated DNA sequences, a naturally occurring product is taken and transformed into something repetitive with a new utility. This new utility, as in *Chakrabarty*, is the handiwork of man, not the handiwork of nature.[172]

Further, in *Chakrabarty*, the Supreme Court emphasized how broad the § 101 enumerated categories were.[173] In fact, the Court went as far as to say that "Congress intended [the] statutory subject matter of § 101 to 'include anything under the sun that is *made by man*.'"[174] This once again emphasizes the distinction between the handiwork of man and the handiwork of nature.[175] Because isolated DNA sequences do not exist in nature, and are solely a product of human intervention, they easily fall under "anything under the sun that is made by man."[176]

The Court next provided an equally broad definition of article of manufacture: "[T]he production of articles for use from raw or prepared

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166. *Id.* at 130.

167. *See* Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 224 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, No. 2010-1406, 2011 WL 3211513, at *1 (Fed. Cir. July 29, 2011).

168. *Funk Bros. Seed Co.*, 337 U.S. at 130; *see Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 231.

169. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 231.

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

171. *See id.* at 310.

172. *Id.*

173. *Id.* at 308.

174. *Id.* at 309 (quoting S. REP. NO. 1979, at 5 (1952) (emphasis added)).

175. *See id.*

176. *Id.*

materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery."[177] The Court goes on to say that articles of manufacture are "the production of articles for use from raw or prepared materials"[178] achieved "by giving to these materials new forms, qualities, [or] properties." Isolated DNA sequences exist in single strand form, as opposed to the double-helix form in which DNA exists in nature—a "new form." Isolated DNA sequences can be used for research in ways that native DNA cannot; the result is "new qualities, [or] properties."[179] Isolated DNA sequences undoubtedly fall under the binding Supreme Court precedent in *Chakrabarty* defining an article of manufacture.[180]

VII. CONSTITUTIONAL PERSPECTIVE

The purpose of the patent system has been described in terms of the public good.[181] In *Kewanee Oil Co. v. Bicron Corp.*, the Supreme Court stated, "The productive effort fostered [by the patent system] will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens."[182] In addition to providing for the public good, the patent system also serves utilitarian functions.[183] The Supreme Court recognized this in *Kewanee Oil*, stating, "The patent laws promote . . . progress by offering [to inventors] a right of exclusion . . . as an incentive . . . to risk the often enormous costs in terms of time, research, and development."[184] Furthering the utilitarian function of the patent system is the constitutionally stated purpose: "To promote the Progress of Science . . . by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[185] Keeping this utilitarian purpose in mind is necessary to evaluate the appropriate economic and public policy concerns in order to determine whether a patent is the proper incentive for a specific invention.

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177. *Id.* at 308.
178. *Id.*
179. *Id.*
180. *Id.*
181. *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974).
182. *Id.* at 480.
183. *Id.*
184. *Id.*
185. U.S. CONST. art. I, § 8, cl. 8.

VIII. ECONOMIC AND PUBLIC POLICY CONCERNS

Under a constitutional perspective, the patent eligibility analysis of isolated DNA simply becomes whether inventors will be encouraged to study isolated DNA sequences if in turn they can receive an exclusive right to benefit, for a limited time, from their invention. It goes without saying that people will likely be more inclined to invent if they can realize a financial gain from such work. That is not to say that all inventors will cease to invent if they are unable to realize financial gain from their inventions. To analyze this issue, I will assume arguendo that both categories of inventors exist and that the proportion of the former category is not insubstantial.[186] With this stipulation, what must be considered is whether the public as a whole is better off with the knowledge gained from research in the field of isolated DNA sequences. The answer to this is undoubtedly yes. The possibility of screening for the predisposition to certain ailments can hardly be argued to be detrimental to society.

With the assumption that monetary gain does indeed encourage scientific advancement and that scientific advancement in the field of isolated DNA research is beneficial to the public, the next consideration is whether patent protection is the appropriate means to secure such scientific advances. Innovation in the field of scientific research can also be achieved through governmental grants. While governmental grants and patents both promote progress in science, the means by which the progress is achieved and the resulting burdens vary drastically.

In the case of grants, the granting institution, typically the federal government, decides what course of research should be taken. In essence, the government is determining what fields of research are worth researching and what research projects are likely to succeed. In the patent system, unlike grants, the inventors themselves determine what research is a worthwhile investment. This difference, however slight, may have significant implications. The inventors are significantly more likely to have a better understanding of what research is worthwhile. The inventors themselves have the knowledge and experience necessary to make these decisions. Specifically in a field as complex as the research of isolated DNA sequences, inventors are likely to have a much better

186. This is a broad statement. However, the author of this Comment believes it is abundantly clear that much innovation is fueled by financial gain. For example, consider the pharmaceutical industry, which is a leader in the patent industry. The incentive to spend vast sums of money and time is fueled by the possibility of financial gain. Further, implicit in the constitutional language is the idea that progress in scientific achievement is incentivized by exclusive rights to inventions. *See* U.S. CONST. art. I, § 8, cl. 8.

working knowledge of the subject matter which would lead to more informed decisions in the research process.

The products resulting from the patent system and the grant systems are likewise different. The incentive for inventors in the patent system is the ability to charge a price that will allow the inventor to recoup research and development costs. Because of this, higher prices are paid by consumers to cover these research and development costs. Accordingly, the benefit to the inventor flows from a successful invention. Under a system of grants, the costs of research and development are paid up front by the government, or other supporting institution, before a working invention is created. In essence, grants pay for a possible successful outcome of research, while the patent system pays for the actual successful outcome. The burden on society of a grant is realized before any beneficial invention is achieved. With the patent system, society is only burdened upon the successful completion of an invention.

Similarly, the groups upon which the burden falls differ between the two systems. Under the grant system, if the grant is a government grant, taxpayers as a whole are paying for the research and the possible beneficial outcome. Under the patent system, those who directly benefit from a patented invention are responsible for the burden.

IX. ALTERNATIVE FORMS OF PROTECTION

Not only is the patent system a better mechanism for protecting the fruits of an inventor's labor, it is also far superior to the route that will likely be employed absent patent protection: trade secret law. If isolated DNA sequences were determined not to be patentable subject matter, there would be little incentive to disclose any inventions or progress stemming from the isolated DNA sequences. Inherent in the patent system is a trade-off; the inventor receives exclusive rights for a limited time in exchange for the inventor's disclosure of the invention.[187]

Without patent protection for isolated DNA sequences, not only is this incentive missing, but further, there would be a disincentive for inventors to disclose their work. If an inventor were to disclose an invention, without patent protection, everyone would be free to exploit the inventor's invention.[188] The problem here is that many inventions, specifically in the medical field, require enormous research and development costs, including approval by the Food and Drug Administra-

187. *See* 35 U.S.C. § 112 (2006).

188. The term "inventor" is used here for simplicity. Realistically, this would not be an individual inventor. Rather, this would likely be a large research firm with many inventors working on many fields of research.

tion. Without an exclusive right to market the invention, the inventor's competition would be able to "steal" the idea behind the invention, market their own invention, and sell the invention at a competitive price. Because the competitor did not have to incur the substantial research and development costs that the inventor did, selling the product at a competitive price would allow the competitor to profit. Because the competitor is selling the invention at a competitive price, this would force the inventor to likewise sell the invention at a competitive price. Unfortunately for the inventor, selling the invention at the competitive price would not provide sufficient capital for the inventor to recoup his or her research and development costs.

Today, the inventor himself would not likely be providing the operating costs for research and development. Investors and venture capitalists would most likely be providing the operating capital for research and development. However, no matter where the money comes from, people will not be willing to spend or invest if there is no protection for their investment in the form of a likely return on investment.

With no patent protection, the only way to avoid being undercut by the competition is a lack of disclosure. This is commonly referred to as a trade secret. At first glance, this does not seem to be an issue. What is wrong with inventor's protecting their inventions by secrecy? However, there can be many problems with an inventor holding information as a trade secret.

The first problem is constitutional: "To promote the Progress of Science."[189] It can hardly be argued that keeping secrets "promote[s] the Progress of Science." This once again requires a discussion of the exchange between an inventor and the public. In exchange for disclosure of knowledge, the inventor is afforded exclusive rights for a limited time. This disclosure[190] is what "promote[s] the Progress of Science."[191] With a trade secret, there is no disclosure. When there is no disclosure, this constitutional purpose cannot be advanced. Thus, removing isolated DNA sequences from the category of patentable subject matter would do less to further this constitutionally stated purpose than affording isolated DNA sequences patent protection.[192]

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189. U.S. CONST. art. I, § 8, cl. 8.

190. *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974).

191. U.S. CONST. art. I, § 8, cl. 8.

192. Although cases involving isolated DNA sequences as the subject matter of a patent have been litigated in court, to my knowledge, the issue has never been whether the isolated DNA sequences are patentable subject matter. This is of course exclusive of the patents in *Associations for Molecular Pathology*. Nevertheless, in cases in which the subject matter of a patent was an

The second problem is also a constitutional issue. The United States Constitution provides to an inventor "for limited Times . . . the exclusive Right to his or her discovery."[193] The importance of this limited times language is to ensure that an invention will enter the public domain at some point in time—hopefully at the point where the inventor has recouped his or her R&D costs.[194] When the invention enters the public domain it is free for all to exploit, and competitive pricing takes over. With a trade secret, there is no limited times provision. A trade secret can remain a trade secret as long as it truly remains a secret. Theoretically, a trade secret could last indefinitely.[195] This would mean that the public would never be able to take advantage of the invention at a competitive price. The patent system, however, insures that within a specified time of filing a patent application, the invention will be in the public domain, and thus, subject to competitive pricing.[196]

X. CONCLUSION

"In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress contemplated that the patent laws should be given wide scope."[197] This wide scope is exemplified in the congressional record, stating that § 101 "include[s] anything under the sun that is made by man."[198] Isolated DNA sequences are made by man; they are an article of manufacture. Therefore, isolated DNA sequences fall within the wide scope of patentable subject matter enumerated in § 101 of the Patent Act.

Moreover, public policy and economic concerns show that society as a whole will benefit from upholding the patentability of isolated DNA sequences. Indeed, society as a whole has much to gain from the disclosure required by patent applications, and much to lose from trade secrets.

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isolated DNA sequence, the court did not hesitate to uphold the validity of the patent when all other requirements were met.

193. U.S. CONST. art. I, § 8, cl. 8.

194. *See* 35 U.S.C. § 154 (2006).

195. A trade secret would at most last the length of its useful life. This however, is essentially the same a trade secret lasting infinitely.

196. 35 U.S.C. § 154.

197. Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).

198. *Id.* at 309.