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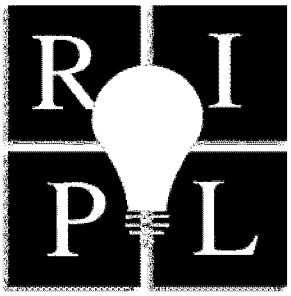


# REDEFINING UTILITY IN DETERMINING THE PATENTABILITY OF DNA SEQUENCES

DIANA A. VILLAMIL

ABSTRACT

On September 7, 2005, the Federal Circuit in *In re Fisher* upheld the PTO's final rejection for lack of utility of a patent application for certain DNA sequence fragments generated from maize plants. The court, supporting a heightened utility standard, adopted the "real-world" test for establishing substantial and specific utility required by the PTO. This decision severely limits the granting of patent rights to DNA sequence fragments, which are capable of having value within the biotech community as research tools. This comment proposes the restoration of a less stringent utility standard to more correctly reflect the purposes of patent law and advocates the use of licensing regulations as a solution to the DNA-patenting dilemma.




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# REDEFINING UTILITY IN DETERMINING THE PATENTABILITY OF DNA SEQUENCES

DIANA A. VILLAMIL*

## INTRODUCTION

The growing debate on genetic research and engineering is complemented by the equally passionate dispute on whether DNA sequences should be protected by patents. In 1990, the United States embarked on a thirteen-year venture called the Human Genome Project ("HGP"), the purpose of which was to identify all the genes in the human genome,[1] determine the sequence of base pairs for the entire human genome, and "store [that] information in databases" for further advancements in biotechnology.[2] This project significantly impacts life-sciences research, as the potential for commercialization of DNA-based technologies is projected to exceed $45 billion by 2009.[3] This projection has prompted both public and private entities to pursue patent protection of isolated DNA sequences in hopes of someday capitalizing on the new technology.[4] As a result, millions of gene and genome-related patent applications have been filed in the United States.[5]

The United States Patent and Trademark Office ("PTO") initially rejected patent applications for DNA sequences on the premise that the claimed inventions lacked

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[1] Genelabs Techs., Inc., Glossary of Terms, http://www.genelabs.com/resources/glossary.html (last visited Feb. 28, 2006). The genome is the "complete set of genetic information of an organism." *Id.*

[2] Human Genome Project Information, About the Human Genome Project Research, http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml (last visited Sept. 26, 2005).

[3] Human Genome Project Information, Potential Benefits of Human Genome Project, http://www.ornl.gov/sci/techresources/Human_Genome/project/benefits.shtml (citation omitted) (last visited Sept. 26, 2005).

[4] *See* G. Kenneth Smith & Denise M. Kettleberger, *Patents and the Human Genome Project*, 22 AIPLA Q.J. 27, 48 (1994). In response to internal publication pressures and to encourage rapid development of products for the treatment of disease, the National Institutes of Health ("NIH") initially applied for patent protection of 351 partial cDNA fragments in June of 1991. *Id.* at 46. Although most condemned this practice, in response, patent applications began to surface from throughout the world. *Id.* at 48. The NIH, after receiving a wall of rejections from the PTO, decided to discontinue the pursuit of the patents, hoping to put an end to the international rush to patent DNA fragment sequences with no known function. *See id.* at 50. This action came too late. *Id.*

[5] Human Genome Project Info., Genetics and Patenting, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml#2 (last visited Oct. 28, 2005).

utility.[6] However, these rejections did not prevent many HGP participants to rush to file as many DNA sequence patent applications as possible.[7] The first true gene patent on a cDNA[8] gene sequence, encoding the endorphin gene of the mouse genome, was issued in 1982.[9] However, many researchers assert that the first therapeutically important DNA patent was issued in 1985,[10] concerning a recombinant DNA molecule useful in producing proteins.[11] One way the PTO has attempted to restrict the number of DNA sequence patents it grants every year is by expanding the utility requirement.[12] As the PTO and the courts struggle to strike a balance between protecting innovation and ensuring access to technology,[13] there remains much speculation as to how DNA sequence patents will ultimately affect this balance.

This comment addresses the history of the utility requirement and how an attempt by the PTO to provide guidance in analyzing DNA sequence patent

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[6] Leslie Roberts, *Gene Patents: Rumors Fly over Rejection of NIH Claim*, 257 SCI. 1855, 1855 (1992) (noting the August 20, 1992 initial rejection of NIH's DNA sequence patent application by the PTO for lack of utility). The PTO stated that:

> it would be necessary for one to do further work in order to establish utility for many of the nucleotides embraced by the claims. The instant application does not teach one of skill in the art the significance of any putative result of any of the tests or processes alluded to in the application.

Rebecca S. Eisenberg and Robert Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 14–15 (1996).

[7] *See* Christopher Anderson, *NIH Drops Bid for Gene Patents*, 263 SCI. 909, 909 (1994). "NIH was not alone in trying to patent [DNA sequences]. Several companies have said they are pursuing similar patents, and many others are thought to be doing so privately." *Id.*

[8] *See infra* notes 43–45 and accompanying text for a more detailed discussion of cDNA.

[9] Adrenocorticotropin-lipotropin Precursor Gene, U.S. Patent No. 4,322,499 (filed Dec. 22, 1978) (issued Mar. 30, 1982).

[10] Recombinant DNA Molecules and Their Use in Producing Human Interferon-like Polypeptides, U.S. Patent No. 4,530,901 (filed Feb. 4, 1980) (issued July 23, 1985).

[11] *See* Warren Kaplan, *Biotech Patenting 101*, ¶ 7, http://www.gene-watch.org/programs/patents/patenting101.html (last visited Nov. 20, 2005). "Through the end of December 2000, approximately 25,000 DNA-based patents were granted." Kale Franz & Peter Faletra, *DNA Dilemma: A Perspective on Current U.S. Patent and Trademark Office Philosophy Concerning Life Patents*, 2 U.S. DEPT. OF ENERGY J. OF UNDERGRADUATE RES. 25, 25 (2002), *available at* http://www.scied.science.doe.gov/scied/JUR_v2/pdfs/Franz.pdf.

[12] *See generally* Revised Utility Examination Guidelines, 66 Fed. Reg. 1,092 (Jan. 5, 2001) [hereinafter 2001 Guidelines] (amending 60 Fed. Reg. 36,263 (July 14, 1995)). In the 1995 Utility Examination Guidelines, a two pronged inquiry for utility was established, where an asserted utility was required to be "specific" and "credible" in order to satisfy the test. *See* Utility Examination Guidelines, 60 Fed. Reg. 36,263, 36,264 (July 14, 1995) [hereinafter 1995 Guidelines]. This analysis was expanded on in subsequent versions of the Utility Examination Guidelines. *See* Revised Utility Examination Guidelines; Request for Comments, 64 Fed. Reg. 71,440, 71,441 (Dec. 21, 1999) [hereinafter 1999 Interim Guidelines]. In 1999, the PTO issued Interim Guidelines in response to public comment requesting revision of the 1995 Guidelines. *Id.* The latest version of the Utility Examination Guidelines was issued in 2001, re-establishing the requirement that the asserted utility be "substantial" in addition to being "specific" and "credible." *See* 2001 Guidelines, at 1,098.

[13] *See generally* 35 U.S.C. § 154 (2000). Access to patented work is acquired through licensing agreements. *See id.*; *see also* United States v. Westinghouse Elec. Corp. 648 F.2d 642, 647 (9th Cir. 1981) (stating that "[t]he right to license [a] patent, exclusively or otherwise, or to refuse to license at all, is 'the untrammeled right' of the patentee"). However, there is no requirement that the patent holder grant a license to whoever wishes to obtain one. *See id.*

applications has given rise to a new level of inquiry. Part I provides a basic overview of molecular biology and the requirements for obtaining a patent. Part II addresses the benefits and dangers of allowing DNA sequences to be patented. Part III outlines the steps that the PTO and Congress have taken to address some of those dangers. Part IV considers a specific example of how courts have struggled to define what the new utility requirements entail. Part V offers suggestions for finding the appropriate balance between promoting technological advancement in genetics and allowing others to benefit from those advancements. Part VI concludes with a summarization of significant points.

## I. BACKGROUND

This section provides the scientific and legal fundamentals for the rest of the comment. Parts A and B introduce the basics of molecular biology and DNA manipulation respectively. Part C outlines the purposes of patent law. Parts D through F describe the patentability requirements of novelty, nonobviousness, and utility respectively.

### *A. Molecular Biology Foundations*

Deoxyribonucleic acid ("DNA") is contained within the cells that make up all living things.[14] DNA, enclosed within a cell's nucleus, encodes the "information necessary to build the cells and tissue of an organism."[15] Four single chemical units called nucleotides[16] are linked linearly into polymers,[17] composing DNA. The precise arrangement of nucleotides forms the hereditary units or genes, controls an "organism's identifiable traits," and allows for the genetic stability of that organism.[18] Every inherited trait is encoded by at least one gene.[19]

The linear polymer strands of DNA form a double-helical structure.[20] The

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[14] Earthnet.net, Cells, http://www.earthnet.net/cell.html (last visited Feb. 24, 2006).

[15] HARVEY F. LODISH ET AL., MOLECULAR CELL BIOLOGY 8, 100 (4th ed. 2000).

[16] *See id.* at 101. Each nucleotide consists of a phosphate group linked to a five-carbon sugar molecule (deoxyribose) which is in turn linked to one of four organic bases: adenine, guanine, cytosine, and thymine (abbreviated A, G, C, and T respectively). *Id.*

[17] *Id.* A polymer is a "large molecule composed of multiple identical or similar units (monomers) linked by covalent bonds." *Id.* at G-14.

[18] *See id.* at 100; *see also* ANTHONY J. F. GRIFFITHS ET AL., AN INTRODUCTION TO GENETIC ANALYSIS 2 (7th ed. 2000). A gene is a small segment of DNA that can exist in various forms, called alleles. *Id.* "Allelic variation causes heredity variation within a species. At the protein level, allelic variation becomes protein variation." *Id.*

[19] *See* GRIFFITHS ET AL., *supra* note 18, at 11 (discussing how one gene can affect a particular trait).

> Although allelic differences cause phenotypic differences such as pigmented and albino, this does not mean that only one gene affects skin color. It is known that there are several. However, the *difference* between pigmented . . . and albino is caused by the *difference* at one gene; the state of all the other pigment genes is irrelevant.

*Id.*

[20] LODISH ET AL., *supra* note 15, at 103.

proposal of the DNA double-helix structure in 1953 by James Watson and Francis Crick marks the beginning of modern molecular biology and biotechnology.[21] Studying this structure, scientists were able to understand how DNA replicates, how proteins are made, and how traits are passed from one generation to the next.[22]

The DNA double helix structure is governed by a process called complementation.[23] The order of the nucleotide bases determines the structure of proteins responsible for directing cell metabolism through enzyme activity.[24] DNA not only acts as a template for DNA replication but for ribonucleic acid ("RNA") as well.[25] Messenger RNA ("mRNA") copies the DNA template and carries the DNA's message outside of the cell's nucleus.[26] In a process called translation, transfer RNA ("tRNA"), attached to amino acids, interprets the mRNA.[27] Amino acids are the building blocks of proteins; this relationship is akin to that of nucleotides as the components of DNA.[28] Each triplet code of nucleotides of tRNA has a different amino acid attached to it.[29] The amino acids[30] attached to the tRNA form protein

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[21] LODISH ET AL., *supra* note 15, at 103. Watson and Crick based their double helical structure "on the analysis of x-ray diffraction patterns coupled with careful model building." *Id.*

[22] Public Understanding of Biotechnology, Fact File: DNA Basics, http://www.pub.ac.za/factfile/dna.html (last visited Sept. 26, 2005).

[23] *See* GEOFFREY M. COOPER, THE CELL: A MOLECULAR APPROACH 95–96 (2d ed. 2000). When a strand contains all the details necessary to explicate the sequence of bases on the other strand, this is known as complementation. *Id.* Within the double helical structure, each adenine base is paired with its thymine base complement, and each guanine base is paired with its cytosine base complement. *Id.* at 95. During DNA replication, the strands of the double helix unwind and each strand acts as a template. *Id.* at 96. Free A, T, C, and G nucleotides within the cell pair up with their complementary bases on the single stranded DNA, producing two identical sequences of double stranded DNA. *Id.*

[24] LODISH ET AL., *supra* note 15, at 101. Enzymes are "biological macromolecule[s] that act . . . as . . . catalyst[s]." *Id.* at G-6.

[25] *Id.* at 101. RNA is another polynucleotide, structurally similar to DNA. *Id.* The only difference is that the five-carbon sugar in RNA is ribose instead of deoxyribose and the thymine base is replaced with a uracil base. *Id.* Single stranded RNA is formed by complementary base pairing with the DNA template in a process called transcription. *Id.* at 100. However, only a portion of the DNA sequence, the genes, is actually embodied by mature RNA. *See* GRIFFITHS ET AL., *supra* note 18, at 8. "In the genes of many eukaryotes, the protein-encoding sequence is interrupted by segments (ranging in number from one to many) called introns. The origin and function of introns is still unclear. They are excised from the primary transcript. The split-up coding sequences between the introns are called exons." *Id.*

[26] LODISH ET AL., *supra* note 15, at 100.

[27] *See id.* at 116–17. Translation refers to the process of arranging amino acids from the base sequence of mRNA and the joining of those amino acids to form a protein. *Id.*

> Because 4 nucleotides . . . could represent only 4 of the 20 possible amino acids in coding the linear arrangement in proteins, *a group* of nucleotides is required to represent each amino acid . . . . [T]he actual genetic code used by cells is a *triplet* code, with every three nucleotides being "read" from a specified starting point in the mRNA. Each triplet is called a codon.

*Id.*

[28] *Id.* at 51.

[29] *Id.* at 116–17.

> Transfer RNA (tRNA) is the key to deciphering the code words in mRNA. Each type of amino acid has its own type of tRNA, which binds it and carries it to the growing end of a [protein] chain if the next code word on the mRNA calls for it. The correct tRNA with its attached amino acid is selected at each step because

polymers.[31] The overall notion of converting DNA to mRNA to protein is often referred to as the central dogma of molecular biology.[32]

Small changes in the DNA sequence, called mutations, can lead to dramatic changes in the structure of the protein produced or in the level of protein expression.[33] Many genetic diseases, including certain cancers, arise from the spontaneous mutations in germ cells[34] because of a change in protein expression.[35] These mutations can be imparted to future generations.[36] Researchers have devoted many resources to deciphering the genetic code and understanding biochemical pathways.

### *B. DNA Manipulation*

Many secrets are locked in the DNA sequence; due to the multitude of biotechnological advances made in the previous decades, researchers are now unlocking some of those secrets.[37] Tools such as recombinant DNA techniques, classical gene analysis, and gene mapping allow researchers to isolate and characterize the genes that encode particular proteins.[38] These tools can also identify

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> each specific tRNA molecule contains a three-base sequence that can base-pair with its complementary code word in the mRNA.

*Id.* at 116.

[30] *See generally id.* at 51–53 (describing the different types of amino acids, how they are linked together, and how they determine the shape and function of a protein). The twenty amino acids have the same general structure; the differences in the amino acid shapes, sizes, charges, hydrophobicities, and reactivities can be attributed to the different side chain groups attached to each amino acid. *Id.* at 51. Amino acids are chemically linked via peptide bonds. *Id.* at 53.

[31] *Id.* at 117. The actual process of translation can be divided into three stages: initiation, elongation, and termination. *See* COOPER, *supra* note 23, at 282. This process is facilitated by protein complexes and specialized RNA that recognize particular tRNA and mRNA sequences, provide the energy necessary for protein synthesis, and aid in the correct folding of protein as it is being synthesized. *Id.* at 286–87, 290.

[32] LODISH ET AL., *supra* note 15, at 101.

[33] *See id.* at 255; *see also* GRIFFITHS ET AL., *supra* note 18, at 12.

> The mutational site in the DNA can be of a number of types. The simplest and most common type is nucleotide-pair substitution, which can lead to amino acid substitution or to premature stop codons. Small deletions and duplication also are common. Even a single base deletion or insertion produces widespread damage at the protein level; because mRNA is read from one end "in frame" in groups of three, a loss or gain of one nucleotide pair shifts the reading frame, and all the amino acids translationally downstream will be incorrect.

*Id.*

[34] LODISH ET AL., *supra* note 15, at G-8. Germ cells are precursor cells that give rise to either sperm or ova in animals. *Id.*

[35] *See id.* at 258.

[36] *Id.*

[37] *Id.* at 207.

[38] *Id.* at 208. Recombinant DNA technology refers to:

> A body of techniques for cutting apart and splicing together different pieces of DNA. When segments of foreign DNA are transferred into another cell or organism, the substance for which they code may be produced along with substances coded for by the native genetic material of the cell or organism. Thus,

gene mutations that could lead to abnormal proteins.[39]

Recombinant DNA technology allows for the preparation of large numbers of identical DNA molecules, through cloning, in order to produce enough material to study.[40] If a researcher wants to identify the DNA that encodes the proteins of a particular cell type, he can isolate the mRNAs expressed in that cell.[41] Through a process called reverse transcription, researchers can make DNA copies from expressed mRNAs.[42] These copies are called complementary DNAs or cDNAs.[43] Researchers customarily clone cDNA through various recombinant techniques, and compile the cDNA into libraries for later use as probes to study which genes are expressed in certain tissues at any given time.[44] The cDNA libraries are tissue-

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> these cells become "factories" for the production of the protein coded for by the inserted DNA.

Cambridge Healthtech Institute: Biopharmaceutical/Genomic Glossaries Homepage, Recombinant DNA Technology, http://www.genomicglossaries.com/content/instrument_tech.asp (last visited Sept. 26, 2005). "Classical genetics consists of techniques and methodologies" of studying genes, heredity, and variation between organisms, predating the introduction of molecular biology. Answers.com, Genetics, http://www.answers.com/topic/genetics (last visited Nov. 20, 2005).

Gene mapping refers to "various techniques for determining the relative order on a chromosome (genetic map), the absolute position of the genes (physical map), or the relative position of restriction sites (restriction map)." LODISH ET AL., *supra* note 15, at G-11.

[39] *See generally* LODISH ET AL., *supra* note 15, at 235–36. Vast amounts of DNA sequence data can be stored, organized, analyzed, and distributed using computer data banks in the rapidly growing area of computer science called bioinformatics. *Id.* at 235. "Newly derived sequences can be compared with previously determined sequences to search for similarities, called homologous sequences." *Id.* Often, the sequences stored in these databases can suggest functions for newly identified genes or proteins. *Id.* Comparative analysis across gene sequences can reveal deviations from normal gene expression. *See id.*

[40] *See id.* at 207–08.

> The discovery of two types of enzymes . . . permitted the now common technique of DNA cloning. One type called restriction enzymes, cuts the DNA from any organism at specific sequences of a few nucleotides, generating a reproducible set of fragments. The other type, called DNA ligases, can insert DNA restriction fragments into replicating DNA molecules producing recombinant DNA. The recombinant DNA molecules can then be introduced into appropriate cells, most often bacterial cells; all descendents from a single such cell, called a clone, carry the same recombinant DNA molecule. Once a clone of cells bearing a desired segment of DNA is isolated, unlimited quantities of this DNA can be prepared. In addition, DNA sequences up to about 100 bases long can now be synthesized by entirely automated procedures.

*Id.* at 207.

[41] *Id.* at 219.

> Each of the hundreds of different cell types found in multicellular organisms must be generated in the right number. . . . Specialized cells often have a distinctive morphology and express proteins devoted to the specific . . . functions carried out by a particular cell type. The extensive cell specification that occurs . . . depends on both quantitative and qualitative differences in gene expression, controlled largely at the level of transcription.

*Id.* at 543. Different cell types produce different mRNAs, depending on the kinds of protein that need to be produced to carry out the particular cell function. *See id.*

[42] *Id.* at 219. Reverse transcription uses an enzyme, reverse transcriptase, found in "retroviruses that catalyze the synthesis of a double-stranded DNA from a single-stranded RNA template." *Id.* at G-15.

[43] *Id.* at 219.

[44] COOPER, *supra* note 23, at 122.

specific, and hopefully such knowledge will allow scientists to regulate gene expression, as well as control protein synthesis.[45]

An expressed sequence tag ("EST") is a short cDNA sequence that represents part of a gene and can be used as a marker for DNA sequences.[46] ESTs are valuable in that they enable the "identification of new genes related to a cloned gene of interest."[47] ESTs, however, do not provide much insight as to the function of the gene or the protein it encodes.[48]

### *C. DNA Sequences—Patentable Subject Matter?*

The primary purposes of patent law are to reward invention, encourage disclosure of inventions thus stimulating further advancements, and protect ideas in the public domain.[49] The authority for conferring patent protection comes from the United States Constitution, granting Congress the exclusive power "to promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[50] Congress, in exercising that power by passing the Patent Act, outlined the requirements for obtaining patent protection and described the patentee's rights that ensue from the satisfaction of those requirements.[51]

A patent grants "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention in the United States" to the patent-holder for a period of 20 years from the application filing date.[52] Patentable subject matter includes "any . . . process,

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[45] LODISH ET AL., *supra* note 15, at 219.

[46] COOPER, *supra* note 23, at 171. The term, expressed sequence tag is descriptive in that it refers to a relatively short portion of genomic DNA sequence that is expressed in the form of mRNA. *See* LODISH ET AL., *supra* note 15, at 227. Bioinformatic "databases of partial cDNA sequences (EST databases) are particularly useful in designing probes for screening libraries." *Id.* at 235.

[47] COOPER, *supra* note 23, at 171. This is done is by introducing a radioactive EST probe into a DNA sample. *Id.* at 117. The probe will hybridize (bond) to its target complementary base sequence in the DNA sample, showing that the gene corresponding to the EST probe was being expressed at the time of mRNA extraction by virtue of its radioactivity. *Id.*

[48] Cherylyn A. P. Esoy, Comment, *The PTO's 2001 Revised Utility Examination Guidelines for Gene Patent Applications: Has the PTO Exceeded the Scope of Authority Delineated by the Court's Interpretation of a "Useful" Invention?*, 33 SETON HALL L. REV. 127, 135 (2002).

[49] Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979).

[50] U.S. CONST. art. 1, § 8, cl. 8; *see also* Butterworth v. United States, 112 U.S. 50, 59 (1884). In *Butterworth*, the court articulated:

> [t]he legislation based on this provision regards the right of property in the inventor as the medium of the public advantage derived from his invention; so that in every grant of the limited monopoly two interests are involved, that of the public, who are the grantors, and that of the patentee. There are thus two parties to every application for a patent, and more, when, as in case of interfering claims or patents, other private interests compete for preference.

*Id.*

[51] 35 U.S.C. §§ 101–103, 154 (2000).

[52] 35 U.S.C. § 154; *see* Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661, 665 (1944). "The grant of a patent . . . [creates] a right to be free from competition in the practice of the invention." *Id.* "These laws perhaps regard the reward to the owner as a secondary consideration, but they were intended definitely to grant valuable, enforceable rights in order to afford greater encouragement to

machine, manufacture, composition of matter or any new and useful improvement thereof" provided that it satisfies the statutory requirements of utility, novelty, and nonobviousness.[53]

The first query is whether the invention claimed falls in one of the four statutory classes that Congress intended to be patentable, as described in section 101 of the Patent Act.[54] Historically, this requirement has been broadly interpreted.[55] In the landmark case *Diamond v. Chakrabarty*, the Supreme Court affirmed a judgment which allowed the patent applicant's claims for a human-made, genetically engineered bacterium capable of breaking down multiple components of crude oil.[56] The *Chakrabarty* decision centered on the facts that the bacterium had "markedly different characteristics from any found in nature" and the discovery was Chakrabarty's handiwork, not that of nature.[57] This decision opened the door for patents grounded in genetic technology.[58] Perhaps, by the same reasoning as that in *Chakrabarty*, DNA sequences, by no means found isolated in nature, will fall within the scope of patentable subject matter.[59]

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the production of works of benefit to the public." Zacchini v Scripps-Howard Broad. Co., 433 U.S. 562, 577 (1977).

[53] §§ 101–103.

[54] § 101. As previously discussed, the four statutory classes are any process, machine, manufacture, or composition of matter. See *id.*; *see also In re* Bergy, 596 F.2d 952, 964 (C.C.P.A. 1979), *overruled by* Diamond v. Chakrabarty, 444 U.S. 1028 (1980) (stating that the first query in determining patentability is whether "the inventions claimed [are] of a kind contemplated by Congress as possibly patentable if they turn out to be new, useful, and unobvious within the meaning of those terms as used in the statute").

[55] *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980). This first hurdle of patentability has proved not to be difficult to overcome because the Supreme Court has interpreted these four classes to "include anything under the sun that is made by man." *Id.* (quoting S. REP. NO. 82-1979, at 5 (1952)). Thus, manifestations of nature, falling outside the scope of this definition, are not patentable. *Id.* at 309; *see also* J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 138 (2001) (explaining *Chakrabarty* and noting that the court rejected the argument that Congress must expressly authorize protection of new patentable subject matter); *see also* Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (stating that "[a] principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right"); Mitchell v. Tilghman, 86 U.S. 287, 391 (1874), *overruled in part by* Tilghman v. Proctor, 102 U.S. 707 (1881) (noting that "a mere function, principle, or result . . . is obviously forbidden by the patent law, as it would close the door to all subsequent improvements").

[56] *Chakrabarty*, 447 U.S. at 305. The bacterium was of the genus Pseudomonas and was alleged to contain at least two stable energy-generating plasmids (circular DNA) that provide separate hydrocarbon degradative pathways. *Id.* This characteristic was not found in naturally occurring bacteria and was claimed to provide "more efficient and rapid oil-spill control." *Id.*

[57] *Compare id.* at 310 (rejecting the argument that a micro-organism was not patentable because it was analogous to a natural, physical phenomenon), *with* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (noting that "manifestations of . . . nature, [are] free to all men and reserved exclusively to none").

[58] *See* Reid G. Adler, *Biotechnology As an Intellectual Property*, 224 SCI. 357, 359 (noting that the position of the PTO to denote animals as unpatentable subject matter was maintained even after *Chakrabarty*; however, eukaryotes expressing recombinant DNA or novel genes should be considered patentable subject matter under the rationale of *Chakrabarty*).

[59] *See* Daniel R. Kimbell, *Patenting Genes: Risks and Rewards vs. Politics and Policies* (2001), http://cph.com/sub/index.jsp?contentid=mSY5GufMhoc9GDwgKn8skt6k (noting that "[a]lthough proteins, genes, and other compounds found in the body are not patentable in their naturally occurring form, purified, isolated proteins, genes, and gene fragments may be patentable if they meet the legal requirements for patentability").

### *D. Novelty*

At the time of creation or discovery, an invention must be novel in order to be patentable; the purpose of this requirement is to keep that which is already in the public domain in the public domain.[60] By definition, an invention that is anticipated by the prior art[61] is not novel.[62] "[T]o be patentable, [an invention] must go a substantial step beyond the prior art."[63]

### *E. Nonobviousness*

35 U.S.C. § 103 codified the requirement "that a mere improvement over prior art which involves nothing more than what would have been obvious to a person skilled in art" cannot be patented.[64] The question of obviousness requires a four part factual inquiry: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of obviousness, including commercial success, long-felt but unresolved need, failure of others, copying, and unexpected results "to give

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[60] *See* DONALD S. CHISUM, CHISUM ON PATENTS § 3.01 (2004). The novelty requirement is codified under Title 35, section 102 of the United States code. 35 U.S.C. § 102 (2000); *see* Nickola v. Peterson, 580 F.2d 898, 909 (6th Cir. 1968) (stating that "[a] device lacks novelty if there is, or has been, a substantially identical prior device").

[61] Mohasco Indus., Inc. v. E. T. Barwick Mills, Inc. 221 F.Supp. 191, 195 (N.D. Ga. 1963).

> Generally, all patents, publications and public uses which have been in existence prior to a patentee's date of invention of [sic] more than a year prior to his filing date are referred to as 'prior art.' If a patentee's alleged invention is identically disclosed in the prior art, it clearly is not new. In such a situation, the alleged invention is said to lack novelty and the patent must be declared to be invalid.

*Id.*

[62] *See* CHISUM, *supra* note 60, § 3.01. *See generally* Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000) (expressing that an anticipation "requires that the four corners of a single, prior art document describe every element of the claimed invention either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation").

[63] Dorr Co. v. Yabucoa Sugar Co., 119 F.2d 521, 528 (1st Cir. 1941); *see also* King-Seeley Thermos Co. v. Refrigerated Dispensers, Inc., 354 F.2d 533, 537 (10th Cir. 1965). "An invention or discovery is new or possesses the requisite element of novelty if it involves the presence of some element, or the new position of an old element in combination, different from anything found in any prior structure." *Id.*; *see also* Knight-Morley v. Ajax Mfg. Corp., 84 F. Supp. 215, 219 (D. Mich. 1948). ("[E]very improvement is not patentable. The improvement must be some substantial discovery or invention, which adds to our knowledge and makes a step in advance in the useful arts.").

[64] 35 U.S.C. § 103 (2000). A patent is invalid:

> if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

*Id.*

light to . . . the origin of the subject matter sought to be patented."[65]

### *F. Utility Requirements*

A claimed invention must be "useful" to be patentable.[66] This means that the invention must be operative or in accordance with its intended purpose; that the human purpose served must not be "illegal, immoral, or contrary to public policy;" and it must confer some public benefit.[67] While this utility requirement typically poses little hindrance to electrical or mechanical patent applications, the burden for proving utility is inherently higher for biological and chemical inventions[68] because there is "no reliable way of predicting utility based upon chemical formulas alone."[69]

The test for determining utility is ever evolving. In *Lowell v. Lewis*, the court broadly interpreted the needed utility requirement and required nothing more than a showing that the invention was not "frivolous or injurious to the well-being, good policy or sound morals of society."[70] However, the Supreme Court in *Brenner v. Manson* rejected this *de minimus* standard in concluding that a chemical compound that only had utility as a potential object for use-testing[71] did not satisfy the utility requirement.[72] Instead, the *Brenner* Court set out a new standard that required an

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[65] Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966). The court in *Graham* held a patent consisting of a combination of old mechanical elements invalid where the only difference between it and the prior art would have been obvious to a person reasonably skilled in the art. *Id.* at 25.

[66] *See id.* at 9. "Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly." *Id.*

[67] CHISUM, *supra* note 60, § 4.01; *see* Phillips Petroleum Co. v. U.S. Steel Corp., 673 F. Supp. 1278, 1325 (D. Del. 1987) (using a usefulness test under 35 U.S.C. § 101). Under 35 U.S.C. § 101,

> whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefore. To be "useful" under 35 U.S.C.[] § 101, the invention must (1) be operable and capable of use, i.e., it must perform a designated function; (2) achieve some minimum human purpose; and (3) that purpose must not be illegal, immoral or contrary to public policy. In short, the product or process must be operable, i.e., it must be capable of being used to effect the object proposed.

*Id.*

[68] CHISUM, *supra* note 60, § 4.01.

[69] Eli Lilly & Co. v. Generix Drug Sales, Inc., 460 F.2d 1096, 1101 (5th Cir. 1972) (noting that "such lack of predictability of useful results from the making of even the slightest variation in the . . . structure or spatial arrangement of a complex molecule . . . deprives the instant claims of obviousness and anticipation of most of their vitality").

[70] Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568). The court, in resolving whether the invention in question, a pump, satisfied the utility requirement, rejected the contention that the invention must satisfy general utility. *Id.* The court stated that "for the ordinary purposes of life, [the invention] must supercede the pumps in common use." *Id.*

[71] *See In re* Fisher, 421 F.3d 1365, 1373 (Fed. Cir. 2005) (defining use-testing as "objects upon which scientific research could be performed with no assurance that anything useful will be discovered in the end").

[72] *See* Brenner v. Manson, 383 U.S. 519, 534–35 (1966) (reasoning that until an invention has been developed and refined to the point of substantial utility, there is inadequate rationalization for permitting an applicant to monopolize what may prove to be an extensive field). The invention at issue, whose patentability required examination by the court, was a chemical compound whose sole utility was its potential role as an object of use-testing. *Id.* at 535. The court rejected the assertion that applying the lesser utility standard adopted by Lowell "would encourage inventors of new

invention to have "substantial utility" in its currently available form.[73] In so concluding, the Court reasoned that a patent "is not a reward for the search, but compensation for its successful conclusion."[74]

*In re Kirk* further expanded on the "substantial utility" standard.[75] Specifically, the court refused to find utility in a product with only a speculative use.[76] The court required that proof of utility be convincing to one skilled in the art and, based on the facts of the case, determined that this burden of proof was not satisfied.[77]

Because the question of DNA sequence patentability closely revolves around the issue of utility, this requirement will be discussed in greater detail in sections III and IV of this comment.

## II. RISKS AND BENEFITS OF DNA SEQUENCE PATENTING

This section discusses the practical implications of granting patents in DNA sequences. Parts A and B discuss the risks and benefits respectively.

### *A. Risks*

Challengers of DNA sequence patenting explicate many arguments in opposition[78] to granting patents in this area including moral disquiet, public health,

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processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge." *Id.* at 533.

[73] *Id.* at 534–35; *see also* Cross v. Iizuka, 753 F.2d 1040, 1044 (Fed. Cir. 1985) (following *Brenner* in requiring that an invention have some practical or substantial utility in order to be considered useful for patent purposes).

[74] *Brenner*, 383 U.S. at 535–36 (acknowledging the fact that scientific information short of being called "useful" needs funding in order to conduct further research and noting that something that is not presently "useful" may become so some time in the future).

[75] *In re* Kirk, 376 F.2d 936, 945 (C.C.P.A. 1967) (holding that, in an invention for creating steroid compounds, simply claiming that the compounds had value as intermediates that "[could] be used to produce some intended product of no known use" was insufficient for the purposes of meeting the utility requirement).

[76] *Id.* at 942, 945. The court asserted that:

> it was [not] the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.

*Id.* at 942.

[77] *Id.* (declaring that "[i]t cannot be presumed that a steroid chemical compound is 'useful' under § 101, or that one of skill in the art will know 'how to use' it, simply because the compound is closely related only in a structural sense to other steroid compounds known to be useful").

[78] *See generally* Mark A. Chavez, *Gene Patenting: Do the Ends Justify the Means?*, 7 COMP. L. REV. & TECH. J. 255, 260–67 (2003) (presenting an overview of arguments in opposition to gene patenting).

and general legal policy.[79]

One of the strongest arguments opposing DNA sequence patenting is the assertion that such patenting hinders innovation rather than promoting it.[80] DNA sequence patents are often referred to as "gatekeeper patents" because DNA manipulation lies at the heart of the cures for many human diseases; there is no substitute for genes because there can be no improvement on the composition of DNA itself.[81] Patent-holders can control the use of the invention by withholding or granting licenses,[82] in exchange for capital, to third parties who seek to use the invention.[83] The argument postulates that by denying licenses or by charging exorbitant amounts of money in order to obtain a license, holders of DNA sequence patents have the ability to deprive researchers and physicians of any use of that sequence for diagnosis, treatment, or development of disease treatments.[84]

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[79] *See* Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NATURE REV. GENETICS 803, 803–05 (2002) (addressing the negative impact gene patenting would have on research, medical treatments, and disease diagnosis).

[80] *Id.* at 805; *see also* Mildred K. Cho et al., *Effects of Patents and Licenses on Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 7 (2003) (describing how the results of an independent study revealed that virtually none of the U.S. laboratory representatives who responded to the study, including those from commercial laboratories, "thought that the effect of patents and licenses on the cost, access, and development of genetic tests have been positive" and that they thought "gene patents hinder rather than facilitate clinical genetic testing"). The performers of this study conducted a survey of selected directors of laboratory facilities listed on the GeneTests.org website. *Id.* at 4. Participants of the survey included representatives from federal, university, nonprofit, private hospital and corporate laboratories. *Id.* They were asked whether patents or licenses had prevented or caused the laboratory to choose not to develop a clinical genetic test. *Id.* Sixty-five percent of the respondents analyzed "said that their laboratories had been contacted by a patent or license holder regarding the laboratory's potential infringement of a patent by performance of a genetic test." *Id.* at 5. Twenty-five percent of respondents claimed that such notification prevented them from continuing to perform clinical tests or services that were the subject of infringement. *Id.* When asked to rate the effect of gene patenting, and clinical gene testing in general, mean ratings revealed that the respondents believed gene patenting decreased patient access to gene testing, decreased the ability of laboratories to develop tests and research, and increased the costs associated with testing development and administration. *Id.*

[81] Lorelei Perez Westin, Note and Comment, *Genetic Patents: Gatekeeper to the Promised Cures*, 25 T. JEFFERSON L. REV. 271, 274–275 (2002).

[82] Fed. Land Bank of Wichita v. Bd. of County Comm'rs of Kiowa County, State of Kan., 368 U.S. 146, 154 (1961).

> The word 'license,' means permission, or authority; and a license to do any particular thing, is a permission or authority to do that thing; and if granted by a person having power to grant it, transfers to the grantee the right to do whatever it purports to authorize. It certainly transfers to him all the right which the grantor can transfer, to do what is within the terms of the license.

*Id.*.

[83] Westin, *supra* note 81, at 272; *see also In re* Indep. Serv. Orgs., 203 F.3d 1322, 1326 (Fed. Cir. 2000) (stating that "[n]o patent owner . . . shall be . . . deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . refused to license or use any rights to the patent").

[84] Westin, *supra* note 81, at 272; *see also* Council for Responsible Genetics, *DNA Patents Create Monopolies on Living Organisms*, April 2000, http://www.actionbioscience.org/genomic/crg.html (taking the position that patenting in general makes "products more expensive and less accessible").

Generally, this is a recurrent practice.[85]

Furthermore, there is concern that granting patents in this area will compromise effective medical care.[86] To date, there are a number of predictive gene-testing options that are available or are being developed for diseases such as Tay-Sachs disease,[87] cystic fibrosis,[88] Huntington's disease,[89] Alzheimer's disease,[90] and predispositions to certain cancers.[91] Patents on DNA sequences would allow patent-holders to require that testing procedures be performed at their own laboratories by their own personnel.[92] A patent-holder's ability to bar others from testing for the presence of a specific disease gene has increased concerns over the reasonable access to such tests and the quality of testing procedures.[93]

Opponents of DNA sequence patenting also assert that the growing trend towards the commercialization of research has led to the practice of promoting secrecy and hindering the exchange of information amongst researchers in

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[85] *See generally* Cho et al., *supra* note 80, at 5, 7. There is evidence to support the proposition that license withholding practices on patented materials exist and have the tendency to hinder research. *Id.*

[86] *See* Amanda S. Pitcher, Comment, *Contrary to First Impression, Genes Are Patentable: Should There Be Limitations?*, 6 J. HEALTH CARE L. & POL'Y 284, 298 (2003). There are concerns that once a patent issues, laboratories that once charged affordable prices for testing for a particular gene abnormality "will find themselves embroiled in licensing fees, which they will either be unwilling to pay, or will pay despite exorbitant costs that will have to be absorbed elsewhere." *Id.* "Many patients, therefore, may be forced to pay the costs passed onto them, or seek less effective, less reliable, or perhaps unconventional methods of treatment." *Id.*

[87] LODISH ET AL., *supra* note 15, at 169. Tay-Sachs disease affects the central nervous system and is caused by a defect in an enzyme which catalyzes the break down of certain fatty substances in the brain and nerve cells. *Id.* Children affected by this inherited disease will often become demented and blind by the age of two and will rarely survive past their third birthday. *Id.*

[88] COOPER, *supra* note 23, at 490. Cystic Fibrosis is "the most common lethal inherited disease in Caucasians," and is characterized by "the production of abnormally thick sticky mucus by several types of epithelial cells" in the lining of the respiratory and gastrointestinal tracts as well as in the sweat glands. *Id.*

[89] GRIFFITHS ET AL., *supra* note 18, at 45. Huntington's disease is characterized by neural degeneration which leads to convulsions and premature death. *Id.* The symptoms of the disease usually do not emerge until after an individual has had children. *Id.* Any carrier of the gene will exhibit the disease. *Id.*

[90] Alzheimer's Disease Education & Referral Center, http://www.alzheimers.org/generalinfo.htm (last visited Oct. 25, 2005). Alzheimer's disease largely affects older individuals and is a form of dementia that typically involves the part of the brain that controls memory, thought and language. *Id.*

[91] *See* Access Excellence Resource Center, *Understanding Gene Testing: What Types of Diseases Can Be Predicted with Gene Tests?*, http://www.accessexcellence.org/AE/AEPC/NIH/gene12.html (last visited Oct. 25, 2005).

[92] Lori B. Andrews, *The Gene Dilemma: Balancing Commercial Incentives with Health Needs*, 2002 HOUS. J. HEALTH L. & POL'Y 65, 89 (2002) [hereinafter Andrews, *Gene Dilemma*].

> Like many gene patent holders, the company holding the exclusive license on a gene associated with Alzheimer's disease, will not let any laboratory except its own perform the test. Doctors and labs across the country face a lawsuit if they try to determine whether one of their patients has the genetic form of Alzheimer's, even though testing can easily be done by anyone who knows the gene sequence without using any product or device made by the patent holder.

*Id.*

[93] *Id.*

biotechnology.[94] Thus, until researchers try to acquire patent rights, publication of research findings, may be delayed.[95] Many opponents further argue that the commercialization of genetic research diminishes the collaborative efforts in scientific research.[96]

Another argument against the patenting of DNA sequences attacks the statutory ability to patent the products of genetic research.[97] The assertion is that DNA sequences are not only compositions of matter, but are also information; to allow "the patenting of such useful information is a departure from the patent rules."[98] Additionally, opponents of DNA sequence patenting contend that purified genes and isolated gene fragments are no different from naturally occurring sequences and thus, because they exist in nature, they are statutorily barred from patent protection.[99] As previously discussed, naturally occurring manifestations fall outside the scope of patentable subject matter.[100]

Finally, there are ethical concerns behind DNA sequence patenting.[101] DNA sequence patenting has been attacked on religious grounds based on the notion that genetic manipulation is the same as "playing God," and that the fruits of such work should not be rewarded with patent control.[102] Many challengers also maintain the belief that granting patent rights in genetic material is tantamount to supplying property rights in life, which could lead to the exploitation of human beings as commodities.[103] Lastly, some believe allowing patents on genetic material will lead to further injustice in the distribution of wealth in the world.[104] The contention is that DNA sequence patenting denies the benefits of biotechnological ("biotech") research

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[94] *See* Cho et al., *supra* note 80, at 8 (maintaining that the findings of their study indicated that "information-sharing between laboratories seemed to be inhibited" by patents and licensing).

[95] Andrews, *Gene Dilemma*, *supra* note 92, at 80. Studies indicate that genetic scientists with funding from industries were more likely to delay publishing then those without such funding. *Id.*

[96] *See* Eric G. Campbell et al., *Data Withholding in Academic Genetics: Evidence from a Nat'l Survey*, 287 JAMA 473, 473 (2002). In a survey study involving geneticists, researchers found that of those study participants that intentionally withheld data, over fifty-three percent reported having done so to protect the commercial value of their results. *Id.*

[97] Pitcher, *supra* note 86, at 298; *see also* Rebecca S. Eisenberg, *Re-examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 785 (2000). The DNA sequences identified by high-throughput sequencing look less like new chemical entities than they do like new scientific information. *Id.*

[98] *Id.*

[99] *See* Pitcher, *supra* note 86, at 298.

[100] *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); *see also supra* note 57 and accompanying text.

[101] *See* Chavez, *supra* note 78, at 263.

[102] *Id.* at 265. "Some would argue that, as human knowledge increases, the area within human control begins to intrude upon God's territory." *Id.*

[103] *See id.* at 266 (expressing the contention that by patenting genes, one is reducing life to a commodity like any other inanimate object). Some would argue that patenting genetic material violates the "fundamental principle of morality that human beings not be used simply as a means to one's own ends." Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 440 (2002).

[104] *See* Patricia A. Lacy, Comment, *Gene Patenting: Universal Heritage vs. Reward for Human Effort*, 77 OR. L. REV. 783, 801–02 (1998). This is often referred to as the distributive justice argument. *See id.* at 801. The benefits of genetic research should be justly distributed world-wide. *See id.*

to under-developed countries to the advantage of a few industrialized nations.[105] However, this argument is fundamentally flawed because patenting an invention in one country does not prevent the use of that invention in another country.

### *B. Benefits*

Despite the opposition, many advocate the benefits of patenting DNA sequences.[106] The primary argument focuses on the financial aspects of biotech research. Scientific research is an expensive endeavor, and funding for such research is often provided by individual investors, companies, and government grants.[107] Such funding would not be available without the anticipation of financial returns from the commercialization of the fruits of research.[108] Commercialization would be impossible if not for the temporary monopoly rights granted to inventors as a reward for their hard work and risks taken.[109]

An additional argument in favor of DNA sequence patenting is that patents encourage disclosure of information, and without patents, researchers would be required to rely on trade secret protections.[110] If disclosure took place without

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[105] *See id.*

> To implement distributive justice, less-developed countries must not be excluded from the benefits of gene research. Gene patenting is ethically suspect if it concentrates genome benefits in the few countries affluent enough to have sufficient resources to secure gene patents, when all humans are entitled to share the benefits. Under the principles of distributive justice, all Earth's citizens should enjoy the fruits of genome research, unencumbered by intellectual property rights.

*Id.* at 802.

[106] *See* Byron V. Olsen, *The Biotechnology Balancing Act: Patents For Gene Fragments, and Licensing the "Useful Arts,"* 7 ALB. L.J. SCI. & TECH. 295, 321–22 (1997) (explaining how patent law provides the financial incentive to engage in biotechnological research and development).

[107] *See* Barbara Looney, *Should Genes Be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement*, 26 LAW & POL'Y INT'L BUS. 231, 242 (1994) (stating that in order to make useful progress in gene research, private sector investment incentives, including patenting, must exist); *see also* Chavez, *supra* note 78, at 261.

> Typically, capital markets raise this money and investments exist only if the prospect of large profits looms on the horizon. Companies owning gene patents have the potential for large profits since the patents provide exclusive rights; not surprisingly, investors are attracted to such companies with these exclusive rights.

*Id.*

[108] *See* Looney, *supra* note 107, at 242. It has been argued that without patent protection and the potential for commercial return, U.S. investors would be reluctant to invest in gene research. *Id.*

[109] *Id.* One of the policies that patent law tries to promote is the encouragement of "men to pursue ideas which may produce utility" by giving inventors the exclusive rights to profits. Graham v. John Deere Co., 383 U.S. 1, 9 (1966).

[110] John J. Doll, *The Patenting of DNA*, 280 SCI. 689, 690 (1998) (explaining that scientists may be less inclined to disclose their DNA products without patent protection). Furthermore, "[i]ssuance of patents to such products . . . results in the dissemination of technological information to the scientific community for use as a basis for further research." *Id.*; *see also* Chavez, *supra* note 78, at 261–62. By relying on trade secret protections, investors, instead of publicly disclosing inventions, must conceal the inventions in order to maintain control over them. *Id.* at 262.

protection, other researchers would be able to reap the benefits of the disclosure without absorbing any of the costs associated with isolating DNA sequence.[111] "Under an intellectual property regime that allows gene fragment patenting, researchers and their investors reap the monetary rewards of genetic research, and . . . the public gains the benefits of the newly acquired scientific knowledge . . . ."[112] Fairness principles would dictate such a result.[113] If only trade secret protections were used, the public would not gain the benefit of newly acquired scientific knowledge. Thus far, equally good policy, legal, and ethical arguments exist on both sides of the debate. The task is trying to find a compromise that protects knowledge in the public domain and encourages further biotech research.

## III. PTO AND CONGRESSIONAL RESPONSES

This section addresses some of the ways the PTO and Congress have tried to strike a balance between the opposing views concerning the patenting of genes and gene fragments. Part A summarizes the PTO's response while Part B summarizes Congress's limited reactions.

### *A. PTO Recharacterizes Utility Standard*

The PTO, overseeing the registration and maintenance of patents, must apply the statutory requirements for patentability and pertinent case law when examining patent applications.[114] To ensure that examiners follow the patentability standards, the PTO established the Utility Examination Guidelines in 1995 ("1995 Guidelines"), specifically targeting biotechnology patent applications.[115] The liberal standard outlined in the 1995 Guidelines promulgated a two-pronged test for establishing utility.[116] The asserted utility required credibility and specificity.[117] Credibility was established if the existence of utility would be convincing to one of ordinary skill in the art in light of documentary evidence provided in the record.[118] The specificity requirement only needed an unambiguous communication of a particular purpose for

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Therefore, in an effort to prevent the "free-rider" situation, the intentional delay in public disclosure of inventions would lead to duplicative efforts in the same area of research. *Id.*

[111] *Id.*

[112] *Id.* at 265.

[113] *See* Lacy, *supra* note 104, at 802. "It seems fundamentally unfair to require researchers and investors to expend enormous resources, publicize results, and provide benefit to the public without the guarantee of potential return on the investment." *Id.*

[114] *See generally* Timothy A. Worrall, *The 2001 PTO Utility Examination Guidelines and DNA Patents*, 16 BERKELEY TECH. L.J. 123, 131 (2001) (describing the role of the PTO in patent law administration).

[115] *See* 1995 Guidelines, 60 Fed. Reg. 36,263, 36,264 (July 14, 1995).

[116] J. Timothy Meigs, *Biotechnology Patent Prosecution in View of PTO's Utility Examination Guidelines*, 83 J. PAT. & TRADEMARK OFF. SOC'Y 451, 458–59 (2001).

[117] *Id.* at 459.

[118] *In re* Jolles, 628 F.2d 1322, 1326 (C.C.P.A. 1980).

the invention.[119] Furthermore, under the 1995 Guidelines, the burden was on the examiner to make a prima facie showing of no-utility in order to rebut the presumption of utility.[120] This approach deviated from the "substantial" utility standard adopted by the Unites States Supreme Court in *Brenner*.[121]

The 1995 Guidelines spawned a great deal of criticism from the public and provoked a flood of applications claiming credible utility for DNA sequences, particularly ESTs.[122] In response to these criticisms, the PTO issued a higher standard in the 1999 Revised Interim Utility Examination Guidelines ("1999 Guidelines").[123] These guidelines, returning to the *Brenner* standard, revised the 1995 Guidelines and provided two tests for establishing utility: the "well-established" utility test and the "specific, substantial, and credible" utility test.[124] These alternative tests were affirmed in the latest version of the Utility Examination Guidelines published in 2001 ("2001 Guidelines").[125]

Under both the 1999 and 2001 Guidelines, satisfaction of the specificity requirement occurred when the asserted utility was "particular to the subject matter claimed."[126] The Revised Interim Utility Guidelines Training Materials ("Training Materials") that accompanied the 1999 Guidelines expressly noted that patent applications for DNA sequences, claiming utility as a gene probe or marker to recover larger gene fragments, would not suffice to satisfy the utility requirement without also identifying the particular gene target; such a claim lacked specificity.[127] In order to satisfy the "substantial utility" requirement, the 1999 and 2001 Guidelines demanded that a claim have a "real world use."[128] Although the PTO did not conclusively deny the patentability of gene fragments, the PTO made the prospect of overcoming the utility hurdle significantly more difficult.

The 2001 Guidelines and the heightened utility standard are not the best ways

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[119] *See* 1995 Guidelines, 60 Fed. Reg. at 36,264. "If the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., a 'specific utility') and that assertion would be considered credible by a person of ordinary skill in the art, [the examiner will] not impose a rejection based on lack of utility." *Id.*

[120] *In re* Brana 51 F.3d 1560, 1566 (Fed. Cir. 1995) (recognizing that the law presumes the correct assertion of utility in patent disclosure and that it is the burden of the PTO to challenge this presumption); *see also In re* Marzocchi, 439 F.2d 220, 224 (C.C.P.A. 1971). "[I]t is incumbent upon the Patent Office . . . to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." *Id.*

[121] *See* Brenner v. Manson, 383 U.S. 519, 534 (1966).

[122] Demaine & Fellmeth, *supra* note 103, at 325. "[T]he PTO was awash in applications for patents on DNA sequences by NIH and commercial companies [and]. . . . [b]y October of 1996, the PTO faced 350 pending gene patent applications that collectively claimed more than 500,000 sequences." *Id.*

[123] 1999 Interim Guidelines, 64 Fed. Reg. 71,440, 71,440 (Dec. 21, 1999).

[124] *Id.*

[125] 2001 Guidelines, 66 Fed. Reg. 1,092, 1,098 (Jan. 5, 2001).

[126] *iBrief: Biotechnology: The Fate of Gene Patents Under the New Utility Guidelines*, 2001 DUKE L. & TECH. REV. 8, ¶ 12 (2001) [hereinafter *iBrief*].

[127] Demaine & Fellmeth, *supra* note 103, at 327; *see also* U.S. PAT. AND TRADEMARK OFF., REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS 5 (1999), *available at* http://www.uspto.gov/web/menu/utility.pdf [hereinafter TRAINING MATERIALS].

[128] *See* Esoy, *supra* note 48, at 153 (highlighting the "real world" benefit requirement, consistent with the Supreme Court's position in *Brenner*); *see also* TRAINING MATERIALS, *supra* note 127, at 6 (characterizing substantial utility as one "that defines a 'real world' use").

to ensure the reasonable accessibility of research materials while guaranteeing that researchers will make reasonable returns for their efforts. As mentioned previously, without patent protection, researchers would be forced to resort to other forms of protection, such as trade secrets,[129] and avoid disclosure all together. One of the purposes of patent law is to ensure disclosure of inventions takes place, a purpose that trade secret law does not serve well.[130]

The heightened utility standard in the 2001 Guidelines effectively prohibits the patenting of DNA sequences, even as research tools, because in order to satisfy the utility requirement, the claimed DNA sequence must correspond to a known gene. The ability to prove correspondence is often a difficult task to complete and would presumably require a lengthy amount of time.[131] However, failure to file a patent application in the United States within one year of publication of any description of the invention or before any use of the invention takes place will result in a loss of right to patent.[132] A potential patent applicant must choose between disclosing his invention and losing the right to patent that invention forever. Such a scenario favors nondisclosure. Without disclosure, others are not able to make advancements that expand on the technology the invention offers. Therefore, the PTO "is not upholding its Constitutional responsibility of promoting the progress" of useful arts, and Congress must address this issue.[133]

### *B. Congress Introduces Bills*

In 2002, two bills that, if enacted, would challenge the patenting of isolated gene fragments were introduced in the House of Representatives.[134] The first bill, called the Genomic Science and Technology Innovation Act of 2002, requires the Director of the Office of Science and Technology Policy to conduct a study assessing "the impact of Federal policies, including intellectual property policies, on the innovation process for genomic technologies."[135] In particular, the bill seeks to study the effects of alternative intellectual property systems compared to the current system,

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[129] *See supra* notes 110–11 and accompanying text.

[130] *See supra* notes 110–11 and accompanying text. Trade secret protection may last indefinitely as long as there is neither disclosure of the secret information nor third party development through reverse engineering. *See* Andrew Beckerman-Rodau, *Prior Restraints and Intellectual Property: The Clash Between Intellectual Property and the First Amendment from an Economic Perspective*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1, 61–62 (2001).

[131] *iBrief*, *supra* note 126, ¶ 32.

[132] 35 U.S.C. § 102 (2000).

> A person shall be entitled to a patent unless . . . the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

*Id.* at (a)–(b).

[133] Franz and Faletra, *supra* note 11, at 25.

[134] Rochelle K. Seide with Michelle LeCointe, *Two New Bills Present Challenges to DNA Patentability*, GENOMEWEB DAILY NEWS ¶ 2, May 24, 2002, http://www.genomeweb.com/articles/view-article.asp?Article=200252412129.

[135] Genomic Science and Technology Innovation Act of 2002, H.R. 3966, 107th Cong. (2002).

considering factors such as costs, availability of funding, access to genomic materials, and rate and quality of innovation.[136] This bill purports to evaluate ways to "minimize some of the negative impacts of patents on the practice of medicine and the advancement of science" rather than directly challenge the validity of DNA sequence patents.[137]

The second bill, called the Genomic Research and Diagnostic Accessibility Act of 2002, seeks to amend title 35 to limit the scope of patent protection of genes and gene fragments.[138] The amendment would "provide for non-infringing uses of patents on genetic sequence information for purposes of research and genetic diagnostic testing, and . . . require public disclosure" of all sequence information filed in a patent application within thirty days of such filing.[139] Compared to the current system, this proposal severely limits a patent applicant's right to secrecy by compelling publication of the patent application approximately seventeen months earlier than normally would be required.[140]

How this second bill will encourage innovation in the field of genetics remains unclear. The exemption for infringement is constrained to strictly research uses and will not extend to entities or individuals who wish to use the patented sequence for commercial purposes.[141] However, much of genetic research is performed with the anticipation of commercial exploitation of the knowledge gained from such research.[142] Therefore, this provision may have little or no effect on the encouragement of innovation, and may fail to address the concerns regarding

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[136] *See* Seide with LeCointe, *supra* note 134, ¶¶ 3–4; *see also* H.R. 3966 (noting that the purpose behind the legislation was to supplement Congress's limited knowledge of the impact of intellectual property rights on genomic technologies).

[137] Ted Agres, *Reexamining Genetic Patents*, DRUG DISCOVERY AND DEV., June 1, 2002, at 15 (quoting 148 CONG. REC. E353, E354 (daily ed. Mar. 14, 2002) (statement of Rep. Rivers)). *But see* Seide with LeCointe, *supra* note 134, ¶ 8. Seide draws attention to potential problems with this bill. *Id.* She argues that exploration into such factors as "the costs of downstream products, and choice of research area" in conjunction with "the lack of study standards and protocols in the bill could readily lead to a biased assessment against gene patents." *Id.* Biased results could emerge because factors such as availability of funding and reduction in availability of materials are present in other fields of technology, yet inventions within those fields are not subject to the same kind of analysis. *See generally id.* Seide recommends "an objective, non-biased study" to consider whether the present patent system leads to more chilling of advances in genetics than it does in other fields. *Id.* ¶ 10. Yet, despite these reservations, this bill appears to be the only step that Congress has taken towards understanding the relationship between patent protection and genetic research.

[138] Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002).

[139] *Id.*

[140] *See* 35 U.S.C. §§ 122, 202, 205 (2000) (providing that a patent application will be published eighteen months after the earliest filing date and granting general rights of confidentiality to a patent applicant).

[141] H.R. 3967.

[142] *See* Seide with LeCointe, *supra* note 134, ¶ 13. "A great deal of genomics research is undertaken, even in academia, with the idea of eventual commercialization." *Id.* Even those who engage in technological development through the use of federal funds are able to gain title and exploit their research for profit. *See* Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 158–59 (2004). This entitlement was granted by the Government Patent Policy Act of 1980, also known as the Bayh-Dole Act, which went into effect in 1981. *Id.* at 159. The intended effect of this legislation was to promote collaborative efforts between the private and public sector in biotechnology and to promote the use of inventions that arose from federally funded research. *Id.* at 155; *see also* 35 U.S.C. § 200 (2000).

patenting DNA sequences under the current patent system.[143]

Currently, neither bill has been enacted, nor has any apparent action taken place with respect to the bills since their introduction in 2002.[144] The courts are left with the burden of balancing the public and private interests supporting and opposing DNA sequence patenting without any direction from Congress on how to best resolve this matter.

## IV. JUDICIAL INTERPRETATION

This section examines how the courts have struggled to define what the 2001 Guidelines' utility standard requires with respect to DNA sequence patent applications. The case of *In re Fisher* involved a patent application for ESTs generated from maize pooled leaf tissue.[145] The utility claims asserted in that application included: serving as molecular markers for mapping the entire maize genome; identifying polymorphisms;[146] restricting protein expression; and locating genetic molecules of other plants and organisms.[147] The examiner, in rejecting the asserted claims, determined that the uses declared were non-specific because they applied generally to nucleic acids; thus, the utility requirement was not satisfied.[148] The examiner also noted that "there was no known use for the proteins produced as final products resulting from processes involving the claimed ESTs,"[149] and that "determining whether the claimed [ESTs] have . . . polymorphisms would require 'determining whether there was a polymorphism within such a sequence and then determining how to use this information in a patentably meaningful way.'"[150] Thus, the examiner concluded that because identifying a real-world use required further research, the substantial utility requirement was also not fulfilled.[151]

Fisher appealed to the Board of Patent Appeals and Interferences ("BPAI") where the court upheld the examiner's final rejection.[152] On further appeal, before the U.S. Court of Appeals for the Federal Circuit, the case was reviewed using a "substantial evidence" standard.[153] The court, in reaffirming the examiner's

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[143] *See* Seide with LeCointe, *supra* note 134, ¶ 13; *see also supra* notes 129–133 and accompanying text (describing the concerns with current patent system and the heightened utility requirement as they apply to DNA sequences).

[144] *See* Genomic Science and Technology Innovation Act of 2002, H.R. 3966, 107th Cong. (2002); H.R. 3967.

[145] *In re* Fisher, 421 F.3d 1365, 1367 (Fed. Cir. 2005).

[146] Polymorphism is a term used to describe a situation where two or more distinct variant forms exist. *See* GRIFFITHS ET AL., *supra* note 18, at 11. In the context of molecular genetics, polymorphism refers to the difference in DNA sequences among individuals. *Id.*

[147] *In re Fisher*, 421 F.3d at 1368.

[148] *Id.* (particularly asserting "that any EST may serve as a molecular tag to isolate genetic regions").

[149] *Id.*

[150] *Ex parte* Fisher, App. No. 2002–2046, at *3 (B.P.A.I. Mar. 31, 2004), *available at* http://lorac.typepad.com/patent_blog/files/fisher_est_sequences.pdf (last visited Oct. 28, 2005).

[151] *In re* Fisher, 421 F.3d at 1368.

[152] *Ex parte* Fisher, App. No. 2002–2046, at *2.

[153] *In re* Fisher, 421 F.3d at 1369; *see also In re* Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000) (concluding that when "review of [BPAI's] decision is confined to the factual record compiled by the Board, . . . the 'substantial evidence' standard is appropriate for . . . review of Board factfindings").

rejection, adopted the real-world test for determining substantial utility as articulated by the PTO.[154] Further, the court stated that, for an invention to qualify as specific, "an application must disclose a use which is not so vague as to be meaningless."[155] Therefore, a claimed utility must provide a particular, well-defined benefit to society.[156]

In determining whether Fisher's asserted uses satisfied this standard, the court turned to the examples set forth in the Training Materials and the Manual of Patent Examining Procedure ("MPEP").[157] Analogizing the *Fisher* case to the example in the MPEP relating to cDNA fragments, the court held that "a claim directed to a polynucleotide disclosed to be useful as a 'gene probe' or 'chromosome marker,' as is the case here, fails to satisfy the specific utility requirement unless a specific DNA target is also disclosed."[158]

The majority's inflexible opinion in *Fisher* fails to address the research value that ESTs and other DNA sequences have within the biotech community. In his dissenting opinion, Judge Rader defended the utility of the claimed ESTs as research

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"Substantial evidence is 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *In re* Kumar, 418 F.3d 1361, 1365–66 (Fed. Cir. 2005) (quoting Consol. Edison Co. v. NLRB, 305 U.S. 197, 229 (1938)).

[154] *In re Fisher*, 421 F.3d at 1371.

[155] *Id.*; *see In re* Kirk, 376 F.2d 936, 941 (C.C.P.A. 1967) (stating that phrases such as "biological properties" or "biological activities" are nebulous expressions that do not convey usefulness of the compounds nor give any indication of how to use them).

[156] *In re Fisher*, 421 F.3d at 1371.

> The courts interpret the statutory term "useful" to require disclosure of at least one available practical benefit to the public. The Guidelines reflect this determination by requiring the disclosure of at least one specific, substantial, and credible utility. If no such utility is disclosed or readily apparent from an application, the Office should reject the claim.

2001 Guidelines, Comment 9, 66 Fed. Reg. 1,092, 1,094 (Jan. 5, 2001).

[157] *In re Fisher*, 421 F.3d at 1372; *see* TRAINING MATERIALS, *supra* note 127, at 51–53; *see also* U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2107.01 (8th ed. 2001), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r3_2100.pdf [hereinafter MPEP].

[158] *In re Fisher*, 421 F.3d at 1373. The 2001 Guidelines appear to contradict the PTO's position regarding the utility of DNA sequences as markers in responding to the comments received as requested in the 1999 Interim Guidelines:

> Several comments stated that DNA should be considered unpatentable because a DNA sequence by itself has little utility. *Response:* A DNA sequence—*i.e.,* the sequence of base pairs making up a DNA molecule—is simply one of the properties of a DNA molecule. Like any descriptive property, a DNA sequence itself is not patentable. A purified DNA *molecule* isolated from its natural environment, on the other hand, is a chemical compound and is patentable if all the statutory requirements are met. An isolated and purified DNA molecule may meet the statutory utility requirement if, *e.g.,* it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene. Therefore, a DNA molecule is not *per se* unpatentable for lack of utility, and each application claim must be examined on its own facts.

2001 Guidelines, Comment 8, 66 Fed. Reg. 1,092, 1,094 (Jan. 5, 2001). The court also acknowledged that it would have considered, as proof of practical utility, evidence that the invention reached commercial success, but because Fisher failed to offer any such evidence, commercial success did not support the utility of the ESTs. *In re Fisher*, 421 F.3d at 1378. The court did not address any public policy consideration for or against the patenting of ESTs in its opinion. *See id.*

tools in studying and isolating other molecules.[159] As research tools, Rader stated, "[ESTs] have a 'specific' and 'substantial' utility sufficient for § 101."[160] Rader analogized the claimed ESTs to a microscope because both are useful tools that lead scientists to a greater understanding of the corn genome.[161] Furthermore, the dissenting opinion criticizes the majority's use of value judgments in concluding that the functions the ESTs admittedly provided were not valuable.[162] Judge Rader concluded that the majority erred in holding that "a research tool has a 'specific' and 'substantial' utility only if the studied object is readily understandable using the claimed tool—that no further research is required."[163]

While the court's decision in *Fisher* seems to be another obstacle in the road leading to DNA sequence patents, there remains much confusion as to how the utility scheme applies to DNA sequences. This confusion is apparent in the different interpretations by the *Fisher* majority and dissenting opinions of the same utility guidelines provided by the PTO. Unfortunately, Congress has done very little to address this issue. Nevertheless, Congress is in the best position to implement an appropriate solution to protect the interests of researchers, promote further innovation in biotechnology, and address any concerns offered by opponents of DNA sequence patenting. However, until Congress can implement any effective resolution, the decision in *Fisher* must be reversed.

## V. PROPOSAL

Given the many arguments in favor of granting patent rights for DNA sequences, it seems unlikely that excluding DNA sequences from the definition of patentable subject matter offers the best means of alleviating the negative impact that DNA sequence patents may have on future innovation. As discussed in Part

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[159] *In re Fisher*, 421 F.3d at 1379 (Rader, J., dissenting).

[160] *Id.* Judge Rader acknowledged, however, that the utility would be limited to a research setting. *Id.*

[161] *See id.* at 1380. Judge Rader asserted that:

> [t]hese research tools are similar to a microscope; both take a researcher one step closer to identifying and understanding a previously unknown and invisible structure. Both supply information about a molecular structure. Both advance research and bring scientists closer to unlocking the secrets of the corn genome to provide better food production for the hungry world. If a microscope has § 101 utility, so too do these ESTs.

*Id.*

[162] *Id.*

[163] *Id.* The majority adopts the PTO's position in the MPEP as to the patentability of research tools:

> An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense. Instead, [the PTO] must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

MPEP, *supra* note 157, at § 2107.01.

III.A above, the PTO has imposed increasingly more stringent conditions for meeting the patentability requirement. This, along with the narrow interpretation in *Fisher*,[164] has effectively denied patent rights for DNA sequences, failed to identify the value in granting such rights, and disregarded the public and private interests in reaching a compromise in this matter. This proposal offers a two-step suggestion for correcting this predicament.

The first step requires that the United States Supreme Court reverse the decision in *Fisher* or otherwise limit that decision. The *Fisher* majority incorrectly applied the *Brenner* standard and failed to properly analyze the utility claims as specified under the MPEP.[165] If left unchallenged, the decision will leave a precedent that will severely limit, if not completely prevent, the patenting of some DNA sequences, particularly ESTs. Congress must balance the apprehensions concerning DNA sequence patenting with the benefits that patent protection offers to the biotech community. Until Congress can find a more appropriate solution to this dilemma, the Supreme Court must establish guidelines for examining DNA sequence utility claims such that the exclusive right to a patent DNA sequences remains a viable option.

The second step requires congressional involvement. Congress, the only governmental body with explicit authority to address this issue, must take action and find a resolution which will promote research and discovery while allowing reasonable access to the products of such research. The subsequent sections discuss three potential resolutions that Congress can adopt. Part A discusses prospective licensing schemes. Part B discusses enforcing an experimental use exception. Part C discusses ways in which the scope of patent rights as they apply to gene fragments may be limited. Out of these three resolutions, a licensing regime that incorporates patent pooling[166] is the most promising.

### *A. Licensing Regulations*

One of the principal arguments against DNA sequence patenting is that the practice would take the use of information away from researchers. This argument declares that once an inventor obtains the exclusive rights to a DNA sequence, the inventor is left with little incentive to license the sequence at a reasonable price or to

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[164] *See In re Fisher*, 421 F.3d at 1373.

[165] The MPEP particularly explains that a claim for a DNA sequence patent must specify a particular DNA target but does not require disclosure of the particular function of the DNA target. *See* MPEP, *supra* note 157, § 2107.01. Moreover, the Brenner court rationale, on which the *Fisher* court relied on, does not apply to DNA sequence patents whose asserted utilities have little to do with the underlying function of the specific DNA function. *See* Brenner v. Manson, 383 U.S. 519, 535 (1966); *see also supra* notes 72–73 and accompanying text. While Brenner held that a chemical process that produced products of unknown function were unpatentable, in *Fisher*, the ESTs were not a process or method but products themselves. *In re Fisher*, 421 F.3d at 1369. The asserted utility for those ESTs were to serve as research tools as probes and markers for specific DNA targets and not as methods or intermediates for producing those targets. *Id.* 1368. These uses as research tools are "real world" uses. "Unlike the methods . . . in Brenner . . . , Fisher's claimed EST's *are* beneficial to society." *Id.* at 1380 (Rader, J., dissenting).

[166] *See infra* note 175 for further discussion of patent pooling.

license it at all.[167] One solution is for Congress to issue licensing regulations specific to DNA sequence patents.[168]

Under a compulsory licensing scheme, all DNA sequence patent holders would be required to license their inventions to commercial researchers either in return for set uniform licensing rates[169] or for royalty payments that would vary depending on the financial success of the products developed from such licenses.[170] Uniform licensing rates make less sense in the context of DNA sequence patents because different sequences have different values, depending on where the sequences are located in the genetic code. A patent for a large portion of a tumor suppressor gene,[171] for example, would be much more valuable than a patent for a non-coding, non-regulatory DNA sequence. It would not be appropriate to charge the same fee to license either of these two patents.[172]

Under the variable royalty payment licensing regime, commentators have proposed that collective rights organizations ("CROs"),[173] privately organized institutions, "would negotiate licenses for the use of proprietary technologies in commercial research" and set varying exchange rules based on what rights are being transferred.[174] Patent pools[175] are a type of CRO that collect licensing rights and

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[167] *See supra* notes 83–85 and accompanying text.

[168] *See* Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1295 (1996).

[169] Such a scheme would be governed by statute and would reduce the transaction costs associated with drafting, negotiating, monitoring, and enforcing licenses. *Id.* Contracting among owners and users of a patented invention for the purpose of exchanging rights involves high transaction costs. *Id.* at 1302. However, uniform terms and costs would greatly reduce the need for lengthy negotiations and dramatically lower the costs of exchanging rights. *Id.* at 1302–03.

[170] David C. Hoffman, Note, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing a Broad Experimental Use Exception*, 89 CORNELL L. REV. 993, 1032 (2004).

[171] Inactivation of a tumor suppressor gene leads to tumor development. COOPER, *supra* note 23, at 669.

[172] Under an economic system that relies primarily on market forces to allocate goods and to determine prices for those goods, it would follow that, since demand would dictate the cost, licensing fees for the more valuable, coveted tumor-suppressor gene sequence would expectedly be higher than that of a non-coding sequence, for example. *See generally* Answers.com, Market Economy, http://www.answers.com/topic/market-economy (last visited Jan. 17, 2006) (describing a market economy and the relationship between supply and demand).

[173] Collective rights organizations are "knowledgeable industry participants [that] set the rules of exchange." Merges, *supra* note 168, at 1295. Through expert tailoring, these CROs set the royalty rates. *Id.* at 1296. This scheme is not statutory and has therefore "proven to be more flexible over time;" it avoids a "legislative lock-in," and is less susceptible to congressional lobbying. *Id.* at 1299.

[174] Hoffman, *supra* note 170, at 1039.

[175] *See* Jeanne Clark et al., *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?*, United States Patent and Trademark Office, Office of Patent Legal Administration at 4 (Dec. 5, 2000), http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf. The PTO defines a patent pool as:

> an agreement between two or more patent owners to license one or more of their patents to one another or third parties. Alternatively, a patent pool may also be defined as "the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool."

price them for sale to the public to more efficiently transfer these rights.[176] The rules of exchange are "established by the members of the organization, and thus, are the products of internal negotiations by knowledgeable people in the industry."[177]

Patent pools offer the best solution for ensuring reasonable access to DNA sequences for research. First, the "gatekeeper" or "blocking" patent problem commonly associated with DNA sequence patents would be diminished.[178] A single entity can provide licenses necessary for practicing biotechnology.[179] Furthermore, this situation could potentially lead to a greater rate of advancement because pool members would have equal access to research tools. Also, as previously discussed, CROs lower transaction costs often associated with obtaining licenses on patented resources.[180] Moreover, Congress has the authority to authorize mandatory pooling of DNA sequence patents.[181]

### *B. Experimental Use Exception*

Many commentators have advocated establishing a broad experimental use defense or exception to patent infringement.[182] This proposition derives from the fair use exception recognized under American copyright law.[183] Indeed, there are

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*Id.* at 4 (quoting Joel I. Klein, Address to the American Intellectual Property Law Association: On the Subject of Cross-Licensing and Antitrust Law (May 2, 1997)).

[176] *See* Mireles, *supra* note 142, at 141.

[177] Merges, *supra* note 168, at 1300.

[178] The gatekeeper problem occurs when overlapping patent claims prevent any use of one patent without infringing another. *See supra* notes 80–81 and accompanying text.

[179] Clark et al., *supra* note 175, at 8.

[180] *See supra* note 173.

[181] *See* Clark et al., *supra* note 175, at 5–6. However, problems with antitrust laws, such as the Sherman Act, designed to prevent the creation of monopolies and restraints on interstate commerce, may arise in a patent pool establishment if the pool is anticompetitive. *Id.* Such "[a]nticompetitive effects may . . . occur if the pooling arrangement deters or discourages participants from engaging in research and development." *Id.* at 7. There are guidelines that pooling agreements should follow to avoid antitrust scrutiny: a proposed licensing program should be likely to integrate complementary patent rights, and "the resulting competitive benefits are likely to be outweighed by the competitive harm posed by other aspects of the program." *Id.* As long as these guidelines are followed, the risk of inflating the costs of reasonably priced goods or the risk of price-fixing will diminish.

[182] *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1078 (1989) (recommending "an experimental use exemption from patent infringement liability" to verify the accuracy of a specification or the validity of patent claims, but not for "research use of a patented invention with a primary . . . market among research users," and suggesting that when exempt experimental use leads to significant improvement in the patented technology, the patent holder "might be . . . award[ed] a reasonable royalty").

[183] *See* 17 U.S.C. § 107 (2000). Under this provision, non-copyright owners are, in effect, granted a privilege to use copyrighted material without having to pay royalties or licensing fees if that use is a fair use. *Id.* Factors to consider when determining whether a use is a fair use are: "the purpose and character of the use . . . ; the nature of the copyrighted work; the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and the effect of the use upon the potential market for or value of the copyrighted work." *Id.* Market failure, including "(i) high transaction costs that frustrate private bargaining; (ii) positive externalities that prevent the infringer from being able to pay the copyright owner's price for a license; and (iii) the

situations in which "the public benefit from the infringement may be so great that it outweighs the patentee's interest in its exclusive rights."[184] The law recognizes the judicially-created patent experimental use exception in limited situations.[185] This exception requires a "traditional basic research" use, with no commercial implications, for the purpose of testing the adequacy of the specification.[186]

Commentators assert that the definition of experimental use for the purposes of the exception should be broadened to reflect a balancing between the private benefits of granting exclusive use and the public interests in nonexclusive use.[187] Courts, thus far, have been reluctant to expand the experimental use exception to reflect copyright fair use.[188] In the case of *Embrex, Inc. v. Service Engineering Corp.*, Judge Rader wrote in his concurring opinion that Patent Law leaves "no room for any de minimis or experimental use excuses . . . because intent is irrelevant to patent infringement."[189] Rader argues that the issue of the extent of infringement should be discussed only as it pertains to damages.[190] Furthermore, if the doctrine of experimental use retains validity, Rader argues that "the slightest commercial implications will render the . . . doctrine inapplicable."[191]

Notwithstanding the benefits that broadening the experimental use exception would have in theory, problems could arise from such an expansion. One potential

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failure of any market for the particular use to develop," has justified the fair use privilege. Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1188 (2000). Commentators of market failure justification have warned that the privilege should be limited to instances when the copyright holder has an "antidissemination motive" rather than a desire related to the goals of the copyright. *See id.* at 1189.

[184] O'Rourke, *supra* note 183, at 1198. Thus far, the Patent Act allows for certain exceptions to patent infringement. The first exception, stating that "[i]t shall not be an act of infringement to make, use, or . . . sell a patented invention . . . solely for uses reasonably related to the development and submission or information under a Federal law which regulates the manufacture, use, or sale of drugs . . .," allows for otherwise infringing activities necessary to obtain Federal Drug Administration approval. 35 U.S.C. § 271(e)(1) (2000). The other exception, limits the remedies that a patent holder is entitled to for infringing medical activity performed by a medical practitioner or related entity. *See* 35 U.S.C. § 287(c)(1) (2000).

[185] *See* Poppenhusen v. N.Y. Gutta Percha Comb Co., 19 F. Cas. 1059, 1063 (C.C.S.D.N.Y. 1858) (No. 11,283) (noting that use of a patented invention "merely for experiment, and not with a view to profit" does not give rise to patent infringement liability). An example of a situation in which the experimental use exception would exist is "for the purpose of ascertaining the sufficiency of the [invention] to produce its described effects." Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600). Thus, "[t]he experimental use doctrine thus gives the patentee's competitors a right during the patent term to vindicate the public's interest in having an enabling disclosure." Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 222 (1987) [hereinafter Eisenberg, *Norms of Science*]. Another example is when the subsequent user is trying to fashion alternatives to the patented invention with no commercial motive. *Id.* at 224.

[186] Eisenberg, *Norms of Science*, *supra* note 185, at 224.

[187] Eisenberg, *Norms of Science*, *supra* note 185, at 224.

[188] *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984) (refusing to "construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes").

[189] Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1352 (Fed. Cir. 2000) (Rader, J., concurring).

[190] *See id.* at 1353.

[191] *Id.*

problem is in the standard's application. Once research has any commercial value, a court would have difficulty in deciding how much commercial value is too much and how much public interest in the infringing use is too little when determining whether the exception should take effect. The difficulty is not in the justification of the exception but in setting the limits of where permissible experimental use ends and where impermissible infringing use begins.[192] Therefore, patent pooling is a more practical solution to the DNA sequence patent problem than broadening of the experimental use exception.

### *C. Limiting the Scope of Rights for DNA Sequence Patents*

Rather than working around the current patent system, many individuals advocate the system's expansion via the adoption of nonexclusive patents.[193] Under the normal patent scheme, the first to invent and satisfy the statutory requirements can obtain exclusive property rights to that invention; under a nonexclusive scheme, the inventor will only be protected "against free-riding competitors, but not against competitors who independently develop the same technology."[194]

Proponents of this system acknowledge that nonexclusive protection would cause inventors to slow development efforts to avoid expending excessive costs for the purpose of securing the temporary monopoly that patent law confers.[195] However, the argument is that this decision would more accurately reflect a competitive marketplace where inventors are forced to balance the risks and benefits of commencing a prospective project.[196] Others in favor of nonexclusive patenting contend that, unlike situations where there is a short supply of substitutes and the threat of monopoly is high, "the possibility of anticompetitive behavior in the

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[192] *See* Eisenberg, *supra* note 182, at 224.

> Too narrow a defense could stifle basic research and impair the community's mechanisms for validating and building upon new knowledge. Too broad a defense could cause industrial sponsors to lose interest in biotechnology research or to rely on secrecy in lieu of patent protection. There may be no way to avoid both of these potential problems completely.

*Id.*

[193] *See* John S. Leibovitz, Note, *Inventing a Nonexclusive Patent System*, 111 YALE L.J. 2251, 2268 (2002).

[194] *Id.*

[195] *Id.* at 2269.

> If consumers value an invention so much that they are willing to pay higher prices—enough to offset expedited development—then the inventor should speed up his efforts in order to get to market sooner. If there is an acute risk that an invention is not especially valuable to society, the inventor might slow development, reduce costs, and allocate resources to other projects in his research portfolio in order to achieve an optimal risk-reward balance. A nonexclusive patent system allows the development pace to be optimized by a rational economic actor . . . , without the racing incentives presented by the prospect of gaining or losing a monopoly on a technological improvement.

*Id.*

[196] *Id.*

commercialization of technologies" would be minimized.[197]

How such a system would be implemented remains unclear. One commentator advocates a system of partial disclosure, falling somewhere in between the full disclosure that exclusive patents requires and the nondisclosure that characterizes trade secrets.[198] In such a system, only a functional overview and not a complete technical specification would be published.[199] Although the PTO would require a technical specification, with a full written description, drawings, and novel claims, this specification would remain on file with the PTO rather than made available to the public.[200] This would enable prospective inventors to search the PTO database to determine whether a particular tool and potential licensing opportunity exists.[201]

The difficulty with this approach is that it would require "a radical reformulation of our current system of intellectual property protection."[202] No recognized practice of granting nonexclusive patents exists under the current system of patent law. Article I, § 8, cl. 8 of the United States Constitution expressly confers to Congress the power to grant inventors the *exclusive* right to their discoveries.[203] A narrow interpretation of the Constitution would lead one to conclude that Congress does not have the power to grant inventors any *nonexclusive* rights to their discoveries.

Other suggestions for limiting the scope of patent protection as applied to DNA sequence patents involve either narrowing the definition of what is protected under patent law[204] or shortening the length of patent protection.[205] Supposedly, such

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[197] *Id.* at 2270. Leibovitz further asserts that "[t]he presence of competition in a nonexclusive patent system . . . provides great incentive for patent holders to license their inventions," without the need for compulsory licensing, in order to avoid redundant projects. *Id.* at 2272. The idea is that either way, the inventor of a particular technology will face competition, but it would make more sense for that inventor to make money from his competitors through licensing than to withhold licenses. *See id.* Likewise, it would be economically more favorable for competitors to license the technology from the original inventor than to expend even more money developing a technology that already exists. *Id.* This situation, Leibovitz maintains, works to avoid redundant development efforts. *Id.*

[198] *Id.* at 2277.

[199] *Id.* at 2277–78. Leibovitz states that:

> the functional overview would explain in very general terms what an invention does without detailing how it works. It would contain basic facts about the inventor and the invention, similar to the opening sections of the patent specification required under the current rules (excluding the detailed description and drawings). It would also contain a substantive overview of the purpose and general function of the invention, similar to the "brief summary of invention" section required under current rules.

*Id.*

[200] *Id.*

[201] *Id.*

[202] Hoffman, *supra* note 170, at 1043.

[203] U.S. CONST. art. 1, § 8, cl. 8.

[204] Those that offer this proposition state that patent protection for DNA sequences would cover only a specific use or function of that sequence. AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS COMMITTEE ON GENETICS, PATENTS, MEDICINE, AND THE INTERESTS OF PATIENTS: APPLYING GENERAL PRINCIPLES TO GENE PATENTING, COMMITTEE OPINION NO. 277 (Nov. 2002), *reprinted in* ETHICS IN OBSTETRICS AND GYNECOLOGY 113 (2d ed. 2004), *available at* http://www.acog.org/from_home/publications/ethics/ethics111.pdf. This concept is encompassed in a use patent where, unlike composition-of-matter patents that:

limitations would help to prevent a complete monopoly over any given DNA sequence.

Significant barriers to limiting the extent of patent protection within a particular field of technology exist. All of these rights-limiting suggestions would require legislative amendments to the current patent system as it applies to biotechnology, gene fragments in particular. However, there are restrictions as to what Congress can legislate.

The 1994 Agreement on the Trade-Related Aspects of Intellectual Property ("TRIPs"), identifying standards for intellectual property protection, binds member countries of the World Trade Organization ("WTO"), including the United States.[206] Article 8 of the TRIPs Agreement provides that "[m]embers may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."[207] However, Article 27 of the TRIPs Agreement states that "patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology."[208] The meaning of "field of technology" remains unclear.[209] One could argue that restricting the rights granted to DNA sequence patents would constitute discrimination as to a field of technology—namely biotechnology. Thus, if legislation limiting the potential patent rights of DNA sequences is enacted, a TRIPs Agreement violation argument will certainly follow.[210] However, such barriers do not facilitate Congress's ability to

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> may be enforced broadly against a variety of uses of the claimed product, . . . [t]he enforcement of a use patent is narrower, being limited to the patented use. Although a use patent restricts the right to use a patented method using a product of composition, it does not restrict access to the product or composition itself.

*Id.*

[205] *See* Laurie L. Hill, *The Race to Patent the Genome: Free Riders, Hold Ups, and the Future of Medical Breakthroughs*, 11 TEX. INTELL. PROP. L.J. 221, 251–52 (2003). Commentators who are in favor of a shorter patent term suggest that this would amplify the availability of newly discovered DNA sequences because the sequences will be received into the public domain at an earlier time. *Id.* at 251. The current duration of patent protection is generally 20 years from the application filing date with the PTO. 35 U.S.C. § 154(a)(2) (2000).

[206] CHISUM, *supra* note 60, § 1.01.

[207] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization Annex 1C, Legal Instruments—Results of the Uruguay Round, Vol. 31, 33 I.L.M. 81, art. 8, ¶ 1 (1994), *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter TRIPS].

[208] *Id.* at art. 27, ¶ 1. Nevertheless,

> [WTO m]embers may exclude from patentability inventions the prevention . . . of the commercial exploitation of which is necessary to protect [public order] or morality, including to protect human . . . life or health . . . [,] diagnostic, therapeutic . . . methods for the treatment of humans or animals . . . [,] and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

*Id.* ¶¶ 2–3.

[209] Cynthia D. Lopez-Beverage, *Should Congress Do Something About Upstream Clogging Caused by the Deficient Utility of Expressed Sequence Tags?*, 10 J. TECH. L. & POL'Y 35, 71 (2005).

[210] "The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of

implement a compulsory patent pooling system.

## VI. CONCLUSION

We are living in a genomics age where DNA technology is changing the way we understand the causes of cancer and other diseases, treatment options, and the basics of heredity. More than a molecular composition of matter, DNA is information that should be freely accessible to all. Even so, deciphering the DNA code into useful information is a costly endeavor. Patent law offers researchers the ability to recover costly research expenses, make profits with which to fund further research, and attract investors to expand on this research. However, the advantages of the patent system are not without a fair share of shortcomings. Congress is in the best position to offer reconciliation between those that have need of patent protection on DNA sequences and those that oppose the negative effects this patent protection generates.

The most logical solution is to allow patents on DNA sequences without the stringent evaluation that the PTO and courts have adopted. Instead, the PTO should follow a utility standard that more correctly reflects the purpose of patent law, "to promote the progress of useful arts."[211] To compensate for the diminished use of information arising from the temporary monopoly granted to patent holders,[212] Congress should implement a compulsory licensing regime for DNA sequences that incorporates patent pools. This system would allow inventors to recover the costs of developing the DNA discoveries, while simultaneously allowing reasonable access to those discoveries. The trouble with executing such a system is not in its justification, but rather in its implementation. The only governmental body with the authority to compel DNA sequence patent holders to enter into patent pools is Congress. However, the only governmental body able to offer a prompt remedy to the rigid guidelines set forth by the PTO and narrowly interpreted in *Fisher* is the United States Supreme Court. In order to achieve long term goals in biotech research, both congressional and judicial attention is imperative.

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consulting on matters relating to the trade-related aspects of intellectual property rights." TRIPS, *supra* note 207, art. 68. TRIPS member nations must provide patent protection in accordance with the agreement and are subject to review by the Council for TRIPS. *See id.* art. 64, ¶ 3.

[211] *See In re* Fisher, 421 F.3d 1365, 1379 (Fed. Cir. 2005) (Rader, J., dissenting).

[212] In reality, accessibility is not diminished per se because the information is disclosed rather than kept secret. *See supra* note 110 and accompanying text.