

**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?**

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INTRODUCTION

The cornerstone of the American patent law system is to encourage technological innovation by financially rewarding inventors for the full disclosure of their ideas.¹ By enacting Article I, Section 8, Clause 8 of the Constitution, the Framers envisioned a system that “promote[s] the Progress of Science and useful Arts.”² The astounding advancements in many areas of technology show that their vision became a reality. With these few words, Congress faced the challenging task of establishing a system that encourages ingenuity and rewards innovation, while conferring a useful benefit to society as a whole.

Over two hundred years later, patent legislation has evolved into a complex, carefully constructed statutory scheme that is indispensable for sustaining research efforts in both the public and private sectors.³ To maintain integrity in the system, Congress

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¹ DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 1 (2001). The actual right awarded to a patent holder is the right to exclude others from “making, using, offering for sale, or selling the invention” in the United States. See *infra* text accompanying note 97. This in turn often results in financial gain through the licensing or assignment of these rights to others. See generally CHISUM, *supra*, at 2-6; see also Kevin C. Hooper, *Utility and Non-operability Standards in Biotechnology Patent Prosecution: CAFC Precedent Versus PTO Practice*, 36 IDEA 203, 206 (1996) (“In theory, [the patent system] . . . is a quid pro quo method used by the government to encourage early and complete disclosure of inventions that meet the statutory criteria for patentability.”).

² U.S. CONST. art. I, § 8, cl. 8.

³ See Hooper, *supra* note 1, at 203-04 (explaining that patent protection is an

developed requirements that an invention must satisfy in order to receive patent protection.⁴ In particular, the invention must be novel,⁵ nonobvious,⁶ and useful.⁷ As patent law attempts to keep pace with rapid developments in technology, the meaning of these seemingly simple concepts is often imbued with uncertainty.

The Human Genome Project,⁸ for example, reveals valuable information about genes that are involved in life-threatening diseases and other genetic disorders. Such a database of information is fertile ground for raising highly complex patent law issues. Private and public entities are already taking advantage of this information by filing patent applications for full or partial length gene sequences.⁹ In response, the Patent and Trademark Office (“PTO”)¹⁰ recently issued new Utility Examination Guidelines (“Guidelines”) that purport to aid Examiners as they review applications claiming gene sequences.¹¹ Under these new Guidelines, the claimed invention must have “specific, substantial, and credible” utility.¹² The reasoning behind issuing the new Guidelines is clear—to ensure patents are not

important factor toward the ultimate success in the biotechnology industry, because most companies cannot afford the monetary risks required to develop commercially useful products without such protection). Furthermore, patent protection is also critical to secure investments from venture capitalists in order to create start-up companies that develop promising technologies in the market place. *Id.* at 205.

⁴ An invention must satisfy several requirements in order to be deemed patentable. See generally 35 U.S.C. §§ 101-03, 112 (1994); see also Nathan Machin, *Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act*, 87 CAL. L. REV. 421, 423-24 (1999) (describing six requirements for patentability as patentable subject matter, utility, novelty, a timely filed patent application, nonobviousness, and a description of “the best method of making or using the invention so as to enable one or ordinary skill in the art to practice the invention”). Although an invention must meet all of these requirements, this Comment will only address patentable subject matter, novelty, nonobviousness, and utility. For a detailed discussion of the written description requirement, see Lisa A. Karczewski, *Biotechnological Gene Patent Applications: The Implications of USPTO Written Description Requirement Guidelines on the Biotechnology Industry*, 31 MCGEORGE L. REV. 1043, 1060-64 (2000).

⁵ 35 U.S.C. § 102 (2001).

⁶ *Id.* at § 103.

⁷ *Id.* at § 101.

⁸ See *infra* note 38.

⁹ G. Kenneth Smith & Denise M. Kettelberger, *Patents and the Human Genome Project*, 22 AIPLA Q. J. 27, 50 (1994) (describing the increase in patent applications after the NIH’s initial applications for cDNA fragments).

¹⁰ The PTO is the agency within the United States Department of Commerce responsible for granting and issuing patents, as well as registering trademarks. 35 U.S.C. §§ 1(a), 2(a)(1) (2001).

¹¹ Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001) [hereinafter Utility Examination Guidelines I].

¹² *Id.*

granted for gene sequences that do not possess substantial utility.¹³ The question remains, however, whether the PTO acted within its authority in issuing the new Guidelines. The PTO is bound by congressional intent and judicial interpretation of the meaning of “utility.”¹⁴ While the modern judicial trend reflects a more relaxed standard for utility, the PTO’s heightened utility standard may be the subject of legal challenges as PTO Examiners continue to reject claims for truly patentable inventions based on alleged lack of utility.

This Comment will examine the interplay between the PTO’s revised Guidelines that pertain to patent applications for human genes, and the legal basis behind the utility requirements for patentability. Part I will explain the scientific background regarding genes and their functions. Part II will give an overview of the American patent system. Focusing on the utility requirement for patents, this section also traces relevant case law dealing with the legal construction of the concept of “utility.” Part III will discuss the proliferation of patent applications for human gene sequences and the PTO’s response. This section will also explore the practical effect of the new Guidelines by reviewing actual claim rejections that the PTO issued under section 101.¹⁵ Part IV will discuss the implications of the PTO’s actions and the legal challenges the PTO may face by raising the utility requirement “hurdle,” specifically for gene patents. This Part suggests that the PTO replace the revised Guidelines with a methodology that is defined by the Supreme Court’s ruling in *Brenner v. Manson*,¹⁶ which focused on the utility requirement for patentability, the legislative history of the utility doctrine, and the Court of Appeal for the Federal Circuit’s (“Federal Circuit”) most recent articulation of the utility standard.

¹³ See M. Scott McBride, Comment, *Patentability of Human Genes: Our Patent System Can Address the Issues Without Modification*, 85 MARQ. L. REV. 511, 532 (2001) (“[The] new [utility] standard is likely to protect researchers performing bona fide research on particular genes against those who patent ESTs to lay claim to those genes of which they have no knowledge.”).

¹⁴ See generally Orin S. Kerr, *Rethinking Patent Law in the Administrative State*, 42 WM. & MARY L. REV. 127, 138-41 (describing the role of the PTO).

¹⁵ 35 U.S.C. § 101 provides that “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101 (2001).

¹⁶ 383 U.S. 519 (1966).

I. AN INTRODUCTION TO GENES

A. *The Fundamentals of Molecular Biology*

To understand the legal issues surrounding the patentability of human genes, it is important to have a basic understanding of molecular genetics. The human body, complete with physical traits and characteristics, represents the final product of a series of complex biochemical functions that occur at the cellular level. Genes are the functional units of heredity. They are composed of deoxyribonucleic acid ("DNA"), the molecule possessing functional properties that earn its distinction as the cell's master molecule.¹⁷ DNA indirectly codes or dictates the structures of molecules that are made by proteins, including sugars and fats.¹⁸ DNA not only governs the structure, but also the timing and quantity of the molecule's synthesis.¹⁹

The individual building blocks, or nucleotides, that comprise DNA consist of a phosphate group, a deoxyribose sugar, and one of the four nitrogen bases known as adenine, cytosine, guanine, and thymine.²⁰ These bases link together, in a particular order, to create a specific gene.²¹ The DNA molecule typically has from 3000 to several million nucleotide units arranged in a double helix.²² The helix consists of two chains of alternating phosphate and deoxyribose units in continuous linkages.²³ The nitrogen bases project inwardly toward the axis of the helix.²⁴ Adenine always unites with thymine, and cytosine with guanine.²⁵ The sequences of the bases on the chain vary with the individual, and it is this sequence that expresses the genetic code.²⁶

After a complex series of events called transcription²⁷ and

¹⁷ HARVEY LODISH ET AL., *MOLECULAR CELL BIOLOGY* 9-10 (3d ed. 1995).

¹⁸ DNA "indirectly" codes for proteins because DNA is first transcribed into another nucleic acid, RNA, which then is translated into protein. *Id.* at 10, 12.

¹⁹ *Id.* at 10.

²⁰ *Id.* at 102-05.

²¹ *Id.* at 4.

²² *Id.* at 104-05.

²³ LODISH ET AL., *supra* note 17, at 104-05.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.* at 102.

²⁷ During transcription, one strand of DNA is used as a template to create a complementary RNA, or more specifically, messenger RNA ("mRNA"). *See generally id.* at 119, G-12.

translation,²⁸ the gene ultimately creates specific proteins that execute the program of cellular activities for which the gene encodes.²⁹ Proteins, or the “working molecules” of a cell, are responsible for the basic biological functions of living organisms.³⁰ In addition to building and maintaining the structure of the cell and its organelles,³¹ proteins catalyze many intracellular and extracellular chemical reactions that are vitally intertwined in the physiology of cells. Proteins make cells move, perform work, and direct synthesis of other proteins and molecules.³² They determine cell constitution and function and move molecules across membranes.³³ Given their central role in the complicated orchestration of cellular events, proteins are fundamental to the biology of life.

Because of the devastating effects that could result from a single mistake during these cellular events, many scientists and researchers devote countless hours toward understanding biochemical processes. A single mutation or deviation in the gene sequence has the potential of creating a new protein that can result in a life-threatening disease, rather than the healthy function encoded by the original genetic sequence.³⁴ For example, because of gene mutations, a person diagnosed with phenylketonuria is incapable of digesting a dietary constituent.³⁵ Another example of a genetic mutation may result in a dysfunctional molecule that normally helps to organize the inside of a muscle cell.³⁶ Instead of a healthy muscle, the disease of muscular dystrophy would devastate the individual.³⁷ Thus, there is a compelling need to understand the biochemical processes at the cellular level, because they are the starting point of many disorders and diseases that affect so many human lives.

A genome is the entire genetic makeup of an organism. A bacterium’s genome consists of approximately six hundred thousand DNA base pairs, in contrast to the human and mouse genome which

²⁸ Translation refers to the phase of protein synthesis when the mRNA encodes the amino acid sequence that determines the protein to be made. *See generally id.* at 120.

²⁹ LODISH ET AL., *supra* note 17, at 51.

³⁰ *Id.*

³¹ Organelles are the membrane-limited structures found within a cell’s cytoplasm, including mitochondria, lysosomes, and golgi bodies. *See id.* at 8-9.

³² *Id.* at 9, 119-38.

³³ *Id.* at 9.

³⁴ *Id.*

³⁵ LODISH ET AL., *supra* note 17, at 9.

³⁶ *Id.*

³⁷ *Id.*

consists of about three billion DNA base pairs.³⁸ Considering the vast differences in complexity between the bacterium and human species, the large discrepancy in the number of base pairs is not surprising. Rather, the difference illustrates the governing role genes play in the evolution of living organisms. Despite the large number of available base pairs in the human genome, only two to five percent of the genome encodes protein.³⁹ The non-coding regions of the DNA serve other functions such as regulating gene expression.⁴⁰

B. *The Human Genome Project*

The Human Genome Project⁴¹ — initiated by the U.S. Department of Energy and the National Institutes of Health (“NIH”) — is a worldwide coordinated effort to sequence the entire human genome and to catalog its estimated 100,000 genes found in the human chromosomes.⁴² Originally designed to be a thirteen-year project, advances in biotechnology and laboratory techniques substantially shortened the estimated time for completion.⁴³ In the year 2000, it was predicted that the entire human genome sequence would be completed within four to six years.⁴⁴ Thus far, researchers have collected vast amounts of genetic information. A method for gene identification, known as complementary DNA (“cDNA”) sequencing, now quickly and easily identifies genes.⁴⁵ In 1991, Dr.

³⁸ Human Genome Project Information Website, *The Science Behind the Human Genome Project: Basic Genetics, Genome Draft Sequence, and Post-Genome Science*, at <http://www.ornl.gov/hgmis/project/info.html> (last modified May 6, 2002) (on file with author).

³⁹ Andrew T. Knight, *Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines In Light of Brenner*, 73 IND. L.J. 997, 1003 (1998).

⁴⁰ Andrew G. Clark, *The Search for Meaning in Noncoding DNA*, available at http://www.linkage.rockefeller.edu/wli/dna_corr/clark01.pdf (last visited Jul. 28, 2002) (on file with author).

⁴¹ See Human Genome Project Information Website, *About the Human Genome Project*, at <http://www.ornl.gov/hgmis/project/about.html> (last modified July 26, 2001) (on file with author).

⁴² See John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 115 (2001); see also Joseph P. Pieroni, *The Patentability of Expressed Sequence Tags*, 9 FED. CIR. B.J. 401, 403 (2000); John J. Doll, *The Patenting of DNA*, 280 SCIENCE 689-90 (1998).

⁴³ See Golden, *supra* note 42, at 115 (noting that these advances have eased much of the process of isolating, identifying, and sequencing genes by “substantially routinizing a variety of tasks that had previously required considerable effort and ingenuity”).

⁴⁴ See Pieroni, *supra* note 42, at 403.

⁴⁵ See Adams et al., *Complementary DNA Sequencing: Expressed Sequence Tags and Human Genome Project*, 252 SCIENCE 1651 (1991) (describing technique for identifying expressed sequence tags); see also Knight, *supra* note 39, at 1003.

Craig Venter and his associates at the NIH developed this approach.⁴⁶ The process involves cDNA sequences which are “edited” copies of a gene, rather than the full-length genomic DNA sequence.⁴⁷ The shorter sequences, which only contain protein-coding regions, allow for quicker identification and characterization of genes.⁴⁸ The widespread use of cDNA sequencing identified approximately 50,000 human genes as of September 1995.⁴⁹

On June 25, 2000, President Clinton announced that researchers sequenced the human genome in its entirety.⁵⁰ The Human Genome Project and Celera Genomics Corporation, a privately funded company which set forth a “rough draft” of the human genome, accomplished this historic achievement.⁵¹ Although sequencing the entire human genome is a landmark achievement in and of itself, the real challenges facing scientists — including understanding the gene and protein functions — remain ahead.⁵² Elucidating the DNA sequence alone does not provide researchers with much information on how to develop treatments or cure diseases.⁵³ This can only be accomplished by understanding the biological functions which correspond to the newly identified genes.⁵⁴ Thus, the focus for researchers in the years to come will shift away from the genetic blueprint of the human genome itself, and move toward the protein functions encoded by the genes.

⁴⁶ See Pieroni, *supra* note 42, at 401.

⁴⁷ See Knight, *supra* note 39, at 1003 (noting that these shorter sequences can be characterized more rapidly than longer genomic sequences).

⁴⁸ *Id.*

⁴⁹ *Id.* at 1004.

⁵⁰ See Human Genome Project Information Website, White House Press Release, *President Clinton Announces the Completion of the First Survey of the Entire Human Genome*, available at <http://www.ornl.gov/hgmis/project/clinton1.html> (last modified Feb. 28, 2001) (on file with author).

⁵¹ See Golden, *supra* note 42, at 115.

⁵² The process of cDNA sequencing received much criticism from eminent members of the field. One critic in particular was James Watson who, along with Francis Crick, determined the double-helical structure of DNA. When Watson commented on the NIH’s patent applications for certain gene sequences, he noted “that ‘virtually any monkey’ can run an automated sequencing machine,” and that the real importance lies in the interpretation of the sequence. See Knight, *supra* note 39, at 1004.

⁵³ Dr. Venter analogized this information to “getting a list of phone numbers for a certain city with no names attached,” and argued that a cDNA sequence alone does not tell a researcher what the sequence does “unless it’s a sequence from a gene whose function is already known.” *Id.*

⁵⁴ *Id.*

C. *Recombinant DNA Technology Allows for Genetic Analysis*

Recombinant DNA technology allows researchers to unlock the mystery behind DNA and protein functions.⁵⁵ In the 1970s, technical advances in laboratory techniques led to breakthroughs in molecular biology.⁵⁶ Recombinant DNA technology allows scientists to purify a specific gene, determine its sequence and explore its functional regions.⁵⁷ This form of genetic engineering is accomplished through the manipulation and cloning of DNA.⁵⁸ A particular enzyme, called a restrictive enzyme, cleaves the DNA at specific sequences and yields a reproducible set of fragments.⁵⁹ These DNA fragments insert into a vector DNA molecule⁶⁰ which has the ability to replicate when it is inserted into a host cell.⁶¹ The DNA fragment of interest along with the vector molecule form what is known as the recombinant DNA.⁶² The recombinant DNA enters into host cells, which are most often bacterial cells.⁶³ Under appropriate conditions, bacterial cells replicate exponentially and yield large numbers of the recombinant DNA molecules.⁶⁴ Once the desired sequence is cloned and cleaved, the fragment of interest can be isolated and analyzed, thus providing large quantities of the gene at scientists' disposal.⁶⁵

D. *Expressed Sequence Tags*

Given the central role that Expressed Sequence Tags ("EST") played in shaping the new Guidelines, it is helpful to have a basic understanding of the meaning of ESTs.⁶⁶ At any given time during the life of a cell, only a subset of genes within an entire genome is active.⁶⁷ The genes that are being expressed have been transcribed

⁵⁵ See LODISH ET AL., *supra* note 17, at 221.

⁵⁶ *Id.*

⁵⁷ *Id.* at 222.

⁵⁸ See *id.* at 221-25.

⁵⁹ *Id.* at 221.

⁶⁰ Bacterial plasmids are commonly used as cloning vectors. *Id.* at 222. These are small, circular extrachromosomal DNA molecules that replicate autonomously in a bacterial cell. *Id.*

⁶¹ LODISH ET AL., *supra* note 17, at 222.

⁶² *Id.* at 221-22.

⁶³ *Id.* at 221.

⁶⁴ *Id.*

⁶⁵ *Id.* at 240.

⁶⁶ For additional background information on ESTs, see Machin, *supra* note 4, at 434-35.

⁶⁷ Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735, 748 (2000).

from DNA and take the form of mRNA within the cell.⁶⁸ Scientists can survey the active genes of a cell by extracting mRNA, converting it to cDNA, and sequencing it.⁶⁹ ESTs are essentially a short length⁷⁰ of the cDNA that represent part of a gene that was being expressed at that given time.⁷¹ Thus, ESTs are not individually selected, but result from a random selection.⁷² Because ESTs are only a fraction of the gene to which they correspond, ESTs do not provide much useful information regarding the full extent of a gene's functions.⁷³ ESTs, however, can be useful for isolating full-length genes, or for marking coding regions of genomic DNA sequences.⁷⁴ Beyond these primarily intermediate functions, ESTs do not play a significant part in the quest for understanding the true nature of gene and protein functions.⁷⁵

II. THE AMERICAN PATENT SYSTEM

A. *Foundation and Development of the Current Patent System*

The United States Constitution embodies the source of federal patent legislation. Article I, Section 8, Clause 8, grants Congress the exclusive power “[t]o promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁷⁶ In the interest of developing a uniform system of law governing patents and copyrights, this provision of the Constitution earned the approval of the Framers without debate.⁷⁷ The Framers clearly recognized the necessity of such a system in light of the increased rate of industrialization and the potential interstate conflicts that were to inevitably occur as a result of the dissimilarities in state patent

⁶⁸ *Id.* For the definition of mRNA, see *supra* note 27.

⁶⁹ Holman & Munzer, *supra* note 67, at 748.

⁷⁰ ESTs are generally 400-500 nucleotides in length, compared to full-length genes which are generally 2,000 to 25,000 nucleotides in length. *Id.* at 749.

⁷¹ *Id.*

⁷² *Id.*

⁷³ Holman & Munzer, *supra* note 67, at 750; *see also* Leora Ben-Ami et al., *Biotech Patent Law Developments*, 573 PLI/PAT 555, 558 (1999).

⁷⁴ Holman & Munzer, *supra* note 67, at 749.

⁷⁵ *Id.* at 749-50; *see also* Ben-Ami et al., *supra* note 73, at 558.

⁷⁶ U.S. CONST. art. I, § 8, cl. 8.

⁷⁷ CHISUM ET AL., *supra* note 1, at 16-17; *see also* Charles C. Wong, *State Immunity Doctrine: Demoting the Patent System*, 53 ME. L. REV. 111, 117-20 (2001) (discussing the evolution of the federal patent law system beginning with the constitutional grant for the enactment of patent legislation).

customs.⁷⁸ Thus, following the proposal of this provision, the power to enact patent legislation became one of the enumerated powers of Congress on September 5, 1787.⁷⁹

Congress passed the first patent statute, the Patent Act of 1790, on April 10, 1790.⁸⁰ The Act authorized the granting of patents for “any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used.”⁸¹ The Act also created a patent board, rather than a patent office, that was responsible for examining patent applications.⁸² In response to the workload that proved to be burdensome for a three-member panel, a registration system was implemented with the promulgation of the 1793 Patent Act.⁸³ The registration system lasted for forty-three years, until Congress enacted the 1836 Patent Act, which is known as “the foundation of the modern patent system in the United States.”⁸⁴ One of the major changes under the revised Patent Act included the reimplementing of the examination requirement, namely that the application be examined for utility and novelty.⁸⁵ In 1850, the Supreme Court established an additional patentability requirement in *Hotchkiss v. Greenwood*,⁸⁶ the “flash of genius” standard, which much later evolved into the nonobviousness requirement.⁸⁷ The patent code was again revised in 1870.⁸⁸ This revision imposed the requirement that the patent applicant define his invention with more clarity by focusing on the patent’s claims.⁸⁹

Patent law underwent a major statutory revision in 1952.⁹⁰ Congress drafted the 1952 Act in response to an “anti-patent fervor”

⁷⁸ See CHISUM ET AL., *supra* note 1, at 16; see also Wong, *supra* note 77, at 118 (describing the Patent Clause as “both a grant of power and a limitation” with the specific objective of encouraging innovation, while avoiding monopolies that would stifle competition).

⁷⁹ CHISUM ET AL., *supra* note 1, at 16.

⁸⁰ *Id.* at 18.

⁸¹ *Id.* (quotations in original).

⁸² *Id.*

⁸³ *Id.* at 19.

⁸⁴ *Id.*

⁸⁵ CHISUM ET AL., *supra* note 1, at 20. Additionally, the 1836 Patent Act designated the Patent Office as a separate bureau of the Department of State, created the office of the Commissioner of Patents, created the patent numbering system, and also allowed for an applicant to appeal to a three member board if his application was rejected. *Id.* at 20-21.

⁸⁶ 52 U.S. 248 (1850).

⁸⁷ CHISUM ET AL., *supra* note 1, at 20.

⁸⁸ *Id.* at 21.

⁸⁹ *Id.*

⁹⁰ *Id.*

that was developing in the Supreme Court.⁹¹ The 1952 Patent Act, which serves as the current patent legislation codified under Title 35 of the United States Code,⁹² strengthened the patent system with respect to patentability and infringement issues.⁹³ In 1982, Congress established the Federal Circuit and vested in it exclusive jurisdiction over patent appeals.⁹⁴ Prior to 1982, the regional circuits heard patent appeals and issued disparate standards for patentability.⁹⁵ The Federal Circuit now provides a single forum to uniformly interpret the patent law on appeal, giving new force and validity to the patent law system in the United States.⁹⁶

B. Patentable Subject Matter and § 112 Requirements

A patent confers upon the patent holder “the right to exclude others from making, using, offering for sale, or selling the invention

⁹¹ *Id.* at 21-22. Between 1890 and 1930, the Court looked favorably at the patent system. This changed from 1930 to 1950, when the Court began to view the granting of patents with suspicion, largely because of the monopolistic nature of patents. *Id.* at 21. This negative outlook manifested in several Supreme Court decisions. For example, the Court’s decision in *Mercoïd Corp. v. Mid-Continent Investment Co.*, 320 U.S. 661 (1944), expanded the doctrine of patent misuse. In *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946), the Court invalidated the practice of “means plus function” claim drafting. Additionally, the Court required synergism for the patentability of combination patents in *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Co.*, 340 U.S. 147 (1950). CHISUM ET AL., *supra* note 1, at 21-22.

⁹² 35 U.S.C. § 1 *et seq.* (2001).

⁹³ Some provisions of the 1952 Act were enacted in response to the Supreme Court decisions that restricted certain patent law principles. *See supra* note 91. For example, the invalidation of “means plus function” which resulted from the *Halliburton* decision was overturned with the enactment of § 112. CHISUM ET AL., *supra* note 1, at 21-22. Sections 271(b), (c), and (d) reversed the Supreme Court’s broad reading of patent misuse and contributory infringement in *Mercoïd*. *Id.* Additionally, § 103 implemented an objective standard of nonobviousness which removed the synergism requirement set forth in the *Great Atlantic* decision. *Id.*

⁹⁴ The Federal Courts Improvement Act [hereinafter “the Act”] established the Federal Circuit. Pub. L. No. 97-164, 96 Stat. 25 (1982) (Apr. 2, 1982). *See generally* Dennis DeConcini, *Symposium Issue: Celebrating the Tenth Anniversary of the Court of Appeals for the Federal Circuit*, 14 GEO. MASON L. REV. 529 (1992). In an effort to ease the enormous caseload burdening the appellate courts of the federal judicial system, the Act consolidated the Court of Claims and the Court of Customs and Patent Appeals under the jurisdiction of the Federal Circuit. *Id.* The Act also sought to achieve national uniformity in the law, particularly in the area of patents. *Id.* at 532. During the time preceding the promulgation of the Act, patent law was in a state of complete disarray. *Id.* Thus, in order to regain consistency in the law and a more effective judicial system, the Federal Circuit became the appellate court with exclusive jurisdiction over patent appeals from federal district decisions. *Id.* at 534.

⁹⁵ CHISUM ET AL., *supra* note 1, at 22.

⁹⁶ Providing a single forum in which patent appeals could be heard improved the problems associated with forum shopping. *Id.*

throughout the United States or importing the invention into the United States” for a period of 20 years from the filing date of the application.⁹⁷ In order to receive a patent for an invention, the invention must fall within the statutory scope of patentable subject matter set forth in 35 U.S.C. § 101, which provides that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”⁹⁸ Generally, the claimed invention must satisfy the following requirements for patentability: novelty,⁹⁹ nonobviousness,¹⁰⁰ and utility.¹⁰¹

Several threshold issues must be addressed before determining whether the invention is patentably distinct from prior art. Initially, one must determine if the invention itself is the kind of invention that Congress contemplated as patentable.¹⁰² The invention must be a “process, machine, manufacture or composition of matter,” that is, one of the four categories of statutory subject matter articulated in section 101.¹⁰³

In the landmark case *Diamond v. Chakrabarty*,¹⁰⁴ the Supreme Court interpreted these statutory classes broadly to “include anything under the sun that is made by man.”¹⁰⁵ Chakrabarty sought a patent for a genetically engineered bacterium that was capable of degrading several components of crude oil.¹⁰⁶ The Court noted that naturally occurring subject matter generally does not qualify as patentable subject matter.¹⁰⁷ The Court, however, held that Chakrabarty’s genetically engineered bacterium was patentable subject matter, because as a result of the inventor’s own work it possessed markedly

⁹⁷ 35 U.S.C. § 154(a)(1)-(2) (2001).

⁹⁸ *Id.* at § 101.

⁹⁹ *See id.* at § 102.

¹⁰⁰ *See id.* at § 103.

¹⁰¹ *See id.* at § 101.

¹⁰² CHISUM ET AL., *supra* note 1, at 728.

¹⁰³ 35 U.S.C. § 101 (2001); *see* Karczewski, *supra* note 4, at 1054 (discussing the categories and limits of statutory subject matter and the inclusion of biotechnological inventions under the ruling in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)).

¹⁰⁴ *Chakrabarty*, 447 U.S. 303.

¹⁰⁵ *Id.* at 309 (citing Committee Reports, S. REP. NO. 82-1979 (1952); H.R. REP. NO. 82-1923 (1952)); *see also* Ben-Ami et al., *supra* note 73, at 557 (“[T]he Supreme Court’s 1980 decision in *Diamond v. Chakrabarty* opened the door for the patenting of virtually every kind of living matter . . .”).

¹⁰⁶ *Chakrabarty*, 447 U.S. at 305.

¹⁰⁷ *Id.* at 309.

different properties from the original bacterium.¹⁰⁸ Following this line of reasoning, biotechnological inventions may fall within the broad scope of patentable subject matter, because scientists go through the steps of isolating the gene from other molecules with which it is associated in its naturally occurring state.¹⁰⁹

Next, section 112 requires that the claims adequately teach one of ordinary skill in the art how to make and use¹¹⁰ the invention and to illustrate the best mode¹¹¹ of the invention. The claims must be definite¹¹² in scope and distinct from all other issued or allowable claims.¹¹³

C. *The Requirements of Novelty and Nonobviousness*

Once a patent application satisfies the requirements of 35 U.S.C. §§ 101 and 112, the claims must also satisfy the novelty requirements as set forth in 35 U.S.C. § 102.¹¹⁴ In general, the PTO will not grant patents for inventions that are not new or, in patent law language, have been “anticipated by the prior art.”¹¹⁵ To avoid anticipation, the invention must not have been known or used by others before the date of the invention.¹¹⁶ Also, the inventor will be statutorily barred from receiving a patent if an event occurs that triggers section 102(b).¹¹⁷ For example, the invention must not have been publicly used or offered for sale more than a year before the date of filing.¹¹⁸ Although many refer to section 102 “as a statutory mine field through which patent applicants must navigate in order to obtain a patent,” it is in place to ensure that patents are awarded to inventors for only novel inventions, provided that inventors file their patent

¹⁰⁸ *Id.* at 309-10.

¹⁰⁹ *Id.* at 310.

¹¹⁰ *See* 35 U.S.C. § 112 (2001).

¹¹¹ *See id.*

¹¹² *See id.*

¹¹³ *See supra* note 4.

¹¹⁴ The novelty requirement is embodied in subsections (a), (e), and (g) of § 102, and is triggered by the works of others. Subsections (b) and (d) of § 102 involve the inventor’s loss of right, which can result from the inventor’s own actions, such as failing to file an application within the statutory timeframe. *See generally* CHISUM ET AL., *supra* note 1, at 327; *see also* Mattias Luukonen, Note, *Gene Patents: How Useful Are the New Utility Requirements?*, 23 T. JEFFERSON L. REV. 337, 348 (2001) (discussing the novelty requirement for patentability).

¹¹⁵ 35 U.S.C. § 102(a) (2001); *see* CHISUM ET AL., *supra* note 1, at 323.

¹¹⁶ *Id.* at § 102(a).

¹¹⁷ *Id.* at § 102(b).

¹¹⁸ *Id.*

applications with diligence.¹¹⁹

The second hurdle, nonobviousness, prevents a person from obtaining patent protection for an invention that could already be considered to be in the public domain.¹²⁰ To satisfy section 103, the invention must be different, although not necessarily better, from the prior art.¹²¹ In *Hotchkiss*, the inventor sought a patent for substituting the metallic knob of a doorknob with a clay or porcelain knob.¹²² The Supreme Court denied the patent because of the absence of ingenuity on the part of the inventor.¹²³ The Court reasoned that the inventor must display some ingenuity or skill beyond that of an “ordinary mechanic.”¹²⁴ This holding essentially created the patentability requirement of nonobviousness.¹²⁵

D. The Utility Requirement

This Comment focuses on the utility requirement for patentability, as it applies to patent applications for gene sequences. An invention must be useful to be patentable. The requirement of utility is rooted in the constitutional goal of “promot[ing] the Progress of . . . useful Arts,”¹²⁶ and is currently codified in section 101 of the Patent Act.¹²⁷ Judicial interpretation of cases brought before the Supreme Court, the Federal Circuit, and its predecessor, the Court of Customs and Patent Appeals (“CCPA”),¹²⁸ largely defines the true meaning of this seemingly simple concept. From the earliest interpretation of utility in *Lowell v. Davis*¹²⁹ to the modern interpretation articulated in *Brenner v. Manson*,¹³⁰ the utility

¹¹⁹ CHISUM ET AL., *supra* note 1, at 323. Under § 102(b), the current time frame in which an inventor must file his application without losing his rights is twelve months after a triggering event. 35 U.S.C. § 102(b) (2001).

¹²⁰ CHISUM ET AL., *supra* note 1, at 514.

¹²¹ *Id.* at 515.

¹²² *Hotchkiss v. Greenwood*, 52 U.S. 248, 264 (1850).

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ CHISUM ET AL., *supra* note 1, at 515.

¹²⁶ U.S. CONST. art. I, § 8, cl. 8.

¹²⁷ 35 U.S.C. § 101 provides that, “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101 (2001).

¹²⁸ Donald L. Zuhn, Jr., *DNA Patentability: Shutting the Door to the Utility Requirement*, 34 J. MARSHALL L. REV. 973, 984 (2001); *see also* Machin, *supra* note 4, at 437 (listing the three sources of the current utility doctrine as the language in the Constitution, the Patent Act, and court decisions).

¹²⁹ 15 F. Cas. 1018 (D. Mass. 1817) (No. 8568).

¹³⁰ 383 U.S. 519 (1966).

requirement is undoubtedly a dynamic standard that continues to be redefined as the technological environment of the modern age changes.

Justice Story articulated one of the first interpretations of utility in *Lowell*.¹³¹ In 1817, Justice Story applied a *de minimis* standard to the utility requirement.¹³² He stated that a useful “invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society.”¹³³ This interpretation deemed an invention to be useful if it was neither harmful nor immoral to society.¹³⁴ Based on this morality standard, Justice Story also recognized that individuals would be able to obtain patents for inventions that were not “useful” in a practical sense.¹³⁵ Justice Story found this acceptable based on the reasoning that the “useless” invention “will silently sink into contempt and disregard,” bearing little importance or cost to the public.¹³⁶

Courts followed this low standard for patentability without much disruption for nearly 150 years.¹³⁷ In *Brenner v. Manson*,¹³⁸ however, the Supreme Court transformed the utility requirement into a more meaningful standard for patentability.¹³⁹ The Court held that a chemical process which produced a certain class of compounds was not useful under section 101.¹⁴⁰ Specifically, the process yielded certain steroid compositions which did not possess any tumor-inhibiting qualities.¹⁴¹ Chemically-related compounds, or homologues, however, produced these tumor-inhibiting effects in

¹³¹ *Lowell*, 15 F. Cas. 1019.

¹³² *Id.*

¹³³ *Id.* at 1019; see also Machin, *supra* note 4, at 435-36 (discussing the doctrine of moral utility as a doctrine intended to protect society from harm).

¹³⁴ *Lowell*, 15 F. Cas. at 1019.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ Zuhn, *supra* note 128, at 986.

¹³⁸ 383 U.S. 519 (1966).

¹³⁹ See Machin, *supra* note 4, at 428-30 (discussing the practical utility requirement that was created by the Supreme Court in *Brenner*).

¹⁴⁰ *Brenner*, 383 U.S. at 532.

¹⁴¹ *Id.* at 522. In this case, the Court specifically noted that their ruling was based on the fact the compound showed no utility, other than its potential role as a tumor-inhibiting compound in mice. Thus, the Court suggests that a different outcome may have resulted if the compound was useful as a tumor-inhibitor or useful in some other way. *Id.* at 532 n.17 (“In light of our disposition of the case, we express no view as to the patentability of a process whose sole demonstrated utility is to yield a product shown to inhibit the growth of tumors in laboratory animals.”). This highlights the emphasis the Court placed on the showing of some degree of utility as opposed to no utility at all. *Id.*

mice.¹⁴² The applicant attempted to obtain a patent for this process although he “did not disclose a sufficient likelihood that the steroid yielded by his process would have similar tumor-inhibiting characteristics.”¹⁴³

The Patent Office Examiner rejected the patent application for failing to disclose the utility associated with the chemical compounds produced by the process.¹⁴⁴ The CCPA rejected the Examiner’s position on utility by concluding that “where a claimed process produces a known product[,] it is not necessary to show utility for the product, so long as the product is not alleged to be detrimental to the public interest.”¹⁴⁵

The Supreme Court enunciated a practical standard for determining whether the disclosure of utility was sufficient. Although the Court decided *Brenner* over thirty years ago, years before the technological advances involving recombinant DNA technology, the Supreme Court’s opinion echoed concerns that are fully applicable to the current issues surrounding gene patents. Turning its focus away from a moral standard for utility, the Court reasoned that the nature of chemical inventions demanded a more thoughtful inquiry into utility.¹⁴⁶ The *quid pro quo* rationale behind patent legislation is to grant an inventor a patent monopoly in exchange for the benefit of his useful invention to society.¹⁴⁷

Without knowing the full extent of an invention’s utility, the Court opined that the public is threatened with danger by the grant of a monopoly that “may engross a vast, unknown, and perhaps unknowable area.”¹⁴⁸ Such a patent has the potential of stifling whole areas of scientific development, without providing any real benefit to society.¹⁴⁹ According to the Court, this is not the type of result contemplated by the Framers or by Congress when enacting patent legislation.¹⁵⁰ Rather, a patentable invention must possess “substantial utility” from which society may obtain a specific benefit.¹⁵¹

¹⁴² *Id.*

¹⁴³ *Id.* at 532.

¹⁴⁴ *Id.* at 521.

¹⁴⁵ *Id.* at 522 (internal quotations omitted).

¹⁴⁶ *Brenner*, 383 U.S. at 533-36.

¹⁴⁷ *Id.* at 534.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.* at 534-35; see also Ben-Ami et al., *supra* note 73, at 559 (“The *Brenner* standard is often referred to as ‘substantial utility’ or ‘practical utility’”) (internal quotations in original).

Recognizing the importance of scientific contributions falling short of a useful invention, the Court nonetheless clarified that “a patent is not a hunting license . . . [nor] a reward for the search, but compensation for its successful conclusion.”¹⁵²

In the following year, two CCPA decisions, *In re Kirk*¹⁵³ and *In re Joly*,¹⁵⁴ followed and expanded the “substantial” utility standard articulated in *Brenner*. Both cases involved patent applications for steroidal compounds which the applicants alleged were useful as intermediates for preparing other compounds with biological properties.¹⁵⁵ The CCPA concluded that, for purposes of the utility requirement, it is insufficient to assert that a chemical intermediate exists and is capable of producing “some intended product of no known use.”¹⁵⁶ Nor is it sufficient, the court added, to assert that the product of the chemical intermediate belongs to a class of compounds that may one day be the subject of research to determine specific use.¹⁵⁷ In the realm of patent legislation, the court noted that it is not the responsibility of the public, the PTO, or the courts “to play . . . [a] guessing game” in determining the utility of an invention.¹⁵⁸

Judge Rich and Judge Smith, the only CCPA judges who had patent law experience, offered important dissenting opinions in *Kirk* and *Joly*.¹⁵⁹ Judge Rich, one of the principal drafters of the 1952 Patent Act, made several cogent observations.¹⁶⁰ Judge Rich reviewed both the legislative history and court decisions pertaining to the meaning of “useful.”¹⁶¹ According to Judge Rich, the term “utility” was a prerequisite to patentability from the first patent legislation in 1790 to the current legislation enacted in 1952.¹⁶² Throughout that 162-year span, there was an absence of legislative history suggesting that the utility requirement should be changed.¹⁶³

Judge Rich also noted that the *Brenner* Court could not find

¹⁵² *Brenner*, 383 U.S. at 536.

¹⁵³ 376 F.2d 936 (C.C.P.A. 1967).

¹⁵⁴ 376 F.2d 906 (C.C.P.A. 1967).

¹⁵⁵ *Kirk*, 376 F.2d at 939; *Joly*, 376 F.2d at 907.

¹⁵⁶ *Kirk*, 376 F.2d at 945.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* at 942.

¹⁵⁹ CHISUM ET AL., *supra* note 1, at 714.

¹⁶⁰ Judge Giles Sutherland Rich is extensively regarded as “the founding father of modern patent law.” *Id.* at 22-23.

¹⁶¹ *Kirk*, 376 F.2d at 954-55.

¹⁶² *Id.* at 954 (Rich, J., dissenting).

¹⁶³ *Id.*

assistance in the legislative materials of section 101 which was enacted under the 1952 Act. Judge Rich opined that this was so because “the legislature was then taking no action with respect to that provision except to reenact it without change, wherefore the true ‘legislative materials’ necessarily consist only of its long history of construction and repeated reenactment without change.”¹⁶⁴ Furthermore, case law indicated that “any degree of utility to anybody was legal ‘utility.’”¹⁶⁵ Thus, Congress enacted the present statute, 35 U.S.C. § 101, without any intention to change the law.¹⁶⁶ Judge Rich suggested that the majority in *Kirk* was engaging in judicial law-making, as there was no basis in either the legislative history or case law for further raising the standards of utility.¹⁶⁷

Judge Rich also criticized the majority’s reliance on the *quid pro quo* philosophy.¹⁶⁸ The majority erroneously factored the degree of an invention’s utility as part of the *quid pro quo* of patent system.¹⁶⁹ To the contrary, Judge Rich pointed out that the degree of utility is not of public concern.¹⁷⁰ “The only *quid pro quo* demanded by statute is full disclosure of a new and unobvious invention which is of some use to someone.”¹⁷¹ Judge Rich noted that a patentee has never been required to explain the full extent of utility of his invention, most often because this is rarely known until years after the invention has been made.¹⁷²

Lastly, Judge Rich expressed concern regarding the definition of “practical,” “substantial,” or “specific” utility and the foreseeable administrative problems that may ensue from these “impossible-to-define” criteria.¹⁷³ According to Judge Rich, if the problem of chemical utility could not be resolved by the courts, Congress should address the issue.¹⁷⁴ Judge Rich offered his own interpretation of the best rule from an administrative standpoint, that all “chemical compounds are per se ‘useful’ within the meaning of 35 U.S.C. 101 . .

¹⁶⁴ *Id.*

¹⁶⁵ *Id.* (internal quotations in original).

¹⁶⁶ *Id.* (arguing that cases, texts, and administrative practice clearly demonstrate that Congress did not intend to impose any changes on the utility requirement with the promulgation of the Patent Act of 1952).

¹⁶⁷ *Kirk*, 376 F.2d at 954.

¹⁶⁸ *See generally id.* at 955.

¹⁶⁹ *Id.* at 955.

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ *Kirk*, 376 F.2d at 957.

¹⁷⁴ *Id.*

. . .”¹⁷⁵ Judge Rich reasoned that such a rule would encourage researchers to develop, disclose, and market new compounds which could then be put to experimental use.¹⁷⁶ New uses would be developed, thereby conferring a benefit to the public by advancing the art.¹⁷⁷ Judge Smith joined Judge Rich and issued his own dissenting opinion in *Joly*, in which he purported to demonstrate how the majority’s opinion “amount[ed] to no less than a usurpation of the authority exclusively granted to Congress by Art. I, Sec. 8, Clause 8, of the Constitution.”¹⁷⁸

While *Kirk* and *Joly* clearly embraced the more stringent interpretation of the utility standard set forth in *Brenner*, the ruling of the CCPA in *In re Krimmel* initiated the modern trend of liberalizing the utility test for pharmaceuticals.¹⁷⁹ In that case, the PTO denied a patent application for eye medicine.¹⁸⁰ Although the applicant demonstrated that the medicine worked on rabbits, the PTO and Board of Appeals found that use insufficient to satisfy the utility requirement.¹⁸¹ The CCPA reversed, holding that that the medication was useful for a purpose set forth in the patent application.¹⁸² The court stated that “one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment of humans.”¹⁸³

In 1985, the Federal Circuit examined the “practical utility” standard in *Cross v. Iizuka*.¹⁸⁴ This case involved an appeal of an interference proceeding¹⁸⁵ between parties claiming priority for certain imidazole derivative compounds.¹⁸⁶ The compounds allegedly inhibited the synthesis of thromboxane synthetase, an enzyme

¹⁷⁵ *Id.* at 957.

¹⁷⁶ *Id.* at 957-58.

¹⁷⁷ *Id.*; see also CHISUM ET AL., *supra* note 1, at 713-14.

¹⁷⁸ *Joly*, 376 F.2d at 910.

¹⁷⁹ 292 F.2d 948 (C.C.P.A. 1961).

¹⁸⁰ *Id.* at 949.

¹⁸¹ *Id.* at 949-50.

¹⁸² *Id.* at 953-54.

¹⁸³ *Id.* at 953.

¹⁸⁴ 753 F.2d 1040 (Fed. Cir. 1985).

¹⁸⁵ An interference is a procedure that can be declared between two or more parties before the Board of Patent Appeals when the parties claim the same patentable invention. 37 C.F.R. § 1.601(i) (2002). During the proceeding, issues of patentability and priority of invention are determined. *Id.*

¹⁸⁶ *Cross*, 753 F.2d at 1041.

implicated in the formation of platelet aggregation.¹⁸⁷ On the issue of utility, the Federal Circuit held that *in vitro*¹⁸⁸ testing, supplemented with *in vivo* pharmacological activity involving structurally similar compounds, was sufficient to establish practical utility under § 101.¹⁸⁹ The court relied in part on the accepted practice of *in vitro* testing in the pharmaceutical industry as being a reasonable predictor of utility in mammals.¹⁹⁰

The Federal Circuit's more recent decision in *In re Brana*¹⁹¹ exemplifies the modern trend of a more relaxed utility standard. Applicants appealed the denial of a patent application for anti-tumor compounds.¹⁹² The PTO based the denial on the fact that the application did not identify a specific human disease or condition which was treatable by the compounds.¹⁹³ The claimed agents were, however, screened for anti-tumor activity with *in vivo* testing in mice.¹⁹⁴ The PTO concluded that *in vivo* testing in animals was insufficient to establish utility for treating cancer in humans.¹⁹⁵ In essence, the PTO argued that efficacy in animals is not a reasonable predictor for utility in treating corresponding human diseases or conditions.¹⁹⁶ Relying on *Krimmel*, the Federal Circuit disagreed and concluded that the applicant had, in fact, satisfied the utility standard through the use of *in vivo* tests in experimental animals.¹⁹⁷ "Title 35 does not demand that such human testing occur within the confines of . . . [the PTO] proceedings."¹⁹⁸ The court noted that approval by the Food and Drug Administration ("FDA"), in the context of pharmaceutical inventions, is not a prerequisite to the utility requirement under section 101.¹⁹⁹ Moreover, it is expected that these types of inventions will require further testing and experimentation

¹⁸⁷ *Id.* at 1042.

¹⁸⁸ *Id.* at 1043 n.6 (noting that *in vitro* generally refers to a testing environment outside of the living organism, whereas *in vivo* refers to the environment inside a living organism).

¹⁸⁹ *Id.* at 1051.

¹⁹⁰ *Id.* at 1050 (noting that *in vitro* is generally less expensive, less complex and more time-efficient than *in vivo* testing methods).

¹⁹¹ 51 F.3d 1560 (Fed. Cir. 1995).

¹⁹² *Id.* at 1562.

¹⁹³ *Id.* at 1563.

¹⁹⁴ *Id.* at 1562.

¹⁹⁵ *Id.* at 1567.

¹⁹⁶ *Id.*

¹⁹⁷ *Brana*, 51 F.3d at 1567-68; see also *supra* text accompanying notes 179-83.

¹⁹⁸ *Id.* at 1567.

¹⁹⁹ *Id.* at 1568.

before reaching a stage that is useful to humans.²⁰⁰ Requiring scientists to prove the advanced stages of utility would stifle significant areas of research due to high costs and low incentives to discover new inventions.²⁰¹

The Federal Circuit articulated its retreat from the CCPA's stringent interpretation of utility, and moved toward the direction of Judge Rich's view in *Kirk*, by setting forth a two-step analysis for determining the utility of an invention.²⁰² First, the PTO has the burden of challenging "a presumptively correct assertion of utility in the disclosure."²⁰³ Second, "after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility . . . the burden shift[s] to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility."²⁰⁴ Thus, with the initial burden on the PTO to cast doubt based on scientific evidence of an invention's utility, the dynamic utility requirement became less of an insurmountable hurdle as it once was before the days of *Brenner*.²⁰⁵

In keeping with this more relaxed view of the utility requirement, the Federal Circuit recently upheld the validity of a patent in *Juicy Whip, Inc. v. Orange Bang, Inc.*,²⁰⁶ for an invention that did not possess a substantial utility.²⁰⁷ Although this case did not involve a biotechnological invention, the *Juicy Whip* opinion elucidates the Federal Circuit's most recent interpretation of the utility standard. The invention claimed was "a post-mix beverage dispenser that [was] designed to look like a pre-mix dispenser."²⁰⁸ The District Court for the Central District of California concluded that the invention lacked utility because it deceived customers and increased sales by imitation.²⁰⁹

The Federal Circuit reversed the district court's ruling.²¹⁰ In articulating the standard for utility, the court stated that "[t]he threshold of utility is not high: [a]n invention is 'useful' under

²⁰⁰ *Id.*

²⁰¹ *Id.*

²⁰² *Id.* at 1566.

²⁰³ *Brana*, 51 F.3d at 1566.

²⁰⁴ *Id.*

²⁰⁵ See *supra* text accompanying notes 131-36.

²⁰⁶ 185 F.3d 1364 (Fed. Cir. 1999).

²⁰⁷ *Id.* at 1368.

²⁰⁸ *Id.* at 1365.

²⁰⁹ *Id.*

²¹⁰ *Id.*

section 101 if it is capable of providing some identifiable benefit.”²¹¹ Under this standard, “[t]he fact that one product can be altered to make it look like another is in itself a specific benefit sufficient to satisfy the statutory requirement of utility.”²¹² Furthermore, when the court addressed public policy concerns regarding deceptive trade practices, the court noted that the utility requirement is not a means through which the PTO must take on the role of arbiters of deceptive trade practices.²¹³ Rather, it is the responsibility of “[o]ther agencies, such as the Federal Trade Commission (FTC) and the [FDA],” to protect customers from fraud, deception, or other harms.²¹⁴ The court concluded with the clear assertion that, until it is declared by Congress that inventions are unpatentable for reasons such as deceptiveness, there is no basis under section 101 to deny these inventions patent protection.²¹⁵ Accordingly, the prevailing view deems that any disclosed identifiable benefit satisfies the utility requirement and that the PTO has the burden of refuting the presumptive presence of such utility.

III. THE PATENT “GOLD RUSH” AND THE RAISED UTILITY STANDARDS

A. *The Rise of Patent Applications for Gene Sequences in the PTO*

After developing a sequencing method that allowed for rapid identification of active gene sequences in the human genome,²¹⁶ the NIH quickly sought patent protection for more than three hundred of these partial DNA sequences.²¹⁷ This move by the NIH initiated the ongoing debate over whether partial DNA sequences are patentable when the sequence alone reveals no information about the corresponding full-length gene and its protein function.²¹⁸

²¹¹ *Id.* at 1366 (internal quotations in original).

²¹² 185 F.3d at 1367.

²¹³ *Id.* at 1368.

²¹⁴ *Id.*

²¹⁵ *Id.*

²¹⁶ See *supra* notes 45-49 and accompanying text.

²¹⁷ The NIH applications included broad claims that had the effect of covering genes and protein beyond the length of the specified sequence. See Zuhn, *supra* note 128, at 977-78 (stating that although the NIH was unaware of the full length gene to which the EST corresponded, it sought patent protection over the partial gene sequence, the full length sequence of the corresponding gene and the protein products, which the full length sequence encoded); see also Pieroni, *supra* note 42, at 411 (“[A] very broad claim might cover the actual protein coded for by that gene . . . based on very little of the gene itself. In fact, this is what the NIH had attempted to claim in its earliest applications . . .”).

²¹⁸ See Bernadine Healy, *On Gene Patenting*, 327 N. ENGL. J. MED. 664, 665 (1992).

Although the NIH apparently did not understand the full biological utility of the claimed sequence, it did specify various utilities associated with the ESTs. In particular, the NIH asserted that the sequences could serve as probes to differentiate between brain tissue and other types of tissue.²¹⁹ Alternatively, the NIH asserted that the sequence could be used to construct oligonucleotides necessary for various laboratory techniques.²²⁰

After two rounds of rejection on its initial filing by the PTO, the NIH ultimately abandoned its initial efforts toward procuring patent protection for EST sequences.²²¹ Their withdrawal, however, did not discourage public and private companies from following their lead.²²² Rather, genomics companies and institutions rapidly filed patent applications for full or partial gene sequences.²²³ Some of the most active players in the race were Human Genome Sciences,²²⁴ InCyte Genomics,²²⁵ Celera Genomics,²²⁶ and the University of California.²²⁷ The PTO issued the first patent for an EST to InCyte Pharmaceuticals, Inc. on October 6, 1998.²²⁸ Contrary to the intense opposition the NIH faced when it filed its first applications for ESTs,²²⁹ the PTO issued U.S. Patent No. 5,817,479²³⁰ (the '479 Patent)

²¹⁹ See Zuhn, *supra* note 128, at 978 (citation omitted).

²²⁰ *Id.* at 978-79 (noting that "EST sequences could be used to design oligonucleotides for use in chromosomal analysis, the polymerase chain reaction, recovery of the corresponding full-length gene, as diagnostic markers for disease, or in the design of antisense therapeutics") (citations omitted).

²²¹ *Id.* at 982. The NIH announced that seeking patent protection for gene sequences without known function was "not in the best interests of the public or science." *Id.* at n.65 (quotations in original). During the filing of these applications, the NIH was a target of much criticism of the biotech industry. See generally *id.* at 979-83; see also Ben-Ami et al., *supra* note 73, at 558 ("[T]he NIH provoked a blizzard of criticism from scientists when it filed patent applications covering thousands of ESTs.").

²²² Zuhn, *supra* note 128, at 983.

²²³ See Antonio Regalado, *The Great Gene Grab*, TECH. REV., available at <http://www.technologyreview.com/magazine/sep00/regalado.asp> (Sept./Oct. 2000) (on file with author).

²²⁴ Human Genome Sciences, Inc. in Rockville, Maryland, is the commercial counterpart to The Institute of Genomic Research in Gaithersburg, Maryland, which is a non-profit research institution that was created by Dr. Venter after he left the NIH in 1992. Zuhn, *supra* note 128, at n.69.

²²⁵ InCyte Genomics of Palo Alto, California, holds close to 400 patents for gene sequences. Regalado, *supra* note 223.

²²⁶ See *supra* text accompanying note 51.

²²⁷ See Regalado, *supra* note 223.

²²⁸ Ben-Ami et al., *supra* note 73, at 560 n.17.

²²⁹ The NIH received much criticism from a number of members of the scientific community for seeking patent protection for partial gene sequences without knowing the full biological activity of the corresponding full-length gene. See

with relatively little resistance.²³¹ In particular, the asserted utilities specified in the '479 Patent apparently satisfied the PTO's requirement for utility, since no rejections based on lack of utility were made.²³² The '479 Patent, entitled "Human Kinase Homologs," differed from the NIH filing in that it did not contain very broad claims.²³³ Rather, the patent claimed forty-four EST sequences that could be used to identify novel protein kinases.²³⁴ Additionally, the PTO Examiner concluded that the ESTs "can be used to generate kinase homologs."²³⁵ Although the '479 Patent appeared to have passed the utility requirement hurdle with relative ease, this was not the case for the many EST patent applications that followed.²³⁶ The issuance of the '479 Patent was, however, a clear indication from the PTO that under certain circumstances, EST sequences are deemed worthy of patent protection.²³⁷

B. The Utility Examination Guidelines

In response to the increasing number of patent applications for biotechnological inventions, the PTO established Utility Examination Guidelines in 1995 ("1995 Guidelines").²³⁸ The 1995 Guidelines established a two-pronged inquiry for utility.²³⁹ According to the inquiry, the invention had to assert a utility that was "specific" and

generally Zuhn, *supra* note 128, at 978-82 (noting that critics of the NIH filing included James Watson; Nobel Laureate Paul Berg; C. Thomas Caskey, who is President of the Human Genome Organization; and the Industrial Biotechnology Association); *see also* Pieroni, *supra* note 42, at 411 (stating that the NIH also received pressure from patent and research agencies outside of the United States, including Britain's science minister, Alan Howarth).

²³⁰ U.S. Patent No. 5,817,479 (issued Oct. 6, 1998).

²³¹ *See* Ben-Ami et al., *supra* note 73, at 560-61.

²³² The '479 Patent states that the claimed sequences can be used as "hybridization probes, for chromosome and gene mapping, in PCR technologies, in the production of sense or antisense nucleic acids, in screening for new therapeutic molecules, etc." U.S. Patent No. 5,817,479 (issued Oct. 6, 1998).

²³³ *See* Pieroni, *supra* note 42, at 412.

²³⁴ U.S. Patent No. 5,817,479 (issued Oct. 6, 1998). For further discussion on the InCyte patent, *see* Holman & Munzer, *supra* note 67, at 770-71.

²³⁵ Ben-Ami et al., *supra* note 73, at 561 (quotations in original).

²³⁶ *See* Holman & Munzer, *supra* note 67, at 771 (explaining how the InCyte patent is distinguishable from other EST patents because the sequences are "all from a known protein family (kinases) with a known function (signaling)").

²³⁷ Ben-Ami et al., *supra* note 73, at 560.

²³⁸ Utility Examination Guidelines, 60 Fed. Reg. 36323 (July 14, 1995) [hereinafter Utility Examination Guidelines II].

²³⁹ 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).

“credible” to satisfy the utility requirement.²⁴⁰ To assess “specific” utility, patent Examiners need to determine whether a particular purpose for the invention was clearly articulated.²⁴¹ Credibility, on the other hand, was demonstrated if one of ordinary skill in the art would have been convinced of the asserted utility based on all of the facts and reasoning provided in each case.²⁴²

The Commissioner of the PTO, Bruce Lehman, explained that the 1995 Guidelines reflected the PTO’s position that proper deference should be accorded to the experts in the field of biotechnology.²⁴³ In reviewing patent applications, the role of patent Examiners was very clear—to evaluate the credibility of an asserted utility.²⁴⁴ This approach was a far cry from the “substantial” utility approach articulated in *Brenner*. It appeared that the PTO adopted a highly deferential, rubber stamp approach for the determination of an invention’s utility.²⁴⁵ The public quickly criticized the 1995 Guidelines because the guidelines did not require a showing of “substantial” utility.²⁴⁶ Thus, the 1995 Guidelines had the practical effect of lowering the utility requirement or “propping open the ‘door’ to section 101,”²⁴⁷ which was indicative of the PTO’s implicit acceptance over the patenting of EST sequences.²⁴⁸

The PTO modified their position once again on January 5, 2001 when it published the current, revised version of the Guidelines.²⁴⁹

²⁴⁰ *Id.* at 459. More specifically, the Guidelines instructed patent Examiners not to reject an application for lack of utility “[i]f the applicant has asserted that the claimed invention is useful for any particular purpose . . . and that assertion would be considered credible by a person of ordinary skill in the art” Utility Examination Guidelines II, *supra* note 238.

²⁴¹ See Meigs, *supra* note 239, at 460.

²⁴² *Id.*

²⁴³ See Knight, *supra* note 39, at 1015.

²⁴⁴ *Id.*

²⁴⁵ *Id.*

²⁴⁶ Ben-Ami et al., *supra* note 73, at 559 (“Critics of the PTO guidelines [were] quick to point out that the standard of utility embodied in the guidelines [fell] short of that imposed by the Supreme Court in *Brenner*.”).

²⁴⁷ See Zuhn, *supra* note 128, at 992; see also Knight, *supra* note 39, at 1015 (explaining that the 1995 Guidelines made rejections based on utility highly unlikely).

²⁴⁸ See Zuhn, *supra* note 128, at 983 (“[The] new Utility Examination Guidelines . . . seemingly removed some obstacles from the patenting of EST sequences.”).

²⁴⁹ Utility Examination Guidelines I, *supra* note 11. The publication noted that the Guidelines were to be used for internal practices to assist PTO personnel in determining whether an invention complies with the utility requirement under § 101. *Id.* “The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable.” *Id.* at 1098.

Prior to publication, the PTO issued Interim Guidelines and requested comments from the public.²⁵⁰ The Interim Guidelines differed from the 1995 Guidelines by restoring the *Brenner* rationale and adding the requirement of “substantial” utility.²⁵¹ The PTO received comments from seventeen organizations and thirty-five individuals.²⁵² Most comments approved of the incorporation of a “substantial” utility requirement along with the shift toward the stringent interpretation of utility.²⁵³ It was apparent that the industry had the same concerns regarding overbroad patent protection for partial length gene sequences that were expressed ten years earlier, when the NIH filed the first applications for ESTs.²⁵⁴

Under the revised Guidelines, a biotechnological invention must possess a “well-established utility.”²⁵⁵ This can be established if the utility is “specific, substantial, and credible.”²⁵⁶ The standard for credibility has not varied greatly from the standard set forth in the 1995 Guidelines.²⁵⁷ “Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record.”²⁵⁸ The main difference lies in the “specific” and “substantial” utility prongs of the test.²⁵⁹

The scope of a “specific” utility has expanded under the new Guidelines.²⁶⁰ Contrary to the liberal standard for “specific” utility adopted in the 1995 Guidelines,²⁶¹ an inventor must do more than clearly assert a particular purpose for the invention.²⁶² Under the new Guidelines, the utility must be specific to the claimed subject matter.²⁶³ This means that an asserted utility as a gene probe, for example, would only be acceptable if a specific DNA target is

²⁵⁰ Revised Interim Utility Examination Guidelines, 64 Fed. Reg. 71440 (Dec. 21, 1999).

²⁵¹ *Id.*

²⁵² Utility Examination Guidelines I, *supra* note 11, at 1092.

²⁵³ *Id.*

²⁵⁴ See *supra* note 229.

²⁵⁵ Utility Examination Guidelines I, *supra* note 11, at 1098.

²⁵⁶ *Id.*

²⁵⁷ See *supra* text accompanying note 242; see also Stephen G. Kunin, *Written Description Guidelines and Utility Guidelines*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 77, 97 (2000) (“The revision is not intended to change current PTO practice with regard to assessing the credibility of any asserted utility.”).

²⁵⁸ Utility Examination Guidelines I, *supra* note 11, at 1098.

²⁵⁹ See Kunin, *supra* note 257, at 96-97.

²⁶⁰ *Id.* at 96-99.

²⁶¹ See *supra* text accompanying note 241.

²⁶² See Kunin, *supra* note 257, at 96-99.

²⁶³ See Meigs, *supra* note 239, at 464.

disclosed.²⁶⁴ Similarly, a diagnostic utility would be considered a specific utility only if a specific disease or condition is likewise disclosed.²⁶⁵ Under this standard, generalized utilities, such as the utilities asserted in *Kirk*, would be grounds for rejection under section 101.

The last hurdle under the new Guidelines is the “substantial” utility requirement. Although the PTO does not clearly define “substantial” utility, the Guidelines suggest that the invention must have a real world use.²⁶⁶ The amount of additional research required to yield an immediate benefit is one factor toward the determination of whether an invention has real world use.²⁶⁷ “Throw-away” utilities, such as the use as ballast or “the use of a complex invention as a landfill,” are insufficient to meet this requirement.²⁶⁸ By requiring the invention to possess a real world benefit, the Supreme Court’s rationale in *Brenner* has once again become the standard for utility in the PTO. If an inventor fails to show “well-established” utility, the patent Examiner would reject the claims under section 101.²⁶⁹ Thus, partial length gene sequences are deemed unpatentable if the asserted uses for the sequence fall short of the *Brenner*-like standard incorporated in the current Guidelines.

C. The Practical Effect of the “Credible, Specific, and Substantial” Utility Standard

The critical issue regarding the new Guidelines is the actual effect the raised utility standard has on patent applications. The Guidelines do not clearly delineate a bright line standard between a substantial and a non-substantial utility. Rather, every patent Examiner is provided with instructions in the form of training materials that assist them in making utility determinations.²⁷⁰ For example, in the Revised Interim Utility Guidelines Training Materials, the synopsis states, “It is . . . assumed that some ‘utility’ is

²⁶⁴ *Id.*

²⁶⁵ *Id.*

²⁶⁶ See generally Utility Examination Guidelines I, *supra* note 11, at 1098; see also Timothy A. Worrall, *The 2001 PTO Utility Examination Guidelines and DNA Patents*, 16 BERKELEY TECH. L.J. 123, 133 (2001) (“[T]he training materials require that a claimed invention have a substantial utility that defines a ‘real world use.’”) (citing United States Patent and Trademark Office, Revised Interim Utility Guidelines Training Materials (Jan. 21, 2000), available at <http://www.uspto.gov>).

²⁶⁷ See Kunin, *supra* note 257, at 98.

²⁶⁸ Utility Examination Guidelines I, *supra* note 11, at 1098.

²⁶⁹ *Id.*

²⁷⁰ See *infra* note 271.

disclosed in the specification or is recognized to be well-established in the art. The Examiner should determine whether any asserted utility is specific and substantial, and if so, determine whether such asserted utility is credible.”²⁷¹ Actual examples of claim rejections based on lack of utility under section 101 help to clarify this general instruction.

In the first example, a patent application claimed specific nucleic acid compounds which purported to encode a certain type of protein.²⁷² During prosecution, the Examiner rejected the claims because the “nucleic acids [were] not supported by a specific asserted utility because the disclosed uses of the nucleic acids are not specific and are generally applicable to any nucleic acid.”²⁷³ Specifically, the Examiner ultimately arrived at the following conclusion:

[N]o substantial utility has been established for the claimed subject matter. For example, any nucleic acid can produce a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility.²⁷⁴

In response to the rejection, the applicant asserted that the claimed invention did possess a well-established utility.²⁷⁵ The applicant noted that the claimed sequences comprised certain functional and structural features, which were intrinsic to the family of genes that encoded this specific class of proteins.²⁷⁶ Furthermore, the applicant stated that the sequences were useful in selecting and making oligomers for a gene-chip assay which would aid in monitoring the expression levels of these proteins.²⁷⁷ Notwithstanding these asserted utilities, the Examiner maintained the

²⁷¹ Revised Interim Utility Guidelines Training Materials, *available at* <http://www.uspto.gov/web/menu/utility.pdf> (last visited Jul. 7, 2002) (on file with author).

²⁷² Because the case in which this information is taken is still pending, identifying information has been redacted to preserve confidentiality. The Office Action, dated January 23, 2001, is on file with the author.

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ Applicant’s response, dated June 25, 2001, is on file with the author.

²⁷⁶ *Id.*

²⁷⁷ *Id.*

rejections under section 101.²⁷⁸

A similar rejection was sustained in a second patent application where the claimed invention involved another class of proteins and the polynucleotides encoding them.²⁷⁹ The Examiner rejected the claims because “none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities.”²⁸⁰ Furthermore, the Examiner noted that the “non-specific uses [asserted] . . . are applicable to proteins in general and [are] not particular or specific to nucleic acid(s) and/or protein(s) being claimed.”²⁸¹ In response, the applicant indicated specific ways in which the encoded proteins could be used.²⁸² The applicant noted that the novel proteins are capable of inducing biological activities such as bone, cartilage, or connective tissue formation.²⁸³ The proteins could also be used for increasing the activity of additional bone morphogenetic proteins.²⁸⁴ Additionally, the invention possesses a well-established utility as a research tool that is used in characterizing an important class of human proteins with which it shares significant structural and functional similarities.²⁸⁵ Thus, contrary to the Examiner’s basis for rejection, the applicant illustrated ways in which these utilities would not be shared by any general protein. Whether these assertions are enough to overcome the utility rejections is yet to be determined.

IV. LEGAL CHALLENGES TO THE NEW UTILITY GUIDELINES

As the federal agency responsible for the administration of patent laws,²⁸⁶ the PTO plays a crucial role in the granting of patent rights for inventions that are truly worthy of protection. The responsibility of differentiating between patentable and non-patentable inventions has become a more challenging task due to the unique nature of gene sequences. It is clear that gene patent applications must be handled with caution. DNA patentability

²⁷⁸ *Id.*

²⁷⁹ Identifying information has been redacted to preserve confidentiality. The Office Action, dated April 18, 2001, is on file with the author.

²⁸⁰ *Id.*

²⁸¹ *Id.*

²⁸² Applicant’s responses, dated August 20, 2001 and April 11, 2001, are on file with the author.

²⁸³ *Id.*

²⁸⁴ *Id.*

²⁸⁵ *Id.*

²⁸⁶ *See* 35 U.S.C. § 1(a) (2001).

invokes concerns such as the distortion of research priorities, stifled scientific research, the potential for increased licensing complexity and costs, and costly ownership disputes.²⁸⁷ Undoubtedly, researchers should be rewarded for their efforts to identify potentially useful sequences. Because of the implications arising from gene patents, however, their reward should be commensurate with the benefit received from the disclosure of the sequence. The raised utility standard illustrates the PTO's attempt to resolve these issues.

It is clear that the PTO does not have unfettered discretion on these matters. The Federal Circuit clearly stated that "[t]he Guidelines, like the Manual of Patent Examining Procedure ("MPEP") are not binding on th[e] court, but may be given judicial notice to the extent they do not conflict with the statute."²⁸⁸ The PTO is bound by the laws that Congress enacted and the judicial interpretation of such laws.²⁸⁹ An analysis of the current state of the law suggests that the "credible, specific and substantial" utility standard demands a showing of utility beyond what Congress intended.

Although the current guidelines may appear to be consistent with the Supreme Court's holding in *Brenner*, the facts of that case suggest that the Court did not intend to create a raised utility standard that is applicable to all inventions.²⁹⁰ Rather, as Judge Rich noted in his dissent in *Kirk*, the facts of *Brenner* must be distinguished from other cases addressing the utility requirement.²⁹¹ In particular, *Brenner* involved an interference proceeding where the main issue focused on Manson's supporting affidavits which failed to disclose any utility for the compounds that resulted from his claimed process.²⁹² This was distinguishable from the circumstances in *Kirk*, where there was "admitted disclosure of utility of the compounds as

²⁸⁷ See Daniel R. Kimball, *Patenting Genes: Risks and Rewards vs. Politics and Policies*, available at http://www.cph.com/Publications/patenting_genes.html (last visited Nov. 18, 2001) (discussing arguments for and against the patenting of ESTs) (on file with author).

²⁸⁸ *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1324 (Fed. Cir. 2002).

²⁸⁹ According to the specific powers enumerated in the Patent Act, the PTO "may establish regulations, not inconsistent with the law, which shall govern the conduct of proceedings in the Office." 35 U.S.C. § 2(b)(2)(A) (2001).

²⁹⁰ See *Kirk*, 376 F.2d at 948 (Rich, J., dissenting) ("I cannot believe that the purpose of the Supreme Court majority in *Manson* was to decide future issues in patent law unwittingly, [by] virtue of lower court expansion of its dictum, without knowing the implications of such decisions.").

²⁹¹ *Id.*

²⁹² *Id.*; see also *supra* note 141.

intermediates to make certain steroids.”²⁹³

Furthermore, decisions by the Federal Circuit in cases following *Brenner* articulate a return to the low pre-*Brenner* utility standard, which generally posed no obstacle to those seeking patent protection for their inventions. Thus, it appears that the PTO has arbitrarily raised the bar for the utility standard, by imposing Guidelines that adhere to the stringent interpretation of the utility standard when there is an absence of legislative history suggesting that inventions must show a higher degree of utility to be patentable.

By judging patent applications against the “specific, substantial, and credible” utility standard, the PTO is effectively denying patents to inventions that should receive patent protection. The PTO has exceeded its authority by rejecting patent applications for inventions that possess sufficient utility under the current legal standard of utility and by demanding the “specific, substantial, and credible” utility under the Guidelines. The PTO is not authorized to engage in legislative and judicial rulemaking by substituting their judgment for utility in place of Congress and the judiciary. The *ultra vires* actions may cause substantial damage to applicants who wish to share the benefits of their research, but with the *quid pro quo* of a patent.

This Comment proposes that the PTO remove the requirement of a “credible, specific, and substantial” utility. Because the term “substantial” was used throughout the *Brenner* decision, the PTO incorporated “substantial utility” into the Guidelines. What constitutes “substantial utility,” however, is a matter that is defined by the *Brenner* decision, the legislative history of the utility requirement under section 101,²⁹⁴ and the Federal Circuit’s interpretation of utility as discussed in cases following *Brenner*. Injustice may result when “substantial” is interpreted to mean a certain degree of utility. As Judge Rich explained in his dissent in *Kirk*, section 101 does not require a specific degree of utility for patentability.²⁹⁵ Any degree of utility, and not an absence of utility as was the case in *Brenner*, would satisfy the requirement.²⁹⁶ As a practical matter, much additional time and expense would be required to reach conclusions as to how a specific encoded protein would act biologically.

²⁹³ *Id.* at 949.

²⁹⁴ See *infra* text accompanying notes 305-09.

²⁹⁵ *Kirk*, 376 F.2d at 954.

²⁹⁶ See *infra* text accompanying notes 303-04.

A. *Judge Giles S. Rich: A Closer Look at Brenner and the Legislative History of the Utility Requirement*

Given his significant involvement in drafting the 1952 Patent Act, his longevity on the bench, and his stature as a jurist, significant attention must be paid to the observations made by Judge Rich in his dissenting opinion in *Kirk*, which support a lower standard of utility under section 101.²⁹⁷ In its entirety, Judge Rich's dissenting opinion articulates rationale for not extending the "substantial" utility requirement beyond the facts of *Brenner*.²⁹⁸ Judge Rich began by noting that *Brenner* was factually distinguishable from *Kirk*, and therefore was not controlling.²⁹⁹ In particular, "the distinction which must be borne in mind is that between some disclosure of utility and none."³⁰⁰ Judge Rich observed that Manson's patent application and supporting affidavits did not disclose any utility for the products of his claimed process.³⁰¹ This was a significant distinction from the patent in *Kirk*, where there was admitted disclosure of utility for the compounds, namely as intermediates in the preparation of certain steroids.³⁰² Based on the premise accepted by Judge Rich, that "any degree of utility, however slight, complies with the requirement that an invention be 'useful,'" the invention in *Kirk* should have been found to possess sufficient utility as a chemical intermediate.³⁰³ This is distinct from Manson's invention, which Judge Rich agreed did not possess sufficient utility, because no utility was asserted for the compounds produced by the claimed process.³⁰⁴

Judge Rich continued his analysis by discussing the absence of legislative history in support of the majority's ruling in *Kirk*.³⁰⁵ He traced the evolution of the statutes, beginning with the 1790 Patent Act, up to the current statute, the Patent Act of 1952.³⁰⁶ He stated that the identical term "useful" was used in each statute to describe one of the requirements for patentability.³⁰⁷ Furthermore, Judge Rich observed that the term "useful" was consistently interpreted by courts to mean that "any degree of utility to anybody was legal

²⁹⁷ *Kirk*, 376 F.2d at 947-66.

²⁹⁸ *Id.*

²⁹⁹ *Id.* at 953.

³⁰⁰ *Id.* at 948.

³⁰¹ *Id.*

³⁰² *Id.* at 949.

³⁰³ *Kirk*, 376 F.2d at 955.

³⁰⁴ *See generally id.* at 948-49.

³⁰⁵ *Id.* at 950-55.

³⁰⁶ *Id.* at 954.

³⁰⁷ *Id.*

‘utility.’”³⁰⁸ Because there was no indication that Congress intended to change the utility requirement, Judge Rich argued that the Supreme Court in *Brenner* did not intend to overturn nearly 200 years of established law by demanding an assertion of “substantial” utility for all inventions seeking patent protection.³⁰⁹

Turning his focus to public policy, Judge Rich criticized the *quid pro quo* philosophy relied upon by the majority in support of requiring “substantial” utility for patentability.³¹⁰ Judge Rich reasoned that “[t]he only *quid pro quo* demanded by the statute is full disclosure of a new and unobvious invention which is of some use to someone.”³¹¹ An invention that lacks utility will ultimately be of little value to the patent holder.³¹² Thus, the public should not be concerned with the specific degree of utility possessed by the invention. Judge Rich explained that as a practical matter, the full extent of utility is often unknown, as uses generally evolve after inventions are disclosed to the public.³¹³ Based on this reasoning, “substantial” utility plays no role in the *quid pro quo* equation of patent law. Rather it is disclosure of the invention to the public that the inventor must exchange for a government-granted monopoly over the invention.

Judge Rich’s *quid pro quo* analysis, however, may not be as persuasive an argument in this context because of the nature of human genes. In a situation where an inventor is granted a patent for a minimally useful invention, Judge Rich suggested that the patent will correspondingly be of minimal value to the inventor because the patentee generally will not receive any commercial benefit from the public.³¹⁴ This argument holds true for individual, self-standing inventions, such as those in the mechanical or electrical arts, because their existence is independent of other potential inventions.

Such is not always the case, however, with regard to gene sequences. There are a finite number of genes in the human genome.³¹⁵ Staking claims to portions of the human genome can have serious ramifications, particularly when the full extent of their

³⁰⁸ *Id.*

³⁰⁹ *Kirk*, 376 F.2d at 949.

³¹⁰ *Id.* at 955.

³¹¹ *Id.*

³¹² *Id.*

³¹³ *See generally id.*

³¹⁴ *Kirk*, 376 F.2d at 955.

³¹⁵ *See supra* note 42 and accompanying text.

biological activity is unknown. Patents covering gene sequences that form a portion of a full gene have the potential of stifling scientific research.³¹⁶ Where their target gene of interest encompasses a patented sequence, molecular biologists now have to worry about whether they are infringing on someone's patent. This concern, however, must be balanced against the right of an inventor to reap the benefits of his research in a pioneer field. Utility will always be an issue when a new class of compounds with unique properties is discovered. Demanding a higher standard of utility, however, is unwarranted and penalizes the pioneer industry. Future researchers will have to tread more lightly in the face of broad pioneering patents. The fact that later researchers must be more wary is an insufficient basis for the PTO to substantially modify a key requirement for patentability. Rather, it suggests that any such action should be undertaken by Congress after an appropriate study.³¹⁷ Alternatively, the issue should be brought to the public's attention and opened up for public discussion or debate.

³¹⁶ Gene patents have been the subject of controversy for many members of the scientific community. One example is the lawsuit involving the University of Rochester ("the University") against the pharmaceutical company, G.D. Searle. See Regalado, *supra* note 223. The University claims that Searle's painkiller drug, Celebrex, infringes on the patent it holds over the Cox-2 gene. *Id.* The lawsuit has been described as a tactical measure by the University to coerce Searle into paying royalties. *Id.* If royalties are not paid by Searle, the University demands that the drug be removed from the market, regardless of the fact that it is used by approximately seven million arthritis sufferers. *Id.* Another example is the lawsuit involving the commercial genetic test for the Canavan disease, a neurological disorder affecting Ashkenazi Jewish children. See American Medical Association, *Gene Patent Leads to Legal Action*, available at <http://www.ama-assn.org/ama/pub/category/3358.html> (last visited Nov. 18, 2001). The Miami Children's Hospital (MCH) owns a patent over the gene causing the disease. *Id.* The lawsuit focuses on the MCH decision to enforce a licensing fee for every test performed. *Id.* The lawsuit seeks to prevent MCH from impeding access and care to affected individuals by imposing financial restrictions. *Id.*

Several members of the field expressed the need for reform over gene patents, including Michael S. Watson, chair of the patent subcommittees of the American College of Medical Genetics and professor at the Washington University School of Medicine. See Douglas Steinberg, *Biotech Faces Evolving Patent System*, THE SCIENTIST 14[5]:8, available at <http://www.the-scientist.com> (Mar. 6, 2000) (on file with author). Watson conducted a survey over board-certified professionals in molecular diagnostics. *Id.* Based on the responses, forty-one percent felt that patents negatively impacted training programs, and fifty-four percent stated that they were deterred from pursuing a scientific interest because of patents. *Id.*

³¹⁷ See, e.g., Zuhn, *supra* note 128, at 996 (noting that in the past "Congress created separate intellectual property systems for plant varieties and semiconductor chip masks").

B. The Decisions of the Federal Circuit Clearly Articulate a Low Standard for Utility

Although the Federal Circuit has not specifically ruled on the degree of utility required for biotechnological inventions, the court recently articulated in very clear terms the degree of utility required for inventions generally. In *Juicy Whip*, the Federal Circuit took the position that “[t]he threshold for utility is not high.”³¹⁸ Rather, under section 101 of the Patent Act, an invention simply must be capable of providing an identifiable benefit.³¹⁹ Interestingly, while the Federal Circuit cited *Brenner* in support of its rationale, the phrase “substantial” utility is not mentioned at any point in the opinion.

Although the patent in *Juicy Whip* involved a type of beverage dispenser, an invention far from the complexity of biotechnological inventions, the court’s rationale for finding sufficient utility is nonetheless applicable to gene patents. The Federal Circuit focused on the public policy concern of patenting inventions which could be used to defraud or deceive.³²⁰ The court explicitly rejected the notion that such a possibility could deprive an invention of utility.³²¹ The *Juicy Whip* decision further noted that there are protections in place to address these concerns, namely administrative agencies such as the FTC and FDA.³²² Thus, it is outside the province of the judiciary and the PTO to protect society from such harm by denying patent protection.

The court concluded that “Congress is free to declare particular types of inventions unpatentable for a variety of reasons, including deceptiveness Until such time as Congress does so, however, we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility.”³²³ This highly deferential position afforded to Congress, in combination with the less stringent utility standard followed by the Federal Circuit in its decisions following *Brenner*, make it likely that the PTO is acting in an *ultra vires* manner by incorporating a “substantial” utility requirement in its guidelines. The Federal Circuit has clearly articulated that modification of the utility standard is a matter that is best addressed by Congress, rather than by the courts.

³¹⁸ *Juicy Whip*, 185 F.3d at 1366.

³¹⁹ *Id.*

³²⁰ *Id.* at 1366-68.

³²¹ *Id.* at 1367.

³²² *Id.* at 1368.

³²³ *Id.*

In the recent Federal Circuit decision, *Enzo Biochem, Inc. v. Gen-Probe Inc.*,³²⁴ the court addressed an analogous patentability issue relating to the written description requirement under 35 U.S.C. § 112.³²⁵ The invention involved nucleic acid probes that were used for selective hybridization with the genetic material of gonorrhea-causing bacteria.³²⁶ To fulfill the written description requirement, Enzo Biochem (“Enzo”) deposited the claimed nucleotide sequences in a public depository.³²⁷ Enzo argued that the reference to the deposit in the specification inherently described the invention, thereby satisfying the section 112 requirement.³²⁸ The defendant, however, argued that this reference was insufficient for purposes of section 112, and the patent was thus invalid.³²⁹

Noting its departure from existing precedent, the court held that the written description requirement was met. The court concluded that “reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of section 112, paragraph 1.”³³⁰ The court considered the history of the practice of depositing biological materials, the general goals of the patent system, and the “practical difficulties of describing unique biological materials in a written description.”³³¹

This decision supports the policy argument that can be made in the case of the utility requirement. By focusing on these factors, the court placed great weight on the practical considerations associated with scientific research. Private and public institutions make huge expenditures to arrive at the discoveries that promote the well-being of humans. The general goal of promoting the progress of science

³²⁴ 296 F.3d 1316 (2002).

³²⁵ The written description requirement of 35 U.S.C. § 112, ¶ 1 states that, The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112 (2001).

³²⁶ *Enzo*, 296 F.3d at 1320.

³²⁷ *Id.* at 1322.

³²⁸ *Id.* at 1325.

³²⁹ *Id.* at 1322.

³³⁰ *Id.* at 1325.

³³¹ *Enzo*, 296 F.3d at 1325.

can be realistically achieved if researchers are financially stable enough to continue research efforts. Researchers rely on the protection granted by patents to proceed with endeavors, some of which do not produce a profitable result.

The court in *Enzo Biochem* realized that, although the court may have previously considered a reference to deposit as insufficient for purposes of the written description requirement, circumstances exist in the realm of biotechnological research which justify the opposite result. What is important is the fact that the public had access to the claimed materials. Similar circumstances exist with gene sequences. Although the full utility of the gene sequence may not be known, scientists rely on patent protection to continue the research that may ultimately unveil the full utility of the gene. In the meantime, the information that is known is made available to the public, and the public is able to partake in similar research efforts with the hopes of uncovering the gene's full utility.

C. *Proposed Resolution: Utility Analysis for Gene Patents*³³²

The foregoing analysis discusses three guiding principles that help define the current law regarding the utility requirement for patentability. First, the Supreme Court in *Brenner* clearly articulated that an invention is deemed to have substantial utility "where specific benefit exists in currently available form."³³³ Thus, patents should not issue for inventions that possess no utility at all—such as steroidal compositions whose homologues, as opposed to the steroid itself,

³³² A number of alternative measures have been offered by commentators in the field. See, e.g., Zuhn, *supra* note 128, at 995-98 (discussing proposals set forth by commentators on EST patentability, including the adoption of a *per se* utility standard for chemical compounds, the application of copyright laws in place of patent laws for DNA sequences, the alteration of statutory subject matter categories, and applying a "prospective" utility requirement). One argument is that Congress should create a separate intellectual property system for biotechnological inventions, as Congress once did for two other areas of technology, namely semiconductor chip masks and plant varieties. See *id.* at 996. The PTO, however, has suggested that such a need for a specialized patent law system is unnecessary. See John J. Doll, *supra* note 42 (arguing that similar concerns over gene patenting were used thirty to forty years ago with emerging polymer chemistry technology, which developed without the need for a new form of intellectual property). John J. Doll, Director of Biotechnology for the PTO, noted that the same patentability analysis must be performed for every patent application, regardless of the nature of the invention. *Id.* "In every field of technology — whether emerging, complex, or competitive — all the conditions for patentability (such as statutory subject matter, utility, enablement, written description, novelty, and non-obviousness) must be met before a claim is allowed." *Id.* at 689-90. Thus, there is no need for the creation of an entirely separate system for DNA sequences applications.

³³³ *Brenner*, 383 U.S. at 534-35.

showed tumor-inhibiting effects in mice. Second, based on the absence of legislative history suggesting that the utility doctrine requires a higher standard for utility, an invention need only possess some type of utility, rather than a specific degree of utility. Third, the Federal Circuit articulated in its recent decisions that inventions need only meet a relatively low threshold for utility. Thus, an invention must be capable of providing only an identifiable benefit to satisfy the utility requirement of section 101.

The Guidelines for determining adequate utility to be used by the PTO during prosecution should be based on these three principles. The current Guidelines have the effect of requiring a certain degree of utility be present for the claimed sequences. The language cited in the PTO Training Materials illustrates this concept: "It is . . . assumed that some 'utility' is disclosed in the specification or is recognized to be well-established in the art. The Examiner should determine whether any asserted utility is specific and substantial, and if so, determine whether such asserted utility is credible."³³⁴ To be in accordance with the law, a standard which provides that "some 'utility' . . . disclosed in the specification" be present should plainly satisfy the requirements under section 101.³³⁵ By these standards, a nucleic acid sequence, with a disclosed utility as a research tool for investigation of a specific family of human proteins, should satisfy the utility Guidelines. Although later researchers may need to exercise due care to avoid infringement conflicts, this is always an issue in a viable patent system. It is not the role of the PTO to police enforcement of patents. Rather, the authority to change fundamental patent standards lies with Congress. Until changes are made, the PTO is responsible for granting patents for inventions that meet the patentability requirements enacted by Congress and interpreted by the courts.

CONCLUSION

It is left to the imagination whether the Framers envisioned the type of inventions that seek patent protection today. What is known, however, is that there is a pressing need to determine the proper standards for granting patents for advances in technology. Little guidance can be found in the sources of patent law. With the rise of recombinant DNA technology, inventions composed of DNA emerged. Common sense indicates that limited monopolies over

³³⁴ See *supra* note 271.

³³⁵ *Id.*

these portions of DNA should be granted only with a fair *quid pro quo*; a satisfaction of 35 U.S.C. §§ 101, 112, 102, and 103. These sections of the Patent Act adequately protect the public from inventions that are not worthy of protection. There is no need to tamper with the utility standards enunciated by the courts and previously adopted by the PTO. Without any overt legislative action taken by Congress, however, the PTO took the initiative of denying patent protection for biotechnological inventions with identifiable utility by issuing stricter Utility Examination Guidelines. The PTO essentially raised the utility hurdle for which an invention must pass. In light of the actual holding of *Brenner*, the Federal Circuit decisions following *Brenner*, and the congressional silence on the matter, the PTO lacks the authority to substantially alter one of the fundamental requirements of patentability. Thus, the PTO is acting outside its scope of authority by denying patent protection for inventions that do not meet its raised utility standard.