NOTE

Resuscitating the Patent Utility Requirement, Again: A Return to *Brenner v. Manson*

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INTRODUCTION

Recent innovations in the field of biological technologies ("biotech") have created new and troublesome patent protection issues.[1] Since the late 1970's, innovative breakthroughs in biotech have advanced at an unprecedented rate.[2] These biotech innovations produce an array of beneficial products such as pharmaceuticals, medical therapeutics, medical diagnostic products, and agricultural products.[3] Producing and marketing these products requires years of development and substantial amounts of capital investment.[4] Consequently, biotech companies attempt to protect their investments by acquiring monopolistic patent rights on their innovative products.[5] The first step in acquiring a patent in the United States is to submit an application to the Patent and

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[1] *See* Timothy A. Worrall, Note, *The 2001 PTO Utility Examination Guidelines and DNA Patents*, 16 BERKELEY TECH. L.J. 123, 127-28 (2001) (discussing unmanageable DNA sequence patents and possibility of incorrectly applied utility standards).

[2] *See* S.M. Thomas et al., *Ownership of the Human Genome*, 380 NATURE 387, 387-88 (1996) (discussing growth of biotech in terms of increasing patent application on deoxyribonucleic acid compounds).

[3] *See* Jonathan M. Barnett, *Cultivating the Genetic Commons: Imperfect Patent Protection and the Network Model of Innovation*, 37 SAN DIEGO L. REV. 987, 989 n.4 (2000) (noting variety of technologies and products encompassed by biotech industry).

[4] *See* Michael J. Malinowski & Maureen A. O'Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 YALE J. ON REG. 163, 205 (1996) (discussing "drug lag" requiring seven to twelve years and as much as $400 million to bring one new drug to market from initial discovery of gene); Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 181 (2001) (discussing large amount of capital required for genetic research and product development); Eric R. Paley, Note, *Rethinking Utility: The Expediency of Granting Patent Protection to Partial cDNA Sequences*, 44 SYRACUSE L. REV. 1003, 1007 (1993) (asserting that cost to identify one gene through functional approach historically ranged from $40,000 to $50,000); Eliot Marshall, *Patent Office Faces 90-Year Backlog*, 272 SCI. 643, 643 (1996) (discussing cost of automated sequencer used in identifying genes through partial gene sequence identification method); Jeff Nesbit, *No One Should Hold a Patent on Humans*, WASH. TIMES, Sept. 27, 1996, at B8, *available at* 1996 WL 2966695 (discussing $10 million investment made by Bill Gates in single biotech company).

[5] *See* Barnett, *supra* note 3, at 989 (inferring that explosive growth in biotech industry "coincided with, and may have relied closely upon, the patentability of certain types of genetic material and certain research techniques for genetic alteration").

Trademark Office ("PTO").[6]

The PTO has recently found itself overwhelmed with a multitude of problematic biotech patent applications.[7] Particularly troublesome to the PTO is the increasing number of patent applications directed towards deoxyribonucleic acid ("DNA") discoveries.[8] The problem the PTO faces regarding DNA patent applications is the lack of immediate societal usefulness in their discovery.[9] Their questionable usefulness presents problems for biotech companies in filing DNA patent applications because utility, or usefulness, is a requirement for a patent to issue.[10] Therefore, proving usefulness is a unique hurdle in the acquisition of DNA patent rights.[11]

Once a patent issues, it grants legal rights upon the patent holder to exclude all others from making, using, or profiting from the claimed invention.[12] This right of exclusivity exists for twenty years from the filing date of the patent.[13] This right extends to chemical compounds meeting the three statutory requirements of novelty, non-obviousness, and utility.[14] DNA itself is a unique collection of chemical compounds, and thus capable of patent protection.[15] The character and biological function of DNA, however, raises several issues peculiar to chemical

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[6] BLACK'S LAW DICTIONARY 1148 (7th ed. 1999). The PTO is the government office charged with the review and granting or rejection of patent applications. *Id.*

[7] *See* John Murray, Note, *Owning Genes: Disputes Involving DNA Sequence Patents*, 75 CHI.-KENT L. REV. 231, 231 (1999) (discussing overwhelming number of partial gene sequence applications plaguing PTO examiners); Worrall, *supra* note 1, at 127-28 (discussing critical mass of DNA applications submitted to PTO); Marshall, *supra* note 4, at 643 (describing how one company alone applied for over 400,000 patents on DNA).

[8] *See* Worrall, *supra* note 1, at 128 (claiming that PTO may grant large number of incorrectly examined patents on DNA unless there are specific guidelines for proper utility standards).

[9] *See* Leora Ben-Ami et al., *Biotech Patent Law Developments*, 573 FIFTH ANNUAL INST. FOR INTELL. PROP. L. 555, 558 (1999). Ben-Ami asserts that, while partial gene sequences may be useful as "probes," typically the function (and usefulness) of the sequence is unknown without further research. *Id.*

[10] 35 U.S.C. § 101 (2000); *see also* discussion *infra* Part I.C.3 (examining utility requirement of patents).

[11] *See generally* Worrall, *supra* note 1, at 127-31 (discussing difficulties in proving utility for DNA patent applications).

[12] 35 U.S.C. § 154(a)(1) (2000).

[13] § 154(a)(2).

[14] *See* Worrall, *supra* note 1, at 128 (stating that DNA claims must meet three basic statutory patentability requirements).

[15] *See id.* at 136 (applying chemical compound case law regarding utility to DNA patent applications because DNA has specific chemical structure that imparts specific properties).

compound patents.[16]

A controversial issue that arises in DNA patenting relates to whether patenting DNA discoveries results in limiting or increasing societal benefits.[17] Proponents of DNA patenting believe that patent protection will encourage innovative research in the field.[18] Proponents also believe that innovation in DNA technology will benefit the public with new drugs, vaccines, and diagnostic tests.[19] Conversely, opponents of DNA patenting believe that patent protection will destroy collaborative research efforts and retard innovation by encouraging secrecy and delaying information dissemination.[20] Consequently, these clashing concerns and beliefs have led to much debate over how, when, and if DNA discoveries should receive patent protection.[21]

This Note argues that the PTO's current understanding of case law on the patent utility requirement is correct, but continues to be misapplied by the PTO in actual practice. Part I begins with an overview of DNA and differentiates between complete and partial DNA discoveries. Part I also discusses the fundamental principles behind patent law, its roots in the United States Constitution, and judicial interpretation of patent rights. Part II discusses the PTO's understanding of existing case law as it relates to DNA patenting. Specifically, Part II focuses on guidelines and training materials that the PTO has promulgated as being reflective of its current understanding of the patent utility requirement. Part III argues that the Training Materials incorrectly apply the 2001 Guidelines

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[16] *See, e.g.*, Leslie Roberts, *NIH Gene Patents, Round Two*, 255 SCI. 912, 912-13 (1992) (discussing controversy around DNA sequence patents); *see also* discussion *infra* Part I.A. (describing chemical make-up of DNA).

[17] *See* Ruth Macklin, *The Ethics of Gene Patenting*, *in* GENETIC INFORMATION: ACQUISITION, ACCESS, AND CONTROL 129, 134 (Alison K. Thompson & Ruth F. Chadwick eds., 1999) (posing pivotal question for any consequentialist argumentation pertaining to patent law). Macklin lays out several non-ethical factors that must be considered when grappling with this issue. *Id.* at 134-36. These include delays in disseminating information, development of new drugs, promoting versus stifling international collaboration, and assigning different weights to different consequences. *Id.*

[18] *See* George Poste, *The Case for Genomic Patenting*, 378 NATURE 534, 534-36 (1995) (describing risks of not protecting innovative scientific research).

[19] *See id.*

[20] *See* Letter from Bruce Alberts, President, National Academy of Sciences, to Q. Todd Dickinson, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks (Mar. 22, 2000) (on file with author) (stating that "[t]o the maximum extent possible, the human genome sequence should be freely available for use by all both as part of our basic human heritage and to fully realize the enormous benefits that this information promises").

[21] *See generally* Kate H. Murashige, *Genome Research and Traditional Intellectual Property Protection – A Bad Fit?*, 7 RISK 231 (1996) (describing issues regarding patent protection of DNA and exploring both pros and cons between allowing and disallowing protection).

and case law to hypothetical patent claims on DNA. Additionally, Part III defends the 2001 Guidelines as a correct understanding of pertinent case law and shows how it will advance the goals of patent law. Finally, Part III explains why the 2001 Guidelines will succeed in addressing moderate concerns regarding the ethical issues of DNA patenting.

I. BACKGROUND

This section discusses DNA technology and the patent utility requirement. Part A discusses advances in DNA technology and describes the two processes used to discover the hidden information of DNA. Part B begins with a broad overview of the three requirements needed to acquire a patent, and then delves into the evolution and case law regarding the patent utility requirement.

A. Overview of DNA and Genetic Research

DNA is the basic building block of all organisms.[22] DNA encodes for all hereditary characteristics of an individual organism.[23] It is present in every human cell and encodes approximately 30,000 genes, the basic units of heredity.[24] Each gene codes for a specific protein that will fulfill a predetermined biological function.[25]

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[22] *See* BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 10-11 (3d ed. 1994) (stating that DNA contains fundamental genetic information necessary to almost all biological processes); Andrew T. Kight, Note, *Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines in Light of* Brenner, 73 IND. L.J. 997, 1001-02 (1998) (explaining basics of DNA character strands).

[23] *See* ALBERTS, *supra* note 22, at 10-11 (discussing hereditary aspect of DNA information and how it contributes to individual organism).

[24] HUMAN GENOME PROJECT INFORMATION, *available at* http://www.ornl.gov/hgmis/ (last modified Sept. 11, 2002) (stating goals of project which include identifying all the approximately 30,000 genes in human DNA). *But see* BENJAMIN LEWIN, GENES VI 687-88 (1997) (estimating human gene number at 125,000). *See generally* ALBERT L. LEHNINGER ET AL., PRINCIPLES OF BIOCHEMISTRY 791 (2d ed. 1993) (stating that gene is "fundamental unit of information in living systems"); 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, 745 (2000) (describing biological function and method for transcribing DNA). Understanding this basic aspect of DNA led to the identification of virtually all disease-causing genes. *See Biotechnology: OECD Encourages Debate on Genetic Testing; Notes Ethical, Privacy Concerns*, BNA PATENT, TRADEMARK & COPYRIGHT LAW DAILY, Feb. 5, 2001, at d4 (discussing recent report by Organization for Economic Cooperation and Development on genetic testing). Examples of the identified genes include hemoglobin disorders and breast cancer. *See id.*

[25] *See* LEHNINGER ET AL., *supra* note 24, at 789; *see also* STUART IRA FOX, HUMAN PHYSIOLOGY 58-60 (Colin H. Wheatley ed., 1996) (describing basic elements making up DNA and how they interact with each other). *See generally* DONALD VOET & JUDITH G.

The molecular structure of DNA is comprised of subunits known as nucleotides.[26] Each nucleotide consists of three smaller subunits: deoxyribose, a phosphate group, and a nitrogenous base.[27] These subunits bond in a specific order that encodes genetic information.[28] The bonding results in a structure consisting of two winding chemical chains connected by a series of chemical bonds.[29] This structure, known as a double helix, resembles a spiraling ladder.[30]

With the double helix, DNA serves as a transcript for genetic information.[31] Through the biological processes of transcription and translation, genes induce genetic expression of physical characteristics, such as green eyes or sickle-cell anemia.[32] This understanding of genetic

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VOET, BIOCHEMISTRY 17-18 (1990) (describing transcription and translation, which are two stages of expressing genetic information).

[26] *See* FOX, *supra* note 25, at 58 (discussing role of nucleotides in formation of DNA); LEWIN, *supra* note 24, at 77.

[27] *See* LEWIN, *supra* note 24, at 77; VOET & VOET, *supra* note 25, at 17-18. Deoxyribose is a five-carbon sugar with one end connecting to a phosphate group and the other end bonding with one of four nitrogenous bases. VOET & VOET, *supra* note 25, at 17-18; *see* LEWIN, *supra* note 24, at 77. The nitrogenous bases consist of two types of cyclic nitrogen-containing molecules: pyrimidines (which are single carbon rings) and purines (which are double carbon rings.) *Id.* The four bases are adenine, guanine, cytosine, and thymine. LEWIN, *supra* note 24, at 76. The former two are purines and the latter two are pyrimidines. *Id.*

[28] VOET & VOET, *supra* note 25, at 18.

[29] *See* LEWIN, *supra* note 24, at 80-81 (explaining formation of chemical bonds in DNA). *See generally* J. D. Watson & F. H. C. Crick, *Molecular Structure of Nucleic Acids*, 171 NATURE 737-38 (1953), *reprinted in* THE DNA MOLECULE, STRUCTURE AND PROPERTIES, ORIGINAL PAPERS, ANALYSES, AND PROBLEMS 30 (David Freifelder ed., 1978) (detailing double helix three-dimensional structure of DNA).

[30] *See generally* CHARLES R. CANTOR & CASSANDRA L. SMITH, GENOMICS, THE SCIENCE AND TECHNOLOGY BEHIND THE HUMAN GENOME PROJECT 1-3 (1999) (describing covalent structure and double helical structure of DNA); RICHARD R. SINDEN, DNA STRUCTURE AND FUNCTION 11-30 (1994) (discussing general structure of double-stranded DNA). In this spiraling ladder, the deoxyribose and phosphate group combine to form a sugar-phosphate chain, which serves as the backbone of DNA, or the long side of the ladder. *See* LEWIN, *supra* note 24, at 78-80. The nitrogenous bases project out from the chain and form hydrogen bonds with other nitrogenous bases also projecting out from a second sugar-phosphate chain. *Id.* at 80-81. These hydrogen bonds, each made by two of the four nitrogenous bases, create the rungs of the spiraling ladder. *Id.*; *see* VOET & VOET, *supra* note 25, at 18. In forming the hydrogen bonds, each nitrogenous base is specific to one another. LEWIN, *supra* note 24, at 80; VOET & VOET, *supra* note 25, at 18. A rung consists of one of the following combinations of nitrogenous bases: adenine-thymine, thymine-adenine, cytosine-guanine, or guanine-cytosine. LEWIN, *supra* note 24, at 80; VOET & VOET, *supra* note 25, at 18. As the two chains wind themselves in opposing spirals, they form the double helix which holds genetic information. *See generally* Watson & Crick, *supra* note 29, at 737-38.

[31] LEWIN, *supra* note 24, at 76; VOET & VOET, *supra* note 25, at 17-18.

[32] VOET & VOET, *supra* note 25, at 18.

expression operates as the basis for inventing new methods of genetic manipulation and modification or suppression of gene expression.[33] The ever increasing public demand for this genetic information creates a great incentive to decode all human genetic information.[34]

Since 1990, the U.S. Human Genome Project has deciphered human genetic information.[35] The Genome Project specified several goals, including identifying all of the approximately 30,000 genes in human DNA.[36] Originally, scientists used the functional approach to identify complete gene sequences.[37] The functional approach identifies a complete gene by working backwards from a functional protein with a known biological function.[38] Scientists trace the known protein back to the gene that codes for its creation and function.[39] However, this process is both laborious and expensive.[40] Before 1990, scientists identified approximately 2,000 genes using this process.[41] In an effort to improve upon this dismal rate, scientists continually searched for a faster and

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[33] *See* ALBERTS, *supra* note 22, at 291-92 (describing limitless possibility for uses in methods for manipulating DNA); VOET & VOET, *supra* note 25, at 18.

[34] *See* Elizabeth Pennisi, *Finally, the Book of Life and Instructions for Navigating It*, 288 SCI. 2304, 2304-05 (2000) (describing private and public efforts to map human genome); J. Craig Venter et al., *Shotgun Sequencing of the Human Genome*, 280 SCI. 1540, 1540-42 (1988) (describing Dr. Venter's efforts at Celera, Inc. to sequence human genome through use of automated sequencing technology); *see also* Li Hui, *China, Denmark Team Up to Tackle the Pig*, 290 SCI. 913, 913-14 (2000) (discussing consortium between China and Denmark to sequence pig genome); Gretchen Vogel, *Sanger Will Sequence Zebrafish Genome*, 290 SCI. 1671, 1671 (2000) (discussing Sanger Centre's endorsement of project to map Zebrafish genome).

[35] *See generally* Ben-Ami, *supra* note 9, at 558 (stating that NIH instituted human genome project in 1990); HUMAN GENOME PROJECT INFORMATION, *available at* http://www.ornl.gov/hgmis/ (last modified Sept. 11, 2002) (discussing Project's goals and current status).

[36] HUMAN GENOME PROJECT INFORMATION, *available at* http://www.ornl.gov/hgmis/ (last modified Sept. 11, 2002).

[37] *See* Kight, *supra* note 22, at 1003 (contrasting two methods used for gene identification); *see, e.g.*, Reid G. Adler, *Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization*, 257 SCI. 908, 908 (1992) (noting traditional approach for gene identification via back-tracing known proteins to correlative genes by isolation and purification).

[38] *See* Kight, *supra* note 22, at 1003 (discussing step-by-step process for gene identification through functional approach).

[39] *See id.*

[40] *See* Paley, *supra* note 4, at 1007 (1993) (discussing cost to identify one gene through functional approach as ranging between $40,000 and $50,000); *see also* Kight, *supra* note 22, at 1004 (discussing slow rate at which genes were identified using traditional functional approach).

[41] *See* Kight, *supra* note 22, at 1004 (discussing evolution of gene sequencing, from functional approach to Dr. Venter's EST method).

more economic method of gene identification.[42]

In 1990, Dr. J. Craig Venter discovered a new method for gene identification.[43] While working for the National Institute of Health ("NIH"), he proposed an alternate method of gene identification known as expressed sequence tags ("ESTs").[44] ESTs are made from copies of messenger-RNA ("mRNA"), which results from transcription of DNA and contains genetic information.[45] Because they are not complete genes in themselves, ESTs narrow the search for genetic information to only those portions of DNA that actually encode functional proteins.[46] Dr. Venter explained that only three to five percent of the information in human DNA in a gene actually coded for functional proteins.[47] He further claimed that the remaining ninety-five percent of DNA in a gene was unimportant.[48] Thus, an EST only identifies a partial gene sequence, unlike the functional approach that identifies the complete gene sequence.[49] Scientists favor this new method because it is both expedient

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[42] *See id.* at 1003 (discussing incentive to find faster, cheaper method for gene identification).

[43] *See* Daniel L. McKay, Comment, *Patent Law and Human Genome Research at the Crossroads: The Need for Congressional Action*, 10 SANTA CLARA COMPUTER & HIGH TECH. L.J. 465, 474 (1994); Paley, *supra* note 4, at 1006-07.

[44] *See* Kight, *supra* note 22, at 1003 (describing Dr. Venter's new methodology for gene identification). For a more in-depth analysis of EST/cDNA gene identification, see Matthew Erramouspe, Comment, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipation Races*, 43 UCLA L. REV. 961, 984-85 (1996).

[45] See Mark D. Adams, *Expressed Sequence Tags as Tools for Physiology and* Genomics, *in* AUTOMATED DNA SEQUENCING AND ANALYSIS 73 fig.10.1 (Mark D. Adams et al. eds., 1994) (explaining formation of EST in abstract); John Carey et al., *The Gene Kings*, BUS. WK., May 8, 1995, at 72, 74-75. mRNA is a molecule that cells create by copying the parts of DNA that are genes. In his method, Dr. Venter made copies of mRNA, known as complimentary DNA (cDNA), and put them into a sequencing machine which read parts of the DNA. *See* Carey et al., *supra*, at 74-75. *See generally* LEWIN, *supra* note 24, at 135, 170-71 (explaining the production of mRNA and cDNA). ESTs are the partial cDNA sequences. Adams, *supra*, at 71; *see also* Holman & Munzer, *supra* note 24, at 748 ("[A]n EST is a short stretch of cDNA that was not individually selected for sequencing, but was randomly isolated with many other stretches of cDNA from a cDNA library or from the tissue itself.").

[46] *See* Holman, *supra* note 24, at 748-49 (describing how EST method works in identifying partial sequences of genes).

[47] *See* Tom Wilkie, *Whose Gene Is It Anyway?*, INDEPENDENT (London), Nov. 19, 1995, at 75, *available at* 1995 WL 10814293 (paraphrasing Dr. Venter's statement regarding rationale for favoring new method of EST gene identification over traditional functional approach).

[48] *Id.*

[49] *See, e.g.*, Tim Beardsley, *Piecemeal Patents: The U.S. Reconsiders Patents on DNA Fragments*, 267 SCI. AM. 106, 106 (1992) (noting that ESTs contain fragments of gene sequence). *See generally* Adams, *supra* note 45, at 71-75 (explaining mechanisms of ESTs and evaluating accuracy of EST sequences).

and inexpensive.[50]

However, the EST method is not without its drawbacks or critics.[51] Under the functional approach, the gene's function is known prior to its identification.[52] In contrast, the EST method uses a randomly selected protein of unknown function to identify an EST of unknown function.[53] Unless an EST is from a gene of known function, that EST cannot identify the function of the protein that its partial gene sequence encodes.[54] Because more than half of Dr. Venter's initial 600 ESTs derived from unique genes that had never before been identified, their function was unknown.[55] In light of these drawbacks, criticism over EST patenting promptly followed the first EST patent applications.[56] Familiarity with patent law, specifically its purpose and goals, is essential to understanding the critics' attacks on EST patent applications.

B. Overview of the U.S. Patent System

The Framers of the Constitution adopted Article I, section 8, clause 8 to protect authors and inventors by empowering Congress to grant authors and inventors exclusive rights over their respective creations and inventions.[57] Congress exercised some of this power with the Patent Act

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[50] *See* Charles Petit, *David Botstein: A Map for an Incredible Journey*, S.F. CHRON., Aug. 18, 1996, at 3Z1, *available at* 1996 WL 3225920 (interviewing geneticist David Botstein who claims difference between EST and functional method is similar to "the difference between driving to Butte, Montana, now as opposed to the way Lewis and Clark got [there]"); *see also* Paley, *supra* note 4, at 1007 (stating EST method identifies genes at roughly twenty dollars per gene); Wilkie, *supra* note 47, at 76 (reporting Venter's belief that EST method would "cut the cost of sequencing an unknown gene from $50,000 to $20"). By the year 2000, both public and private efforts aimed at completing the map of the human genome had claimed success. Press Release, The White House, President Clinton Announces the Completion of the First Survey of the Entire Human Genome (June 25, 2000) *available at* http://www.ornl.gov/hgmis/project/clinton1.html (last modified Feb. 28, 2001).

[51] *See* Kight, *supra* note 22, at 1003-04 (highlighting criticism of EST method).

[52] *See id.*

[53] *See id.* at 1004.

[54] Leslie Roberts, *Genome Patent Fight Erupts*, 254 SCI. 184, 184 (1991).

[55] *Id.* at 185.

[56] *See* Kight, *supra* note 22, at 1004. Critics of EST patenting believed that interpreting the gene and determining the biological function of its protein was of supreme importance, not simply identifying the sequence. *Id.* These critics felt that Dr. Venter's EST method required little skill or innovation. *See* Roberts, *supra* note 54, at 184. They further claimed that EST patents would render impossible the free flow of scientific information, thereby inhibiting international collaboration. *See* Wilkie, *supra* note 47, at 75. Dr. Venter, through NIH, submitted and later withdrew the first EST patent application. *See* Christopher Anderson, *NIH Drops Bid for Gene Patents*, 263 SCI. 909, 909 (1994).

[57] *See* U.S. CONST. art. I, § 8, cl. 8 (stating that "Congress shall have the power . . . To promote . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right

("Act").[58] The Act seeks to encourage innovation and promote public disclosure of technological advances that are beneficial to society.[59] Furthermore, the Act contains non-specific language so that it can conform to new and unforeseen advancements in technology.[60] Thus, even the complex innovations and biological discoveries in the biotech industry may satisfy the requirements of the Act and receive patent protection.[61] The PTO is responsible for ensuring that a patent issues only after a claimant meets all the requirements of the Act.[62]

The PTO may grant proprietary rights over a claimant's invention for a period of twenty years.[63] These rights, when granted, allow the claimant-turned-patentee to exclude all others from making, using, or selling the patented invention without the patentee's express permission.[64] However, before the PTO grants a claimant these broad rights, the claimant must disclose an invention that is novel, non-obvious, and useful.[65] If the claimant meets these requirements, the claimant enters into a contract with society that simultaneously discloses

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to their . . . Discoveries"); *see also* Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980) (discussing patent law originations in Constitution).

[58] *See generally* Edward C. Walterscheid, *The Use and Abuse of History: The Supreme Court's Interpretation of Thomas Jefferson's influence on the Patent Law*, 39 IDEA 195 (1999) (discussing evolution of Congress's Patent Act from legislative inception in 1790).

[59] *See* DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 71, 72-74 (1998).

[60] *See Chakrabarty*, 447 U.S. at 309 (noting that Committee Reports indicated that Congress intended for Act's subject matter to include "anything under the sun that is made by man"); Ben-Ami, *supra* note 9, at 557 (stating accepted axiom that there be only one patent law for all technologies and inventions); *see also* Sara Dastgheib-Vinarov, Comment, *A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143, 150 (2000) (describing non-specificity of Patent Act language).

[61] *See* 60 AM. JUR. 2D *Patents* § 76 (1987) (stating that human-made living matter and genetic technology "is patentable subject matter under the patent statute"); *cf.* Ben-Ami, *supra* note 9, at 557-82 (discussing patentability issues, in regards to DNA claims, over requirements of utility, obviousness, written description, and best mode). The Supreme Court found that living organisms are fairly embraced within the language of patentable subject matter in the Patent Act. *See Chakrabarty*, 447 U.S. at 318.

[62] *See* Worrall, *supra* note 1, at 123 (asserting that PTO has initial responsibility to determine validity of patent claims). The three technical requirements of the Act are novelty, non-obviousness, and utility. 35 U.S.C. §§ 101-103 (2000).

[63] *See* 35 U.S.C. § 154(a)(2). For purposes of this Note, claimants are those individuals with pending patent applications.

[64] *See id.* § 271(a); *Chakrabarty*, 447 U.S. at 307. For purposes of this Note, patentees are those individuals who have been granted patents over their inventions.

[65] *Id.* §§ 101-103. Furthermore, the claimant must submit a written description of the invention. *Id.* § 112. The description must enable a person of ordinary skill, in the art of the invention's subject matter, to reproduce the invention contemplated by the claimant. *See id.*; CHISUM ET AL., *supra* note 59, at 76.

the invention and grants the claimant a right of exclusivity.[66]

In this way, issuance of a patent creates a *quid pro quo* contract between the patentee and society.[67] The patentee describes the invention sufficiently and discloses that information to the public.[68] In return, society grants the patentee a temporary monopoly on the invention so that the patentee may recoup his or her investment.[69] The purpose of the contract is to promote public disclosure of new and useful inventions.[70] The contract promotes disclosure by providing monetary compensation in the form of a finite monopoly for the inventor.[71] This monopoly encourages biotech companies, like all other inventors, to disclose their inventions.[72]

In 1997, the PTO announced that it would allow claims on ESTs based upon their usefulness in locating their complete gene sequence in a given DNA sample.[73] The problematic issue is whether a patentee of an EST could sue scientists working on the complete gene, which includes the patentee's EST, for patent infringement.[74] Ultimately, the responsibility to review the PTO's decisions and establish a patent standard decisive on this issue falls on the courts.[75] Congress created a special court, known as the Court of Appeals for the Federal Circuit ("Federal Circuit"), to fulfill this role.[76] This court hears all patent appeals.

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[66] *See* CHISUM ET AL., *supra* note 59, at 72.

[67] *See* Brenner v. Manson, 383 U.S. 519, 534 (1966) (discussing *quid pro quo* contract envisioned by Constitution and implementing Patent Act); *see also* CHISUM ET AL., *supra* note 59, at 72.

[68] *See* CHISUM ET AL., *supra* note 59, at 72.

[69] *See id.*

[70] *See id.* at 62-64; *see also* Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980) (discussing Congress's intent in fostering positive effect on society by encouraging introduction of new products and processes into economy).

[71] *See* CHISUM ET AL., *supra* note 59, at 62-64; *see also Chakrabarty*, 447 U.S. at 307.

[72] *See* CHISUM ET AL., *supra* note 59, at 62-64.

[73] *See Gene Fragments Patentable, Official Says*, 275 SCI. 1055, 1055 (1997). The process of using an EST to locate its complete gene sequence is known as Gene Probing. *See id.*

[74] *See, e.g.*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998) (discussing how biomedical research has moved from commons model to privatization model and that grant of patent upstream might stifle life-saving innovation in course of research and development downstream).

[75] *See* Worrall, *supra* note 1, at 131 (stating that while PTO serves as initial reviewers of patent applications, courts must ultimately determine how statutory requirements apply in controversial cases).

[76] ROBERT PATRICK MERGES, PATENT LAW AND POLICY 12 (2d ed. 1997); Dastgheib-Vinarov, *supra* note 60, at 150.

C. Fluctuating Standards in Patent Requirements

The Federal Circuit, established in 1982, addresses issues regarding patent law forum shopping, lack of uniformity in decision-making, and the high invalidity rate among litigated patents.[77] The Federal Circuit serves as a *de facto* court of last resort for patent law because the United States Supreme Court seldom grants *certiorari* in patent cases.[78] Thus, the Federal Circuit often sets the minimum standards for satisfying the patent requirements.[79] Each patent application must meet three specific technical requirements for a patent to issue: novelty, non-obviousness, and utility.[80]

1. Novelty

Under 35 U.S.C. § 102, a claimant's invention must not exist in the prior art.[81] Prior art refers to knowledge that is available to a person of ordinary skill in the relevant art at all times, including patented inventions.[82] The statute requires that the claimed invention not be in the public domain, or previously patented, at the time of filing.[83] Thus, the PTO rejects the entire claim if even a small portion of that claim already exists in the prior art.[84] Under this constraint, broad and expansive patent claims often fail the novelty requirement and meet with rejection.[85] However, for those inventions that clear the novelty hurdle,

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[77] *See* Dastgheib-Vinarov, *supra* note 60, at 150.

[78] *Id.* The United States Supreme Court, however, has recently begun to more closely scrutinize decisions of the Federal Circuit. *See, e.g.*, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 122 S. Ct. 1831, 1843 (2002) (vacating decision by Federal Circuit).

[79] *See* Dastgheib-Vinarov, *supra* note 60, at 150.

[80] 35 U.S.C. §§ 101-103 (2000); *see* Dastgheib-Vinarov, *supra* note 60, at 150 (describing three necessary requirements for grant of patent rights). In addition to the three specific requirements, claimants must satisfy a number of specification requirements. These requirements include: (1) written description; (2) enablement; and (3) best mode. *Id.* § 112 ¶1. The claimed invention must also fall within patentable subject matter. *Id.* § 101.

[81] *See* 35 U.S.C. § 102.

[82] BLACK'S LAW DICTIONARY 106 (7th ed. 1999).

[83] Rochelle K. Seide & Melissa Szanto, *Drafting Claims for Biotechnology Inventions*, FIFTH ANNUAL PATENT PROSECUTION WORKSHOP: ADVANCED CLAIM AND AMENDMENT WRITING 357, 376 (Practising Law Institute Patents, Copyrights, Trademarks, and Literary Property Course Handbook Series No. G-426, 1995). One can appropriate things in the public domain without liability for infringement. BLACK'S LAW DICTIONARY 1243 (7th ed. 1999).

[84] *See* Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AM. INTELL. PROP. L. ASS'N Q.J. 1, 21 (1995).

[85] *See id.* (explaining that broadly drafted patent applications are more easily invalidated by showing infringement of prior art by any portion of broad application). The

the next step is showing that the claimed invention is also non-obvious.[86]

2. Non-Obviousness

Under 35 U.S.C. § 103, a claimant's invention must be non-obvious to persons skilled in the art of that subject matter at the time of the invention.[87] The threshold question is whether one skilled in the art could obviously bridge the intellectual gap between the claimed invention and the prior art.[88] The courts have enumerated several secondary factors relevant to the determination of obviousness, such as commercial success, long felt but unfulfilled need, and the failure of others to create the invention.[89] If a claimant proves her invention to be both novel and non-obvious, she must finally prove that her invention is useful to society.[90]

3. Utility

A claimant's invention or discovery must be a useful process, machine, or manufacture to be of patentable subject matter.[91] The utility requirement considers three interrelated factors.[92] First, the invention must serve a practical purpose.[93] Second, it must be operable or capable of use.[94] Third, it must be supported by a disclosure adequate to enable a skilled practitioner to use it with no more than routine experimentation.[95] Due to the long duration between the discovery of a gene sequence and the culmination of useful products from that discovery, the utility requirement is problematic to biotech claimants.[96] It is debatable

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patent examiner can quickly determine if broad DNA claims infringe on prior art by use of large computer databases that can be cross-referenced. *See* Carey et al., *supra* note 45, at 73, 76 (discussing advent of private industry databases of identified gene sequences).

[86] *See* § 103.

[87] *Id.*

[88] *See* Kight, *supra* note 22, at 1008-09.

[89] *See* Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966) (discussing secondary factors to consider when possibility for subjective error or inherent difficulty clouds finding on issue of non-obviousness).

[90] *See* § 101.

[91] *Id.* Also, the claimant must disclose a written description of the invention in terms such that any person skilled in the art could make and use the invention. *Id.* § 112 ¶ 1.

[92] Eisenberg & Merges, *supra* note 84, at 4.

[93] *Id.*

[94] *Id.*

[95] *Id.*

[96] *See* Murashige, *supra* note 21, at 236 (discussing how problematic issues in patent protection of DNA forces biotech companies to pursue other forms of protection such as

whether or not an EST meets this statutory requirement of usefulness.[97] Confronted with utility requirement factors and the goals of the Patent Act, courts continually strive to create and adhere to a statutorily valid utility standard.

Traditionally, any market value of an invention operated as proof of the invention's utility.[98] Thus, a presumption of utility attached to all profitable inventions.[99] This was because inventions typically went straight from the inventor's hands to the public (e.g., the light bulb and cotton gin).[100] Therefore, examiners paid little attention to utility because if the invention was useful, then by definition, the public would make use of it.[101] Conversely, if the invention was not useful, the invention itself would fall into disuse, making the patent rights worthless.[102] As Supreme Court Justice Story commented, utility was merely incidental to a patent and primarily worked to bar patents on frivolous inventions.[103] In the mechanical world of the nineteenth century, and much of the twentieth century, this concept of utility seemed both rational and effective.[104]

However, time and progress have dramatically altered the inventive landscape.[105] Modern inventions often accrue benefits far earlier than commercial marketability (e.g., a drug awaiting FDA approval).[106] To stimulate development in these cases, society must protect the invention when the benefits arise, even if the invention is not yet commercially marketable.[107] On the other hand, society can be detrimentally affected if

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trade secret); Kight, *supra* note 22, at 1010. Utility and usefulness, for purposes of this paper, both connote the utility requirement of § 101.

[97] *See* Kight, *supra* note 22, at 1010 (discussing issues that arise when societal benefits of invention accrue before invention is commercially marketable or profitable).

[98] *See* Worrall, *supra* note 1, at 129 (discussing courts traditional take on utility requirement).

[99] *See* Kight, *supra* note 22, at 1010; Worrall, *supra* note 1, at 129.

[100] *See* Kight, *supra* note 22, at 1010 (explaining how traditional inventions "proceeded largely from hands of mechanics as things complete in their own right").

[101] *See id.*

[102] *See* Thomas D. Kiley, *Patents on Random Complementary DNA Fragments?*, 257 SCI. 915, 916 (1992).

[103] *See* Lowell v. Lowell, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817).

[104] *See id.* (stating that utility only included in Act as contradistinction to mischievous or immoral); *see also* Kight, *supra* note 22, at 1010-11 (discussing how market function test of utility was sound in mechanical world).

[105] *See* Kight, *supra* note 22, at 1010-11 (describing how technological advancements varied judicial concept of utility).

[106] *See id.* at 1010 (discussing possibility that benefits may arise prior to commercial marketability).

[107] *See id.*

it protects inventions too early.[108] A premature patent may stunt research and development by rewarding individuals who did not necessarily conduct the innovative work resulting in a beneficial product.[109] In analyzing patent utility issues, courts have continually struggled with how society should maximize stimulation for innovation.[110] The instability of the patent utility standard reflects this struggle.[111]

a. Breathing Life into the Utility Requirement

Over time, Justice Story's utility definition evolved into a multi-faceted standard to meet the changing climate of technological advancement.[112] The advent of innovations in the field of chemical compounds proved particularly troublesome to the utility requirement because their uses were often hypothetical.[113] Courts initially required that chemical compound claimants meet the utility requirement by merely describing the physical or chemical characteristics inherent to the compound.[114] However, courts later required that a claimant assert some usefulness in conjunction with the compound's usage.[115] This standard did not last long, and the degree of usefulness continued to rise for chemical compound claimants.[116]

In *Brenner v. Manson*, the issue was the validity of a patent for a chemical compound that lacked an assertion of utility.[117] The claimant had applied for a patent on a process for making certain steroids.[118] The PTO Board of Patent Appeals and Interferences ("Board") denied the application because the application failed to assert a utility for the

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[108] *See id.* (discussing negative implications for premature patents).

[109] This situation may occur when a patent holder licenses out her proprietary rights to others. *See id.*; *see also infra* text accompanying note 230 (describing hypothetical example of negative impact from granting patents too early).

[110] *See* Worrall, *supra* note 1, at 129-31 (discussing numerous decisions where courts attempt to refine utility standard to ensure real-world value).

[111] *See* Kight, *supra* note 22, at 1010-16 (discussing rise and fall of utility requirement as meaningful standard for chemical compound and, by analogy, DNA patents).

[112] *See id.* at 1011 (describing non-uniform application of Justice Story's original definition of utility).

[113] *Id.*

[114] *See, e.g.*, Potter v. Tone, 36 App. D.C. 181, 184-85 (D.C. Cir. 1911).

[115] *See In re* Bremner, 182 F.2d 216, 217 (C.C.P.A. 1950).

[116] *See, e.g.*, Kight, *supra* note 22, at 1011 (discussing particular scrutiny paid to chemical compounds with claimed value in treatment of human disease).

[117] Brenner v. Manson, 383 U.S. 519, 520 (1966).

[118] *Id.*

process.[119] The United States Court of Customs and Patent Appeals ("CCPA"), predecessor to the Federal Circuit, reversed the Board.[120] The CCPA held that a claimed process producing a known product did not require utility so long as it was not detrimental to the public.[121] The Commissioner of Patents petitioned the Supreme Court to review the CCPA's reversal.[122]

The Court reversed the CCPA and held that substantial utility is an absolute requirement of the Patent Act.[123] The Court further held that no patent would issue until a claimant disclosed an innovation that had been refined and developed to a point "where [a] specific benefit exist[ed] in [a] currently available form."[124] The Court also disagreed with claimant's argument that a chemical process "was 'useful' within the meaning of § 101 either (1) because it work[ed] . . . or (2) because the compound yielded belong[ed] to a class of compounds now the subject of serious scientific investigation."[125] The Court reasoned that a patent "is not a hunting license . . . [it] is not a reward for the search, but compensation for its successful conclusion."[126] However, the Court failed to assert what degree of usefulness was necessary to meet the test of substantial utility.[127]

b. Refining the Utility Requirement

Subsequent cases further refined the utility requirement articulated in *Manson*.[128] The CCPA found that assertions of non-specific biological usefulness would not satisfy the *Manson* utility requirement.[129] However, a credible assertion that a chemical compound could be useful

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[119] *Id.* at 521-22.

[120] *Id.* at 522. Congress created the CCPA in 1929 to hear customs and patent appeals. BLACK'S LAW DICTIONARY 364 (7th ed. 1999). The Federal Circuit superseded the CCPA in 1982. *Id.*

[121] *Manson*, 383 U.S. at 522.

[122] *Id.* at 523.

[123] *Id.* at 535 (overruling CCPA by finding that claimed process in this case was not exempt from utility requirements of Patent Act).

[124] *Id.* at 534-35.

[125] *Id.* at 532-35 (dismissing claimant's second and third arguments for utility).

[126] *Id.* at 536.

[127] *See* Worrall, *supra* note 1, at 130 (noting that both "specific" and "substantial" practical utility are required by *Manson* but adding that *Manson* court failed to define "degree of use necessary to establish 'substantial' utility").

[128] *See id.* at 130-31 (discussing various cases following *Manson* that extended *Manson* rationale to other claims such as intermediate chemical compounds and pharmaceutical drugs).

[129] *See In re* Kirk, 376 F.2d 936, 945 (C.C.P.A. 1967).

in treating a specific human disease, such as cancer, would satisfy the requirement.[130] The CCPA also defined practical utility as utility that is both substantial and specific.[131] Of particular interest in the context of ESTs (where gene-probing is typically the asserted utility) are claims on chemical compounds intermediate to the production of known useful chemical compounds.[132]

The CCPA addressed the issue of intermediate utility in *In re Joly*.[133] The issue in *Joly* was whether a chemical compound, useful as an intermediary to produce a steroid similar to known useful steroids, satisfied the utility requirement.[134] The claimant had applied for a patent on chemical compounds alleging usefulness on grounds that the compounds acted as intermediaries in preparation of a specific group of steroids that were similar to known useful steroids.[135] The Board affirmed the patent examiner's rejection of the claim because the claim failed to meet the utility requirement.[136] The claimant appealed to the CCPA, asserting that the application disclosed utility.[137] The claimant argued that the intermediate compound was useful because it could produce steroids similar to known useful steroids, such as cortisone and prednisone.[138]

The CCPA rejected the claimant's argument and affirmed the Board.[139] The CCPA held that non-useful intermediaries of products with close relation to a known useful product did not satisfy the utility requirement.[140] The CCPA reasoned that if an intermediate process for producing products of only conjectural use is not itself useful, then the process is not useful.[141] The CCPA further reasoned that it is not enough to disclose an intermediary's existence and function to produce some product of no known use.[142] Therefore, under this ruling, it is apparent

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[130] *See In re* Brana, 51 F.3d 1560, 1565 (Fed. Cir. 1995).

[131] *See, e.g., In re* Ziegler, 992 F.2d 1197, 1201 (Fed. Cir. 1993).

[132] *See* Worrall, *supra* note 1, at 130, 137-38 (discussing judicial expansion of *Manson* to chemical compositions as intermediaries and analogizing between chemical intermediaries and EST gene probes).

[133] 376 F.2d 906, 908 (C.C.P.A. 1967).

[134] *Id.* at 907-08.

[135] *Id.* at 907.

[136] *Id.* at 909.

[137] *Id.* at 907-08.

[138] *Id.* at 908.

[139] *Id.*

[140] *Id.*

[141] *Id.*

[142] *Id.*

that the claimant must assert utility satisfactorily in the intermediary's final product to obtain a patent for a non-useful intermediary.[143]

To date, no court has made a direct ruling regarding the utility of DNA compositions or ESTs.[144] To help examiners evaluate these unanswered questions, the PTO published guidelines and training materials for the utility requirement.[145] The guidelines themselves do not constitute law, but instead represent the PTO's current understanding of the law on issues regarding utility.[146] That understanding has proven flexible under the weight of biotech industry influence and societal clamor.[147]

c. Demoting the Utility Requirement Without Authority

PTO examiners use a series of guidelines and training materials during patent prosecution.[148] The guidelines attempt to maintain uniformity in statutory interpretation and compliance with case law.[149] The training materials define standards used in the guidelines and discuss how the guidelines apply to specific claims by use of several hypothetical examples.[150] Over the last seven years, the PTO has published and twice revised the utility guidelines.[151]

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[143] *Id.* at 908; *see* Worrall, *supra* note 1, at 130 (stating that claimants must assert utility for final product of claimed intermediates to satisfy utility requirement); Kight, *supra* note 22, at 1012 (discussing *Joly* as companion case to *Manson* that further defines *Manson* utility requirement standard).

[144] *See* Worrall, *supra* note 1, at 131. *But see Ex parte* Deuel, 27 U.S.P.Q.2d (BNA) 1360, 1365 (Bd. Pat. App. & Interf. 1993), *overruled by In re* Deuel, 51 F.3d 1552, 1560 (Fed. Cir. 1995) (overruling PTO on issue of non-obviousness, leaving question of utility open); *Ex parte* Maizel, 27 U.S.P.Q.2d (BNA) 1662, 1668 (Bd. Pat. App. & Interf. 1992) (remarking that gene sequences encoding growth factor proteins might lack practical utility).

[145] UNITED STATES PATENT AND TRADEMARK OFFICE, REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS 3, *available at* http://www.uspto.gov/web/menu/utility.pdf (last visited Sept. 5, 2002) [hereinafter "Training Materials"] (describing purpose of guidelines and training materials in synopsis).

[146] Utility Examination Guidelines, 60 Fed. Reg. 36,263, 36,264 (July 14, 1995) [hereinafter "1995 Guidelines"]. The PTO states that "[t]he guidelines . . . do not alter the substantive [utility] requirements of 35 U.S.C. [§§] 101 and 112, nor are they designed to obviate review of applications for compliance." *Id.*

[147] *See* Kight, *supra* note 22, at 1014-16 (discussing demise of *Manson* utility under biotech industry pressure).

[148] *See id.*

[149] *See id.*

[150] *See* Worrall, *supra* note 1, at 132-33 (explaining purpose of training materials).

[151] *See id.* at 131-32.

The PTO first published the utility guidelines in 1995.[152] Severe pressure from groups such as the Biotechnology Industry Organization ("BIO") heavily influenced the 1995 Guidelines.[153] These groups became incensed at PTO examiners who challenged the scientific conclusions of recognized experts in the field of the given art.[154] As a result of the 1995 Guidelines, however, opinions of recognized experts began satisfying the utility requirement.[155]

Under the 1995 Guidelines, a claim passed the utility requirement if it was credible.[156] The 1995 Guidelines defined credibility as an assertion of utility that is believable to a person of ordinary skill in the art based on the totality of evidence.[157] Thus, credible utility became an alternative to the practical, substantial, and specific utility required by *Manson*.[158] Essentially, the PTO became a rubber stamp, deferring to the credibility of recognized experts in the field.[159] Asked if ESTs would satisfy utility under the 1995 Guidelines, the PTO replied that any invention with a credible theory of utility would satisfy the requirement.[160]

The PTO intended for the 1995 Guidelines to fashion the utility requirement into a more reasonable standard.[161] However, the standard for patent utility is a concept with its roots in the Constitution, defined by the Supreme Court.[162] Therefore, it would be unconstitutional for the PTO to reshape the utility requirement simply to pacify industry concerns.[163] Alleging the PTO ignored *stare decisis*, many critics found that the 1995 Guidelines went too far in alleviating industry concerns.[164]

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[152] *See id.* at 131; Kight, *supra* note 22, at 1014-16.

[153] *See* Kight, *supra* note 22, at 1014-15 (discussing how BIO argued for less stringent utility requirements on patenting biotechnology inventions at PTO hearing).

[154] Organizations like BIO complained of the PTO's near implicit requirement for human clinical testing to show therapeutic utility. Reginald Rhein, *PTO No Longer Requires Clinicals to Clear Patents*, BIOTECHNOLOGY NEWSWATCH, Jan. 2, 1995, at 1-2.

[155] *See* 1995 Guidelines, *supra* note 146, at 5 (enumerating credible utility as satisfactory in meeting patent utility requirement).

[156] *See id.*

[157] *See id.*; *see also* 50 PAT. TRADEMARK & COPYRIGHT J. (BNA) 295, 303 (July 20, 1995) (discussing 1995 Guidelines' definition of credible utility).

[158] *See* Kight, *supra* note 22, at 1015-16.

[159] *Id.* at 1015.

[160] *Id.* at 1020 (quoting Jeff Cushin, PTO attorney-advisor).

[161] *See id.* at 2 (describing PTO Commissioner Bruce Lehman's stated intent in publishing guidelines to reestablish reasonable level of deference for recognized experts in relevant fields).

[162] *See supra* Part I.B. (explaining Patent Act's roots in Constitution).

[163] Kight, *supra* note 22, at 1017.

[164] *See id.* at 1016 (contrasting Supreme Court's mandate that utility be substantial and specific with 1995 Guidelines that allow credible utility as alternative).

They argued that the Guidelines would allow for patents on non-specific and non-substantial utilities, a direct violation of established case law.[165] Critics further claimed that the 1995 Guidelines issued biotechnology patents too liberally.[166]

The PTO responded to this criticism by drafting new guidelines.[167] The PTO released the Revised Interim Utility Guidelines ("Interim Guidelines") and 1999 Training Materials ("Training Materials").[168] In the release, the PTO expressly invited public comment on the Interim Guidelines and Training Materials.[169] After considering the proffered commentary, the PTO promulgated the current Utility Guidelines in January of 2001 ("2001 Guidelines").[170]

II. 2001 UTILITY GUIDELINES AND TRAINING MATERIALS

The patent utility requirement has fluctuated over time, especially as it relates to DNA.[171] Case law raised the utility requirement from a non-existent standard to an unacceptably high standard.[172] The unacceptably high standard led to the decisions that returned the utility requirement to a more moderate and meaningful standard.[173] However, the PTO's

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[165] Revised Utility Examination Guidelines; Request for Comments, 64 Fed. Reg. 71,440, 71,441 (Dec. 21, 1999) [hereinafter "Interim Guidelines"]. See "I. Discussion of Public Comments" for a discussion of public criticism inciting the incorporated changes.

[166] Worrall, *supra* note 1, at 131-32.

[167] *Id.*

[168] *See supra* notes 145 and 165 (identifying sources of Interim Guidelines and Training Materials).

[169] *See* Interim Guidelines, *supra* note 165, at 71,440; *see, e.g.*, Letter from Charles E. Ludlam, Vice President for Government Relations, to The Honorable Q. Todd Dickinson, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks (Mar. 22, 2000) (on file with author) (responding on behalf of BIO to request for comments on 1999 Interim Written Description Guidelines); Letter from Jack Spiegel, Ph.D., Director, Division of Technology Transfer, National Institute of Health, to The Honorable Q. Todd Dickinson, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks (Mar. 22, 2000) (on file with author) (responding to request for comments on 1999 Interim Written Description Guidelines).

[170] Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112 ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1,099, 1,099 (Jan. 5, 2001) [hereinafter "2001 Guidelines"]. These guidelines are to supersede the "Revised Interim Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112 ¶ 1 'Written Description' Requirement", 64 Fed. Reg. 71,427, 71,427 (Dec. 21, 1999). The 2001 Guidelines are essentially the same as the Interim Guidelines.

[171] *See* Kight, *supra* note 22, at 1010-14 (describing fluctuating character of utility requirement as meaningful standard for DNA patents).

[172] *See* Eisenberg & Merges, *supra* note 84, at 5 (discussing court's requirement that chemical compounds used on humans carry higher burden of utility).

[173] *See* Worrall, *supra* note 1, at 129-31 (discussing court's return to meaningful utility

1995 Guidelines interpreted the utility standard to be far less stringent than previously established in *Manson*.[174] The PTO endeavored to rectify the errors of the 1995 Guidelines by revising them with the 2001 Guidelines and 1999 Training Materials.[175]

The 2001 Guidelines swung the pendulum back towards the more rigorous utility standard set forth under *Manson*.[176] Under the 2001 Guidelines, claimants must disclose either a well established utility, or a practical utility (i.e., specific and substantial utility) that one skilled in the art would consider credible.[177] The burden of proof for initial rejection of the claim rests with the examiner.[178] Thus, the examiner must prove a lack of utility by a preponderance of the evidence and then allow the claimant to submit additional proof of utility.[179] Lastly, the PTO must presume the claimant's assertions of utility are true unless one of ordinary skill in the art might reasonably doubt the assertion.[180]

In addition to the 2001 Guidelines, examiners and prosecutors have access to the 1999 Training Materials to help discern patentable from non-patentable utility.[181] The Training Materials cite and develop thirteen hypothetical applications.[182] Twelve of the thirteen applications focus on biotechnology patents, with two of them specific to DNA.[183] The two DNA examples discuss EST claims.[184] While one example involves an EST that is useful as an intermediate to identification of its complete gene sequence, the other example's EST is ninety-five percent homologous to an EST that produces protein of well-known usefulness.[185]

The Training Materials are helpful in defining the different forms of utility in the 2001 Guidelines.[186] The Training Materials define credible

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standards in *Joly* and *Brana*).

[174] *See* Rhein, *supra* note 154, at 1-2 (describing how industry pressure forced PTO's hand in publication of less stringent guidelines); *supra* text accompanying note 153.

[175] *See* Worrall, *supra* note 1, at 133-34 (stating that "2001 Guidelines correctly restate utility requirement according to established case law").

[176] *See id.* at 132.

[177] 2001 Guidelines, *supra* note 170, at 1098.

[178] *Id.*

[179] *Id.*

[180] *Id.* at 1098-99.

[181] *See* Worrall, *supra* note 1, at 132-33.

[182] Training Materials, *supra* note 145, at 13-74.

[183] *Id.*; Worrall, *supra* note 1, at 133.

[184] Training Materials, *supra* note 145, at 50-55; *see* Worrall, *supra* note 1, at 133.

[185] Training Materials, *supra* note 145, at 50, 53-54.

[186] *See id.* at 5-8.

utility as utility that a person of ordinary skill in the art would believe to be currently available.[187] Specific utility means a usage that is specific to the claimed invention.[188] Substantial utility requires a real world use.[189] Utilities that require further research to confirm a real world usage do not meet the standard of substantial utility.[190] Lastly, the Training Materials define a well established utility as one that is well known, immediately apparent, or implied either alone or with the knowledge of one skilled in the art.[191] It is unclear how this increased utility standard will play out for EST patent applications.[192]

III. AN INCOMPLETE STEP IN THE RIGHT DIRECTION

The 2001 Guidelines and Training Materials, as a package, fail to completely follow the reasoning in *Manson*. Illustrative of this misinterpretation are the two hypothetical examples in the Training Materials. These examples could lead examiners to reject applications for the wrong reasons. Nevertheless, the 2001 Guidelines successfully address many of the issues involving the utility requirement. The 2001 Guidelines properly reallocate the rewards of innovation to the actual innovator. Additionally, the 2001 Guidelines effectively address the moderate concerns of gene patenting.

A. Imperfect Training Materials

One commentator's examination of the Training Materials reveals discrepancies that may result in an improper application of the 2001 Guidelines.[193] The Training Materials deal with gene patent application issues in two examples.[194] The examples, however, illustrate that the PTO still does not have a firm grasp on the application of case law to gene patenting.[195]

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[187] *Id.* at 5.

[188] *Id.* at 5-6.

[189] *Id.* at 6-7.

[190] *Id.* at 6.

[191] *Id.* at 7-8.

[192] *See generally* Worrall, *supra* note 1, at 133-43 (discussing impact of 2001 Guidelines on gene patenting, including possible misapplication and public comments).

[193] *See generally* Worrall, *supra* note 1, at 141-43 (analyzing misapplication of Training Materials).

[194] *See* Training Materials, *supra* note 145, at 50-55 (discussing hypothetical DNA fragment and DNA sequence containing full open reading frame).

[195] *See* Worrall, *supra* note 1, at 140-43 (discussing misapplication of case law in Training Materials).

1. Example Nine of Training Materials — Gene Probes

Hypothetical example nine discusses a patent application on an EST derived from a complete gene sequence.[196] The claimant asserts utility for the EST as a probe used to detect the complete gene sequence.[197] The PTO rejects the claim because the target gene does not itself possess a known or asserted utility.[198]

This analysis is inconsistent with precedent on analogous patent applications of chemical compounds.[199] A probe, acting as a useful intermediate, need only possess specific, substantial, and credible utility.[200] Furthermore, the Federal Circuit noted that an applicant need not prove the cause of the invention, implying that known utility was not required.[201]

Under the PTO's analysis in the Training Materials, examiners would reject the hypothetical application for the wrong reasons.[202] The commentator's scrutiny reveals an unmentioned flaw in example nine's application.[203] The Federal Circuit found that advancing future research was an insufficient assertion of usefulness in a claimed invention.[204] In example nine, the probe EST only operates to identify its own complete gene sequence.[205] Arguably, this function relates to future research and might not satisfy *Manson*'s specific and substantial utility requirement. Therefore, the application should be rejected on these grounds rather than those asserted in the Training Materials.[206]

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[196] Training Materials, *supra* note 145, at 50 (describing hypothetical DNA fragment application).

[197] *Id.*

[198] *Id.* at 52. Furthermore, the PTO ultimately rejects the claim because the applicant fails to disclose the mechanism whereby the EST operates as a probe. *Id.* at 53 (stating that "one skilled in the art would not know how to use the claimed invention").

[199] *See* Worrall, *supra* note 1, at 140-41.

[200] *See id* at 141.

[201] *See, In re* Cortright, 165 F.3d 1353, 1359 (Fed. Cir. 1999) (finding that it was unnecessary for claimant to prove cause of hair growth to demonstrate utility); Worrall, *supra* note 1, at 141.

[202] *See* Worrall, *supra* note 1, at 141.

[203] *See id.*

[204] *In re* Kirk, 376 F.2d 936, 945 (C.C.P.A. 1967); *In re* Joly, 376 F.2d 906, 908 (C.C.P.A. 1967); Worrall, *supra* note 1, at 141.

[205] Training Materials, *supra* note 145, at 50 (specifying EST used as probe in identifying its own full length gene); *see* Worrall, *supra* note 1, at 141.

[206] *See id.*

2. Example Ten of Training Materials — Utility by Homology

Hypothetical example ten discusses a patent application on an EST asserting usefulness in production of a protein similar to a protein of known usefulness.[207] The application asserts that the EST in question produces a protein ninety-five percent homologous to ligase enzymes with known useful function.[208] Furthermore, the application asserts fifty percent homology to alpha-actin proteins also with known useful function.[209] Under the PTO analysis, examiners would accept the EST in question because high homology to a gene sequence with known function meets the utility requirement because the utility is well-known in the art.[210]

As the commentator noted, the PTO has again side stepped the threshold issue of determining specific and substantial utility in the EST in question.[211] Utility based on homology fails to address this threshold issue.[212] Small differences between homologous gene sequences can significantly impact biological functions.[213] Furthermore, highly homologous gene sequences may produce proteins with distinctively different biological functions.[214] Therefore, utility of an EST based upon high homology to an EST that encodes a protein of known function might not be specific and substantial. Under example ten's analysis, the PTO may find itself granting patent rights that courts will ultimately invalidate.[215] Thus, examiners may inefficiently accept patent claims as a result of following example ten's approach.

B. Maintaining the Incentive-to-Invent — The Reward Theory

Compared with the Training Materials, the 2001 Guidelines are more consistent with *Manson*'s reasoning. One well established theory for granting patent monopolies is to encourage innovation and technological

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[207] *See* Training Materials, *supra* note 145, at 53-54 (describing hypothetical application of DNA fragment with full open reading frames).

[208] *Id.* at 54.

[209] *Id.*

[210] *Id.* at 54-55.

[211] *See* Worrall, *supra* note 1, at 142.

[212] *See id.*

[213] *See* LEWIN, *supra* note 24, at 89-93 (explaining that acquired mutations in DNA can alter function of protein encoded by its gene).

[214] *See id.*; Worrall, *supra* note 1, at 143.

[215] *See* Worrall, *supra* note 1, at 143. *But see* 2001 Guidelines, *supra* note 170, at 1104 cmt. 30 (discussing public criticism of Training Materials and PTO's intention of taking criticisms under advisement when it revises Training Materials).

advancement.[216] In granting this monopoly, society receives the benefits flowing from the innovation.[217] Furthermore, because the monopoly is temporary, society also benefits from full disclosure of the innovation.[218] Accepting this scheme of patents, society should strive to grant the incentive such that it results in maximum benefits to the public.[219]

The 2001 Guidelines, reflective of *Manson*, raise the utility bar to a greater showing of practical utility.[220] The benefits to society of such an arrangement can be seen in the partial gene sequence (i.e., EST) patent conflicting with subsequent complete gene sequence research. Assume the PTO grants a patent on an EST prior to the research needed to create a useful and practical product. Existence of the EST patent discourages everyone, other than the EST patent holder, from researching the complete gene because patent protection is no longer available.[221] If the EST patent holder neglects to carry out the necessary research, the patentee will rob society of a great benefit (at least until the patent lapses).[222]

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[216] *See* Phanesh Koneru, *To Promote the Progress of Useful Articles?: An Analysis of the Current Utility Standards of Pharmaceutical Products and Biotechnology Research Tools*, 38 IDEA 625, 631-33 (1998) (discussing well-established "reward theory" for granting patent monopolies). *See generally* Richard R. Nelson, *The Economics of Invention: A Survey of the Literature*, 32 J. BUS. 101, 101-19 (1959) (surveying economic studies explaining two aspects of inventions: that business decisions such as demand and cost drive pursuit of new inventions, and that uncertainty exists when inventing new things).

[217] *See generally* Edward C. Walterscheid, *To Promote the Progress of Science and Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution*, 2 J. INTELL. PROP. L. 1, 13 (1994).

[218] *See* Giles S. Rich, *The Principles of Patentability*, 42 J. PAT. OFF. SOC'Y 75, 83-84 (1960).

[219] *See* Koneru, *supra* note 216, at 647-48 (discussing difficulty of determining practical utility). Koneru envisions a utility scale, where commercial utility is located on one end, and research utility located on the other. Practical utility, says Koneru, exists at some point in between the two ends. *Id.*

[220] *See* Worrall, *supra* note 1, at 133 (describing additional requirements in 2001 Guidelines compared to 1995 Guidelines).

[221] *See* Kight, *supra* note 22, at 1006-07 (discussing incomplete development of patent protected inventions not yet capable of benefiting society).

[222] *See id.*; *see also* Holman & Munzer, *supra* note 24, at 774-93 (arguing that patents on partial gene sequences decreases incentives for research on complete gene sequence and leads to incomplete use of genetic discoveries); Murashige, *supra* note 21, at 236 (arguing that patents on EST claims grant "too much protection for . . . too little contribution"); Adler, *supra* note 37, at 910 (discussing study that reported sixty percent of pharmaceutical products would not have been developed without availability of patent protection). Also, the EST patent holder may find herself with a windfall if she licenses out the patent to complete the invention into a useful product, thereby accruing benefits for innovation of another. Kight, *supra* note 22, at 1006-07. *But see* Koneru, *supra* note 216, at 661 (arguing that fears about patents on research intermediaries effectively blocking future research areas are untenable and unrealistic).

Some criticize that *Manson* misapplies the reward theory.[223] These critics believe that the utility of an invention should be borne out by the commercial success of the invention.[224] If the invention proves to be a commercial success, it will benefit the public.[225] Conversely, if the invention is useless to society, then the patent, and the monopoly, become worthless.[226] Furthermore, these critics also maintain that a heightened utility requirement increases the likelihood of duplicative work as inventors secretly race to useful, patentable products.[227]

These critics apparently assume that the useless aspect of a claim limits the claim itself; thus any monopoly is also useless.[228] The patent system, however, cannot be assumed perfect.[229] Inevitably, patents in the biotech field may be granted in such a broad manner that society loses numerous benefits included, but unrealized, in the claim.[230] These critics also overemphasize *Manson*'s holding.[231] *Manson* does not require absolute proof of societal benefit and usefulness.[232] *Manson* merely resuscitates the utility requirement from nullity into a meaningful hurdle.[233]

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[223] Koneru, *supra* note 216, at 650.

[224] *See id.*; Rich, *supra* note 218, at 84-85.

[225] *See* Rich, *supra* note 218, at 84-85.

[226] *See id.*

[227] *See* Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 313 (1992).

[228] *See* Koneru, *supra* note 216, at 661-62 (disregarding argument that research patents might effectively block off future research).

[229] *See id.* at 663-64 (discussing that effective solution to imperfect patent system is narrowing scope of product claims to what has been disclosed only).

[230] To illustrate this situation, assume that Claimant claims X (an EST) in a patent application prior to proving practical societal usefulness of X. Furthermore, assume that X happens to be part of the complete gene sequence XYZ. If the PTO grants the patent on X, a third party is less inclined to research the XYZ complete gene sequence for a useful product. *See* Heller & Eisenberg, *supra* note 74, at 699. This is because it is uncertain whether the patent on X would somehow be infringed by a product stemming from XYZ. *See id.* Assume further that Claimant maintains the X patent but fails to research the XYZ complete gene sequence. *See id.* at 700. If Y or Z is in fact useful to society, then society is robbed of the benefits of Y or Z. *See id. But see* Koneru, *supra* note 216, at 650 (arguing that patents without commercial value could not injure public because unwanted patents protect nothing useful).

[231] *See* Kight, *supra* note 22, at 1011-12 (describing *Manson* holding as meaningful concept of utility that prevents monopoly of knowledge).

[232] *See id.* (noting Court's recognition that applying traditional broad definition of utility to claims involving contemporary chemistry would undermine patent system).

[233] *See id.* (noting Court's reasoning that patent system must associate with commerce rather than philosophy, and finding that utility requirement could serve as timing function).

C. Ensuring the Viability of Patent Rights on Genetic Innovations

Aside from countervailing legal arguments concerning patents on genes, there exists a looming shadow of public resentment regarding private profiteering from gene patenting.[234] Nonprofit organizations such as the Council for Responsible Genetics ("CRG") advocate an absolute ban on gene patenting.[235] CRG argues that any patents on genes effectively treats biological organisms as commodities for profit, demoting living beings to little more than gene machines.[236] CRG supports this position with several arguments.[237] First, gene patents make important products more expensive and less accessible.[238] Second, gene patents promote secrecy and hinder the exchange of information.[239] Third, gene patents allow private corporations to exploit taxpayer funded research.[240] Lastly, First World patenting of Third World genetic resources represents theft of community resources.[241] Given sufficient momentum, organizations like CRG may force Congress to enact laws that remove genetic innovations from patent law subject matter altogether.[242]

Religious leaders have also entered the debate, objecting to any form of gene patenting.[243] Religious activists such as Jeremy Rifkin and 200 other religious leaders signed a statement opposing human gene patents.[244] They have vehemently argued that patenting the blueprints of human life is an indefensibly immoral act.[245] These arguments, while resonating with much of the public, fail to consider the ramifications of an absolute ban on gene patenting.

Pursuing their goals zealously, opponents of gene patenting fail to consider the public benefit accrued from encouraging genetic research. To bring useful genetic products to market, biotech industries require

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[234] *See* Dastgheib-Vinarov, *supra* note 60, at 173-74 (discussing public anger over biological patents).

[235] *See id.*

[236] *See* Council for Responsible Genetics, No Patents on Life Petition (Jan. 5, 2002), *available at* http://www.gene-watch.org/petition/index.html.

[237] *See* Dastgheib-Vinarov, *supra* note 60, at 174 (explaining CRG's position on DNA patenting).

[238] *Id.; see also* Rai, *supra* note 4, at 184-85 (discussing issue of access and pricing).

[239] *See* Dastgheib-Vinarov, *supra* note 60, at 174.

[240] *Id.*

[241] *Id.*

[242] *See id.* at 174 (discussing global movement evidenced by organizations like CRG).

[243] *See id.* at 177-78.

[244] *Id.* at 178.

[245] *Id.*

large amounts of capital investment.[246] Without proprietary protection of these investments through patent law, private investors would be less inclined to apply their capital to genetic research.[247] Dr. Venter has poignantly argued that genetic innovations are not developed by the church, but rather by large companies with hundreds of investors.[248]

Disregarding the necessity of incentive for the moment, inevitability may also frustrate opponents of gene patenting. An outright denial of patent rights on genetic research may only succeed in slowing down and complicating the inevitable advancement of modern genetic technology.[249] Supreme Court Chief Justice Burger noted that denying patent rights on biological products would not terminate genetic research or its attendant risks.[250] Chief Justice Burger supported his assertion by referencing abundant genetic research that biotech industries had engaged in prior to any assurances of patent protection.[251] Opponents to gene patenting should set realistic goals of more moderate restrictions on gene patenting.

The 2001 Guidelines will mollify some, but not all, of gene patenting opponents. By heightening the utility requirement for gene patents, society will gain greater assurances of accruing public benefit.[252] This improvement to the *quid pro quo* contract between society and private industries will also lessen the possibility of opportunism and unwarranted private profit.[253] These shifts in the cost-to-benefit analysis

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[246] *See* Malinowski & O'Rourke, *supra* note 4, at 205 (discussing "drug lag" requiring seven to twelve years and $400 million to bring one new drug to market from initial discovery of gene); Rai, *supra* note 4, at 184-85 (discussing large amount of capital required for genetic research and product manufacturing); Paley, *supra* note 4, at 1007 (asserting that cost to identify one gene through functional approach ranges from $40,000 to $50,000); Marshall, *supra* note 4, at 643 (discussing cost of automated sequencer used in identifying genes through partial gene sequence identification method); Nesbit, *supra* note 4, at B8, *available at* 1996 WL 2966695 (discussing $10 million investment made by Microsoft in single biotech company).

[247] *See* Rai, *supra* note 4, at 184.

[248] *See* Dastgheib-Vinarov, *supra* note 60, at 178.

[249] *See* Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980).

[250] *Id.*

[251] *Id.*

[252] *Cf.* Ben-Ami, *supra* note 9, at 558 (discussing questionable benefit to society from ESTs without known uses).

[253] *See* Letter from Bruce Alberts, President of the Council of the National Academy of Sciences, to Q. Todd Dickinson, Commissioner of Patents and Trademarks (Mar. 22, 2000) (on file with author) (stating that "[t]hose who would patent human DNA sequences without real knowledge of their utility are staking claims not only to what little they know at the moment, but also to everything that might later be discovered about the genes and proteins associated with the sequence. They are, in effect, laying claim to a function or use

may attract moderate opponents to genetic patenting away from zealous organizations like CRG. Thus, the 2001 Guidelines will remove much of the wind from the sails of those organizations that intend to shut down gene patenting altogether.[254] Maintaining the viability of patents on genetic innovations will benefit both genetic research and society in general.[255]

CONCLUSION

Despite biotech industry influence, the PTO has accurately returned the patent utility requirement to a meaningful requirement for the benefit of society. The PTO correctly remedied the misapplication of case law in the 1995 Guidelines by superseding them with the 2001 Guidelines. First, the 2001 Guidelines maintain the incentive to innovate while eroding the detriments of granting patent rights too early.[256] Second, the 2001 Guidelines properly reallocate the rewards of innovation to the actual innovator. Third, the 2001 Guidelines takes steps in the right direction to quell a growing movement for banning all patents on genetic innovations. This shift may mollify concerns of the moderate opponents to gene patenting, thus ensuring the viability of genetic innovation. The PTO can now more assuredly guarantee society that sub-par innovators are denied the ability of controlling downstream research on useful genetic innovations.[257]

However, examiners relying on the complimentary Training Materials to the 2001 Guidelines may still grant invalid gene patents.[258] Ultimately, the PTO must completely rectify the misapplication of case law in the 1995 Guidelines by correctly revising the Training Materials.[259] In doing

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that does not yet exist").

[254] *Cf.* Dastgheib-Vinarov, *supra* note 60, at 179 (arguing that, unless Federal Circuit raises nonobvious requirements for gene patents, biomedical research may experience big chill from unnecessarily harsh Congressional legislation regulating gene patenting).

[255] *Cf. id.* (discussing how biomedical research will advance more quickly and efficiently if given proper encouragement).

[256] *See* Worrall, *supra* note 1, at 133 (stating that new 2001 Guidelines "may prevent inventors from seeking patent protection for speculative DNA patents," such as would be allowable under 1995 Guidelines so long as it was credible); *cf.* Koneru, *supra* note 216, at 632 (stating that, unlike 2001 Guidelines, 1995 Guidelines encouraged race to catalogue EST information with little regard for usefulness of information).

[257] Kight, *supra* note 22, at 1024 (claiming that 1995 Guidelines wrongly reward prematurity and mediocrity); Worrall, *supra* note 1, at 143 (discussing how 2001 Guidelines will restrain "shotgun cloners" from blocking encouragement of downstream research).

[258] Worrall, *supra* note 1, at 143 (arguing that new training materials should provide PTO with threshold requirements).

[259] *Id.* (claiming that if Training Materials are not corrected, PTO might issue invalid

so, the PTO may even allay one of Thomas Jefferson's worst fears: a patent system that allows the "granting of monopolies which might withhold technological progress . . . from the general public."[260]

patents).

[260] SILVIO A. BEDINI, THOMAS JEFFERSON STATESMAN OF SCIENCE 207 (1990).