AN END TO GENE PATENTS? THE HUMAN GENOME PROJECT VERSUS THE UNITED STATES PATENT AND TRADEMARK OFFICE'S 1999 UTILITY GUIDELINES

MARY BREEN SMITH*

INTRODUCTION

Scientists working on the Human Genome Project (HGP) have recently determined the complete chemical structure of the human genome and have made the information available to the public. The human genome is a vast storehouse of information. It contains the complete genetic "blueprint" to build a human, coding for every chemical involved in the life process. In fact, the new human genomic information made available by the HGP promises to start "a period of scientific advancement that will alter the way medicine is practiced far into the future."[1]

Many entities, both public and private, seek to use the genetic information from the HGP to find new lifesaving drugs. These private entities include the pharmaceutical, biotechnology, and genomics industries. But the road from the HGP to a marketed drug is far from smooth. The costs of research and development are steep. In addition to the funds for years of research, companies must conduct clinical trials to prove the drug's efficacy and safety, as required for Food and Drug Administration (FDA) approval. These requirements can raise the cost of each new drug to hundreds of millions of dollars. Because of these expenses, companies involved in new drug development require "considerable capital expenditure."[2]

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* Candidate for Juris Doctor, University of Colorado School of Law, 2002; B.S., Biochemistry, University of California at Davis, 1987. The author also worked ten years as a laboratory researcher and two years as a patent agent in the biotechnology industry. Many thanks to Christopher G. Smith.

1. Elizabeth Silverman et al., *Introduction* to Genomics: An Investor's Guide (1996) (on file with author).

2. Bruce Lehman, *Major Biotechnology Issues for the U.S. Patent and Trademark Office*, 33 CAL. W. L. REV. 49, 50 (1996).

Enter patent law. Patents allow companies to recoup their research and development costs by allowing them to exclude competitors. Commentators agree that "the ability to get that capital is very much dependent upon the capacity to get patent protection for a prospective product."[3] The United States Patent and Trademark Office (PTO) recognizes this fact. As the former Commissioner of Patents and Trademarks remarked, "there are few subjects of greater importance to the development of biotechnology than the issuance of patents."[4]

In light of the vital importance of the United States patent system to the biotechnology and related industries, developing effective patent laws is essential. Yet an appropriate patent regime lags behind the pace at which this technology is developing. Although the PTO has been awarding patents to genes for approximately twenty years,[5] the courts have not solved many of the fundamental questions concerning the patentability of genetic information.[6]

One such unresolved question is the matter of the "utility" requirement for DNA[7] sequences. Recently, the PTO issued the 1999 Revised Interim Utility Guidelines ("1999 Guidelines" or "Guidelines"), which has changed the way in which the agency evaluates the "utility" of genetic inventions.[8] The PTO's goal is to make it more difficult to obtain patents to genes by prevent-

3. *Id.*

4. *Id.*

5. Patent claims are viewed similarly to the "metes and bounds" of a land grant. They function to "measure the invention," i.e., define what the inventor considers to be his invention. *See* DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 103 (2d ed. 2001). Inventors have long been able to obtain claims to chemical compounds, and the courts consider genes to be a type of chemical compound. *See* Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991).

6. *See* Rebecca S. Eisenberg, *Re-examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 784 (2000).

7. DNA stands for deoxyribonucleic acid, which is the chemical building block of the human genome.

8. *See* 35 U.S.C. § 101 (1994). Briefly, the "utility" requirement in the patent law states that in order for an invention to be patentable, the invention must be "useful," meaning that it serves society in some way. Mere laboratory curiosities, for example, do not have "utility" under the patent laws. *See generally* CHISUM ET AL., *supra* note 5, at 707. The Patent Office has proposed changes in the Revised Utility Examination Guidelines, 64 Fed. Reg. 71,440 (proposed Dec. 21, 1999). A final version of the 1999 Guidelines was promulgated in January 2001, 66 Fed. Reg. 1092 (Jan. 5, 2001).

ing the patenting of genes having no known use.[9] Specifically, the 1999 Guidelines prevent inventors from obtaining patents to DNA sequences unless the DNA has a "specific" and "substantial" commercial application.[10]

There are benefits to the 1999 Guidelines. For one, they prevent scientists from filing patent applications on the entire human genome sequence.[11] But there are problems with the 1999 Guidelines. This Comment focuses on one of the more serious drawbacks of the 1999 Guidelines, namely that the Guidelines have the potential to prevent gene patents altogether.[12]

It is hard to believe that the PTO, with its 1999 Guidelines, intended to bring an end to gene patents after years of granting them. Instead, such an outcome is likely inadvertent, arising from rapid change in the methods of human genetic research due to the HGP.[13] Before the HGP, researchers determined function first, by noticing a particular biological action, and then found the responsible DNA sequence,[14] a process that could take years.[15] In contrast, the HGP only identifies raw DNA sequence, yet mere DNA sequence data does not necessarily reveal the biological function of that sequence.[16] Thus, although chemical structure is identified, function is not.[17] As

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9. Mattias Luukkonen, Note, *Gene Patents: How Useful Are the New Utility Guidelines*, 23 T. JEFFERSON L. REV. 337, 352 (2001).

10. Revised Utility Examination Guidelines, *supra* note 8, at 71,441. For an explanation of the terms "specific" and "substantial," see *infra* Part II.D.2.

11. Byron Olsen, *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing the Useful Arts*, 7 ALB. L.J. SCI. & TECH. 295, 306 (1997).

12. There are those who favor this result. For example, the graduate student who wrote GigAssembler, the computer program that assembled the human genome, was motivated by the desire to get the information into the public domain in order to prevent the human genome from being "locked up by commercial patents." Nicholas Wade, *Grad Student Becomes Gene Effort's Unlikely Hero*, N.Y. TIMES, Feb. 13, 2001, at F1.

13. Leena Peltonen & Victor A. McKusick, *Dissecting Human Disease in the Postgenomic Era*, 291 SCI. 1224, 1225 (2001).

14. Newer research methods include the ability to "obtain and sequence expressed DNA gene fragments without knowing . . . the biological function of the proteins coded by these sequences." John Murray, Comment, *Owning Genes: Disputes Involving DNA Sequence Patents*, 75 CHI.-KENT. L. REV. 231, 236–37 (1999).

15. For an example of this method, see the discussion of finding the gene for Marfan Syndrome in WILLIAM S. KLUG & MICHAEL R. CUMMINGS, CONCEPTS OF GENETICS 465 (5th ed. 1997).

16. *Id.* at 477.

17. Gretchen Vogel, *Objection #2: Why Sequence the Junk?*, 291 SCI. 1184, 1184 (2001).

a result, the HGP's human genome sequence information consists of vast amounts of DNA of no known function.[18] Yet the 1999 Guidelines require both structure and function for a gene patent.

The approach of the 1999 Guidelines, requiring both structure and function for DNA to be patentable, makes sense in a world where structure and function are identified together. However, in a post-HGP world, this rarely happens. Instead, the function of almost all the DNA sequence from the HGP is unknown, and therefore, under the 1999 Guidelines, is not patentable.[19] Further, it will never be patentable. Section 102 of the Patent Code creates absolute, time-based bars to obtaining patents.[20] Finding a useful function later will not matter.[21]

Preventing patents to gene sequences could have severe consequences to companies trying to develop drugs. Many of the drugs developed by biotechnology and pharmaceutical companies are protein therapeutics.[22] Gene patents are the most desirable way in which to protect protein therapeutics because of the broad scope of coverage they provide.[23] It is a poor business strategy for companies to spend hundreds of millions of dollars developing a drug that can be sold by any of their competitors. Yet, without patent protection, this is precisely what can happen. Competitors would be able to significantly undercut the price because they did not incur the development costs of the drug.[24]

Part I of this Comment explains the financial constraints on the biotechnology industry and gives some scientific background on genes and DNA; Part II examines general requirements for patentability of DNA sequences and the utility requirement in particular. Part III argues that the current utility requirements for patenting DNA sequences, as they interact with the novelty requirements for a patent, will act to prevent claims to any DNA sequence in the future. Part IV

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18. For example, ninety-eight percent of the human genome does not code for proteins. *Id.*

19. *See generally* Revised Utility Examination Guidelines, *supra* note 8.

20. *See* 35 U.S.C. § 102 (1994).

21. Olsen, *supra* note 11 at 326.

22. Protein therapeutics are proteins, the end product of genes, that are used directly as medicines to treat disease. Olsen, *supra* note 11, at 304.

23. *See* CHISUM ET AL., *supra* note 5, at 683 (quoting from *Ex parte* Deule, 33 U.S.P.Q.2d 1445, 1447 (Bd. Pat. App. & Int'f 1993)).

24. *Id.* at 61.

discusses the possible impacts of this claim prevention on the biotechnology industry. Part IV then proposes some solutions.

I. THE GENOMICS, BIOTECHNOLOGY, AND PHARMACEUTICAL INDUSTRIES

The following discussion reviews basic information about genes and DNA, the HGP, and the biotechnology and pharmaceutical industries. Part A of this section introduces basic concepts about genes and DNA and explains recombinant DNA technology, a basic tool of biotechnology. Part B reviews the information obtained from the HGP. Part C considers how the biotechnology industry finds new drugs and examines the costs and pressures on the industry.

A. Basic Overview of Genes, DNA, and Recombinant DNA Technology

1. DNA in a Nutshell

DNA, or deoxyribonucleic acid, is the molecule in a living cell that enables the cell to reproduce itself.[25] DNA has a specific chemical structure, comprising a long chain of chemicals consisting of a sugar molecule, a phosphate group, and one of four nucleotide bases: adenine, guanine, thymine, or cytosine (abbreviated as A, G, T, or C).[26] These four bases are the "alphabet" of DNA; the order and sequence of these four bases in DNA is the basic information allowing for the variety of life on this planet. To form the complete DNA strand, the nucleotide bases on one long chain (or strand) can pair up with those on another strand, such that A pairs with T and C pairs with G.[27] This pairing is also referred to as the "double helix," because as the two strands of DNA pair, they wind around each other. This structure protects the strands from damage and keeps them dormant until needed.[28]

There are approximately three billion nucleotide base pairs in the human genome.[29] These base pairs are organized into

25. KLUG & CUMMINGS, *supra* note 15, at 263.
26. *Id.* at 274.
27. *Id.* at 279.
28. *Id.* at 278.
29. Elizabeth Pennisi, *The Human Genome*, 291 SCI. 1177, 1178 (2001).

units called chromosomes, of which the human cell contains twenty-three.[30] A gene is a small segment of the chromosome and is the functional unit of heredity.[31] Scientists believe that each chromosome contains hundreds to thousands of genes.[32] Genes code for specific proteins, which are molecules comprised of amino acids.[33] To translate the gene sequence into its designated protein, the cell contains machinery that "serially read[s] groups of three adjacent nucleotides [in the gene]. Each combination of three adjacent nucleotides, called a *codon*, specifies a particular amino acid."[34]

Proteins are the chief components of the cell, comprising the cell's primary structural, regulatory, and energy generating molecules. [35] The gene coding for the protein determines the order of the twenty different amino acids, and the order of amino acids determines a protein's function and activity.[36] Scientists have traced many diseases to a deficiency, oversupply, or abnormal regulation of a particular protein in the cell.[37] Thus, one way to treat diseases traced to lack of particular proteins is to exogenously administer those proteins.[38] Many biotechnology companies produce proteins, which are used to treat disease.[39]

2. Introduction to Recombinant DNA Technology

In 1973, researchers Herbert Boyer and Stanley Cohen demonstrated that "a gene could be cut from the DNA of one organism, recombined *in vitro* with DNA of a host organism, and re-introduced into cells of the host to confer the gene's

30. KLUG & CUMMINGS, *supra* note 15, at 222.

31. *Id.* at 6–7.

32. Courtney J. Miller, Comment, *Patent Law and Human Genomics*, 26 CAP. U. L. REV. 893, 896 (1997).

33. KLUG & CUMMINGS, *supra* note 15, at 364.

34. *In re* O'Farrell, 853 F.2d 894, 897 (Fed. Cir. 1988).

35. *See generally* KLUG & CUMMINGS, *supra* note 15, at 379.

36. *Id.* at 374, 384.

37. *See* Lisa A. Karczewski, Comment, *Biotechnological Gene Patent Applications: The Implications of the USPTO Written Description Requirement Guidelines on the Biotechnology Industry*, 31 MCGEORGE L. REV. 1043, 1050–51 (2000).

38. *Id.* at 1050.

39. Jeremy Cubert, *U.S. Patent Policy and Biotechnology: Growing Pains on the Cutting Edge*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 151, 152 (1995).

characteristic trait to the host."[40] With this demonstration, recombinant DNA technology became possible.[41] Using these techniques, scientists can transfer a gene coding for a particular protein from one organism, such as a mouse, into another organism, such as a bacterium.[42] An organism carrying an inserted gene is called a "transgenic" organism.[43]

The development of human insulin to treat diabetes illustrates one use of recombinant DNA technology resulting in a human drug.[44] In one type of diabetes, patients lack the protein insulin, which regulates blood sugar.[45] Researchers isolated the gene coding for insulin and transferred—or cloned—it into bacteria.[46] The bacteria were then grown in large quantity.[47] While growing, the bacteria produced large quantities of insulin, allowing scientists to later separate and purify the insulin for use in humans.[48]

Use of human insulin to treat human diabetes is a significant improvement over the previous technology of treating human diabetes with non-human insulin extracted from animal carcasses.[49] There are many advantages to the use of human, rather than animal, insulin to treat a human disease.[50] Because the amount that can be made by large vats of transgenic bacteria is much greater than is made by each animal, the insulin is produced much more cheaply.[51] Additionally, human insulin and animal insulin are slightly different in structure, creating the possibility of human allergy to the non-human in-

40. Lorance L. Greenlee, *Biotechnology Patent Law: Perspective of the First Seventeen Years, Prospective on the Next Seventeen Years*, 68 DENV. U. L. REV. 127, 127 (1991). *See generally* Stanley N. Cohen et al., *Construction Of Biologically Functional Bacterial Plasmids In Vitro*, 70 PROC. NAT'L ACAD. SCI. 3240 (1973) (describing the original Boyer-Cohen experiment involving recombinant DNA technology).

41. Karczewski, *supra* note 37, at 1049.

42. KLUG & CUMMINGS, *supra* note 15, at 479.

43. The term transgenic is used to "denot[e] acquisition of a foreign gene." JAMES DARNELL ET AL., MOLECULAR CELL BIOLOGY 1030 (2d ed. 1990).

44. Karczewski, *supra* note 37, at 1050–51.

45. *Id.*

46. KLUG & CUMMINGS, *supra* note 15, at 479.

47. *Id.*

48. Karczewski, *supra* note 37, at 1050–51.

49. *Id.*

50. *Id.*

51. *Id.* at 1051.

sulin, which can lead to shock and death.[52] Finally, using an animal source for insulin can cause transmission of animal diseases, such as "mad cow disease," to humans.[53]

B. The Human Genome Project

The HGP is a $250 million publicly funded consortium that includes sixteen principal laboratories that "generat[ed] the bulk of the public's working draft of the human genome."[54] The first "rough draft" of the human genome[55] was complete in the spring of 2000.[56] The information is in the form of a map of the three billion base pairs that make up the human genome, "enough to fill more than 200 telephone books."[57] This information is currently available through GenBank, a public database on the Internet.[58]

Serious limitations exist on the usefulness of the volumes of data emerging from the HGP. One is the sheer mass of apparently useless information.[59] The human genome contains vast amounts of so-called "junk" DNA, which apparently does not code for genes at all.[60] Only three percent or less of the DNA in the human genome appears to code for genes.[61] Scientists place the total number of genes at about one hundred

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52. THE MERCK MANUAL OF MEDICAL INFORMATION, HOME EDITION 828–29 (Robert Berkow et al. eds., 1997) [hereinafter. MERCK MANUAL].

53. *See generally* Philip Yam, *Mad Cow's Human Toll*, SCI. AM., May 2001, at 12. Using an animal source or a human source for a substance to be given to humans exposes the recipient to the danger of acquiring a disease carried by the source. One example is the danger of acquiring AIDS (acquired immune deficiency syndrome) from blood transfusions. *See* MERCK MANUAL, *supra* note 52, at 759.

54. The principal sequencing centers include the Whitehead/MIT Genome Center, the Department of Energy Joint Genome Institute, Washington University, the Sanger Centre, among others. *See* Elizabeth Pennisi, *What's Next for the Genome Centers,* 291 SCI. 1204, 1204 (2001).

55. The first information available on-line is a "rough draft" because it contains the complete genetic information from only one individual. More complete information will contain pooling from several individuals. *See* Kathryn Brown, *The Human Genome Business Today,* SCI. AM., July 2000, at 50, 51.

56. *See id.*

57. *Id.*

58. *See id.* at 51. The Web site is available at http://www.ncbi.nlm.nih.gov/ (last visited Feb. 2, 2002).

59. *See* Ken Howard, *The Bioinformatics Gold Rush*, SCI. AM., July 2000, at 58.

60. Vogel, *supra* note 17, at 1184.

61. Elizabeth Silverman et al., Genomics: An Investor's Guide, at 9 (1996) (on file with author).

thousand,[62] although recent reports suggest there may be even less.[63] The fact that only a small number of genes are of known or suspected biological or medical importance further complicates the search.[64] Thus, finding useful sequence in the human genome is a lot like finding a needle in a haystack. The main task ahead for the biotechnology and pharmaceutical industries is to sift through the haystack of sequence information in order to find the subset of disease-causing genes that could lead to new drug treatments.[65]

Different groups have taken various approaches in sorting through this information to find key proteins. One approach exploits the fact that proteins with similar functions often have similar sequences.[66] Accordingly, to try to predict the function of newly discovered DNA, researchers can compare the DNA for any parallels to known DNAs.[67] For example, many different types of proteases, a very common type of digestive protein, have similar "motifs," or areas of similar sequence.[68] Comparing recently discovered DNA with this known "motif" can turn up a piece of DNA that matches. This matching DNA will probably share the same function.[69]

Genomics companies have taken another approach in their efforts to commercialize the new information from the HGP.[70] Rather than focusing on developing new drugs, these companies sell information and techniques to simplify the search for important genes.[71] For example, companies have created libraries, or databases, that are much smaller than the genomic database, by eliminating the "junk" DNA.[72] Companies can eliminate the junk by selecting only the genes that are in use at any given time, a much smaller subset than the total num-

62. *See* Carol Ezzell, *Beyond The Human Genome*, SCI. AM., July 2000, at 64, 64.

63. More recent estimates are that there may be approximately thirty thousand genes. *See* Nicholas Wade, *Genome's Riddle: Few Genes, Much Complexity*, N.Y. TIMES, Feb. 13, 2001, at F1.

64. *See* Andrew Pollack, *Double Helix With a Twist*, N.Y. TIMES, Feb. 13, 2001, at C1.

65. *See id.*

66. Elizabeth Pennisi, *The Human Genome*, 291 SCI. 1177, 1178 (2001).

67. *See* Howard, *supra* note 59, at 59.

68. Silverman et al., *supra* note 61, at 27.

69. *Id.*

70. *See* Miller, *supra* note 32, at 903.

71. *See* Pollack, *supra* note 64.

72. Murray, *supra* note 14, at 237.

ber of genes in a cell. They do so by exploiting the fact that before a gene makes a protein, it first makes an intermediate molecule called messenger RNA, or mRNA.[73] The cell then decodes the mRNA and creates the appropriate protein.[74] Researchers can break open the cell and capture this mRNA, which is a pool representing all the genes in use at that moment.[75] Next, researchers reverse the process, turning the mRNA back into DNA, called cDNA.[76] Like the mRNA, the cDNA pool is a snapshot of all genes active at that particular time.[77] This pool is only a small subset of the total mass of genomic DNA contained within that cell.[78]

This subset of DNA is likely to be important because most of the genes central in disease processes are active genes. Searching this smaller subset of active genes for disease genes, thus, is more efficient than searching the entire genome.[79] To determine the DNA sequence of these pools of DNA, researchers use DNA sequencing technology to determine a small portion of each cDNA in these cDNA pools.[80] The shorter portions are known as expressed sequence tags, or ESTs.[81]

Genomics companies, such as Human Genome Sciences, Celera Genomics, and Incyte Genomics, create private, proprietary databases of ESTs to enable the more rapid discovery of important genes.[82] Scientists have also created refinements of this basic technique. One such refinement includes the creation of differential expression libraries.[83] In this technique, researchers compare EST libraries from diseased cells (such as cancer cells) with normal cells to find the subset of ESTs that

73. Luukkonen, *supra* note 9, at 343. RNA refers to ribonucleic acid. Two chemical differences separate DNA from RNA. One is the sugar component: in RNA, the sugar is ribose, as opposed to deoxyribose contained in DNA. The other difference is that the base thymine in DNA is replaced by another closely related chemical compound called uracil. *See* KLUG & CUMMINGS, *supra* note 15, at 274.

74. *See* KLUG & CUMMINGS, *supra* note 15, at 324.

75. *Id.* at 441.

76. The term "cDNA" stands for "copied" DNA. *Id.*

77. *Id.*

78. *See* Murray, *supra* note 14, at 236–37.

79. Pollack, *supra* note 64.

80. Silverman et al., *supra* note 61, at 21.

81. *Id.*

82. Brown, *supra* note 55, at 54.

83. Peltonen & McKusick, *supra* note 13, at 1225–26.

vary between the two.[84] This subset of proteins is likely to be important in the disease process.[85]

C. *Overview of Drug Discovery Strategies Using Biotechnology*

1. General Strategies

The new information from the HGP may potentially revolutionize the process of discovery of new drugs.[86] Traditionally, companies have developed proteins as therapeutics for treating disease. Companies have developed many profitable drugs using this approach, and it will no doubt continue to be an important strategy in the future.[87] As explained in Part I.B, above, the HGP (and EST technology) has the potential to speed development of new protein drugs by making discovery of proteins important in disease occur at a more rapid pace.

An additional strategy is emerging from this new genetic information. Pharmaceutical companies, which have traditionally developed non-protein compounds as drugs,[88] can harness genomics to accelerate drug development.[89] Lack of knowledge regarding the exact biochemistry of disease has slowed the discovery of new disease-fighting drugs.[90] Companies can use knowledge gained through the HGP to "develop more accurate laboratory models of disease against which a narrower range of compounds can be screened"[91] and reduce the time and money spent developing drugs.[92]

2. Costs and Pressures Facing the Industry

The biotechnology and pharmaceutical industries, as explained above, are primarily involved in the business of finding

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84. Ezzell, *supra* note 62, at 66.

85. *See, e.g.*, Peltonen & McKusic, *supra* note 13, at 1225.

86. *See* Miller, *supra* note 32, at 894.

87. *See* Cynthia Robbins-Roth, *Buy or Die*, FORBES ASAP (Apr. 3, 2000), *at* http://www.Forbes.com/asap/2000/0403/153.html.

88. Such compounds typically are synthetic, relatively low molecular weight organic compounds. *See* MERCK MANUAL, *supra* note 52, at 23.

89. Miller, *supra* note 32, at 894.

90. *See* Silverman et al., *supra* note 61, at 31–32.

91. *Id.* at 32.

92. David Malakoff & Robert F. Service, *Genomania Meets the Bottom Line*, 291 SCI. 1193, 1193 (2001).

new drugs to treat human disease.[93] The business of finding new drugs, however, is a capital-intensive venture, requiring a significant outlay of funds long before a company can realize profits.[94] These funds are required "not only for the initial research and development, but also to go through the regulatory approval process necessary to get a product—particularly a pharmaceutical product—on to the market."[95]

These companies rely on patents because patents allow the patentee to prevent others from selling the same drug on the marketplace for a certain number of years. This monopoly period allows a company to recoup the up-front investment required for the research and testing of a drug.[96] A start-up biotechnology or genomics company, not having any profits with which to fund development, is dependent on outside capital. Whether investors are willing to invest this money depends on whether companies can secure strong patent protection, allowing investors to profit on their investment.[97]

Despite these financial challenges, the biotechnology industry has "created more than 75 FDA-approved drugs, vaccines, and diagnostic tests that have completely changed the practice of medicine and generated billions in sales revenues."[98] Biotechnology has developed into an industry with significant commercial value.[99] It is clear that the biotechnology and pharmaceutical industries have brought health benefits to patients and economic benefits to investors.

II. THE PATENTABILITY OF DNA

This section briefly reviews the major requirements for a patent and discusses the "utility" requirement in more detail. This section then demonstrates how the operation of the patent laws will preclude patents to gene sequences.

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93. *See generally* Lehman, *supra* note 2.
94. See Malakoff & Service, *supra* note 92, at 1193.
95. *Id.*
96. *See id.*
97. *See id.*
98. Robbins-Roth, *supra* note 87.
99. For example, Amgen's latest twelve months' revenue was $3.8 billion; Genentech's latest twelve months' revenue was $1.9 billion; Chiron's latest twelve months' revenue was $1 billion; and Biogen's latest twelve months' revenue was $0.98 billion. Megan E. Mulligan, *Stock Focus: Big Biotech Companies*, FORBES (Aug. 22, 2001), *at* http://www.Forbes.com/2001/08/22/0822sf.html.

A. *The Purpose of the United States Patent System*

The Constitution of the United States specifically authorizes patents.[100] Congress passed the first patent act in 1793 and passed subsequent patent statutes in 1836, 1870, 1874, and 1952.[101] As read by the courts, Congress intended to allow the patenting of "anything under the sun that is made by man," so long as it complies with the statutory requirements for patentability.[102]

The modern patent is a "government issued grant which confers . . . the *right to exclude* others from 'making, using, . . . or selling the invention' . . . for a period of 20 years."[103] To gain this monopoly, however, the inventor must disclose the details of his invention, which enables others to understand it.[104] Thus, the limited monopoly encourages disclosure of inventions.[105] Disclosure allows others to improve upon them and generate new inventions, thus providing a net benefit to society.[106]

B. *DNA and the Requirements for Obtaining a Patent*

The inventor, in order to receive a patent grant, must demonstrate that the invention falls within the class of patentable subject matter,[107] is nonobvious to an ordinary practitioner in the relevant field,[108] is adequately disclosed,[109] is novel,[110] and demonstrates some utility.[111] These concepts are discussed below.

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100. *See* U.S. CONST. art I, § 8, cl. 8. "To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." *Id.*

101. Diamond v. Chakrabarty, 447 U.S. 303, 308–09 (1980).

102. *Id.* at 309 (quoting S. REP. NO. 1979, at 5 (1952) and H.R. REP. NO. 1923, at 6 (1952)).

103. CHISUM ET AL., *supra* note 5, at 2.

104. *Id.*

105. *Id.* at 62.

106. Graham v. John Deere Co., 383 U.S. 1, 9 (1966).

107. 35 U.S.C. § 101 (1994).

108. 35 U.S.C. § 103.

109. 35 U.S.C. § 112.

110. 35 U.S.C. § 102.

111. 35 U.S.C. § 101.

1. Patentable Subject Matter

Products of nature, including chemicals as they exist in their natural state, are not patentable subject matter.[112] Courts, however, consider a chemical to be patentable when researchers have isolated the chemical from its natural state and determined its chemical structure.[113] Courts have determined that DNA is a type of "chemical compound, albeit a complex one,"[114] and so satisfies the test for patentable subject matter.[115] In line with chemical inventions, the PTO considers only DNA that has been isolated and sequenced in the laboratory to be patentable subject matter under the patent statute.[116]

2. Nonobviousness

Section 103[117] of the 1952 Act states that "[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the [technology existing at the time of invention] are such that the subject matter as a whole would have been obvious . . . to a person having ordinary skill in the [relevant] art."[118] Courts have interpreted § 103 as precluding patent grants to improvements that persons of ordinary skill in the technology could routinely make.[119]

3. Disclosure

Under § 112[120] of the 1952 Act, an applicant must provide "an enabling disclosure before an invention is patentable."[121]

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112. CHISUM ET AL., *supra* note 5, at 724.

113. Amgen v. Chugai Pharmaceutical, 927 F.2d 1200, 1206 (Fed. Cir. 1991).

114. *Id.*

115. *Id.*

116. *See* Miller, *supra* note 32, at 907. The PTO is an administrative agency charged by Congress to interpret and enforce patent laws. PTO decisions are reviewable by federal courts. *See infra* note 140.

117. Detailed analysis of § 103's requirements is beyond the scope of this Comment. This Comment focuses instead on the interaction between the novelty requirement and the utility requirement.

118. 35 U.S.C. § 103 (1994).

119. *See generally* Graham v. John Deere Co., 383 U.S. 1 (1966). This requirement can be a serious obstacle for patent applicants. *See* CHISUM ET AL., *supra* note 5, at 514.

120. A detailed analysis of § 112's requirements is beyond the scope of this Comment. This Comment focuses instead on the interaction between the novelty requirement and the utility requirement.

The disclosure of the invention must be sufficient to allow others who are skilled in the relevant "art," or area of technology, to make and use the invention.[122] The first paragraph of 35 U.S.C. § 112 provides three distinct requirements for the disclosure: the written description requirement, the enablement requirement, and the best mode requirement.[123] The second paragraph of 35 U.S.C. § 112 requires that the inventor "particularly point out and distinctly claim the invention."[124]

4. Novelty

As required by § 102, "a patent applicant [must] . . . contribute something *new* to society."[125] This requirement reflects the belief that "it makes no sense to grant someone a patent on an invention that already exists."[126]

Section 102 is comprised of many elements, of which only §§ 102(a) and (b) are significant here.[127] Section 102(a), in relevant part, mandates that no patent shall be granted when "the invention was . . . described in a printed publication in this or a foreign country, before the invention thereof by the applicant for [a] patent."[128] This prevents an applicant from obtaining a patent when someone else has already described or invented the subject matter of the invention.[129] Section 102(b) bars a patent grant when "the invention [is] . . . described in a printed publication in this [country] . . . more than one year prior to the date of the application for [a] patent."[130] Section 102(b) acts to prevent patents when the invention has been in the public domain for more than a year.[131] This statutory bar operates against the inventor when the inventor delays filing a patent application to his invention. The inventor must file for a pat-

121. Olsen, *supra* note 11, at 316.
122. CHISUM ET AL. *supra* note 5, at 162.
123. *Id.*
124. *Id.*
125. *Id.* at 335.
126. *Id.*
127. I discuss only subsections 102(a) and 102(b); subsections (c)–(g) are not relevant to this Comment.
128. 35 U.S.C. § 102(a) (1994).
129. *See generally* CHISUM ET AL., *supra* note 5, at 323–26.
130. 35 U.S.C. § 102(b).
131. *See* CHISUM ET AL., *supra* note 5, at 325.

ent application within one year of disclosing the invention or forever lose all rights to his invention.[132]

As discussed in Part III, the § 102 novelty requirement, in conjunction with the § 101 utility requirement, presents a major obstacle for inventors attempting to obtain patents to genes in view of the public disclosures of the human genome project.

5. Utility

The utility requirement stems from § 101's "useful" requirement, and is based on the concept that an invention must benefit society.[133] An invention with no practical use does not benefit society.[134] "[T]he utility requirement is not usually an obstacle for mechanical and electrical applications," because engineers do not typically construct devices with no known use.[135] However, the utility requirement is a greater hurdle for chemical and biological inventions.[136] Many chemicals and DNA sequences exist in nature and few of them have well-defined uses for our society. Yet research continues to identify all chemicals and DNA sequences. As a result, many of these compounds enter into public knowledge but lack utility as defined by § 101.

C. Case Law Defining the Utility Requirement

"Use," as applied to biological and pharmaceutical inventions, is an ambiguous word. Courts and the PTO have labored to define what degree of usefulness is required before an invention meets the statutory requirement. Several cases, discussed below, have defined uses that satisfy the useful requirement in § 101 of the statute for chemical and biological inventions.

In *Brenner v. Manson*,[137] the United States Supreme Court held that chemical compounds are not useful per se.[138] The *Brenner* court reversed the decision of the Court of Customs

132. *Id.*
133. *Id.* at 729.
134. *Id.*
135. *Id.*
136. *Id.*
137. 383 U.S. 519 (1966).
138. *Id.* at 531.

and Patent Appeals (CCPA)[139] and upheld the decision of the Patent Board, which found that utility needs to be proven in every case.[140] In *Brenner*, a researcher produced a chemical compound, which was an intermediate for a steroid compound having anti-tumor properties.[141] The plaintiffs made two arguments for utility. First, they argued that the compound was useful per se for the reason that it could be used to further scientific research.[142] Second, they argued the intermediate, after conversion to the final product, was similar chemically to a compound having tumor inhibiting characteristics.[143] The Court rejected both arguments.

To reach its decision, the Court relied on "the general intent of Congress, [and] the purposes of the patent system."[144] Further, the Court expressed concern about a patent's ability "to block off whole areas of scientific development."[145] In light of these concerns, the Court took a restrictive view of utility. It held that a chemical product with no known use, or useful solely for further research, is not a patentable invention.[146] Further, the Court noted that the biological effect of a given compound is unpredictable, in that mere similarity in appearance does not necessarily lead to a similarity in biological activity.[147] In *Brenner*, since there was no proof that the biological activity of closely related compounds was the same, the Court held that mere chemical resemblance to a useful compound was insufficient for demonstrating utility.[148]

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139. Currently, patent appeals go from district courts to the Court of Appeals for the Federal Circuit (CAFC), created in 1982. Before 1982, patent appeals were handled by each federal circuit, which were then appealed to the Court of Customs and Patent Appeals (the CCPA). *See* CHISUM ET AL., *supra* note 5, at 30–33.

140. *Brenner*, 383 U.S. at 522. The Patent Board is also called the Board of Patent Appeals and Interferences, and exists within the United States Patent and Trademark Office. The decisions of the Board may be appealed to either the United States District Court for the District of Columbia or to the Court of Appeals for the Federal Circuit (CAFC). In practice, almost all appeals go before the CAFC. *See* CHISUM ET AL., *supra* note 5, at 128.

141. *Brenner*, 383 U.S. at 531.

142. *Id.*

143. *Id.*

144. *Id.* at 532.

145. *Id.* at 534 (quoting Monsanto Chemical Co. v. Coe, 145 F.2d 18, 21–24 (D.C. Cir. 1944)).

146. *Brenner*, 383 U.S. at 531.

147. *Id.* at 532 n.19.

148. *Id.* at 532.

A later case, *In re Kirk*,[149] extended the holding of *Brenner* to patent applications where the applicant did not adequately define a utility. In *Kirk*, the applicants, rather than claiming a specific utility, had merely noted that their compound had "biological activity," a vague term.[150] The CCPA held that applicants for a patent must claim more than mere "biological activity"; rather the applicant must have "definitely ascertained an actual use for the compound."[151]

In *Brenner* and *Kirk,* courts articulated the "negative" utility test, determining situations where a compound will fail the test for utility. Neither court, however, addressed the question of how much the applicant must know about the usefulness of a chemical for it to *pass* the utility test. A subsequent line of cases in the Court of Customs and Patent Appeals (and later in the Court of Appeals for the Federal Circuit (CAFC)) helped clarify this question, and in the process seemed to soften the holding of *Brenner*.

One such case is *Nelson v. Bowler*.[152] Here, the applicants claimed that a chemical compound had two specific utilities. The first utility claimed was its ability to influence blood pressure in rats *in vivo*. The other utility was its ability to relax smooth muscle cells of gerbils *in vitro*.[153] The patent applicant, however, had not directly linked the utility, a pharmacologic activity[154] in mammals, to any commercial use in humans.[155] The court nonetheless found utility, stating that "[k]nowledge of the pharmacologic activity of any compound is obviously beneficial to the public."[156] This holding provided that a specific pharmacologic activity seen in mammals will satisfy the utility requirement. Further, the court did not limit applicants to claim only the specific activity found. Rather, the test for

149. 376 F.2d 936 (C.C.P.A. 1967).

150. *Id.* at 941.

151. *Id.* at 942.

152. 626 F.2d 853 (C.C.P.A. 1980).

153. *Id.* at 855. *In vivo* means "[i]n the living body, referring to a process occurring therein." STEADMAN'S MEDICAL DICTIONARY 798 (25th ed. 1990). *In vitro* means "[i]n an artificial environment, referring to a process or reaction occurring therein, as in a test tube or culture media." *Id.*

154. Generally, the term "pharmacologic activity[,] refers to properties and [patient] reactions of drugs, especially with relation to their therapeutic value." Cross v. Iizuka, 753 F.2d 1040, 1046 n.12 (Fed. Cir. 1985).

155. *See Nelson*, 626 F.2d at 856.

156. *Id.*

biological activity "[need only be] reasonably indicative of the desired [pharmacologic activity.]"[157]

Cross v. Iizuka[158] had similar facts to *Nelson*, but in *Cross*, the applicant had only performed *in vitro* testing rather than a combination of *in vivo* and *in vitro* tests.[159] The CAFC was asked to determine whether *in vitro* testing alone supported a finding of utility for the claimed compound. The patent applicant had demonstrated that the compound had the biological activity of preventing clumping of platelets, a type of blood cell involved in blood clotting, in a test tube.[160] The court held that where the *in vitro* testing reasonably correlated to the claimed utility, the *in vitro* testing was specific enough to satisfy the utility requirement of § 101 of the Patent Act.[161]

The court in *In re Brana*[162] continued to soften *Brenner*'s rather strict test for utility. In *Brana*, the applicants had tested their compounds *in vitro* in human tumor cells, finding that these compounds killed the tumor cells.[163] The cell lines used for this testing derived from actual cancer cells, but not from the actual cancer type the applicants were seeking to treat.[164] Despite this disparity, the court held the correlation between the test and the commercial application sufficient to find utility.[165] Importantly, the court held that the PTO must presume the applicant's claimed utility is sufficient.[166] The burden was therefore placed on the PTO to rebut the applicant's claimed utility, by "provid[ing] evidence showing that [another scientist] would reasonably doubt the asserted utility."[167]

In summary, the current law regarding the utility requirement compels applicants to specify and demonstrate a specific, commercial utility in order to obtain a patent for a chemical compound. However, applicants are given some leeway because they may rely on *in vitro* testing in mammals or

157. *Id.*
158. 753 F.2d 1040 (Fed. Cir. 1985).
159. *Id.* at 1043.
160. *Id.*
161. *Id.* at 1048.
162. 51 F.3d 1560 (Fed. Cir. 1995).
163. *Id.* at 1565.
164. *Id.*
165. *Id.* at 1566.
166. *Id.*
167. *Id.*

their tissues instead of demonstrating efficacy in humans.[168] Further, the testing to demonstrate utility need not be identical to the eventual commercial application.[169] Finally, the burden is on the PTO to show that the utility claimed by the applicant is insufficient.

D. The PTO's Guidelines for Examining Applications for Compliance with the Utility Requirement

Despite decisions that have modified and softened the *Brenner* rule, until 1995 the Patent Board followed *Brenner* strictly.[170] *Ex parte Aggarwal*[171] provides an example of the stricter *Brenner* rule applied to a DNA patent application. Here, applicants claimed a utility for a recombinant protein,[172] lymphotoxin, to kill tumor cells based on *in vitro* data.[173] However, the Board rejected the sufficiency of the *in vitro* testing, arguing that the testing performed was not reasonably correlative of a practical utility in humans.[174] This Board decision directly contradicted the holding of the CAFC in *Nelson*.[175]

The decision of the Board of Patent Appeals and Interferences in *Ex parte Aggarwal* and other decisions like it raised a "hailstorm of criticism" among the patent bar.[176] The Commissioner of Patents and Trademarks responded. Instead of waiting for reversal by the CAFC, the Commissioner held public hearings to address industry concerns and as a solution issued the 1995 Guidelines for Examining Applications for Compliance with the Utility Requirement ("1995 Utility Guidelines" or "1995 Guidelines").[177] In the 1995 Utility Guidelines, the PTO

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168. Nelson v. Bowler, 626 F.2d 853, 856 (C.C.P.A. 1980).

169. Cross v. Iizuka, 753 F.2d 1040, 1048 (Fed. Cir. 1985).

170. *See* DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW, at 742–46 (1998).

171. 23 U.S.P.Q.2d 1334 (Bd. Pat. App. & Int'f 1992).

172. A recombinant protein refers to a protein that is expressed (produced) by cells that have been genetically altered by insertion of the gene coding for that protein. The cells are cultured, and after a period of growth the protein is chemically removed. *See* KLUG & CUMMINGS, *supra* note 15, at 429.

173. *Aggarwal*, 23 U.S.P.Q.2d at 1338.

174. *Id.*

175. Nelson v. Bowler, 626 F.2d 853, 855 (C.C.P.A. 1980).

176. *See* David G. Perryman & Nagendra Setty, *The Basis and Limits of the Patent and Trademark Office's Credible Utility Standard*, 2 J. INTELL. PROP. L. 509, 525 (1995).

177. Utility Examination Guidelines, 60 Fed. Reg. 36,263 (July 14, 1995).

"adopt[ed] a much more reasonable approach to the utility requirement."[178]

1. The 1995 Utility Requirement Guidelines

The 1995 Utility Guidelines "set forth a lower standard of proof of utility than that previously required by the PTO for biotechnology inventions."[179] Under the 1995 Guidelines, the applicant needed only to "disclose or assert a utility which 'would be considered *credible* by one of ordinary skill in the art.'"[180] The 1995 Guidelines asserted that an applicant's stated utility satisfied the burden of demonstrating utility unless the PTO could rebut by showing that one skilled in the art would consider the utility insufficient.[181]

The remaining question was whether gene fragments, such as ESTs,[182] that possessed only speculative connection to disease, were patentable. Under the previously discussed case law and the 1995 Guidelines, if a patent applicant had both the actual sequence of the gene and could show its relevance to a disease, the gene clearly had utility.[183] Scientists could be certain in some situations that the corresponding full-length gene for an EST sequence was involved in a disease process.[184] When a scientist knew that an EST was involved in a disease, the EST gene fragment had a "research" utility—that is, it was useful as a "probe" in order to find the full length gene.[185] Then both the structure and the utility would be defined for the full-length gene, providing an easy case for patentability.[186] In light of this reasoning, the PTO in early 1997 announced that it would allow claims on ESTs based on their utility as probes.[187]

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178. *See* Perryman & Setty, *supra* note 176, at 525.

179. Michelle Johnson, Note, In Re Brana *And The Utility Examination Guidelines: A Light At The End Of The Tunnel?*, 49 RUTGERS L. REV. 285, 298 (1996).

180. *Id.* (quoting Utility Examination Guidelines, 60 Fed. Reg. 36,263 (July 14, 1995) (emphasis added)).

181. Johnson, *supra* note 179, at 299.

182. ESTs are short portions of genes. *See supra* Part I.B.

183. *See* Murray, *supra* note 14, at 251–52.

184. *See* Silverman et al., *supra* note 61, at 33.

185. For a discussion of the rush to patent ESTs, see generally Murray, *supra* note 14.

186. *Id.* at 239.

187. *See* Gretchen Vogel, *Gene Fragments Patentable, Official Says*, SCI., Feb. 21, 1997, at 1055.

Serious questions arose after the dissemination of the 1995 Utility Guidelines. First, some commentators questioned whether the relaxed "credible utility" guidelines, allowing patents for a "research use" for a partial gene sequence, were following the case law.[188] Many felt that the facts of *Brenner* were similar to a situation in which scientists use an EST as a probe to find the full-length gene.[189] In *Brenner*, the Court held that an intermediate chemical compound that was useful for making another chemical compound of no proven use did not have utility.[190] By analogy, under *Brenner*, EST sequences having no use other than as a research tool to find the full-length gene, itself of unproven utility, would not have utility either. Despite *Brenner's* holding, under the 1995 Guidelines ESTs would be patentable.

Another problem was that researchers, believing that ESTs were now patentable, flooded the PTO with applications to EST sequences. At the end of 1998, for example, just one company, Incyte Pharmaceuticals, "reported that it had filed applications covering 1.2 million partial gene fragments."[191] This "gold rush" overwhelmed the PTO, and created serious delays in processing patent applications.[192]

2. The 1999 Revised Interim Utility Guidelines

In December 1999, the PTO issued the Revised Interim Utility Guidelines Training Materials to patent examiners and made them available to the public.[193] The final version of the 1999 Utility Guidelines was promulgated in January 2001.[194]

The 1999 Guidelines represented a substantial change from the 1995 version. Put simply, a "credible utility" no longer suffices to meet the utility requirement.[195] Instead, when the applicant asserts a credible utility, the 1999 Guidelines require that the utility must be *specific* and *substantial*.[196]

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188. Andrew Kight, Note, *Pregnant With Ambiguity: Credibility and the PTO Utility Guidelines in Light of* Brenner, 73 IND. L.J. 997, 1020 (1998).
189. *See id.*
190. *See generally* Brenner v. Manson, 383 U.S. 519 (1966).
191. Murray, *supra* note 14, at 231.
192. Lehman, *supra* note 2, at 60.
193. Revised Utility Examination Guidelines, *supra* note 8.
194. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).
195. Revised Utility Examination Guidelines, *supra* note 8, at 71,441.
196. *Id.*

The 1999 Guidelines provide that uses of ESTs as "probes, chromosome markers, or . . . diagnostic markers . . . [are] cred[ible]."[197] However, although these are credible uses, they may "fail the *specific* and *substantial* tests."[198]

The "specific" utility test requires a "utility that is *specific* to the subject matter claimed."[199] For an EST or other gene fragment, use as a probe or marker "would not be considered . . . *specific* in the absence of a disclosure of a specific DNA target."[200] In other words, use of the gene fragment in a fishing expedition to find the corresponding full-length gene is merely a general utility, because as a class, all ESTs and gene fragments possess this utility. According to the 1999 Guidelines, use as a probe is not a specific utility.[201]

In addition to the specificity requirement, the utility asserted must also be substantial.[202] A substantial utility "defines a 'real world' use."[203] The Supreme Court has defined "substantial utility" as a "specific benefit . . . in currently available form."[204] Following this definition, the 1999 Guidelines require applicants to show evidence that the gene is useful in treating a specific disease.[205] Non-"real world" uses include the use of EST or gene fragments to find a gene with no known utility and use as a probe.[206] Some commentators have criticized the PTO's position that research use is not a real-world use, because that position overlooks the fact that companies profit by supplying research materials to scientists.[207] Nevertheless, the PTO maintains that a research use is not a "real world" use.

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197. *Revised Interim Utility Guidelines Training Materials* 5, *at* http://www.uspto.gov/web/menu/utility.pdf (last visited Mar. 3, 2002).

198. *Id.*

199. *Id.*

200. *Id.*

201. *Id.*

202. *Id.* at 6.

203. *Id.*

204. Brenner v. Manson, 383 U.S. 519, 534–35 (1966).

205. *See Revised Interim Utility Guidelines Training Materials, supra* note 197, at 6.

206. *See id.*

207. *See* Phanesh Koneru, *To Promote the Progress of Useful Articles?: An Analysis of the Current Utility Standards of Pharmaceutical Products and Biotechnological Research Tools*, 38 IDEA 625, 661 (1998).

The Examiner Training Materials[208] accompanying the 1999 Guidelines provide examples of how to apply the "specific, substantial, and credible" test to genes and gene fragments. One example of a gene lacking utility is a claim to a gene for protein Y that binds protein X, where X has no association with a disease or medical condition.[209] In this scenario, although the gene for protein Y has both a specific and a credible use, it does not have a "real world," or substantial use.[210] However, if the facts were changed so that X was associated with a disease, protein Y, because it binds X, would have a substantial, or real world use, and thus the gene for protein Y would be patentable.[211]

In sum, the PTO, in the 1999 Guidelines, provided that DNA and DNA fragments are not patentable without a specific, real world use.[212] Use as a probe for finding the full-length DNA, or use as a research tool, does not define a specific, real world use, since such utility is general to the class.[213] The result is that such DNA sequences are not patentable.

III. THE UTILITY AND NOVELTY REQUIREMENTS AND OBTAINING FUTURE GENE PATENTS

The 1999 Guidelines preclude applicants from obtaining a patent for the vast majority of DNA obtained from the Human Genome Project, due to the DNA's lack of utility.[214] In addition, § 102 of the Patent Code, as explained below in Section A, operates to forever prevent patents to previously discovered genes.[215] These rules affect what type of patent claim inventors can obtain for gene sequences.[216] Instead of obtaining the stronger composition type claim, inventors are limited to the inferior method type claim.[217] Because weaker claims are not as easily enforced against patent infringers, they have the potential to discourage investment in new drugs and pharmaceu-

208. *Revised Interim Utility Guidelines Training Materials, supra* note 197.
209. *Id.*
210. *See id.* at 4–6.
211. *See id.*
212. *Id.*
213. *See id.*
214. *See generally id.*
215. Silverman et al., *supra* note 61, at 57.
216. Types of claims are explained in *infra* Part III.C.
217. CHISUM ET AL., *supra* note 5, at 105.

ticals.[218] Less investment could, in turn, limit production of new drugs.

A. *Sequence Information from the HGP and from EST Efforts Will Be Unpatentable Under the 1999 Revised Utility Guidelines and the Novelty Requirements for Patents*

Scientists do not know the function of most of the human genome or of the full-length genes represented by ESTs.[219] The 1999 Guidelines reject the patentability of such DNA sequences.[220] Since the vast majority of the DNA resulting from the Human Genome Project currently does not meet the specific and substantial tests for patentability, scientists are unable to obtain patents to these sequences. With additional research, however, many new uses likely can be found for DNA sequences obtained from the HGP. These DNA sequences can yield a wealth of new drugs and treatments for disease. In fact, the CEO of Human Genome Sciences, Inc., William Hazeltine, observed that "[t]he biggest issue for genomics today is no longer genes . . . [it] is what you do with those genes."[221] Research efforts in the genomics, pharmaceutical, and biotechnology industries have thus shifted to determining the functionality of the new DNA sequences. Researchers must determine the genes that are important in disease processes in order to turn sequence information into commercial products, such as drugs and diagnostics.[222]

But § 102, the novelty requirement discussed above in Part II.B.4, will prevent patents to these DNA sequences in the future. Subsections (a) and (b) of § 102 prevent patents when the invention is known by others for more than a year, regardless of who invents the product.[223] As scientists place the human genome in the public domain, it starts the clock for § 102, which bars anyone from obtaining a patent a year after its pub-

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218. *Ex parte* Deuel, 33 U.S.P.Q.2d 1445, 1447 (Bd. Pat. App & Int'f 1993) (discussing the benefits of a DNA product claim. A patent "issu[ing] on the DNA which codes for the protein [gives] the patent owner . . . the exclusive right . . . to the preparation of commercial quantities of the protein.")

219. *See, e.g.*, Murray, *supra* note 14, at 236–37.

220. *See generally* Revised Utility Examination Guidelines, *supra* note 8.

221. Ezzell, *supra* note 62, at 64.

222. *See generally* Howard, *supra* note 59, at 58.

223. *See* 35 U.S.C. § 102(b) (1994).

lication. For many sequences, this one-year bar has passed already. The problem arises, as discussed above in Part III.A, because the 1999 Utility Requirements prevent patenting of DNA where the function of the sequence is unknown. If a scientist finds a real world, specific use, such as curing disease, and if this discovery occurs more than one year from the time the information entered the public domain, the scientist may not obtain a patent.

Section 102 can also operate immediately, without the one-year bar, when two different scientists are involved. Section 102(a) prevents a patent absolutely if the applicant was not the first to invent. This means that if researcher A places a sequence into a public database, followed immediately by researcher B discovering the function of that DNA, § 102 prevents researcher B from obtaining a patent. In sum, the operation of §§ 102(a) and 102(b), together with the 1999 Revised Utility Guidelines, will prevent patents from issuing to genes and proteins as the human genome is placed in the public domain.

B. Inventors Will Only Be Able to Get Method of Use Type Patents to Genes in the Future

The chemical and biochemical arts[224] primarily make use of two types of claims, the composition claim and the method claim.[225] The composition type claim is preferred, due to its greater breadth and greater enforceability, as explained below.

Patent documents include patent claims.[226] The claims in a patent are the most important element, because they "set[] . . . forth the metes and bounds of the patentee's right to exclude."[227] The claims define the invention by "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."[228] Thus, the type and

224. "Arts" is itself a term of art referring to specific categories of technology. *See* CHISUM ET AL., *supra* note 5, at 110.

225. *See id.* at 87–88.

226. *Id.* at 75.

227. *Id.* at 86.

228. 35 U.S.C. § 112, ¶ 2 (1994).

scope of claim that inventors obtain define the property right that they have in their inventions.[229]

1. The Composition Claim

A composition claim is a claim to the compound itself. Inventors must name the compound and disclose the chemical structure to obtain such a claim.[230] An inventor who obtains a composition claim to a DNA sequence or gene can prevent any other person from making, using, or selling that sequence.[231] As a result, "anyone [wishing to use the composition] . . . must then negotiate an assignment or licensing arrangement with the patent holder."[232] Because the composition claim is to the compound itself, a previous invention of that same compound by another, under § 102, will bar a composition claim. This means that discovery of DNA sequences by the HGP will act as a previous invention, barring composition claims to this DNA.

Applicants prefer the composition claim for two reasons. First, a composition claim makes it easy to sue an infringer. The holder of the patent may sue another manufacturer directly.[233] Since the infringement consists of the manufacturer producing the product, the suit can be for "direct" or "literal" infringement.[234] Literal infringement of a patent "occurs when 'every limitation recited in the claim is found in the [infringing product].'"[235]

Second, composition claims give very broad rights. The exclusionary right of a composition claim extends to all uses of the claimed composition, even new uses unknown by the composition claim holder.[236] Therefore, when someone finds a new use for an already-claimed composition, he will not be able to

229. Patent claims are the part of the patent that defines clearly what the inventor considers to be his invention. They are to be compared with the "metes and bounds" of a land grant. *See* CHISUM ET AL., *supra* note 5, at 103.

230. *See id.* at 87.

231. Eisenberg, *supra* note 6, at 788.

232. Olsen, *supra* note 11, at 327.

233. CHISUM ET AL., *supra* note 5, at 830–31.

234. *Id.* at 895.

235. *Id.* (quoting Engel Indus. Inc. v. Lockformer Co., 96 F.3d 1398, 1405 (Fed. Cir. 1996)).

236. DONALD S. CHISUM, CHISUM ON PATENTS § 16.02[1][a] (July 2000).

practice the new use without permission from the original patent holder.[237]

2. The Method of Use Claim

The method of use claim consists of a claim to a method of using a composition, rather than to the composition itself.[238] This is the only type of claim available where a person invents a new use for an old product,[239] and is sometimes called an "improvement" claim.[240] This type of claim is not nearly as powerful as a composition claim.

Method claims do not automatically confer the ability to practice the invention, a concept introduced previously in Part III.B.2. Simply obtaining a patent for a new use does not mean one can practice that use. If one party holds a claim for the composition, then the party holding the method patent, which uses the composition, must obtain permission to use from the first party.[241] For example, if a scientist discovered that a patented protein was able to cure cancer, he can obtain a patent for this method of use. The scientist, however, cannot use the protein to cure cancer without permission from the owner of the composition claim to the protein.[242] Thus, the position of the improvement claim holder is weaker than the holder of the composition claim. Not only must he depend on the permission of someone else to practice his invention, but he takes the risk of being blocked, or, at the very least, will see his profits diluted by a cross-licensing deal.[243]

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237. Infringement occurs when another violates the rights of exclusion of the patentee, which include making, using, selling, offering for sale, and importing the product. *See* 35 U.S.C. §§ 154, 271(a) (1994); *see also* CHISUM ET AL., *supra* note 5, at 829–30.

238. *See* CHISUM ET AL., *supra* note 5, at 105.

239. *Id.* at 89.

240. *See* CHISUM, *supra* note 236, at § 16.02[1][a].

241. *Id.*

242. This principle works both ways. The composition claim holder is similarly blocked in that he cannot practice the new use, due to the improvement patent. Instead of a standoff, most likely the composition claim holder and the improvement claim holder would engage in cross-licensing, allowing practice of the invention by both parties. The profits realized by the owner of the improvement patent would, however, be diluted due to payments to the composition claim holder for the privilege of using the composition. *See id.*

243. *See* Temco Elec. Motor Co. v. Apco Mfg. Co., 275 U.S. 319, 328 (1928) (explaining that the owner of an improvement patent must obtain a license from the basic patent owner, or be liable for infringement).

Another disadvantage to the method claim is the fact that it is more difficult to enforce. Infringers of a method claim are those who use the product, not the manufacturer of the product.[244] For example, the manufacturer of the protein does not infringe the method patent. Rather, the end-user, such as the doctor prescribing its use to cure cancer, infringes. Plaintiffs find it much more difficult to sue many end-users than to sue one manufacturer. However, a doctrine known as contributory infringement, which is codified by statute,[245] allows suits against a manufacturer who *knowingly* provides a product "for use in practicing a patented process."[246]

Serious limitations exist to the doctrine of contributory infringement. In *Aro Manufacturing v. Convertible Top Replacement Co.*,[247] the Supreme Court found that "§ 271(c) does require a showing that the alleged contributory infringer *knew* that the [use] was both patented and infringing."[248] Proving this knowledge on the part of the manufacturer is difficult, especially where there are substantial non-infringing uses of a product.[249]

Some courts have "refused to find contributory infringement where the [product] . . . had a noninfringing use."[250] This principle occurs, for example, when a protein has a use both for curing cancer and for curing warts, with two different parties holding the respective method patents. The respective parties, if sued by the other party, could point to their legitimate use of the protein to defend their sales of the protein, even if they intended to sell for the non-legitimate use. In some cases, courts will find contributory infringement even in the face of non-infringing uses as long as the manufacturer knows that the product will be used in an infringing process.[251] In light of this conflicted case law, however, a suit for contributory infringement may be difficult to win. A method of use patent claim, then, is an uncertain foundation from which to sue infringers.

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244. CHISUM ET AL., *supra* note 5, at 950.
245. 35 U.S.C. § 271(c) (1994).
246. CHISUM ET AL., *supra* note 5, at 950.
247. 377 U.S. 476, 488–90 (1964).
248. *Id.* (emphasis added).
249. CHISUM ET AL., *supra* note 5, at 953–54.
250. *Id.* at 929.
251. *See* Preemption Devices Inc. v. Minn. Mining & Mfg. Co., 630 F. Supp. 463, 471 n.10 (E.D. Pa. 1985).

IV. POTENTIAL IMPACTS ON THE BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES

Patents are important to encourage investment into development of new drugs. Discussed below are potential solutions that preserve composition claims while avoiding associated problems.

A. The Importance of Patents to the Biotechnology and Pharmaceutical Industries

Bruce Lehman, the former Commissioner of Patents and Trademarks, has confirmed that "patenting is [] very important.... The biotechnology industry requires considerable capital expenditure, not only for the initial research and development, but also to go through the regulatory []process necessary to get a product... on to the market."[252] Under the current 1999 Revised Interim Utility Guidelines,[253] however, the PTO has taken a stance against patenting of genes and DNA sequences lacking a so-called "real world" use.[254] The PTO has rejected the utility of using of these sequences as research tools to find other genes and proteins.

As a result of the 1999 Guidelines, scientists will never be able to obtain composition patents to most of the DNA sequence obtained from the HGP. Although the 1999 Guidelines do not block method of use patents, such patents do not offer the advantages of composition patents, and investors may be reluctant to rely on them for protection of their investment.

B. The 1999 Utility Guidelines Intended to Fix the Shortcomings of the 1995 Guidelines

The 1999 Utility Guidelines sought to rectify the shortcomings of the 1995 Utility Guidelines. The 1995 Utility Guidelines eased the utility requirement, and the research commu-

252. Lehman, *supra* note 2, at 50.

253. Revised Utility Examination Guidelines, *supra* note 8, at 71,440.

254. For an explanation of how the PTO has toughened their stance on utility in the 1999 Guidelines, see *supra* Part II.D.2.

nity responded by filing many more applications.[255] The PTO could not handle the application volume.[256]

Additionally, there were questions about the legality and policy of the 1995 Guidelines. Many commentators were concerned that the 1995 Guidelines did not follow the case law on the utility requirement for a patent.[257] Critics questioned the wisdom of allowing patents on genes before discovering a use.[258] Others stated that allowing patents at such an early stage would chill future research and innovation.[259] Still others argued that preventing patents and allowing free availability of genetic information "encourage[d] widespread use of information and minimize[d] transaction costs. . . . Similarly, research and development is cheaper and faster if it uses resources that are freely available[,] . . . [instead of having] to negotiate licenses for access to prior discoveries."[260] In other words, critics feared that scientists would find rights to genes already locked up by patents. By forcing drug developers to license, these early stage patents would raise development costs. As Heller and Eisenberg explained, "[e]ach upstream patent allows its owner to set up another tollbooth on the road to product development . . . slowing the pace of downstream biomedical innovation."[261] The PTO appears to have adopted this viewpoint in the 1999 Revised Interim Utility Guidelines.[262]

C. Problems Created by the 1999 Guidelines

As explained above, the 1999 Revised Utility Guidelines may act to prevent composition claims from issuing to genes and proteins in the future.[263] Therefore, researchers may only

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255. *See* CHISUM ET AL., *supra* note 5, at 726. The 1995 Utility Guidelines are discussed *supra* Part II.D.1.

256. Olsen, *supra* note 11, at 326.

257. *See* Kight, *supra* note 188, at 1020.

258. *See* CHISUM ET AL., *supra* note 5, at 726.

259. *See id.*

260. Rebecca S. Eisenberg, *Intellectual Property at the Public-Private Divide: The Case of Large Scale cDNA Sequencing,* 3 U. CHI. L. SCH. ROUNDTABLE 557, 572 (1996).

261. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 699 (1998).

262. The 1999 Guidelines are discussed *supra* Part II.D.2.

263. Patent practitioners have been able to inventively bypass this hurdle, as discussed in Part IV.D. One such way to "claim around" the patent was suggested by a current practitioner. The suggestion was to claim related sequences

be able to obtain method of use or improvement type patents for DNA sequences.

The consequences of the 1999 Guidelines for the traditional biotechnology industry, which focuses on proteins as therapeutics or diagnostics, could be quite severe. Companies typically spend at least $250 million bringing a new drug to market.[264] Without strong patent protection as conferred by composition type claims, small biotechnology companies "are unlikely to be successful when competing against larger players with superior production, distribution and marketing resources."[265] Further, the rights granted by a method of use patent are less certain and harder to enforce than the rights granted by composition claims. Commentators agree that "[n]arrow property rights are unlikely to result in the funding necessary to provide new biotechnology products."[266] Many, if not most, of the current biotechnology-derived therapeutic products on the market are protected by composition type claims.[267] As a result of the unavailability of composition claims, companies likely will be less willing to invest the huge sums necessary to bring these types of therapeutics to market. This, in turn, would chill the development of new drugs to treat diseases, an unacceptable result.

The 1999 Guidelines, which deter patenting of DNA sequences, will have less of an effect on companies developing non-protein therapeutics. Although these companies may use new sequence information to speed development of chemical therapeutics, their interest is in obtaining patents to the chemical therapeutics, not gene sequences.

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but exclude the literal sequence that rests in the database. A useful molecule will still be patented, because DNA sequences can often have slightly different structures and still have the same function. This approach, however, leaves unanswered whether the Patent Office would find such claims acceptable. One potential problem is that the related sequence may be seen as "obvious" under 35 U.S.C. § 103 and thus not patentable. Other potential pitfalls may interfere with this approach.

264. *See* Amy E. Carroll, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U. L. REV. 2433, 2476–77 (1995).

265. Murray, *supra* note 14, at 255.

266. *Id.*

267. As an example, erythropoietin, the largest selling protein therapeutic, is protected by claims to the sequence. U.S. Patent No. 4,703,008 (issued Oct. 27, 1987 to Fu-Kuen Lin) (assigned to Amgen). Human growth hormone, another biotechnology product, is protected by claims to the protein sequence in U.S. Patent No. 4,665,160 (issued May 12, 1987 to Peter Seeburg) (assigned to Genentech).

D. Proposed Solutions

The PTO's roadblocks to obtaining patents to DNA could discourage the development of new drugs and therapeutics, particularly in the biotechnology industry. Some potential solutions are listed below. Best among them is a congressionally created exception to § 102 of the patent code, which would encourage research and development of new drugs while preventing premature patenting of gene sequences.

1. Abandonment of the 1999 Revised Interim Utility Guidelines

One solution to eliminate the problems arising from the 1999 Guidelines is to simply abandon them and return to the 1995 Utility Guidelines. The 1995 Guidelines proposed a significantly lower utility standard for patenting DNA sequences, requiring only a showing of a "credible" utility. In contrast, the 1999 Guidelines require that in addition to a "credible" use, the use must be "substantial" and "specific." Only under the 1995 Guidelines did a "research use" pass the utility test.

But the 1995 Guidelines are not a perfect solution by any criteria. The 1995 Guidelines, coupled with the PTO statement that ESTs were patentable, led to overwhelming numbers of applications in the PTO. Further, serious questions existed regarding whether the 1995 Guidelines would deter future research and whether they were in line with the Federal Circuit case law. Bringing back the 1995 Guidelines would only reraise those particular issues.

2. Analogizing to the Chemical Arts

Researchers in the chemical field have faced problems similar to those facing gene inventions. Chemists can easily draw up chemical structures on paper long before they have found a way to make them in a laboratory. The PTO, however, asserted that chemical structures drawn up on paper blocked later patenting by the scientist who discovers how to make that chemical. The Federal Circuit corrected the PTO in *In re Sasse*.[268] In this case, the court stated that such "paper" chemi-

268. 629 F.2d 675 (C.C.P.A. 1980).

cals are not a prior art reference against an inventor unless the reference actually teaches how to make[269] that chemical.[270] Thus, the mere existence of a chemical structure on paper does not prevent the later patenting of that chemical when it is made.

One way for the judiciary to intervene to allow gene patents in the face of existing DNA sequence information from the HGP is to extend the holding of *In re Sasse*. The court could find that mere DNA sequence information is similar to a chemical structure existing only on paper. But this would be a fairly radical extension. The "paper" disclosures of chemical structures and DNA sequence from the HGP are not directly analogous. Unlike the chemical at issue in *In re Sasse*, once the sequence of DNA is revealed, it is a simple and routine matter to make it.[271] Despite this difference, *In re Sasse* reveals that the Federal Circuit may stretch to find patentability in some cases.

The case of DNA sequences from the HGP may be an appropriate situation for the court to reach a bit. Currently, understanding of the molecular basis for most disease processes is rudimentary.[272] The existence of DNA sequence in a database is very similar to a chemical existing on paper, in that researchers still face years of research to identify a drug. This similarity may provide a reason for the Federal Circuit to bring *In re Sasse* to the dilemma of DNA sequences blocking future patents.

Extending *In re Sasse* avoids the problems associated with bringing back the less stringent 1995 Utility Guidelines, yet preserves the ability of researchers to obtain composition claims to DNA sequences at a future date. In this way, the biotechnology industry can still obtain the important composition type claims needed to obtain financing for drug development. This approach, however, requires a considerable extension of the case law from the chemical area to the genetic area. Although not out of the question, this limitation makes it is less likely that courts would adopt this position.

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269. Specifically, the reason for rejection in *Sasse* is lack of enablement, one of the requirements for a patent. *See supra* Part II.B.3.

270. *See In re* Sasse, 629 F.2d at 680.

271. JOSEPH SAMBROOK ET AL., MOLECULAR CLONING, A LABORATORY MANUAL § 11.2 (2d ed. 1989).

272. *See* Silverman et al., *supra* note 61, at 2.

3. Patenting Slightly Altered DNA to Avoid DNA Sequence Contained in the Public Databases

Patent practitioners in the biochemical arts have traditionally found clever ways to obtain composition claims to proteins and DNA sequences. Practitioners may continue to use such methods to obtain composition claims despite the presence of DNA sequence in the public domain.

One such strategy is to claim DNA sequences that are ever-so-slightly changed from the DNA sequence in the public domain. This strategy takes advantage of the "degeneracy" of the genetic code, or, in other words, the fact that DNA, even when somewhat different, can often yield the same protein.[273] Even when protein structures are slightly different, the activity of that protein frequently remains the same.[274] Consequently, practitioners can claim related sequences to the DNA in the database. In this way, practitioners can obtain composition claims to functional proteins and DNA, yet avoid claiming the exact, or literal, DNA in the database.

Despite the benefits, there are problems with this approach. First, it is unclear whether the PTO would allow such claims. The PTO may find the closely related sequences "obvious" under 35 U.S.C. § 103, and thus not patentable.[275] Another problem is that even when an inventor had obtained a composition type claim to a related DNA sequence, he may not prevent competition by others. Competitors would still be free to use the DNA sequence in the public domain.

The difficulty of obtaining composition claims to DNA already in the public domain is similar to the problem presented to companies when their patents expire. When patents expire, the information in them becomes part of the public domain. To remain competitive, companies may try to extend their monopoly by developing (and patenting) new chemical forms of the now off-patent drug. These different chemical forms include longer lasting or more powerful forms of the drug. Another strategy is to continue to file "use" patents, extending the effec-

273. *In re* Deuel, 51 F.3d 1552, 1558–59 (Fed. Cir. 1995).
274. *Id.*
275. "Obviousness" is briefly described *supra* in Part II.B.2.

tive life of the original patent.[276] A company facing the problem of having a closely related DNA sequence in the public domain could adopt a similar solution. For example, a company could devote its efforts to finding improved forms of the DNA sequences (and corresponding proteins), thereby maintaining an advantage over competitors using the unpatentable DNA sequence in the public domain. In summary, patent practitioners could adapt time-honored methods of obtaining patents via claiming slightly altered or improved DNA sequences, thus avoiding DNA in the public domain.

4. Adapting to Method of Use Type Claims

It may be that patent practitioners and the courts need not do anything. The industry may accept and adapt to the new reality of method of use claims only. Since method patents are the only claims obtainable, they may become the new norm. In that case, because no one can obtain composition claims, investors may not be deterred by method of use patents. Additionally, because all sequence information is in the public domain, there will be no lurking composition claim holder demanding royalties.

Although the industry may adapt with little disruption, the possibility remains that it will not. Given the desirability of developing new drugs and the importance of the biotechnology and the pharmaceutical industries to the economy, this approach seems risky. The approach makes a blind assumption of little or no change, when in fact the biotechnology industry has traditionally protected its blockbuster drugs with composition of matter type claims. It seems very shortsighted to allow the HGP to have the effect of cutting off these types of patent rights for all time.

5. A Congressionally-Created Exception to Section 102

A final solution is for Congress to adopt a specific exception for DNA sequences from the HGP from the operation of § 102 of

276. For an example of a patent-extending strategy, see *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1570 (Fed. Cir. 1996) (plaintiff purchased additional process patent to drug after original patents had expired).

the Patent Act. Currently, § 102 cuts off patent rights after a certain time. Congress could allow composition patents to HGP-discovered DNA beyond the one-year time bar upon the discovery of a commercial use for that DNA.

In many ways, an exception to § 102 would present the best solution to this problem. Such an exception would reconcile two competing policies: (1) benefiting scientific research generally by releasing the human genome sequence into the public domain[277] and (2) encouraging development of new drugs by allowing patent monopolies. Because DNA released by the HGP would remain generally non-patentable, scientists could work without fear of interfering with any patents, thus encouraging basic research. Yet granting patents to such DNA when and if a commercial use is discovered would reward the inventor who discovers a new way to treat disease. This result is consistent with the United States patent system policy of demanding innovation from inventors before rewarding them with a government-sponsored monopoly. Because much hard work and innovation is still required to find new disease treatments even with knowledge of the human genome sequence,[278] the proposed exception to § 102 would advance the purpose of the United States patent laws.

Congress has a history of creating narrow exceptions carved out from the patent laws in order to benefit specific industries, in recognition of the fact that patents are vital to scientific progress and innovation.[279] Section 102, however, has long been enshrined in patent law. Critics may fear evisceration of § 102 with this proposed exception. Congress could constrain this proposed exception by drafting legislation to allow the exception to apply only to sequence from the HGP. Allowing an exception to § 102 for sequence from the HGP, then, would combine the best of both worlds. It would encourage sci-

277. The publicly funded consortium that sequenced the human genome encouraged public release of human sequence data and discouraged the patenting of genes by the sequencing labs. *See* Eliot Marshall, *Bermuda Rules: Community Spirit, with Teeth*, 291 SCI. 1192 (2001).

278. Stanley Fields, *Proteomics in Genomeland*, 291 SCI. 1221 (2001).

279. For example, § 271(g) was specifically created to allow United States pharmaceutical companies to enforce patents against foreign pharmaceutical companies that, due to a loophole in the patent laws, could manufacture drugs offshore, then import and sell them in the United States. *See* CHISUM ET AL., *supra* note 5, at 966.

entific research and stimulate new drug development, thus fully capitalizing on the promise of the Human Genome Project.

CONCLUSION

The PTO's 1999 Revised Interim Utility Guidelines placed a significant obstacle to patenting DNA sequences derived from the HGP. In many ways, this roadblock serves some important and necessary purposes. It prevents a wholesale "gold rush" toward patenting these sequences before their potential is known. It promotes a more orderly, measured pace of patenting as scientists discover commercial applications for these sequences. Further, a slower pace of patenting allays concerns that early patents, by forcing licenses, will deter future research.

On the other hand, the PTO's new approach has created a situation where many genomic sequences released into the public domain by the HGP cannot be protected by composition claims. Today, composition type claims protect almost all current biotechnology-developed drugs. Under the 1999 Utility Guidelines, companies may be forced to rely on inferior method of use type claims instead. Such radical shifts in the strength of the patents that the biotechnology industry can obtain have the potential to seriously impair the ability of the industry to raise the capital required to develop new drugs.

Arguably, method claims will become the new standard because all applicants are prevented from obtaining composition claims, forcing the industry to adapt to this shift. It is also possible that patent practitioners will learn how to claim slightly altered DNA sequences to avoid DNA previously discovered by the HGP, thereby continuing to obtain composition type claims. However, it is not clear what the result of the PTO's prevention of composition claims will be. It seems a risky strategy to prevent composition claims when the possibility remains that limiting patent rights to DNA will disrupt drug development. A better solution, which would allow patenting of the human genome only for sequences of demonstrated commercial use, is for Congress to adopt an exception to §102. This exception would allow composition of matter claims when requirements of utility are met, despite the presence of the DNA sequence in the public domain.

The Human Genome Project promises a new age in medicine, where both understanding of and treatments for disease progress far more rapidly than in the past. To preserve that promise, it is crucial that the United States patent laws do not discourage development of new lifesaving drugs derived from the information from the HGP. Only a further change in the patent regulatory scheme can ensure the fulfillment of the Human Genome Project's promise.