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Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines in Light of *Brenner*

ANDREW T. KIGHT*

"'The abuse of frivolous patents is likely to cause more inconvenience than is countervailed by those really useful.'"[1]

—Thomas Jefferson

INTRODUCTION

"A simple, everyday word can be[come] pregnant with ambiguity when applied to the facts of life."[2] Although Justice Fortas wrote this more than thirty years ago in response to conflict over the proper application of the United States Patent Act's utility standard, it still rings true today. No longer a standard of meaningful application, the current utility requirement has been shaped and sculpted into a distant cousin of its predecessor, with consequences that threaten not only the integrity of the patent system, but the scientific research community as well.

With the advent of faster and cheaper gene-sequencing methods,[3] bioprospectors are flooding the Patent and Trademark Office ("PTO") with applications at a frenzied rate. Often the applications represent only gene-sequence fragments of undetermined function (often referred to as "expressed sequence tags," or "ESTs"), yet they attempt to lay claim not just to the fragment but to the entire gene and any protein it may encode as well. This may have far-reaching effects, as the protein a gene produces can be purified, mass produced, and sold as a pharmaceutical drug or other useful compound,[4] or the gene itself may be used for gene therapy.[5] The ultimate result is that "the companies which conduct[] the more meaningful and costly scientific work—that of incorporating

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* J.D., December 1997, Indiana University School of Law-Bloomington; B.A., 1993, Hamilton College. Special thanks to my family for their unending love and support, and especially my wife for her guidance and value as a veritable thesaurus. Thank you also to Professors John A. Scanlan and Daniel J. Lueders for their assistance.

1. SILVIO A. BEDINI, THOMAS JEFFERSON 209 (1990) (quoting Thomas Jefferson).

2. Brenner v. Manson, 383 U.S. 519, 529 (1966).

3. See *infra* notes 47-60 and accompanying text for a discussion on gene sequencing.

4. For instance, Amgen, Inc. earns more than $500 million a year from sales of Epogen, a treatment for anemia based on a patented gene. *See* Joan O. Hamilton, *Get a Life*, CAL. LAW., Feb. 1996, at 39, 39.

5. On September 14, 1990, four-year-old Ashanti DeSilva, who was born without a working immune system resulting from a rare disorder known as severe combined immune deficiency ("SCID"), was given new genes to correct the defect. SCID renders cells unable to produce an essential immune-system enzyme and usually results in early death. In order to battle the disease, doctors at the National Institutes of Health ("NIH") injected about a billion genetically altered cells into Ashanti's body by simple intravenous infusion. This was the first time gene therapy had been administered to a human in an attempt to cure disease, and today Ashanti is attending school and leading a normal childhood. *See* Ralph Oman, *Biotech Patenting Issues Raise Ethical Concerns*, NAT'L L.J., May 8, 1995, at C42, C42.

the DNA fragments into practical application—[will] be at the mercy of the patentees, unable to commercialize their product without first paying an exorbitant licensing fee."[6]

While attempts to patent full genes with a characterized function are legally acceptable, attempts to patent a partial gene of unknown function are widely considered to be inappropriate. Public opinion, though, is simply an indication of whether something is proper, not whether something falls within the structure of the law. For this reason, it is unclear whether partial gene sequences are *in fact* patentable.

The legal foundation for the genetic gold rush was laid in 1980 by the Supreme Court in *Diamond v. Chakrabarty*.[7] In that case, the applicant sought protection for a genetically engineered bacterium capable of breaking down crude oil, a property possessed by no naturally occurring bacteria. Noting that Congress expressly intended for the Patent Act to "'include anything under the sun that is made by man,'"[8] Chief Justice Burger established that genetically engineered living organisms may fall within the Patent Act's statutory subject matter. Although the "laws of nature, physical phenomena, and abstract ideas" are outside the scope of patent protection,[9] a nonnaturally occurring manufacture or composition of matter is "not nature's handiwork, but [an inventor's] own; accordingly it is patentable subject matter under § 101."[10]

In the ensuing seventeen years, *Chakrabarty*'s rationale has been used to extend patent protection to "those organisms that an inventor has altered in a new and useful way or to genes when they have been isolated as synthetic molecules, a form in which they do not occur in nature."[11] Coupled with the fact that the medical community is turning its attention to biotechnology as traditional chemical-based pharmacology rapidly reaches its limits in producing breakthrough drugs,[12] the result has been an inundation of patent applications, which the U.S. government initiated almost seven years ago.

Beginning in June, 1991, the NIH filed the first of three applications seeking patent protection for partial gene sequences. Together, the three applications sought protection for 6869 partial complementary-DNA sequences.[13] The PTO initially rejected the applications in late 1993 because they failed to meet the statutory prerequisites for patentability—novelty, nonobviousness, and utility. Although then NIH Director Bernadine Healy stated that the initial response by the PTO was customary and the issues cited "are raised by the PTO in well over

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6. Eric R. Paley, *Rethinking Utility: The Expediency of Granting Patent Protection to Partial cDNA Sequences*, 44 SYRACUSE L. REV. 1003, 1007 (1993).

7. 447 U.S. 303 (1980).

8. *Id.* at 309 (quoting S. REP. NO. 82-1979, at 5 (1952)).

9. *Id.*

10. *Id.* at 300. See also *infra* Part III for a discussion of the utility requirement.

11. Oman, *supra* note 5, at C43.

12. *See* Kathleen Day, *It's All in the Genes*, WASH. POST, Sept. 30, 1996, at F14.

13. *See* Christopher Anderson, *NIH Drops Bid for Gene Patents*, 263 SCIENCE 909, 910 (1994).

90% of all patent applications,"[14] the NIH ultimately abandoned all three applications in February of 1994 on the grounds that seeking patent protection was "not in the best interests of the public or science."[15] The NIH is now discouraging patent applications on partial gene sequences,[16] but regardless of these subsequent actions, the precedent had been set.

There are at least 132 publicly held biotechnology companies currently vying for the prize of patent rights.[17] At least a dozen are outwardly attempting to gain patents on gene fragments,[18] and it is unknown how many are discretely pursuing this prize. Incyte Pharmaceuticals of Palo Alto, California alone intends to file patent applications for as many as 100,000 fragments a year.[19] In 1992, the man responsible for determining the sequences in the NIH applications, Dr. Craig Venter, left the NIH to found a not-for-profit research institute, The Institute for Genomic Research, and a for-profit counterpart, Human Genome Sciences ("HGS"),[20] to be run by William A. Haseltine. This pairing was orchestrated by the late Wallace H. Steinberg, chairman of the venture capital firm HealthCare Investment Corporation. Under the terms of the deal, HGS promised to fund The Institute for Genomic Research with $85 million over ten years in exchange for marketing rights to the Institute's discoveries.[21] Venter expected to sequence 2000 to 3000 fragments per week at the Institute.[22] Since the "potential gold mine that gene-hunters ultimately seek is a patent,"[23] which might be developed into a multimillion-dollar product, there is no reason for biotechnology companies not to file as many patents as they can write. The decision of the PTO to issue less stringent utility guidelines adds implicit support for this rationale.

These guidelines, issued in July, 1995 in response to both growing industry criticism and backlog, make utility-based rejections mere artifacts. The guidelines establish the utility standard as "credible," which is far below that of

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14. Reginald Rhein, *PTO Says No to NIH Gene Application*, BIOTECH. NEWSWATCH, Oct. 5, 1992, at 1, 2.

15. Anderson, *supra* note 13, at 909.

16. *See $60 Million Study Begins on DNA Sequencing*, WASH. POST, Apr. 12, 1996, at A3.

17. *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, 178 (1996).

18. *See* Jeff Nesbit, *No One Should Hold a Patent on Humans*, WASH. TIMES, Sept. 27, 1996, at B8, *available in* 1996 WL 2966695.

19. *See* G. Kenneth Smith & Denise M. Kettelberger, *Patents and the Human Genome Project*, 22 AM. INTELL. PROP. L. ASS'N Q.J. 27, 50 (1994).

20. *See* Malinowski & O'Rourke, *supra* note 17, at 182.

21. *See* Beth Berselli, *Gene Split; Research Partners Human Genome and TIGR Are Ending Their Marriage of Convenience*, WASH. POST, July 7, 1997, at F5. Recently, however, Venter and Haseltine have called off their "marriage of convenience." HGS will not make about $38 million of the payments it had promised to the Institute and will relinquish rights to future work done by the Institute. In return, the Institute is free to publish its findings immediately, but agreed not to enter into any commercial agreements for the next four years on specific therapeutic proteins and associated diagnostic tests now being developed by HGS. As one observer noted, "[e]ven if they had been in love, the breakup was bound to happen. Both of their goals were laudable, but they weren't compatible." *Id.*

22. *See* Smith & Kettelberger, *supra* note 19, at 45.

23. Matthew Erramouspe, Comment, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 UCLA L. REV. 961, 965 (1996).

"substantial" as imposed by Justice Fortas in the much earlier *Brenner* case. Although seemingly improper, the courts have not yet had an opportunity to address the legality of the guidelines. The NIH applications offered the most promising vehicle for resolution of the issue, but this option has since expired. Venter stated that the NIH's failure to push the PTO into making a decision was a "'tragic mistake'" that will lead to "'uncertainty and chaos.'"[24] The NIH fostered a legitimate response, arguing that since they felt patent protection was not in the public interest, they would have been pursuing a cause they hoped to lose. It would have been "unlikely that [a court] decision would have been considered solid, because [the NIH] might have been perceived as half-hearted in [their] attempts; certainly the motivation to succeed will be higher in the private sector."[25]

Indeed, it will be up to the private sector to test the legal waters of this issue. However, there is no indication that an outcome will be forthcoming. To date there have been no patents issued for gene-sequence fragments and it is virtually impossible to determine if there have been any rejections due to the construction of the patent system.[26] Because the NIH is a government institution, its applications were and are available to the public. Private companies, on the other hand, are "likely to be far more secretive. Indeed, if their patents are rejected, they may keep that information to themselves, on the assumption that acknowledging defeat could depress the price of their stock."[27]

This Note examines the new PTO utility guidelines and their effects on both the patent system and the scientific community, and suggests a possible solution that remedies both the illegality of the guidelines and the problems they were designed to correct. Part I offers an overview of the biotechnology industry from both a public and private standpoint, with an emphasis on the methods and costs by which laboratories and companies sequence genes in search of future commercial products. Part II briefly explains the United States Patent Act and its three basic requirements—novelty, nonobviousness, and utility. Part III examines the evolution of utility, tracing the standard from its earliest treatment as a function of the market, to its rise as a meaningful concept in *Brenner v. Manson*,[28] and finally to its current status as a PTO pushover. Part IV analyzes the legality of the guidelines in light of both the controlling legal precedent and relevant policy concerns. This Note concludes that the PTO guidelines are an inappropriate and illegal solution to the problems associated with biotechnology patent applications. In issuing the guidelines, the PTO bowed to pressure from both the biotechnology industry and its own administrative concerns. It is true that the rapid growth of the biotechnology industry essentially held the PTO hostage, with more applications rolling in than out, but there were other legally acceptable, and available, solutions to the problem. By making utility rejections less likely, the guidelines exacerbate the problems they were intended to correct

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24. Hamilton, *supra* note 4, at 43 (quoting Dr. Craig Venter).

25. Anderson, *supra* note 13, at 910.

26. As required by 35 U.S.C. § 122 (1994), patent applications are maintained in confidence until a patent is granted.

27. Anderson, *supra* note 13, at 909.

28. 383 U.S. 519 (1966).

and invite another round of mass filings which promise to further clog the PTO. Guidelines are the answer, but only if they encourage sensible filings accompanied by thorough research. In doing so, the necessary incentive to follow an invention to fruition is provided. Instead, the current utility standard rewards underdevelopment with premature rights and confers a monopoly on the inventor of an undeserving and unknown invention.

I. THE CURRENT STATE OF BIOTECHNOLOGY

"Scientists, among them Nobel laureates, are quoted [as] suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time."[29] The luxury of hindsight and twenty-seven years of subsequent research illustrate that the wisdom of the *Chakrabarty* Court in rejecting this policy argument was well placed. In the past, medical care was generally directed toward immunizing against disease and the suppression of symptoms of those diseases that could not be prevented. Today researchers are identifying the defects that cause disease, and "rather than just treating or suppressing symptoms, the genotech industry aims to identify and attack the root causes of disease."[30] To date genotechnology has provided clues into the cause of Huntington's disease, cystic fibrosis, several cancers, Alzheimer's disease, diabetes, obesity,[31] and even aging.[32] But what is it, exactly, that leads scientists to these discoveries?

A. The Basics of DNA

The human body houses an estimated 100 trillion cells which range in size from 10 to 100 micrometers.[33] Each of these cells, with a few exceptions, contains a copy of 23 pairs of chromosomes comprised of upwards of 100,000 genes.[34] Each gene, in turn, is an extended segment of deoxyribonucleic acid ("DNA") that encodes the information necessary to produce a functional biological product.[35] The length of all of the DNA in our cells is approximately 2×10^{14} (200 trillion) meters, or 2×10^{11} (200 billion) kilometers. To put this miracle of efficiency in perspective, this distance is greater than both the circumference of the earth—4×10^{4} (40,000) kilometers—and the distance between the earth and the sun—1.5×10^{8} (150 million) kilometers.[36]

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29. Diamond v. Chakrabarty, 447 U.S. 303, 316 (1980).

30. Malinowski & O'Rourke, *supra* note 17, at 170-71.

31. *See id.* at 173-74.

32. *See Scientists Link Gene to Aging*, GREENSBORO NEWS & REC., Apr. 12, 1996, at A13, *available in* 1996 WL 5765164.

33. One micrometer is equivalent to 1×10^{-6} meters, or one one-millionth of a meter.

34. *See generally* ALBERT L. LEHNINGER ET AL., PRINCIPLES OF BIOCHEMISTRY 791-98 (2d ed. 1993).

35. *See id.* at 789-90.

36. *See id.* at 794.

In its natural state, DNA forms a tightly coiled, continually spiraling ladder, or double helix. The arms of this ladder are composed of alternating sugar and phosphate groups, while the "rungs" of the ladder are pairs of nitrogenous bases. Although there are only four different bases—adenine (A), cytosine (C), guanine (G), and thymine (T)—which can combine in only two ways—A pairs with T, C pairs with G—the sequence of the "rungs" can vary in countless ways, each combination producing a different outcome. For example, the word "RAT" paints a clear image of a rodent, but "TAR" and "ART," words composed of the same letters in different sequences, conjure up very different meanings.[37] The resulting sequences determine the individual characteristics of every person: whether you will have blue eyes or brown eyes, black hair or blonde hair, a good fastball, a shapely body, or even whether you will be the carrier of a disease.

The sum of all the DNA and genes on all the different human chromosomes is referred to as the human genome, and there is now an international effort to determine the location and function of each and every gene on each and every chromosome of the human genome. As one participant stated, "'To find those genes, you want to have the same kind of map that you would have to find a lost dog or a lost child on 1,000 acres of woods.'"[38]

B. The Human Genome Project and the Evolution of Gene Sequencing

The Human Genome Project ("HGP"), initiated by Congress during 1988-89 and commenced in 1990, was founded in an effort to map all twenty-three pairs of chromosomes within the human genome.[39] There are currently twenty-six countries[40] and over 350 laboratories[41] involved in the project, of which the three primary goals are to produce: (1) genetic-linkage maps to trace inheritance of chromosome regions through pedigree; (2) physical maps of large chromosome regions to enable direct study of DNA structure in search of genes; and (3) substantial DNA sequence information, enabling the correlation of DNA changes with alterations in biological function.[42] Initially, the HGP hoped to identify all of the genes in the human genome by 2005, but they now anticipate finishing seven years ahead of schedule in 1998.[43] At an estimated cost of $3 billion,[44] though, the HGP is not without its critics. "Just knowing the 3 billion bits of DNA's code or identifying the functions of our 100,000 genes won't immediately give humans control of the code's ever-changing music. That's like saying you know how to fly a Boeing 747 just because you know the names of all its

37. *See* Erramouspe, *supra* note 23, at 981.

38. Charles Petit, *David Botstein: A Map for an Incredible Journey*, S.F. CHRON., Aug. 18, 1996, at 3Z1, *available in* 1996 WL 3225920 (quoting Stanford University geneticist David Botstein).

39. *See* Malinowski & O'Rourke, *supra* note 17, at 190.

40. *See* Smith & Kettelberger, *supra* note 19, at 32.

41. *See* Malinowski & O'Rourke, *supra* note 17, at 191.

42. *See id.* at 190.

43. *See* Hamilton, *supra* note 4, at 41.

44. *See id.*

parts."[45] To date, though, the accomplishments and progress of the HGP have been enormous, and for the 1995 fiscal year, while defense research and development was scheduled to receive $39.5 billion, the NIH (the U.S. government's key player in the project) was slated to receive only $11.47 billion to apply to all projects across the board, not just the HGP.[46]

One significant accomplishment of the race to map the human genome has been the very process by which this cartography is accomplished. Traditionally, genes were identified and cloned through a functional approach. Starting with samples of known biological function, a researcher worked backwards to isolate and purify the responsible proteins, and then used degenerate DNA probes to locate the corresponding gene.[47] The cost of identifying a single gene? Between $40,000 and $50,000.[48]

A marked improvement occurred, however, when Dr. Craig Venter, while still at the NIH, developed a novel, structural approach for gene identification known as complementary DNA ("cDNA") sequencing. Using an automated DNA sequencer once referred to as a "$100,000 paperweight,"[49] this process allows genes to be identified quickly and easily. As opposed to a full-length genomic DNA sequence, a cDNA sequence is an "edited" copy of a gene, and contains only the protein-coding regions. As such, these sequences are shorter than genomic sequences and can thus be characterized more quickly.[50]

Venter noted that "'cells are smarter than scientists.'"[51] Although there are roughly three billion "letters" in human DNA, only two to five percent actually represent functional genes. The remaining ninety-five percent is "junk" which apparently codes for nothing.[52] In order to create necessary proteins, cells copy only the necessary DNA into messenger-RNA ("mRNA") molecules which tell the cell what protein to make. In carrying out his research, Venter pinpointed and copied mRNA molecules into sturdier strands of DNA—cDNA. The cDNA was then processed in the sequencing machine. Venter estimates that he and his colleagues identified over 8000 cDNA sequences at the NIH over the years 1990 to 1992,[53] at a cost of roughly twenty dollars each.[54]

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45. Karl Leif Bates & James Tobin, *Overselling the Promise: Genetic Research Spawns Hype, Hope and Human Dilemmas*, DETROIT NEWS, Dec. 15, 1996, at A1, *available in* 1996 WL 2939066.

46. *See Clinton Puts $71 Billion into R&D; Defense Still Gets Larger Piece of Pie*, BIOTECH. NEWSWATCH, Feb. 21, 1994, at 12, 12.

47. *See, e.g.*, Reid G. Adler, *Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization*, 257 SCIENCE 908, 909 (1992).

48. *See* Paley, *supra* note 6, at 1007.

49. Eliot Marshall, *Patent Office Faces 90-Year Backlog*, 272 SCIENCE 643, 643 (1996).

50. For a detailed discussion of cDNA sequencing, see Erramouspe, *supra* note 23, at 983-85.

51. John Carey et al., *The Gene Kings*, BUS. WK., May 8, 1995, at 72, 75 (quoting Dr. Craig Venter).

52. *See, e.g.*, Tom Wilkie, *Whose Gene Is It Anyway?*, INDEPENDENT (London), Nov. 19, 1995, at 75, *available in* 1995 WL 10814293.

53. *See* Smith & Kettelberger, *supra* note 19, at 45.

54. *See* Paley, *supra* note 6, at 1007.

Prior to the widespread use of cDNA sequencing, about 2000 human genes had been identified. By September of 1995, data had been released identifying 50,000 genes.[55] It is now estimated that DNA sequences representing parts of 85-90% of all genes have been identified.[56] As Stanford University geneticist David Botstein said of the improved process, "'It's very much like the difference between driving to Butte, Mont[ana], now as opposed to the way Lewis and Clark got to the same place.'"[57] Admittedly, as with most shortcuts, cDNA sequencing has it drawbacks.

While much more cost effective and efficient, cDNA sequencing paints only a fraction of the picture compared to that of the functional approach, which works backwards from known biological function to gene structure. cDNA sequencing as performed by Venter and his associates, on the other hand, starts with randomly selected cDNA clones of unknown function, runs them through an automated sequencer, and comes away with ESTs of still unknown function. These results are like "getting a list of phone numbers for a certain city with no names attached."[58] As Venter admitted, once he has an EST, he still has "no idea what it does, unless it's a sequence from a gene whose function is already known."[59] Of the first 600 ESTs determined by Venter, however, at least 350 represented unique genes that had never been seen before.[60]

For this reason, cDNA sequencing has a number of vehement critics. Among these critics is James Watson who, together with Francis Crick, deduced the double-helix structure of DNA and proposed a structural basis for its precise replication in 1953. Like many others, Watson believes that "'[w]hat is important is *interpreting* the sequence.'"[61] When he learned that the NIH was seeking patent protection for the sequences, he stated that "'virtually any monkey'" can run an automated sequencing machine, and to allow patents on such sequences is "'pure lunacy.'"[62] As a result of the NIH's patent position, Watson resigned as director of the NIH genome project in April, 1992.[63] "'Some of the biggest names in science tried to eliminate my career,'"[64] Venter stated. "'Not illuminate—eliminate. And I think being shot at for a year in Vietnam . . . prepared me for the hostile scientific community.'"[65]

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55. *See* Hamilton, *supra* note 4, at 41.

56. *See* Malinowski & O'Rourke, *supra* note 17, at 170.

57. Petit, *supra* note 38, at 3Z1 (alteration added) (quoting David Botstein).

58. Hamilton, *supra* note 4, at 40-41.

59. Leslie Roberts, *Genome Patent Fight Erupts*, 254 SCIENCE 184, 184 (1991).

60. *See id.* at 185.

61. *Id.* at 184 (alteration and emphasis added) (quoting James Watson).

62. *Id.* (quoting James Watson).

63. *See* Hamilton, *supra* note 4, at 43.

64. Matt Crenson, *Competition, Controversy for Maverick DNA Researcher Genetics: After Simplifying the Gene-Hunting Process, Craig Venter Runs Afoul of Scientific Rivalry—and the Biotech Industry*, L.A. TIMES, May 4, 1997, at A20 (quoting Dr. Craig Venter).

65. *Id.* (omission in original) (quoting Dr. Craig Venter).

C. Effects on the Private Sector

Critics and monkeys aside, the search for pharmaceuticals through DNA sequencing is a lucrative business. "Biotech-related products generated annual sales of more than $7 billion in 1993, approximately $7.7 billion in 1994, and $8.7 billion in 1995."[66] In 1996, biotechnology sales rose an additional 15% to total more than $11 billion.[67] The total market for DNA diagnostics alone is expected to exceed $700 million by 1998.[68] One analyst stated that patented sequences are like "'the Rosetta Stone of the human genome,'" enabling biotechnology companies "'to "go shopping" for the cell line they are interested in.'"[69] The right sequence can lead to a multimillion-dollar product, and everyone is trying to patent a piece of the market.

"Blood samples taken from asthmatics living on a remote South Atlantic Island, Tristan de Cunha, were developed into asthma treatment technologies that were eventually sold to German pharmaceutical giant Boehringer Ingelheim for $70 million."[70] With hopes of striking similar "human DNA gold," Microsoft chief Bill Gates and another partner invested $10 million in a single company, Darwin Molecular Technologies.[71] One of the most successful biotechnology companies to date, Genentech, Inc., was founded in 1976 with a $1000 investment.[72] In 1995, that company generated $848 million in revenues.[73] In 1996, the number had increased to $896 million.[74] "Not since the dawn of the atomic age have scientists from all over the world sought the same prize."[75] This has led to a flow of scientists out of the public sector and into private companies, and has been accelerated by "commercial recruit[ing] of leading scientists from publicly supported universities and federally backed genome centers."[76]

Consequently, the genotechnology industry is now "built upon a conglomeration of complex alliances between the private and public sectors—alliances among members of industry, academia, and government arranged in a staggering number of ways."[77] But, considering that the "drug lag" takes seven to twelve years and up to $400 million from the time a new drug

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66. Malinowski & O'Rourke, *supra* note 17, at 165.

67. *See* Daniel Green, *The Cloning of U.S. Biotech Success*, FIN. POST, May 20, 1997, at 41, *available in* 1997 WL 4095232.

68. *See* Malinowski & O'Rourke, *supra* note 17, at 165.

69. Hamilton, *supra* note 4, at 39-40 (quoting Michael G. King, a stock analyst for Dillon, Read & Company).

70. Nesbit, *supra* note 18, at B8.

71. *See id.*

72. *See* Malinowski & O'Rourke, *supra* note 17, at 170.

73. *See CAFC Stays Preliminary Injunction in Growth Hormone Suit*, BIOTECH PAT. NEWS, Dec. 1, 1996, *available in* 1996 WL 8692015.

74. *Genetics Institute and Bayer Sign Functional Genomics Agreement*, BIOTECH PAT. NEWS, Aug. 1, 1997, *available in* 1997 WL 9414403.

75. Smith & Kettelberger, *supra* note 19, at 39.

76. Malinowski & O'Rourke, *supra* note 17, at 184.

77. *Id.* at 181.

candidate is discovered in molecular form until the time it enters the market,[78] research often cannot be conducted in the absence of these alliances. These relationships "offer long-term financial incentives to universities, which stand to make money if products result from the efforts, and immediate gain to struggling start-up companies, which are often strapped for cash and need additional brainpower."[79]

The enormous amount of money that genotechnology companies and investors stand to make on their investments has led to competition so intense that patent "applications are being filed on the day the [gene] sequence becomes available."[80] As one scientist said, "'[w]e've gone from gene of the year to gene of the month, and, pretty soon, to gene of the day.'"[81] This, in turn, has led to an enormous backlog in processing patent applications. In October, 1996, there were 350 gene patent applications claiming over 500,000 sequences pending in the PTO, all submitted for approximately $350,000 in application fees. The PTO estimated that it would take one patent examiner 200 years to initially examine these applications, or the entire biotechnology group of the PTO a full year at a cost of over $34 million.[82]

In conjunction with the absence of specific jurisprudence on the subject and the lower standard of utility now required by the PTO, it is logical to assume that this trend will continue indefinitely. Patent protection is a necessary element for genotechnology research,[83] but awarding patent rights too early may actually hinder the efforts such rights are intended to protect. Patents are a reward for innovation and the benefit ultimately conferred on the public.

A promise of patent protection before an invention is capable of providing this benefit encourages incomplete development and provides a disincentive to further research. As an inventor, if I know I can obtain patent protection before my invention actually functions in a way which provides some tangible benefit,

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78. *See id.* at 205 (noting that "'[f]or every 10,000 drug candidates created in the lab, only 1,000 compounds will be tested in animals' and, of these, only one will reach the market") (alteration in original) (citation omitted) (quoting Veronica Henry, *Problems with Pharmaceutical Regulation in the United States*, 14 J. LEGAL MED. 617, 617 (1993)). HGS recently revealed that it is performing animal tests on five proteins and hopes to begin human trials next year on two of them. "Two of the proteins appear to stimulate skin and hair growth and might help [to] heal wounds. One might prevent the destruction of bone marrow during chemotherapy. Another shows promise in repairing damaged nerves, and [the fifth one] might help those suffering from rheumatoid arthritis." Day, *supra* note 12, at F14.

79. *Mass. Firm, Johns Hopkins Announce Kidney Disease Find*, BOSTON GLOBE, Apr. 2, 1995, at 13.

80. Hamilton, *supra* note 4, at 42.

81. Clair Wood, *Surfing the Human Genome Is Paying Off*, BANGOR DAILY NEWS, Apr. 25, 1997, *available in* 1997 WL 4762081 (alteration added) (quoting Harvard University Nobel laureate Walter Gilbert).

82. *See Patent and Trademark Office: PTO Announces New Policy on Processing Gene-Sequence Biotechnology Patents*, 52 Pat. Trademark & Copyright J. (BNA) 715, 716 (Oct. 31, 1996) [hereinafter *Patent and Trademark Office*].

83. One study reported that 60% of pharmaceutical products would not have been developed without patent protection, a figure that carries even more significance for the biotechnology field, since it is still in its infancy. *See* Adler, *supra* note 47, at 910.

why would I spend my time determining what that function is? Instead, I can sit back, license my product out, and wait for someone else to figure out what it really does. On the other hand, if my competitor and I are both in the early stages of product development, what incentive do I have to continue my research once he receives a patent? In that situation, the best I can hope for is that I can afford his licensing fees, if he is willing to license his product to me. Unfortunately, this is exactly the message that the current utility standard is sending.

II. OVERVIEW OF THE U.S. PATENT SYSTEM

At the Constitutional Convention in 1787 a measure was proposed to extend limited protection for intellectual property in the form of patents and copyrights. The measure was adopted without debate and incorporated into the Constitution, which provides, in relevant part: "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[84] The Patent Act, authored by Thomas Jefferson and finalized in 1793, embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement."[85]

Today, the Patent Act is contained in Title 35 of the *United States Code*, and confers a twenty-year exclusive right on one's invention, which includes the derivative right to exclude all others from making, using, or selling the invention.[86] In exchange for these broad rights, the inventor must disclose the invention, in what is known as an enabling disclosure, to the public in "such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."[87]

A patent is thus frequently referred to as a contract or franchise between the inventor and the government, with broad rights extended to the inventor in return for an enabling disclosure, which provides the necessary consideration. As such, it necessarily follows that if an invention is lacking in any of the statutory requirements, the contract fails for a lack of consideration.[88] The three essential consideration requirements necessary to satisfy the Patent Act are novelty, nonobviousness, and utility.[89] Although we are concerned primarily with utility, it is important to generally understand each in order to appreciate the importance of the current problem.

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84. U.S. CONST. art. I, § 8, cl. 8.

85. 5 THOMAS JEFFERSON, THE WRITINGS OF THOMAS JEFFERSON 76 (H.A. Washington ed., New York, Riker, Thorne & Co. 1854).

86. *See* 35 U.S.C. §§ 154(a)(2), 271(a) (1994).

87. *Id.* § 112.

88. *See* 1 ERNEST BAINBRIDGE LIPSCOMB III, LIPSCOMB'S WALKER ON PATENTS § 5.3, at 487 (3d ed. 1984).

89. For a better understanding of these statutory elements, see 35 U.S.C. §§ 102, 103, 101, respectively.

A. Novelty

As set out in 35 U.S.C. § 102, an invention is novel if it does not exist in the prior art.[90] Absolute novelty, though, is not required by the Patent Act. Instead, the Act "requires only that the claimed invention not be in the hands of the public as of the filing date of the patent application."[91] Essentially the applicant must be the first inventor to confer the benefit of the invention on the public.[92] Thus, where the information has not been "published, publicly sold or used, or previously invented and not abandoned, it is not in the hands of the public"[93] and will theoretically satisfy the requirement. While the requirement is simple in concept, it is often confusing in application.

If something within the scope of a patent claim is identically disclosed in a prior-art reference, the entire claim is invalid, even though a significant portion of it may not have been disclosed.[94] In the scientific community, the prior art that must be consulted is constantly being revised and expanded and has amassed a staggering volume. Before rejecting one NIH application, the PTO examiner noted that it would have taken until the year 2035 to perform an exhaustive search of all possible sequences for only a specific limited portion of the claim.[95] Broadly worded and expansive claims, then, face the distinct possibility of failing the novelty requirement due to prior-art references. However, given enough clerks, "patent lawyers who have the relevant prior art references before them may often avoid novelty rejections by tinkering with the claim language to avoid covering subject matter that has been disclosed in the prior art."[96] With the advent of gene-sequence databases,[97] novelty may be a time-consuming nuisance but certainly not a significant obstacle.

B. Nonobviousness

While the novelty requirement asks whether an invention is identically disclosed in the prior art, the nonobviousness requirement of § 103 asks whether "the subject matter as a whole would have been obvious at the time the invention

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90. "Prior art" is a term used to describe references already available in the public domain. *See, e.g., id.* § 103(a).

91. Rochelle K. Seide & Melissa Szanto, *Drafting Claims for Biotechnology Inventions*, *in* 5 PATENT PROSECUTION WORKSHOP 357, 376 (PLI Patents, Copyrights, Trademarks, and Literary Property Course Handbook Series No. G-426, 1995).

92. *See* Gayler v. Wilder, 51 U.S. (10 How.) 477, 497-98 (1850).

93. Seide & Szanto, *supra* note 91, at 376.

94. *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).

95. *See id.* at 22 (noting that the PTO examiner did not, in fact, perform even a remotely exhaustive search of the sequences embraced by the claims, but rather searched the prior art for specific matches to a very small number of the disclosed ESTs before summarily issuing the rejection).

96. *Id.* at 21-22.

97. See *infra* notes 194-98 and accompanying text for a discussion of gene libraries.

was made to a person having ordinary skill in the art to which said subject matter pertains."[98] The modern test for this determination is articulated in *Graham v. John Deere Co.*,[99] which mandates that the "scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined."[100] Applying this test, if the nexus between the invention and the prior art could be bridged by a person of ordinary skill in the relevant field, the claimed invention is deemed obvious and a patent may not issue.

The *Graham* Court recognized, however, the inherent difficulty and the possibility for subjective error in the application of this test. As a result, the Court suggested that one or more economic or motivational "secondary considerations" or "objective factors" might serve to highlight the inventiveness of the subject matter. These secondary considerations include, among other factors, commercial success, long felt but unfulfilled need, and the failure of others to consummate the invention.[101]

In the case of gene sequences, nonobviousness has posed considerable difficulty due to the vague language of § 103, which states that "[p]atentability shall not be negatived by the manner in which the invention was made."[102] This leaves unclear whether the requisite nonobviousness is to be found in the method of obtaining the sequence or in the sequence itself. Unquestionably, cDNA sequencing has become routine,[103] but "[e]ven if the method used to obtain the sequences is obvious, it does not necessarily follow that the sequences themselves are also obvious."[104] Indeed, with gene sequencing, it is highly improbable and nearly impossible for scientists to select precisely which gene sequence they hope to make because the process is random. The prior art is of little if any value in actual sequencing; it merely serves as a reference source by which to determine if a sequence is in fact new.[105]

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98. 35 U.S.C. § 103 (1994).

99. 383 U.S. 1 (1966). The plaintiff, who held a patent on a "Clamp for vibrating Shank Plows," claimed the defendant had infringed upon this patent. The defendant, in turn, challenged the patent's validity. To make his plow better than preexisting plows, the plaintiff had simply interchanged the position of two common components, the shank and the hinge plate. Applying the nonobviousness test, the Court concluded that the plaintiff's plow offered no new mechanical distinctions, and "[c]ertainly a person having ordinary skill in the prior art . . . would immediately see that the thing to do was what Graham did." *Id.* at 25.

100. *Id.* at 17.

101. *See id.* at 17-18.

102. 35 U.S.C. § 103.

103. *See* Roberts, *supra* note 59, at 185; *supra* note 62 and accompanying text.

104. Eisenberg & Merges, *supra* note 94, at 31.

105. *See* Paley, *supra* note 6, at 1011 (citing Adler, *supra* note 47, at 911).

C. Utility

The final obstacle in the patent process is that of utility. Grounded in the Constitution,[106] the requirement is now codified in § 101 of the Patent Act which provides, in relevant part: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor."[107] Essentially, § 101 consists of three interrelated dimensions: first, an invention must serve a practical purpose; second, it must be operable or capable of use; and third, as claimed, the invention must be supported by a disclosure adequate to enable a skilled practitioner working in the field to use it with no more than routine experimentation.[108]

Despite its constitutional underpinnings, courts have paid scant attention to the utility requirement, and instead have allowed it to exist as a function of the market. As such, an invention's utility would ultimately be determined not by any tangible benefits, but by public consumption. This tradition stems from a time when inventions proceeded largely from the hands of mechanics as things complete in their own right. Either the public would want inventions and buy them for their own intrinsic utility or they would not. "In the latter case the inventions would simply sink into disregard and the patents into disuse, with no one but the inventor any the worse for wear."[109]

Progress, however, demands recognition. Often, benefit arises before commercial marketability and in these cases, protection is necessary to stimulate development. However, it is possible to provide protection too early and stunt research and development. By lowering the utility standard to the level of "credible," this is precisely what the current utility guidelines have accomplished.

III. THE RISE AND FALL OF UTILITY AS A MEANINGFUL STANDARD

A. The Market Function of Utility

Throughout the nineteenth century, utility was nothing more than a measuring stick for morality. As Justice Story noted, the Patent Act "uses the phrase 'useful invention' mere incidentally. . . . All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound

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106. *See supra* note 84 and accompanying text. Article I, Section 8, which provides the general purpose of the patent system, is also the precursor of the utility requirement in that it specifically indicates that Congress is to promote the "useful" arts. *See* U.S. CONST. art. I, § 8, cl. 8.

107. 35 U.S.C. § 101.

108. *See* Eisenberg & Merges, *supra* note 94, at 4.

109. Thomas D. Kiley, *Patents on Random Complementary DNA Fragments?*, 257 SCIENCE 915, 916 (1992) (citation omitted).

morals of society. The word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral."[110] As a market function in a mechanical world, this approach to utility is both rational and effective. But as old innovations are surpassed by new advancements, the law is too frequently left behind.

With time, Justice Story's definition of utility evolved in several directions, resulting in nonuniform application of the standard. This was especially true with regard to the chemical arts. Initially, courts required merely a description of the physical or chemical characteristics of a compound.[111] Later, an assertion of a compound's utility in conjunction with its use was required.[112] Compounds that were claimed to have value in the treatment of human disease, however, were treated with particular scrutiny. Before the advent of the Food and Drug Administration, pharmaceuticals were required to carry a higher burden of utility on the ground that "issuance of a patent might mislead the public by appearing to represent a government imprimatur of the value of so-called 'patent medicines.'"[113]

B. Utility as a Meaningful Concept: Brenner v. Manson

In 1966, the Supreme Court recognized that treatment of the utility standard with regard to the chemical arts was erratic, and utilized *Brenner v. Manson*[114] to deal with the situation. In that case, the applicant sought to patent an allegedly novel process for making certain known steroids. The application was initially denied by a PTO examiner, and this decision was affirmed by the Board of Appeals within the PTO. The basis for rejection was the failure to disclose any utility for the chemical compound produced by the process. The Court of Customs and Patent Appeals ("CCPA") reversed this decision. Adopting a market view of utility, the CCPA stated that "'where a claimed process produces a known product it is not necessary to show utility for the product,' so long as the product 'is not alleged to be detrimental to the public interest.'"[115] The Supreme Court granted certiorari "to resolve this running dispute over what constitutes 'utility' in chemical process claims."[116]

The Court recognized the overly broad scope of traditional utility as applied to contemporary chemistry, in which "research is as comprehensive as man's grasp and where little or nothing is wholly beyond the pale of 'utility'—if that word is given its broadest reach."[117] The use of such an expansive definition would undermine the patent system, creating a "monopoly of knowledge . . .

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110. Lowell v. Lowell, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568).

111. *See* Potter v. Tone, 36 App. D.C. 181, 184-85 (D.C. Cir. 1911).

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

113. Eisenberg & Merges, *supra* note 94, at 5 (quoting Mahler v. Animarium Co., 111 F. 530, 537 (8th Cir. 1901)).

114. 383 U.S. 519 (1966).

115. *Id.* at 522 (quoting *In re* Manson, 333 F.2d 234, 237-38 (C.C.P.A. 1964), *rev'd*, 383 U.S. 519).

116. *Id.*

117. *Id.* at 530.

[which] may confer power to block off whole areas of scientific development, without compensating benefit to the public."[118]

In explicitly rejecting this broad view, the modern definition of utility was established. "Unless and until a process is refined and developed to [the point of *substantial* utility]—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."[119] The Court based its standard on the quid pro quo contemplated by both the Constitution and Congress,[120] stating that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. '[A] patent system must be related to the world of commerce rather than to the realm of philosophy.'"[121]

One reading of *Brenner* suggests that the utility requirement operates to distinguish between basic research and applied technology.[122] In this sense, it serves a timing function, "leaving basic research discoveries in the public domain until they have yielded tangible benefits and have thereby left 'the realm of philosophy' and entered 'the world of commerce.'"[123] This reading is especially plausible in light of the Court's specific exclusion of processes "which either [have] no known use or [are] useful only in the sense that [they] may be an object of scientific research."[124]

The *Brenner* standard, often referred to as "substantial utility" or "practical utility," was expanded by the CCPA in the companion cases *In re Kirk*[125] and *In re Joly*.[126] Both cases involved chemical intermediates and processes for making chemical intermediates.[127] In its examination of the claims, the court found no indication of the compounds' utility,[128] and held that inventions whose claimed uses were so "nebulous" as to render them useless, or which required further research to determine a use, were unpatentable.[129] In so holding, the court stated:

> We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless.[130]

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118. *Id.* at 534.

119. *See id.* at 534-35.

120. *See id.* at 534.

121. *Id.* at 536 (alteration in original) (quoting *In re* Ruschig, 343 F.2d 965, 970 (C.C.P.A. 1965)).

122. *See* Rebecca S. Eisenberg, *Genes, Patents and Product Development*, 257 SCIENCE 903, 905 (1992).

123. Eisenberg & Merges, *supra* note 94, at 6 (quoting *In re Ruschig*, 343 F.2d at 970).

124. *Brenner*, 383 U.S. at 535.

125. 376 F.2d 936 (C.C.P.A. 1967).

126. 376 F.2d 906 (C.C.P.A. 1967).

127. A chemical intermediate is "a species that exists for some finite length of time, even if it is very short," and is often created in a reaction pathway as a precursor to a particular step's end-product. L.G. WADE, JR., ORGANIC CHEMISTRY 138 (2d ed. 1991).

128. *See In re Kirk*, 376 F.2d at 941.

129. *Id.* at 941; *see id.* at 945; *In re Joly*, 376 F.2d at 908.

130. *In re Kirk*, 376 F.2d at 942.

This view of substantial utility thrived for over two decades in the federal circuit courts, with little change in its legal interpretation.[131] The PTO, though, while still formally operating under the guise of *Brenner*, seemed to be constricting its application in practice. Two decisions in particular reflect this.

C. Setting the Stage

Ex parte Balzarini[132] involved a claim for pharmaceutical compounds with alleged broad activity for the treatment of retroviral diseases, including AIDS, in both animals and humans. In support of this claim, the applicant offered evidence of in vitro activity, but no evidence of in vivo activity.[133] On this basis, the PTO Board of Patent Appeals and Interferences ("Board") affirmed the examiner's rejection on utility grounds. The fact that the Board stated that human clinical trials were not a necessary prerequisite for a patent was overshadowed by its subsequent statement that "it may very well be that in 1987 or even now those skilled in this art would not accept anything short of such human clinical trials."[134] To many, this appeared to be an implicit requirement for just that.

Ex parte Aggarwal[135] reached a similar result. This case dealt with broad claims to a method of treatment of tumors in animals. The application set out specifically the preparation of the claimed pharmaceutical, a demonstration of in vivo activity in mice, and evidence of in vitro activity. The PTO examiner rejected the application due to the unpredictability of the treatment of tumors at the time of filing, indicating that the limited results produced by the applicant were insufficient to support such a broad range of claims.[136] The Board, relying on *Brenner* and subsequent decisions, affirmed the rejection, stating that such an application is premature until the applicant "can provide evidence showing substantial activity in screening tests customarily used and accepted as predicative of human activity for the type of chemical tested . . . [and] commensurate with the scope of utility asserted and the subject matter claimed."[137]

Despite the PTO's statements in cases such as *Balzarini* and *Aggarwal* that human clinical trials were not a prerequisite, their actions indicated otherwise. Many felt they were holding applicants in the biotechnology field to a higher standard of utility than other applicants, and were "usurping the role of the FDA, in requiring what amounts to proof of 'efficacy' required for approval of a new drug by the FDA, before granting claims for therapeutics."[138]

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131. *See* Karen F. Lech, Note, *Human Genes Without Functions: Biotechnology Tests the Patent Utility Standard*, 27 SUFFOLK U. L. REV. 1631, 1643 (1993).

132. 21 U.S.P.Q.2d (BNA) 1892 (Bd. Pat. App. & Interferences 1991).

133. "In vivo" means "in the living body of a plant or animal." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1190 (unabr. ed. 1993). "In vitro," on the other hand, means "outside the living body; in a test tube or other artificial environment." *Id.*

134. *Ex parte Balzarini*, 21 U.S.P.Q.2d (BNA) at 1897.

135. 23 U.S.P.Q.2d (BNA) 1334 (Bd. Pat. App. & Interferences 1992).

136. *See id.* at 1337.

137. *Id.* at 1339 (citing *In re* Buting, 418 F.2d 540 (C.C.P.A. 1969)).

138. Seide & Szanto, *supra* note 91, at 370.

Recently, the Federal Circuit made painfully clear that the position the PTO adopted in reviewing patent applications was unacceptable. *In re Brana*[139] is a 1995 case dealing specifically with what patent applicants for pharmaceutical inventions do *not* have to prove regarding utility. The PTO initially rejected a claim to a new antitumor pharmaceutical on the ground that the specification failed to describe any specific disease against which the claimed compounds were active.[140] The Board affirmed on this basis, and on the fact that the applicant failed to prove that the claimed compounds were useful. The Federal Circuit reversed, stating that the issue was one which "we would have thought had been settled by case law years ago."[141] Noting that the initial burden was on the PTO to challenge a presumptively correct assertion of utility, the court derided the PTO's application of the standard. "The Commissioner [of the PTO], as did the Board, confuses the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption."[142] The court went on to state that FDA approval "is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development."[143]

D. PTO Utility Guidelines: The Demise of Substantial Utility

While *Brana* was working its way through the courts, discontent was growing among the research community, and on October 17, 1994, the PTO held a hearing in San Diego, California to discuss the problems associated with patenting biotechnology inventions. There, the Biotechnology Industry Organization ("BIO") argued that reliance on *Brenner* to require human clinical trials (explicit or not) was a gross misinterpretation. Instead, BIO argued, the CCPA had drawn the line "'far short of requiring human testing and therapeutic effect.'"[144] This

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139. 51 F.3d 1560 (Fed. Cir. 1995).

140. *See id.* In spite of the facts that the PTO rejected the application based on 35 U.S.C. § 112 (1994) (requiring an enabling disclosure), that the Board affirmed solely on the basis of § 112, and that the Federal Circuit limited their review to § 112, it is nevertheless widely recognized that § 112 and the utility requirement of § 101 are closely interrelated. In fact, the court noted that the "absence of utility can be the basis of a rejection under both 35 U.S.C. § 101 and § 112," and its decision revolved primarily around utility. *In re Brana*, 51 F.3d at 1564 n.12.

141. *In re Brana*, 51 F.3d at 1564.

142. *Id.* at 1567.

143. *Id.* at 1568. The court grounded this decision, in part, on the policy argument that "[if the court were] to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures." *Id.*

144. Reginald Rhein, *PTO No Longer Requires Clinicals to Clear Patents*, BIOTECH. NEWSWATCH, Jan. 2, 1995, at 1, 2 (quoting BIO's brief submitted at the PTO hearing). BIO claimed that *Nelson v. Bowler*, 626 F.2d 853 (C.C.P.A. 1980), required only a demonstration

argument would be affirmed five months later by the Federal Circuit in *In re Brana*.[145]

Out of these hearings arose new utility guidelines which were issued in final form by the PTO on July 14, 1995. The guidelines specifically addressed certain aspects of the PTO's position on utility, and made "clear to the examiners what the law was, and is. . . . [In many instances] these examiners were acting as if they were peer-reviewing papers for journals or they were FDA investigators."[146]

The guidelines now make a utility rejection highly unlikely. Intended to apply uniformly to inventions in any technological field, the legal analysis supporting them makes clear that utility "deficiencies" under § 101 will arise in only two forms: "The first is where it is not apparent why the applicant believes the invention to be 'useful.'. . . The second type of deficiency arises in the rare instance where an assertion of specific utility for the invention made by an applicant *is not credible*."[147] A rejection under § 101 requires the PTO to make a prima facie showing that the claimed invention lacks utility, provide factual support for the findings of the examiner, and provide support for the examiner's conclusion that the stated utility would not be persuasive to one of ordinary skill in the relevant field.[148] However, "[i]f the asserted utility is credible, there is no basis to challenge such a claim on the basis that it lacks utility under Section 101."[149] An assertion is not even necessary in some cases "if the claimed invention has a well-established utility."[150]

PTO Commissioner Bruce Lehman stated that the guidelines "'reestablish the proper level of deference that must be given to expert opinions' . . . . 'We heard, for example, many people say that some examiners routinely challenge the sound scientific conclusions of recognized experts in the field. This practice will not be condoned under the new guidelines.'"[151] Indeed, under the new PTO guidelines very little will be condoned. According to the guidelines themselves, the role of examiners is now to "determine if the asserted utility for the invention is credible . . . . Only those claims for which an asserted utility is not credible should be rejected."[152] With "credible" defined as "whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided,"[153] it seems that examiners have been relegated to a job of rubber stamping rather than applying the Supreme Court-imposed "substantial" standard. As noted previously, such practices do not maintain the integrity of the patent system or promote scientific advancement. Instead, they

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of pharmacological activity, not therapeutic efficacy in humans.

145. 51 F.3d 1560.

146. Rhein, *supra* note 144, at 1.

147. PTO Examination Guidelines on Utility Requirement, 50 Pat. Trademark & Copyright J. (BNA) 295, 297-98 (July 20, 1995) (emphasis added) [hereinafter PTO Examination Guidelines].

148. *See id.* at 296.

149. *Id.* at 300 (emphasis omitted).

150. *Id.* at 302.

151. Rhein, *supra* note 144, at 2 (quoting PTO Commissioner Bruce Lehman).

152. PTO Examination Guidelines, *supra* note 147, at 309.

153. *Id.* at 303.

provide rewards for incomplete development, and a disincentive for further secondary research.

IV. ANALYSIS OF THE PTO GUIDELINES

It seems clear from the language of the guidelines themselves that the meaning of "useful" as applied to 35 U.S.C. § 101, has been changed. Although neither the statutory language nor the legislative intent spell out a clear definition for the term, the Supreme Court long ago supplied the necessary guidance in *Brenner*. Many believe, though, that this is a decision of narrow application due to the fact that the applicant failed to disclose *any* specific utility for his invention. On this ground, it is suggested that the *Brenner* decision is meant to apply only in this limited situation. Since the Court was not confronted with the issue of adjudicating an actual claim, advocates of a low threshold argue that *Brenner* does not establish "substantial utility" as a wholesale standard to be applied across the board.

> I do not believe that in settling Manson's claim to an interference the Supreme Court showed any intention of wholly overturning 175 years of established law on what is 'useful,' especially when it seems not to have found the significant legislative history underlying 35 U.S.C. 101 [sic], which is in history, not in the annals of the legislature.[154]

Although the applicant did not disclose a specific utility, the opinion makes clear that the *Brenner* Court's analysis was not to be so limited. Rejecting the contention that the case was about nothing more than the scope of PTO authority, the Court stated that the underlying concern was "the question of what averments satisfy the statutory requirement that a claimed chemical process be 'useful.'"[155] This suggests that the Court did indeed intend to provide a definitive answer to the utility controversy by delineating precisely what would "satisfy the statutory requirement."

As required by the Supreme Court mandate, a patentable invention must have "substantial utility . . . where specific benefit exists in currently available form."[156] As mandated by the PTO guidelines, however, an invention must only be "credible . . . i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and the reasoning provided."[157] What, if any, are the effects of this substitution of "credible" as a synonymous relative of "substantial"?

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154. *In re* Kirk, 376 F.2d 936, 949 (C.C.P.A. 1967) (Rich, J., dissenting).

155. Brenner v. Manson, 383 U.S. 519, 528 n.12 (1966).

156. *Id.* at 534-35.

157. PTO Examination Guidelines, *supra* note 147, at 303 (emphasis omitted).

A. The Ramifications of PTO Legislation

The important inquiry with regard to the guidelines is not whether they change the meaning of utility in form, but whether they change the meaning in practice. Patent utility is a concept rooted in the Constitution and defined by the Supreme Court. It is clear, then, that the PTO cannot take it upon itself to reshape utility in order to pacify the industry and lighten its own burden;[158] to do so would be per se unconstitutional. Currently, however, it is unclear whether the guidelines have in fact lowered the utility standard in both practice and form, or just form. Ideally, an examination of identical applications submitted before and after issuance of the guidelines and the respective responses of the PTO would provide the answer. If an invention that was nonpatentable before the guidelines is patentable afterwards, clearly the PTO has legally overstepped its bounds. However, since patent applications are kept confidential until the issuance of a patent and rejections are not revealed,[159] this ideal is an impossibility.

An acceptable solution, though, is to examine the now-abandoned NIH applications in light of both pre- and postguideline requirements. As it is impossible to disclose the ultimate utility of an uncharacterized gene sequence, the utilities set forth in the NIH application likely are representative of those encountered in similar gene-sequence applications. This analysis leads us to the conclusion that the NIH applications would have been rejected under *Brenner*, but would be acceptable under the current PTO standard of utility. Thus, since the PTO legally overstepped its bounds in drafting new utility guidelines, it is clear that these guidelines are unenforceable, and a new, legally acceptable standard must be instigated.

B. Pre- and Postguideline Analysis of the NIH Applications

Often, a gene-sequence application contains an astronomical number of sequences intended to be covered by a very small number of utility claims.[160] Unless the function of the gene is known, the claimed utility of a sequence will not indicate its true use. Instead, the utilities are often concocted to carry support for patent protection until the real function of the gene can be determined. While the specified uses themselves are scientifically valid, the unknown characteristics of the claimed sequences require that the utilities be described in broad, general

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158. For a discussion of the backlog currently wreaking havoc within the PTO, see *supra* note 82 and accompanying text.

159. *See supra* note 26 and accompanying text.

160. *See* Robert S. Boyd, *Genes Commercialized: Seeking Patents for Living Things*, PITTSBURGH POST-GAZETTE, Sept. 3, 1995, at A7 (noting that HGS has filed at least 25 applications covering more than 200,000 partial sequences); Neil Gross & John Carey, *Who Owns the Tree of Life?*, BUS. WK., Nov. 4, 1996, at 194, 196 (noting that some applications seek to cover as many as 20,000 fragments). *But see Patent and Trademark Office*, *supra* note 82, at 716-17 (noting that PTO announced that applicants for multisequence gene patents must limit their claims to 10 independent sequences).

terms unsupported by specific experimental data. In the case of the NIH applications, the specifications were "replete with imaginative suggestions for how to use the claimed sequences, individually or in panels, many of which [were] set forth in prophetic (untested) language."[161]

It is important to note that under both pre- and postguideline requirements, only one practical utility is necessary in order to obtain patent protection.[162] The question is, then, are any of the claimed utilities in the NIH application sufficient to satisfy the utility standard? Of the uses set forth in the NIH application, the two which offer the most promise of securing patents are the use of ESTs as probes to obtain full cDNA sequences, and their use as chromosome markers.[163]

Under *Brenner*, the proposed use of the ESTs as probing devices is clearly unacceptable utility because this use offers the product as nothing more than a research tool.[164] "Use of ESTs as probes to obtain full cDNA sequences has no practical benefit unless and until the full sequences themselves may be used for some purpose beyond research."[165] And although it has been stated that "[u]sefulness in patent law . . . necessarily includes the expectation of further research and development,"[166] this does not negate the *Brenner* requirements. If the stated utility of an invention is so speculative as to require the subsequent "research and development" in order to establish a practical utility, a patent may not be issued.[167] In regard to the claimed ESTs in the NIH application, "[s]ubsequent research may well prove some of the genes useful for diagnostic or therapeutic purposes, but the information disclosed in the specification fails to identify which of the genes will be useful, or for which purposes."[168]

Similarly, the use of ESTs as chromosome markers fails for the same reasons. When used as a chromosome marker, a sequence does not have to have an identified function, rather it can be mapped and put to use immediately. In this sense, there is no subsequent research and development needed to establish a practical utility. However, "[a]ny and all portions of DNA, are, strictly speaking, 'chromosome tags,' insofar as they can be used to identify the particular chromosome from which they were derived. Similarly, because the DNA composition of each individual is unique, any portion of the human chromosome

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161. Eisenberg & Merges, *supra* note 94, at 13 (noting that the specified utilities ranged from using ESTs as probes to isolate coding sequences and complete genes, which may then be mapped to chromosomal locations, to using ESTs as chromosome markers, as diagnostic probes, for individual identification for forensic and other purposes, and as reagents to identify tissue specimens by organ type or species).

162. *See* 35 U.S.C. § 101 (1994); Raytheon Co. v. Roper Corp., 724 F.2d 951, 958 (Fed. Cir. 1983).

163. *See* Eisenberg & Merges, *supra* note 94, at 18.

164. Brenner v. Manson, 383 U.S. 519, 535 (1966) ("Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing.").

165. Eisenberg & Merges, *supra* note 94, at 18.

166. *In re* Brana, 51 F.3d 1560, 1568 (Fed. Cir. 1995).

167. *See In re* Zeigler, 992 F.2d 1197, 1203 (Fed. Cir. 1993) ("We are convinced that, at best, Zeigler was on the way to discovering a practical utility for polypropylene at the time of the filing . . . but in that application [he] had not yet gotten there.").

168. Eisenberg & Merges, *supra* note 94, at 18.

can be used as a marker . . . ."[169] Under the rationale of *In re Kirk*, while the claimed utility of ESTs as chromosome markers may read as satisfactory, it would be just the type of nebulous disclosure that demands rejection. "There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher' was recognized, and clearly rejected, by the Supreme Court [in *Brenner*]."[170]

The results are not the same, however, when the claimed utilities are run through the gamut of the PTO utility guidelines. Although the Supreme Court explicitly stated that an invention "which either has no known use or is *useful only in the sense that it may be an object of scientific research*"[171] is not patentable, the PTO guidelines appear to be geared to extend patent protection to just these types of inventions. The legal analysis in support of the guidelines states that many inventions that are to be used in a research setting "have a clear, specific, and unquestionable utility . . . . An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the specific invention is in fact 'useful' in a patent sense."[172] Instead of the substantial utility required by *Brenner*, the guidelines mandate that "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'specific utility.'"[173]

Under this setting, the use of ESTs as both probes and chromosome markers appears to satisfy the PTO-imposed utility standard. Although probes do not offer any practical benefit outside of research until a function is associated with the sequence,[174] and chromosome markers encompass such a tremendous and general target base,[175] both are generally regarded as valid tools of scientific analysis.[176] As such, the claim that an EST can be utilized as a probe or a chromosome marker is undoubtedly credible under the PTO guidelines,[177] and thus "there is no basis to challenge such a claim on the basis that it lacks utility under Section 101."[178]

For various reasons, the PTO has not yet issued a patent covering the claims that might be found in a gene-fragment application. One patent attorney says

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169. Lech, *supra* note 131, at 1652.

170. *In re* Kirk, 376 F.2d 936, 945 (C.C.P.A. 1967).

171. Brenner v. Manson, 383 U.S. 519, 535 (1966) (emphasis added).

172. PTO Examination Guidelines, *supra* note 147, at 298.

173. *Id.*

174. *See* Eisenberg & Merges, *supra* note 94, at 18.

175. *See* Lech, *supra* note 131, at 1652.

176. See LEHNINGER ET AL., *supra* note 34, at 994-96, for a discussion of probes. *See also* Jean Marx, *Familial Alzheimer's Linked to Chromosome 14 Gene*, 258 SCIENCE 550, 550 (1992) ("To identify the chromosome 14 site, Schellenberg and his colleagues . . . made use of the growing number of chromosome 'markers,' DNA sequences that show a lot of variation in the population and whose chromosomal locations are known.").

177. According to the analysis, "[a]n assertion is credible unless (a) the logic underlying the assertion is seriously flawed, or (b) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion." PTO Examination Guidelines, *supra* note 147, at 303.

178. *Id.* at 300.

examiners are "spooked" in light of the new guidelines. "'They're nervous. They feel like they're being forced to make a decision that could be right or wrong.'"[179] The PTO, in turn, denies having put the applications on the back burner, and claims that many of the applications could be rejected. John Doll, director of the PTO's biotechnology patent group, added that the new guidelines still require an invention to have a tangible use. "'We don't grant patents to laboratory curiosities.'"[180] When asked if cDNA fragments could receive patents, however, Jeff Cushin, a PTO attorney-advisor, stated, "'If that theory is credible, that's going to be enough for us.'"[181]

The analysis of two representative utilities under the new guidelines indicates otherwise, however. Both uses as probes and as chromosome markers appear to satisfy the PTO-imposed standard of "credible utility" for a gene-sequence application. While the PTO may not grant patents for unspecific, laboratory curiosities, probes and chromosome markers do not fit this bill under the new guidelines. It logically follows that a patent will eventually issue on an EST, a patent that clearly contradicts the holding of the Supreme Court in *Brenner*.

Beyond the legality of the new utility guidelines, many patent seekers cite policy considerations as necessitating a lower standard. These policy arguments, however, do not advocate a lower standard of utility. Rather, they provide support for a more stringent standard of utility.

C. The Policy of Utility

There is, of course, considerable moral opposition to genetic patenting. Jeremy Rifkin has battled against genetic patents for years, stating that to allow such patents "'will lead us into eugenics.' Genes 'are the commons of the evolution of this planet and these patents are the greatest legal scam of the 20th century.'"[182] In 1995, Rifkin organized a coalition of 200 religious leaders representing 80 denominations in a fight against genetic patents. Biotechnology, they claim, "needs to be restrained by people with facile minds, rather than those concerned with quarterly dividends and profits."[183] Dr. Craig Venter counters this with the logical argument that, "'[d]rugs don't get developed by 12 Catholic bishops, or by Jeremy Rifkin or the NIH. They get developed by companies with hundreds of individual investors.'"[184] It is easy to latch onto a moral argument when confronted with a difficult issue and summarily reject other views. This easy way out, however, does not address the problem intelligently and it is vital to look to other sources for information and answers.

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179. Hamilton, *supra* note 4, at 42 (quoting an attorney "with close ties to the PTO").

180. Renee Deger, *Patent Pending*, VENTURE CAPITAL J., Jan. 1, 1996, *available in* 1996 WL 8623400, at *5 (quoting John Doll).

181. Rhein, *supra* note 144, at 3 (quoting Jeff Cushin).

182. Hamilton, *supra* note 4, at 79 (quoting Jeremy Rifkin).

183. *Id.*

184. *Id.* (alteration added) (quoting Dr. Craig Venter).

A basic tenet of the patent system is that it is designed to provide incentives to invest in socially valuable research and development.[185] According to incentive-based arguments, patent protection is needed to stimulate product development. Whether inventions are patentable "may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives."[186] This defense of liberal interpretation of patent requirements is not novel. As Justice Harlan noted in the *Brenner* dissent:

> To encourage one chemist or research facility to invent and disseminate new processes and products may be vital to progress, although the product or process be without "utility" as the Court defines the term, because that discovery permits someone else to take a further but perhaps less difficult step leading to a commercially useful item.[187]

This argument is not without merit, particularly in the biotechnology industry, where both costs and uncertainty are enormous. "Since genotech companies lack established product lines, they must live off their capital while attempting to develop products, conduct trials, and get products to market."[188] From 1994 to 1995, the survival index for companies in the biotechnology industry dropped from twenty-five months to sixteen months.[189] It is unreasonable to expect commercial success with any consistency, and given that the "drug lag" is seven to twelve years and the cost of getting a product to the market is as much as $400 million,[190] an investment in biotechnology is ultimately a blind investment in risk. "Uncertainty often creates risk which causes investors in truly novel ventures to demand a premium on their returns relative to other, safer investments."[191] These premiums are ultimately provided for through the perquisites of the patent system.

While compelling on its face, it is unclear whether the research and development decisions of firms are, in reality, influenced by patent rights.[192] What is clear is that investors are driven by profit, and profits are not entirely dependent on patents. "[I]f lucrative products are at stake, biotech and pharmaceutical firms will find a way to develop them."[193] While the PTO has been busy trying to decide how to approach the mountain of applications currently cluttering its office, this statement has proven true.

HGS has developed a database of all the sequences they have discovered, irrespective of function. This gene library has turned out to be a red-hot commodity that everyone wants to both browse and copy. SmithKline Beecham committed $125 million to HGS in 1993 for a 7% equity stake and first rights on

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185. *See* Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 736-37 (1990).

186. Adler, *supra* note 47, at 910.

187. Brenner v. Manson, 383 U.S. 519, 539 (1966) (Harlan, J., dissenting).

188. Malinowski & O'Rourke, *supra* note 17, at 178.

189. *See id.*

190. See *supra* note 78 and accompanying text for a discussion on "drug lag."

191. Malinowski & O'Rourke, *supra* note 17, at 231.

192. *See* Eisenberg, *supra* note 122, at 910.

193. Roberts, *supra* note 59, at 188.

promising genes.[194] Together, Upjohn and Pfizer, Inc. have committed $45 million to look into the gene library of HGS's main rival, InCyte Pharmaceuticals.[195] And in 1994, Merck & Co. funded a major gene-sequencing operation in conjunction with the Washington University School of Medicine in St. Louis.[196] Whereas HGS and InCyte offer their information at premium prices, Merck intends to make their sequences available as a public resource. Whether this was an act of altruism, as Merck claims, or a clever ploy to preserve its share of the pharmaceutical market, as their rivals claim,[197] gene libraries are an intellectually valuable means by which gene sequences can be used until their function is determined. It is also clear that these databases can generate the capital needed to continue financing this research until the mystery of function runs its course.

Hand in hand with the incentive argument is the claim that without patent protection the public will be forced to forego the discovery of new drugs due to a lack of necessary capital. However, the recent issue of three patents to HGS suggests otherwise. In April 1996, HGS was awarded patents for three complete genes (as opposed to gene fragments), the proteins those genes make, and the role those proteins play in the human body. The patents give HGS the right to use—or exclusively license the right to use—the genes to make diagnostic tests or therapeutic drugs based on the sequence information.[198] In an area of such uncertainty and risk, the incentive to invest weighs more heavily once function is established. Whereas a patent for an uncharacterized gene may prove useless millions of dollars later, investment in a gene of known function minimizes uncertainty and risk, and maximizes the promise of a financial return. This suggests that "incentives provided by patent protection are most important *after an invention has been made*, as a means of stimulating investment in putting patented inventions to practical use, rather than before the invention has been made, as a means of stimulating the initial research necessary to create the invention."[199]

Incentive arguments cut both ways, particularly in the genotechnology industry. But even if commercial development is better served by extending patent protection to undeveloped inventions (which is unclear), the effects of such a policy on basic scientific research indicate otherwise. The promise of patent protection for partial sequences would likely lead scientists to delay publishing sequence information, resulting in the "openness and free flow of ideas so important to the development of knowledge [being] slowed by this atmosphere of safeguarding information in the hopes of making it proprietary."[200] This has two major consequences: (1) there will be considerable overlapping of

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194. *See* Carey et al., *supra* note 51, at 73.

195. *See id.* at 76.

196. *See id.* at 73.

197. *See* Hamilton, *supra* note 4, at 43.

198. *See* Kathleen Day, *Human Genome Sciences Granted 3 Gene Patents*, WASH. POST, Apr. 17, 1996, at F1.

199. Eisenberg, *supra* note 185, at 738 (emphasis added).

200. Philip L. Bereano, *Guami Tribe Was Surprised to Discover They Were Invented*, SEATTLE TIMES, Aug. 27, 1995, at B5.

research, resulting in an inefficient use of resources; and, (2) the important secondary research that eventually produces a commercial product will begin much later, and the benefit such a product carries will be realized much later.

Opponents might argue that this occurs as a result of the inherent difference between the patent system and the basic scientific research community, and that the same would happen in the presence of patent protection. In fact, "patent law may be more rigorous in enforcing its disclosure requirements than the scientific community . . . . In the long run it is unlikely that patent protection for human DNA sequences will prevent dissemination of this knowledge to the scientific community and the public at large."[201] This rigorous disclosure system, in turn, prevents wasteful duplication of effort. However, if every partial sequence carries with it the promise of patent protection, then "every step along the way draws another patent application, [and] the path toward public possession of real benefit is increasingly obscured by dense thickets of intersecting, overlapping, and cross-blocking patents."[202]

What better illustration of this problem is there than the current backlog plaguing the PTO? Partial-sequence applications have rendered the PTO helpless, and this in turn has taken its toll on valid biotechnology applicants. Group 1800, the biotechnology group of the PTO, is responsible for all biotechnology applications, of which partial sequences make up only a fraction.[203] If the PTO is forced to examine all sequence applications, even those which do not meet the requirements of patentability, obviously other applicants will suffer. Myriad Genetics, Inc. of Salt Lake City, for example, is still waiting for a patent two years after it discovered the BRCA1 gene, which is related to breast cancer. The company wants to use the gene to produce a susceptibility test, but cannot until the patent is issued. In the meantime, however, rival Oncormed, Inc. of Gaithersburg, Maryland, is marketing a similar BRCA1-based test.[204]

By lowering the utility standard to "credible," the PTO has done nothing to alleviate delays such as these. Instead, it has unwittingly worsened them. A lower utility standard will necessarily draw more applications which are not worthy of protection. However, the PTO is still obligated to review them, and in doing so it diverts valuable resources that would be better spent reviewing those applications deserving of patent protection. This trend will undoubtedly continue as long as utility is applied in nothing more than a cursory manner.

CONCLUSION

"Credible utility" advocates may argue that the adverse effects of allowing patents on gene-sequence fragments is theoretical at best, but the reality in the biotechnology industry suggests otherwise. Continued application of the PTO utility guidelines will have detrimental effects not only on basic research but also

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201. Eisenberg, *supra* note 185, at 740-41.

202. Kiley, *supra* note 109, at 916.

203. *See* Deger, *supra* note 180, at *6-*7 (noting that in 1995 the PTO received roughly 10,500 new biotechnology patent applications, and 2400 amended applications).

204. *See* Gross & Carey, *supra* note 160, at 196.

on product development. Further, the incentive arguments often put forth to defend such a low standard are strongest when applied to an invention after it has been made, not before it has been developed. While policy considerations are nothing more than a measure of societal costs and benefits, they often strengthen legal analysis. In this case, policy and case law together mandate that the PTO utility guidelines no longer be recognized as valid. Unquestionably, there were at the time issues that needed to be addressed and solutions that needed to be ratified in the biotechnology patent area. The PTO solution, however, did not solve the problems but rather exacerbated them.

Theoretically, by lowering the utility standard, the backlog plaguing the PTO would subside as patents were filed and issued at a greater rate. Since examiners were no longer permitted to scrutinize applications for utility deficiencies, presumably the examination process would speed up and the waiting period to receive a patent would decrease. Unfortunately, the PTO did not foresee the consequences of this action. A lower utility standard makes receiving a patent easier, which necessarily causes more inventors to seek patents on previously unpatentable inventions. While the move may have temporarily lessened the burden, ultimately a lower standard will have the opposite effect. Instead of rewarding innovation and benefit, the guidelines are designed to award prematurity and mediocrity.

The proper solution is one that addresses industry and administrative concerns as well as the long-term impact on the public to whom the industry is dedicated. Instead of "credible," the PTO should have followed the Supreme Court-mandated threshold of "substantial." In doing so, the PTO also could have given this term a meaningful and modern definition. Even though the guidelines are intended to apply to all fields of technology, they should explicitly state that partial gene sequences do not, and cannot, satisfy the requisite utility standard until their function is determined. Obviously, the possibility of developing and marketing a successful commercial drug will lead to enormous profits, so it is foolish to believe that research will halt without premature patent protection on uncharacterized genes. Unless and until a gene has been fully sequenced and characterized, patent protection is premature and the monopoly such rights confer hinders rather than stimulates the research that leads to function. Unquestionably, function drives value and value drives research. A patent system that erroneously recognizes one term (value) while systematically ignoring the others (function and research) does not provide incentives or integrity. Instead, it provides the setting for a stale scientific environment that encourages underdevelopment of products and benefits. This is surely not the ideal Thomas Jefferson envisioned 210 years ago while contemplating the first Patent Act. It is, in fact, the embodiment of one of his worst fears: a patent system that allows the "granting of monopolies which might withhold technological progress from other inventors and from the general public."[205]

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205. BEDINI, *supra* note 1, at 207.