EVOLVING BIOTECHNOLOGY PATENT LAWS IN THE UNITED STATES AND EUROPE: ARE THEY INHIBITING DISEASE RESEARCH?

"Genetic knowledge will change the world profoundly."[1]

I. INTRODUCTION

Imagine a day when our fear of terminal illness no longer exists. Pretend for a moment that geneticists can mend our tragedy with their knowledge and skill. Are these scenarios plausible for our future? Should we struggle to make this reality even if it means giving up a part of ourselves and the formula of the human race?[2] If the answers to these questions are affirmative, then perhaps the efforts via the Human Genome Project (HGP)[3] and related biotechnology patent laws are serving us well. However, if the answers are negative, perhaps the steps which are being taken to reach these objectives must be better authenticated by balancing ethical concerns with economic incentives for researchers through strategic legislation and patent law modification.

Part II of this note will explore the history of the HGP, while noting critical developments in the multinational project. Particularly, part II will provide scientific information on genetics and its vocabulary as a predicate to recent advances that are related to disease research, and specifically gene therapy research. In part III, biotechnology patent laws in Europe and the United States will be traced across time, while highlighting the present status of biotechnology patent law in both places. International ethical concerns relating to gene patenting as applied to disease research will be weighed against the necessary economic incentives for researchers in part IV of this note. Part V will discuss how biotechnology patent law in Europe and the United States implicates disease research, focusing on the impact broad patents may have on this area of science. Lastly, part VI will provide suggestions for patent law modification and legislative intervention to prevent the inhibition

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1. *The Human Genome: Future Perfect?*, ECONOMIST, July 1-7, 2000, at 16.

2. The formula for the human race can be equated to the human genome sequence. The draft version of the human genome was published in 2000. *See The Human Genome*, ECONOMIST, July 1-7, 2000, at 1. Contrary to the earlier hypothesis that the human genome consisted of approximately 140,000 genes, scientists have concluded it may consist of only 40,000 genes. Roger Highfield, *Human Gene Count was Exaggerated*, DAILY TELEGRAPH, Sept. 26, 2000, at 9, *available at* LEXIS, The Daily Telegraph File.

3. "The human genome project is a multinational project aimed at obtaining a detailed map and a complete DNA sequence of the human genome." Darryl R. J. Macer, *Whose Genome Project?* 5 BIOETHICS 183, 183 (1991), *available at* http://zobell.boil.tsukuba.ac.jp/~macer/Papers/WGP.html.

of disease research while simultaneously acknowledging ethical concerns and the need for economic incentives.

II. BACKGROUND AND DEVELOPMENTS

A. *Genetics Lesson*

1. Understanding Gene Expression

The genome, which is divided into sequences of DNA[4] known as genes, encodes the information for polypeptide[5] sequences of protein and codes the information for its own gene expression.[6] The replication and expression of a cell's hereditary information makes up the totality of a cell's genetics.[7] It is gene expression that manifests human physical characteristics and disease. Therefore, the genetic processes within a cell should be understood before the logistics of the HGP and the related controversy over gene patenting pursuant to disease research can be appreciated.

The genetic processes within a cell include DNA replication,[8] transcription,[9] and translation.[10] The ultimate goal of these processes is protein synthesis.[11] The purpose of DNA replication is to synthesize new DNA

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4. DNA is a macromolecule that is double-stranded, helical-structured, and contains a cell's hereditary information. *See* RONALD M. ATLAS, PRINCIPLES OF MICROBIOLOGY 235 (Wm. C. Brown Publishers, 2d ed. 1996). It consists of "subunits," or nucleotides, which are arranged in a specific order. *See id.* The order of the nucleotides illustrates the cell's genetic information and contains the mechanisms that control gene expression. *See id.*

5. A polypeptide is "[a] chain of amino acids linked by peptide bonds, but of lower molecular weight than a protein." *Id.* at 1229. The number and order of the amino acids within a polypeptide chain are significant because they determine both the structure and functional properties of protein molecules. *See id.* at 1182.

6. *See id.* at 280.

7. *See id.* at 234.

8. DNA replication is a precise process that entails synthesizing daughter DNA molecules that have the same nucleotide sequence as the parental genome. *See id.* at 235.

9. Transcription is the synthesis of relevant RNA (mRNA, rRNA, and tRNA) from a DNA template. *See id.* at 1241. A template is "[a] pattern that acts as a guide for directing the synthesis of new macromolecules." *Id.* at 1240.

10. *See generally id.* Translation is "[t]he assembly of polypeptide chains with mRNA serving as a template." *Id.* at 1242.

11. *See id.* at 273. Protein synthesis, the creation of proteins, occurs during the process of translation. *See id.* These formed protein molecules are important because they can functionally express genetic information. *See id.* The relationship between DNA, RNA, and protein was discovered in 1953 and is often is illustrated in diagram form:

$$\circlearrowright \text{DNA} \xrightarrow[\text{TRANSCRIPTION}]{} \text{RNA} \xrightarrow[\text{TRANSLATION}]{} \text{PROTEIN}$$

See JAMES D. WATSON ET AL., RECOMBINANT DNA 36 (Scientific American Books, 2d ed.1992).

molecules that have the identical nucleotide[12] sequence as the genome of the parental organism. This is done by a semiconservative process,[13] which means that once the process is completed, each of the two new daughter strands will also contain one strand from the original parental double strand.[14] Once DNA replication is completed, transcription can occur.[15]

Transcription occurs by allowing one strand[16] of the newly replicated DNA to serve as a template for the code of the synthesis of RNA,[17] which is important because it directs protein synthesis.[18] Transcription consists of (1) unwinding the double helix DNA molecule for a short nucleotide sequence, (2) alignment of the RNA nucleotides opposite the complementary DNA nucleotides which are being transcribed, and (3) linkage of these nucleotides via phosphodiester bonds by a DNA-dependent RNA enzyme.[19] Ultimately, the termination process releases the RNA and the corresponding enzyme.[20]

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12. Nucleotides are the "building blocks of nucleic acid." *See id.* at 14. DNA (deoxyribonucleic acid) and RNA (ribonucleic acid) are both specialized types of nucleic acids. *See id.* Nucleotides consist of a phosphate group and either a purine or pyrimidine base. *See id.* The union of a large number of nucleotides is known as a polynucleotide. *See id.* DNA and RNA consist of long polynucleotide chains. *See id.*

13. Matthew Meselson and Franklin Stahl of the California Institute of Technology offered proof that DNA replication occurred semiconservatively. *See id.* at 23. The two scientists first grew cultures in an environment which contained heavy isotopes of carbon (13C) and nitrogen (15N). *See id.* Thus, the DNA in the cells grown in the "heavy" culture was heavier than the DNA grown in a "lighter" environment, containing natural isotopes of carbon (12C) and nitrogen (14N). *See id.* Because the heavier DNA had a higher density, it could be separated from the lighter DNA via centrifugation, a scientific procedure that involves high speed spinning to separate two substances with different densities. *See id.* Upon its separation, the cells containing "heavy" DNA were placed in the "light" medium, where it was allowed to multiply for one generation. *See id.* DNA with a density half way between the "heavy" and "light" densities of the original DNA replaced the "heavy" DNA, thus indicating that replication is not a conservative process where complimentary strands of the double helix stay together throughout the process. *See id.* Rather, it is a semiconservative process where the two strands separate during replication and each serve as templates for two new daughter strands. *See id.*

14. *See* ATLAS, *supra* note 4, at 244.

15. *See id.* at 264.

16. The strand of DNA, which is used for the synthesis of RNA, is commonly known as the "sense strand." *See id.* at 258.

17. RNA is a single strand of ribonucleotides that acts as an "informational mediator" between DNA containing stored genetic information and proteins which functionally express this information. *See id.* at 259.

18. *See id* at 258. Specifically, it is messenger RNA, or mRNA, which contains the code which is transcribed from the DNA and which will be "used to specify a sequence of amino acids in protein synthesis." *See id.* at 260. It is transfer RNA, or tRNA, which decodes the mRNA sequence, translating it into a correct amino acid sequence. *See id.* at 261.

19. *See id* at 264. Figure 6-28 illustrates the four processes which occur via the DNA-dependent enzyme, or RNA polymerase. *See id.* The steps include: initiation, elongation, continued elongation, and termination. *See id.*

20. *See id.*

Translation utilizes the RNA produced through transcription.[21] Specifically, the RNA molecules act as templates, which order the amino acids within polypeptide chains of proteins.[22] Ultimately, translation provides protein molecules with genetic information that they can functionally express.[23]

2. *The Genetic Basis for Human Disease*

Disease is linked to mutation, or the permanent change of DNA.[24] Mutations that affect the germ cells[25] may give rise to inherited disease since the information is passed from the parent to the offspring.[26] Mutations that occur in somatic cells[27] play an important role in the origin of cancer.[28]

Thus, if geneticists can pinpoint a site of gene "error," they could theoretically replace such an error with a "normal" gene, ultimately causing

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21. *See id.* at 273.

22. *See* WATSON, *supra* note 11, at 36.

23. *See* ATLAS, *supra* note 4, at 273.

24. *See* STANLEY L. ROBBINS ET AL., PATHOLOGIC BASIS OF DISEASE 125 (W.B. Saunders Company, 5th ed. 1994). Mutations can occur in many ways. One of the causes of mutation is chemical or radiation exposure. *See Sidebar: What is Gene Therapy?*, WNETSTATION, http://www.thirteen.org/innovation/show1/html/2sb-therapy.html (last visited Oct. 28, 2000). There are three major types of mutation that can occur, each differing in the extent of genetic change. ROBBINS, *supra*, at 125. Chromosome mutations are the result of genetic material rearrangement and thus cause visible structural changes in the chromosome. *See id.* at 126. Genome mutations entail loss or gain of an entire chromosome. *See id.* at 125-26. Frameshift mutations occur when a single nucleotide is substituted, inserted, or deleted, causing the entire frame of the DNA strand to be read differently. *See id.* at 126. All mutations do not result in a clinically abnormal phenotype, or disease. *See* PATHOPHYSIOLOGY OF DISEASE: AN INTRODUCTION TO CLINICAL MEDICINE 4 (Stephen J. McPhee et al. eds., 1995).

25. Germ cells differ from somatic cells in that they are specialized reproductive cells. *See* ATLAS, *supra* note 4, at 1237.

26. *See* ROBBINS, *supra* note 24, at 125. Mendelian disorders are inherited diseases that are the result of an expressed mutation with one gene that has a huge effect. *See id.* at 127. Mendelian disorders fall into three genetic categories: (1) autosomal dominant disorders, (2) autosomal recessive disorder, and (3) x-linked disorders. *See id.* at 128-29. Autosomal dominant disorders are likely to result when one parent is affected by the disorder because they are manifested in a heterozygous state. *See id.* at 128. Examples of autosomal dominant disorders include Huntington's disease and polycystic kidney disease. *See id.* at 129 (Table 5-1). Autosomal recessive disorders, the largest class of mendelian disorders, often result from parents who do not have the disease. *See id.* at 129. Autosomal recessive disorders include: cystic fibrosis, sickle cell anemia, and spinal muscular atrophy. *See id.* (Table 5-2). X-linked disorders are sex-linked disorders affecting the X chromosome. *See id.* at 129-30. Examples include: duchenne muscular dystrophy and fragile X syndrome. *See id.* at 130 (Table 5-3).

27. A somatic cell is "[a]ny cell of the body of an organism except the specialized reproductive germ cell." ATLAS, *supra* note 4, at 1237.

28. *See* ROBBINS, *supra* note 24, at 125. Mutations in somatic cells may also give rise to congenital malformations. *See id.*

reversal of the expressed disease.[29] This hypothesis is the basis for gene therapy.[30]

3. *Developments in Gene Therapy*

One aspect of disease research focuses on gene therapy. First attempted in 1990,[31] gene therapy has primarily been used to treat a condition known as severe combined immune deficiency, or SCID.[32] The condition results from an adenosine deaminase (ADA) deficiency, which is an inherited genetic disorder.[33] Those children who lack the gene for ADA develop SCID, causing harm to their lymphocytes, ultimately preventing the immune response.[34] In order to treat this condition, scientists isolate damaged lymphocytes, extract the DNA, add the gene for ADA to the damaged cells via recombinant DNA technology, and inject these cells back into the patient.[35] Expression of the ADA allows for development of the once missing immune response.[36]

While success has been limited for gene therapy,[37] scientists continue to use varied strategies on major diseases. While the list of diseases is numerous,

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29. *See Sidebar: What is Gene Therapy?*, *supra* note 24.

30. *See id.* There are two kinds of gene therapy, ex-vivo and in-vivo. *See* Sabra Chartrand, *Patents: Fighting Disease with Gene Therapy*, http://www.bio.Indiana.edu/studies/ungrad/L104AK/nytimesSS100697.html (Oct. 6, 1997). Ex-vivo gene therapy, which is both expensive and complex, entails removing a cell from an individual and in turn infecting that cell with a virus which has been modified through the addition of a gene that will carry out a specific job within the body. *See id.* The cell that has been changed is then injected back into the patient, such that the added gene will hopefully carry out its job. *See id.* In-vivo gene therapy, which is much cheaper than ex-vivo gene therapy, involves the direct insertion of a virus, which has been disabled of its harmful effects and has been combined with a gene that will perform a specific task. *See id.* Once injected into the patient, the patient's body absorbs the modified DNA at the time when the disease in question becomes a threat, preventing the disease from being manifested. *See id.*

31. *See* Gina Kolata, *In a First, Gene Therapy Saves Lives of Infants*, *http://www.frenchanderson.org/history/therapy.html* (last visited Oct. 21, 2000). The story discusses a life-saving achievement in France via the use of gene therapy in infants with SCID, while presenting the reality that this therapy may not be immediately useful to other diseases. *See id.*

32. *See* ATLAS, *supra* note 4, at 555. Scientists have used a harmless viral vector (via in-vivo gene therapy) to deliver a normal gene to patients with cystic fibrosis. *See* ROBBINS, *supra* note 23, at 125.

33. *See* ATLAS, *supra* note 4, at 555.

34. *See id.*

35. *See id.*

36. *See id.*

37. *See The Human Genome: Ingenious Medicine*, ECONOMIST, July 1-7, 2000, at 5. While scientists have focused heavily on mendelian disorders (disorders affecting a single gene) relative to gene therapy, there has been little progress. *See id.*

some include: cystic fibrosis,[38] AIDS,[39] and pancreatic cancer.[40]

B. The Human Genome Project

The HGP originated in the United States in 1988.[41] HGP began when the U.S. Department of Energy (DOE) decided to draft an ordered set of DNA segments from known chromosomal locations, develop innovative computational methods for analyzing DNA data, and design new techniques and instruments for DNA detection and analysis.[42] However, no one person or group is entirely responsible for the events which inspired HGP, as efforts towards mapping the human genome have been progressing for decades.[43] In

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38. "Cystic fibrosis is a common generalized disorder of exocrine gland function, which impairs clearance of secretions in a variety of organs." *See* ESSENTIALS OF MEDICINE 147 (Thomas E. Andreoli et al. eds., 3d ed. 1993). The strategy used in cystic fibrosis patients involves delivering a normal gene to somatic cells via a harmless viral vector. See ROBBINS, *supra* note 23, at 125.

39. "AIDS is a disease defined by the presence of any of a variety of indicator diseases and the presence of antibodies directed to the virus that causes AIDS." PATHOPHYSIOLOGY OF DISEASE, *supra* note 24, at 42. *See generally HIV Gene Therapy: Antisense Enables Long-Term Survival of Transduced Immune Cells*, GENE THERAPY WEEKLY, *available at* http://www.newsrx.com/main/weekly-reports...ckto=thisweekstopnews&absoluteposition=15 (last visited Oct. 28, 2000)(complex study involving in-vivo gene therapy in HIV positive patients).

40. Researchers performed a study to see if gene therapy could cause an antitumor effect against pancreatic cancer. *See Pancreatic Cancer: Sm-Like Oncogene is Novel Target for Gene Therapy*, GENE THERAPY WEEKLY, *available at* http://www.newsrx.com/main/weekly-reports...ckto=thisweekstopnews&absoluteposition=16 (last visited Oct. 28, 2000). Prior to this study, researchers found that a CaSm oncogene is overly expressed in the majority of pancreatic tumors and thus is required to maintain this tumoral phenotype. *See id.* Therefore, the CaSm oncogene is a prime site for gene therapy. *See id.* In the study, scientists injected the pancreatic cancer cells with a viral vector. *See id.* Ultimately, the study, performed on mice, showed a reduced tumor growth and extended median survival. *See id.*

41. *See* Byron V. Olsen, *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing the "Useful Arts,"* 7 ALB. L. J. SCI. & TECH. 295, 297 (1997).

42. *See* Macer, *supra* note 3. *See also* George Cahill, *A Brief History of the Human Genome Project*, MORALITY AND THE NEW GENETICS: A GUIDE FOR STUDENTS AND HEALTH CARE PROVIDERS, CH. 1 (Bernard Gert et al. eds., 1996). Under the sub-heading titled "Enter the Department of Energy," the author explains that the DOE's contribution to the HGP came about because of experience and politics. *See id.* Since DOE laboratories had been working with the biological effects of irradiation pursuant to the earlier atomic bomb project, they had already provided significant information to the HGP. *See id.* In fact, such advancement included the ability to physically separate chromosomes by their size and staining. *See id.* Politics played a role in the DOE's involvement in HGP. *See id.* After the atomic bomb project expired, large numbers of biologists and physicists remained. *See id.* The HGP provided these scientists with a new project. *See id.*

43. *See* Macer, *supra* note 3. The beginnings of the genome project can be at least traced back to Mendel's genetics on peas, the mapping of the trait for colour [sic] blindness to the X-chromosome Dros-ophilia by T.H. Morgan and workers, to Avery and colleagues that found DNA was the physical substance of genes, to Crick, Franklin, Watson, and Wilkins who

fact, efforts like John Adams's phenomenon on recessive inheritance,[44] Mendel's genetics on peas,[45] and Crick and Watson's discovery of DNA's structure[46] were all significant predicates to the HGP.

Soon after the DOE's initial involvement, the National Institute of Health (NIH)[47] joined the project because it is a major funder of U.S. biomedical research.[48] However, the project extends outside the United States. In fact, by 1997, twenty-six countries were involved in the project.[49] While the project may be international, the U.S. funds an estimated fifty percent of the HGP, which is predicted to end in 2005.[50]

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determined the structure of DNA, to those who discovered the genetic code, to Sanger and others who developed DNA sequencing, and to many others who contributed to our knowledge of genetics and molecular biology. *Id.*

44. *See* Cahill, *supra* note 42. The author describes British physician John Adams's contribution to genetics under the sub-heading "Emerging Concepts." *See id.* Adams observed that certain traits, or diseases, could descend through a family with phenotypically normal parents. *See id.* This served as a crucial brick in the "genetic foundation for inherited disease." *Id.*

45. *See id.* Beneath the sub-heading "Mendel and Pea Counting," the author explores mathematician-monk Gregor Mendel's work on garden peas. *See id.* His efforts in breeding peas gave birth to the notion that inheritance is quantitative, as it consists of "factors," which determine the manifestation of certain physical characteristics. *See id.* "Mendel correctly postulated that two copies of each factor are present in each of the parents and only one copy of each factor in the sex products – the 'gametes', or egg and sperm (pollen in plants) respectively." *Id.*

46. *See* ATLAS, *supra* note 4, at 28-29. James Watson and Francis Crick relied on the simple laws of structural chemistry, their intuition, and the examination of existing evidence to deduct that DNA is a double helical structure. They hypothesized that DNA was helical and accordingly used DNA X-ray diffraction patterns to test this educated guess. Further, they also built models to test their belief that DNA is helical. The often less mentioned scientists, Franklin and Wilkins, also played a role in developing the structure of DNA. *See* Macer, *supra* note 3.

47. The NIH was founded in 1887 and today serves as the "focal point" for U.S. medical research with the mission of discovering knowledge that will lead to better health for all. *See U.S. Department of Health and Human Services: National Institute of Health, Questions and Answers about NIH,* http://www.nih.gov/about/Faqs.htm#NIH (last visited Oct. 2000). The goal of the NIH is to "help prevent, detect, diagnose, and treat disease and disability, from the rarest genetic disorder to the common cold." *Id.* It carries out its mission by "conducting research in its own laboratories; supporting the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad." *Id.*

48. *See* Macer, *supra* note 3.

49. *See* Melissa Sturges, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind,* 13 AM. U. INT'L L. REV. 219, 230 (1997).

50. Macer, *supra* note 3. While the project is supposed to end in 2005, there could be other programs that extend from the HGP. *See The Human Genome Project: Ingenious Medicine, supra* note 37, at 5. Presently, the knowledge from the HGP is developing the area of science known as genomics. *See id.* at 7. Genomic knowledge is helping drug discovery in a variety of ways. *See id.* First, the information gained can identify new targets for small-molecule drugs. *See id.* Second, it aids understanding as to why these small-molecule drugs do not work in everyone. *See id.* Third, it helps scientists better understand side effects. *See*

With finances, time, and efforts from around the world being utilized to further the project, the question arises: "Whose DNA is being sequenced?"[51] For all practical purposes, it is every human being's DNA that is being sequenced.[52] While the DNA that is being sequenced is a combination of various human tissue cell lines, the outcome will represent the sequence of our species as humans rather than one specific individual.[53] Ultimately, all human beings will be able to say that the sequence is ninety-nine percent similar to their own.[54]

In 2000, HGP scientists announced that they had a rough draft of the human genome, or the DNA located in a human cell.[55] Thus, the basis for the HGP goal, which was to "establish physical gene maps of all twenty-four unique human chromosomes in order to create a framework for understanding the genetic bases for human . . . disease," seemingly has been established.[56] Now the eyes of all nations turn toward the future.

While scientists may now have the human genome draft, applying this knowledge to prevent or cure disease will require even more effort.[57] Sydney Brenner, director of the Molecular Sciences Institute in Berkley, California, warns that individuals should not expect a "quick payoff."[58] In fact, when Brenner was asked about the use of this information for the future, he pointed out that it was a "big leap from just having the raw sequence to an

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id. Fourth, it helps introduce therapeutic proteins, a new class of drugs. *See id.* Despite helpful information provided by genomics, some predict that proteomics may be the next wave of scientific genius. *See id.* at 5. This field would "ignore" DNA and RNA altogether and focus specifically on the produced proteins. *See id.* Some biotechnology companies have begun to invest dollars in this field already. *See id.*

51. Macer, *supra* note 3.

52. *See id.*

53. *See id.*

54. *See id.* It is estimated that "0.3-0.5% of the nucleotides in our DNA vary between different people." *Id.*

55. *See The Human Genome*, *supra* note 2, at 1. Scientists also claim that they have already completed 30 other species' genomes. *See id.* In addition, there are nearly 100 more scientists escalating toward completion. *See id.*

56. Matthew Erramouspe, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 UCLA L. REV. 961, 963 (1996).

57. *See generally The Human Genome: Ingenious Medicine*, *supra* note 36, at 5-6. This article suggests that scientists may soon be working extensively in the area of proteomics. *See id.* at 5. Essentially, proteomics would require scientists to focus on the proteins themselves. *See id.* In fact, earlier this year, Celera Genomics raised almost $1 billion for the project of identifying the human proteome, which is analogous to the sequencing of the human genome. *See id.*

58. Oz Hopkins Koglin, *Genome Sequence Just One Small Step, Expert Says*, OREGONIAN, September 27, 2000, *available at* LEXIS, Oregonian File. While Brenner does not believe that the newly sequenced genome is a "revolution," he does point out that it will accelerate research. *See id.* When asked about gene therapy, he expressed that he believed the better approach would be to study stem cells (the parent cells of all bodily tissues) rather than genes. *See id.*

interpretation of it."[59] Overall, the HGP has spawned issues in the area of patent law, leading to an international dispute over the desired status of patent laws.

C. *The Gene Patenting Debate*

The controversy over gene patenting began in early 1992, when the NIH filed two controversial patent applications for over two thousand partial gene sequences, which Dr. Craig Venter, an HGP researcher for the NIH, identified.[60] Many critics of the NIH believed that the grant of patents on partial gene sequences would inhibit necessary communication between the HGP scientists.[61] Ultimately, the U.S. Patent and Trademark Office (USPTO) rejected the two applications, and the NIH, which gave in to the criticism, failed to appeal, reversing its gene patenting policy and refusing to pursue the patent applications further.[62]

The gene patenting debate has become more complex since the NIH filed the controversial patent applications in 1992. In fact, the growing concerns over gene patenting are reflected in the evolving patent laws in the United States and Europe.

III. EVOLVING PATENT LAWS

A. *What is a patent?*

A patent is "a piece of paper signifying a grant to the inventor of certain rights."[63] There is a common misunderstanding that patents grant an inventor the right to do anything with her invention.[64] In fact, it does not give the inventor the right to make, use, or sell her invention.[65] The inventor's right to practice her invention is an inherent common-law right, which she has without a patent, as long as her practice does not infringe upon others' rights.[66] A

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59. *Id.*

60. *See* Erramouspe, *supra* note 56, at 963. *See also* Emanuel Vacchiano, *It's a Wonderful Genome: The Written-Description Requirement Protects the Human Genome from Overly Broad Patents*, 32 J. MARSHALL L. REV. 805, 813-814 (1999). Craig Venter discovered a unique method to quickly obtain resourceful human genome data. *See id.* He focused on securing partial nucleotide sequence information, which he called "expressed sequence tags," or ESTs. *See id.* While ESTs do not define functional genes or proteins, they are still useful in the sense that they provide information about functional genes. *See id.*

61. *See* Erramouspe, *supra* note 56, at 963.

62. *See id.*

63. UNDERSTANDING BIOTECHNOLOGY LAW: PROTECTION, LICENSING, AND INTELLECTUAL PROPERTY POLICIES 89 (Gale R. Peterson ed., 1993).

64. *See id.*

65. *See id.*

66. *See id.*

patent can be thought of as a negative right or a right to exclude others; however, a patent alone does not prevent others from infringing.[67] Only a lawsuit, claiming infringement, can accomplish this goal.[68]

Patents do not have value per se.[69] However, the perceived value of a patent is linked to the anticipated value of the underlying invention.[70] Moreover, patents can create value for companies who obtain them by lowering investment risk and accordingly attracting capital investment.[71]

B. United States Patent Law

The United States Constitution provides Congress with several enumerated powers, one of which states, "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[72] Congress utilized this power for the first time in the Patent Act of 1790.[73] Patents secure exclusive rights to an invention for twenty years.[74] Accordingly, the U.S. Code provides an inventor, who has secured a patent for an invention, a legal

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67. *See id.*

68. *See id.*

69. *See id.*

70. *See id.*

71. *See id.*

72. U.S. CONST. art. I, § 8, cl. 3.

73. *See The 210th Anniversary of the First American Patent Act*, INVENTORS, wysiwyg://9/http://inventors.miningco.com...ce/inventors/library/weekly/aa073100a.htm (last visited Nov 20, 2000). George Washington signed the First United States Patent Grant on July 31, 1790. *See id.* Before Congress enacted U.S. patent laws in 1790, the King of England owned all intellectual property created by the colonists. *See id.* The first patent was granted to Samuel Hopkins, a Vermont man, for a method of creating a chemical used in making soap, glass, fertilizers, and gunpowder. *See id.*

74. *See* Erramouspe, *supra* note 56, at 965. *See also* Jacqueline D. Wright, *Implications of Recent Patent Law Changes on Biotechnology Research and the Biotechnology Industry*, 1 VA. J. L. & TECH. 2 (Spring 1997). The previous term for a patent was seventeen years from the date the Patent and Trademark Office granted the patent. *See id.* The amendment of 35 U.S.C. § 154, via the legislation employing GATT, provided all patents that were granted after June 8, 1995 with a patent term of twenty years from the earliest filing date of the patent application. *See* 35 U.S.C. § 154 (2000); *See id.* This change in patent term length afforded many advantages. First, the change in the patent term provided for consistency among other international patent systems, including Europe and Japan. *See* Wright, *supra.* Secondly, as the author contends, the twenty-year patent term is favorable to biotechnology research since it provides for longer patent protection. *See id.* Third, the twenty-year term reduces the "submarine patent" problem. *See id.* When an inventor intentionally prolongs the application process to prevent the patent from issuing, the patent application becomes a submarine patent. *See id.* Often, companies will allow an industry to use its invention before the patent is issued, wait until the industry relies on the invention, and later demand royalties after the patent has been granted. *See id.*

cause of action against those who infringe upon her patent.[75] This protection is especially important in biotechnology fields because the research involved is costly and time consuming.[76] However, before a biotechnology patent can be obtained, the invention must meet the statutory requirements of patentable subject matter. In addition, other factors, which have drastically changed the U.S. patent law system, must be considered.

1. Statutory Requirements

a. Utility

The United States Code defines the requirement of utility for an invention to be patentable by stating, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."[77] In order to satisfy the statutory requirement of utility, the claimed invention must be operable and have practical use.[78] Operability means that the invention must be "capable of being used to effect the object proposed" in the specification.[79] The requirement of practical utility proposes the question of whether at least one objective described in the invention can be obtained by the claimed invention and then asks whether some more "specific benefit exists in currently available form."[80] Essentially, practical utility requires real-world value.[81]

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75. *See* 35 U. S. C. § 271 (2000). This statute states in part, ". . . whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a) (2000).

76. *See* Wright, *supra* note 74.

77. 35 U. S. C. § 101 (2000). The U.S. now offers provisional patent applications (as opposed to the traditional utility patent) that expire in one year, have decreased costs, and do not require a PTO examination. *See* Vacchiano, *supra* note 60, at 813-814. However, the U.S. does not yet offer a "diminished" type of patent, which is often available in other countries. *See id.* A diminished patent, contrary to a U.S. provisional patent, is reduced in term and examination compared to a utility patent. *See id.*

78. *See* KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT 48-49 (BNA Books, Inc. 1995).

79. *Id.* (quoting Mitchell v. Tilghman, 86 U.S. (19 Wall.) 287, 396 (1873). The inventor specifies objectives of the invention in the patent application. *See* BURCHFIEL, *supra* note 78, at 48. The Federal Circuit has construed that operability is a minimum threshold to patentability since the inventor does not have to meet all of the objectives he sets forth in the specification. *See id.* In fact, he does not even have to meet a substantial number of objectives in the specification. *See id.* In this sense, the requirement of utility is limited. *See id.*

80. BURCHFIEL, *supra* note 78, at 50 (quoting Brenner v. Manson, 383 U.S. 519, 534-35, 148 USPQ 689, 695-96 (1966). The patent applicant must disclose "practical utility." *See id.*

81. *See id.*

The case most often associated with utility is *Brenner v. Manson.*[82] *Brenner* involved claims related to processes that produced steroid compounds. The USPTO denied Manson a patent on the process in question because his application failed to disclose any utility for the steroid compound which the process produced, yet it was known in the art that the class of steroids which the product belonged to were potentially useful for tumor-inhibiting effects in mice.[83] Despite Manson's argument on appeal that this product would be helpful in future research, the Supreme Court held that Manson's invention did not meet the statutory requirement of utility since the product was disclosed as being useful only "as a possible object of scientific inquiry."[84]

The utility requirement presents issues when inventors attempt to patent biotechnology, particularly genes. Genes have satisfied § 101 based on diagnostic utility.[85] Genes that have been discovered for diseases, like cystic fibrosis, have been patented because disease diagnostics itself is of utility.[86]

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82. *See* Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966).

83. *See id.* at 520.

84. *See id.* at 529.

85. *See* Thomas Caskey, *The Great Gene Patent Race*, CHEMISTRY & INDUSTRY, http://ci.mond.org/9520/952021.html (Oct. 16, 1995).

86. *See id.* The U.S. Patent and Trademark Office (USPTO) has recently granted several patents on genes, gene related inventions, and gene therapy methods. For example, Human Genome Sciences, Inc. (HGSI) recently received a patent on a human gene, known as the CCR5 receptor gene, that is believed to be "the critical entry point" for HIV, the AIDS virus. *See Human Genome Sciences Receives Patent on AIDS Virus Entry Point*, PR NEWSWIRE, *available at* http://www.findarticles.com/cf_1/m4PRN/2000_April_7/61379829/print.jhtml (April 7, 2000). The gene, which is found on surface cells, is the starting point for the creation of a protein that serves as a receptor for HIV. *See id.* Researchers had previously learned that individuals who do not have a functional CCR5 receptor gene are resistant to HIV infection. *See id.* Thus, the discovery of the CCR5 gene has prompted researchers to search for a compound, a drug, which would interfere with the receptor in order to possibly treat those infected with HIV. *See id.* HGSI has licensed the use of CCR5 to several of its partners to assist in the drug hunt. *See id.* Another U.S. patent, recently issued to ISIS, is a patent on the DNA sequence for human RNase H1. *See* U.S. Patent No. 6,001,653; *ISIS Promulgates Patent Plethora*, APPLIED GENETICS NEWS, Vol. 20, No. 8, March 2000. RNase H1 is a "cellular enzyme that degrades double-stranded RNA, such as that which forms when antisense oligonucleotides bind to RNA." *Id.* Most antisense drugs are believed to work via this mechanism. *See id.* The patent also extends to vectors and cells containing this DNA sequence and probes to hybridize to the gene or mRNA. *See id.* Further, the patent covers methods of creating any antisense drug or inhibitor using this mechanism, specific chemical classes that work via this method, and procedures of screeening to identify effective antisense inhibitors of genes. *See id.* ISIS has announced that it will "vigorously enforce this patent." *Id.* A third example is a broad patent that USPTO granted to Avigen Inc. and John Hopkins University. *See* U.S. Patent No. 5,962,313; *Avigen Receives a Broad Patent for AAV Gene Therapy for Lysosomal Storage Diseases*, Avigen Inc., Oct. 7, 1999, *available at* http://www.avigen.com/press_LysosomalStorageDiseases.htm [hereinafter *Lysosomal Storage Diseases*]. The patent covers "recombinant adeno-associated virus (AAV) vectors carrying lysosomal enzyme genes for the treatment of lysosomal storage diseases, including Gaucher's

However, certain gene discoveries that lack immediate use for disease therapy are often found to lack utility,[87] as in the *Brenner* decision. Ultimately, the case law definition of utility has great impact on gene patenting.[88]

b. Novelty

An invention must also meet the requirement of novelty, which essentially requires that the patent applicant be the individual who first brought the invention to society's attention.[89] Specifically, 35 U. S. C. § 102 sets forth a variety of situations that would preclude an individual from obtaining a patent. Some of those instances include:

> (1)"the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country . . ." (2) "the invention was patented or described in a printed publication in this or a foreign country . . ." (3) "he has abandoned the invention" (4) "the invention was described in a patent granted on an application for patent by another filed in the United States before the invention . . ." (5) "he did not himself invent the subject matter sought to be patented . . . ."[90]

One restriction that is often placed upon biotechnology inventions is the prohibition on patenting "products of nature."[91] This particularly applies in the

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Tay-Sachs, and Fabry's disease." *Lysosomal Storage Diseases, supra.* Moreover the patent encompasses "the delivery of the vectors to any tissue, regardless of how it is made or how the gene is regulated." *Id.* Avigen also recently received a patent relating to cancer gene therapy. *See* U.S. Patent No. 5,952,221; *Avigen Receives a Broad Patent for AAV Cancer Gene Therapy and a Patent for Adenovirus-free AAV Production*, Avigen Inc., Sept. 20, 1999, *available at* http://www.avigen.com/press_CancerPatent.htm. The patent, which relates to all kinds of cancers, covers "recombinant adeno-associated virus (AAV) vectors carrying therapeutic genes for the treatment of cancer, including genes encoding suicide proteins, antiangiogenic factors, interferons, lymphokines, tumor suppressors and growth factors. The patent is for a two gene system with one gene encoding a therapeutic protein and the other a 'gene switch' which allows the therapy to be terminated." *Id.*

87. *See id.* Diseases, like cancer, where scientists have identified the "lead" gene are important findings since the discovery may lead to methodology that could be of therapeutic use. *See id.* However, as the author points out, granting patents for these lead genes could be detrimental because it could block subsequent research with these genes. *See id.*

88. *See id.*

89. *See* 35 U.S.C. § 102 (1999). *See generally* BURCHFIEL, *supra* note 78, at 60-77 (discussion on novelty).

90. 35 U.S.C. § 102 (1999).

91. The exclusion of "products of nature" from patentability arose in the late nineteenth century when the courts refused to grant patents on newly discovered plants as well as "artificially synthesized compounds" previously derived from natural sources. BURCHFIEL,

case of recombinant processes or genetic engineering that ultimately produces the same known product.[92] Because inventions may be based on the "duplication of compounds that are found in living organisms or are produced by naturally occurring plants or animals," the product of nature doctrine is particularly important in the area of biotechnology.[93]

In re Bergstrom[94] illustrates a situation in which the product of nature doctrine was circumvented. The court in *In re Bergstrom* analyzed whether purified and separated prostaglandin compounds isolated from tissue constituted a novel invention. The court found the materials that were purified differed from the same material which was less pure in its natural state. Thus, the court held that the pure materials were "new" with respect to the natural compound and thus satisfied the novelty requirement.[95]

c. Non-Obviousness

An invention must also meet the requirement of non-obviousness before it can be considered patentable subject matter. The United States Code states:

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.[96]

In *Amgen Inc. v. Chugai Pharm. Co. Ltd.*, [97] a patent infringement case, the court had to determine whether a patent on a purified and isolated DNA sequence and host cells transformed with this DNA sequence were valid under §103. The prior art generally taught that the use of fully degenerate probes of high redundancy could be used to screen a human genomic library.

The inventor used a known baboon EPO gene as a probe, which had been thought to be unsuccessful to those of high skill in the art. In determining the patent's validity under §103, the court used an "obvious to try" and "reasonable expectation of success" analysis in finding the patent to

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supra note 78, at 61. *See* American Wood Paper Co. v. Fiber Disintegrating Co., 90 U.S. (23 Wall.) 566, 594-595 (1874) (holding that a substance extracted from a natural source and the method by which it was obtained can not be called a new manufacture).

92. *See* BURCHFIEL, *supra* note 78, at 60.

93. *Id.* at 61.

94. *See* In re Bergstrom, 427 F.2d 1394, 166 USPQ 256 (C.C.P.A. 1970).

95. *See id.* at 1402.

96. 35 U.S.C. § 103 (2000).

97. *See* Amgen v. Chugai Pharm. Co., 927 F.2d 1200, 18 USPQ 1016 (Fed. Cir. 1991).

be non-obvious.[98] An expert witness for the inventor stated that the "overall homology of baboon DNA and human DNA was 'roughly 90 percent.'"[99] Citing this testimony, the court noted that while it may be feasible or even "obvious to try" probing a human gDNA library with a baboon cDNA probe, the reasonable likelihood of success was not certain.[100] Thus, the DNA sequence was not obvious; accordingly, the host cells containing this non-obvious sequence also met § 103.[101]

2. *Factors Affecting U.S. Patent Law*

a. *Creation of the Court of Appeals for the Federal Circuit*

One of the initial markers of the U.S. patent law system evolution was the creation of the Court of Appeals for the Federal Circuit.[102] Established on October 1, 1982, the court has exclusive jurisdiction of appeals from district court judgments in cases arising under U.S. patent laws and both direct and indirect appeals from decisions of the Patent and Trademark Office Board of Patent Appeals and Interferences.[103] Prior to the creation of the U.S. Court of Appeals for the Federal Circuit, all patent infringement suits were tried in federal district courts with appeals being heard in one of eleven regional or circuit U.S. Courts of Appeal.[104] The U.S. Supreme Court rarely granted certiorari from these courts.[105]

Two reasons prompted the formation of the Federal Circuit. First, early Supreme Court decisions seemed to reflect an anti-patent mentality.[106] At one point, the law required an invention be a "flash of creative genius"[107] and to "push back the frontiers of chemistry, physics, and the like" in order to be patentable.[108] Congress overruled the "flash of creative genius" standard with

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98. *See id.* at 1208. The district court also used an "obvious to try" analysis coupled with a "reasonable expectation of success" analysis. *Id.* It ultimately determined that "there was no reasonable expectation of success in obtaining the EPO gene by the method . . . ." *Id.* at 1209.

99. *See id.* at 1208.

100. *See id.*

101. *See id.* at 1209.

102. *See* Wright, *supra* note 74.

103. *See* BURCHFIEL, *supra* note 78, at 5.

104. *See* PETERSON, *supra* note 63, at 8.

105. *See id.*

106. *See* BURCHFIEL, *supra* note 78, at 6. The anti-patent attitude reflected the New Deal's antipathy for monopolization. The Supreme Court raised the level of scrutiny on patents suspect to contribute to monopoly. *See generally Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 51 USPQ 272 (1941).

107. *Cuno Eng'g Corp.*, 314 U.S. at 91, 51 USPQ at 275; BURCHFIEL, *supra* note 78, at 6.

108. *Great Atl. and Pac. Tea Co. v. Supermarket Equip. Co.*, 340 U.S. 147, 154, 87 USPQ 303, 306 (1950); BURCHFIEL, *supra* note 78, at 7.

the present day objective non-obviousness standard.[109] While the Supreme Court briefly noted this standard, it seemed to revert back to its previous, more conservative views on patents in later cases.[110]

Second, lower courts had issued extremely inconsistent decisions on patent issues. In fact, at one point a patent was almost four times as likely to be enforced in the Seventh Circuit than in the Second Circuit.[111] This led to confusion[112] and forum shopping.[113] Ultimately, the creation of the Federal Circuit promoted uniformity[114] in patent law while allowing specialized judges to hone a complex area of law.[115]

The Federal Circuit has had a noticeable effect on biotechnology patent law.[116] The Federal Circuit has displayed a "pro-patent" mentality quite

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109. *See* BURCHFIEL, *supra* note 78, at 7.

110. *See id.* at 8. *See also Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 189 USPQ 449 (1976). *See generally Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969) (reverting to the traditional standard for patentability).

111. *See* BURCHFIEL, *supra* note 78, at 9.

112. *See id.* Confusion in patent law gave way to the Hruska Commission, created to provide suggested reform options. *See id.* The Hruska Commission proposed that the existing federal appellate system remain the status quo, but specialized courts of appeals should be created for the specialized areas of patent law, environmental, and tax law. *See id.* The Justice Department suggested a similar plan, which would involve merging the Court of Claims and the Court of Customs and Patent Appeals to create a new court, which would have exclusive jurisdiction over appeals from the district courts in patent, environmental, and tax law. At the time, both these courts had substantial experience in patent law cases. *See* PETERSON, *supra* note 63, at 9. While Congress did not create special courts for tax or environmental law, it did respond with the Federal Circuit for the area of patent law. BURCHFIEL, *supra* note 78, at 9. Accepting the Justice Department's proposal, the U.S. Court of Customs and Patent Appeals and the U.S. Court of Claims were combined to form the Federal Circuit as a result of the Federal Courts Improvement Act. *See* PETERSON, *supra*, at 9. Congress hoped the new system, which has been called a "bold experiment," would help the United States compete internationally in the industrial arena. *See* BURCHFIEL, *supra*, at 10.

113. *See* PETERSON, *supra* note 63, at 9. Because some circuits had a seemingly hostile view toward patents while other circuits were considered patent-friendly, the practice of forum shopping began. *See id.* at 8. Those who owned patents attempted to have their cases tried in a jurisdiction that had a patent-friendly attitude. *See id.* at 9. Meanwhile, alleged infringers sought out patent-hostile circuits. *See id.* The combined uncertainty caused patents to lose their value. *See id.* Many chose to no longer seek patents because they did not want to invest in getting a patent when a hostile jurisdiction could quickly take it away. *See id.*

114. *See* BURCHFIEL, *supra* note 78, at 10. Congress definitely had national patent uniformity in mind when it created the Federal Circuit. *See id.* In its beginning, the Federal Circuit made it clear that any decision, other than its own, including the Supreme Court's earlier decisions inconsistent with the reasons that prompted the creation of the Federal Circuit, would all serve as merely persuasive authority. *See id.* Thus, the Federal Circuit has the power to remove the Supreme Court from any or all parts of the administration of the patent legal system. *See id* at 11. Since its creation, the Federal Circuit has succeeded in providing the much-needed uniformity in patent law nationwide. *See id. See also* PETERSON, *supra* note 63, at 10 (noting "substantial improvement" in uniformity on appeals for patent cases).

115. *See id.* at 12.

116. *See* Wright, *supra* note 74.

different from early Supreme Court decisions.[117] This approach allows for the protection of biotechnology inventions, creating the incentive to continue research and development.[118] Moreover, the Federal Circuit has issued decisions awarding high damages to patent owners in patent infringement cases.[119] Large damage awards are an additional protection for biotechnology inventors because they discourage others from infringing upon the inventor's patent.[120]

b. Legislation: Past, Present, and Future

Another factor that significantly affects patent law is changing legislation.[121] Specifically, legislation implementing the General Agreement on Tariffs and Trade (GATT) has impacted the U.S. patent system. Legislation arising from GATT has created statutory modification of the length of the patent term, introduced provisional patent applications, and altered the "date of invention" in foreign countries.[122]

The patent term length changed from seventeen years from the date of patent issuance from the USPTO to twenty years from the earliest filing date

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117. *See id.*

118. *See id.* The new approach, as compared to the patent system before the creation of the Federal Circuit, has increased the overall value of patents. *See* PETERSON, *supra* note 63, at 10. This increased value means more people are seeking patents. *See id.* An increase in patent purchases allows for more licensing opportunities and accordingly more favorable opportunities for these licenses. *See id.* This is positive for biotechnologists, as well as other kinds of scientists, who rely on licenses to use others' inventions in order to further research innovation. *See generally id.* at 30-32 (discussion on licenses for biological materials).

119. *See* PETERSON, *supra* note 63, at 10. Federal trial courts have followed this pattern of awarding huge damages. *See* Wright, *supra* note 74. For example, in a 1990 patent infringement case involving camera technology, Polaroid won $870 million dollars from Kodak. *See id.* In some cases, these large damages have driven companies into bankruptcy. *See id.*

120. *See* Wright, *supra* note 74.

121. *See id.* Specifically, the author argues that legislation implementing GATT has had a huge effect on patent law. She also looks at legislation that was being proposed at the time she wrote the article. *See id.* The legislation, titled the Moorehead Bill, focused on publication of patent applications eighteen months after the earliest effective filing date. Wright, *supra* note 74. The author cites advantages and disadvantages to patent publication. Publication could be advantageous because it can promote innovation within the biotechnology field. *See* Wright, *supra* note 74. Early publication could prevent repetitive experiments while indicating areas of research containing positive results, deterring other researchers away from research "dead ends." *See id.* Publication could also provide inventors "prior art" status, cause potential submarine patents, which allow companies to "hide" their patent and later demand royalties, to be disclosed, and provide U.S. inventors with the opportunity to see information within patent applications filed abroad. *See id.* This is important since information in U.S. patent applications, which are also filed in a country with publication laws or under the Patent Cooperation Treaty, is disclosed eighteen months after filing. *See id.*

122. *See id.*

of the patent application via the GATT enabling legislation.[123] Some have argued that the change in the patent term places the United States in equilibrium with other nations who similarly have twenty-year patent terms.[124] However, others contend that the twenty-year patent term is bad policy because it provides uncertain inventors with an even lengthier patent term.[125] Specifically, the twenty-year patent has been criticized because its lengthiness alone, as compared to the seventeen-year patent, would be less likely to promote biotechnology research.[126]

Provisional patent applications have also been created as a result of GATT legislation.[127] These applications afford advantages specifically to small businesses because the process involves less cost and fewer legal requirements.[128] Essentially, the provisional patent application ensures an inventor one year to carry out further research before he decides whether or not he wishes to invest in a more expensive non-provisional patent.[129]

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123. *See id.* The legislation implementing GATT amended 35 U.S.C. § 154, stating that any patent granted after June 8, 1995, shall have a patent term twenty years from the earliest filing date of the application. *See* 35 U.S.C. § 154 (2000). While the twenty-year patent is more extensive in length than the previous seventeen-year patent, the twenty-year patent begins at an earlier date. Wright, *supra* note 74.

124. *See id.* Both Europe and Japan have twenty-year patent terms, but also have smaller workloads. *See id.* The European Patent Office and Japanese Patent Office do not have the large volume of patents that USPTO deals with annually. *See id.*

125. *See HR 359 and S 284 Would Restore a Minimum 17 Year Patent Term: Why a (20 Years) From Filing Patent Term is Bad Policy*, Intellectual Property Creators, Oct., 6, 1998, *available at* http://www.hecklel.org/congress/104cong/issues104/iss359.htm [hereinafter Patent Term]. The author contends that a twenty-year term could cause several attempts to delay the issuance of a patent, unlike the seventeen-year patent which the applicant receives no matter how long the process takes, ultimately discouraging others from interfering with the process. *See id.* In contending that the twenty-year patent may be delayed, the author predicts: (1) "Patent examiners would give lower priority to examining the more important patents or offer limited claims to get a patent issued because of the work involved and the risk of issuing a controversial patent." (2) "Those effected by the patent could enter into delaying tactics by giving prior art on the patent to the patent office at times most designed to delay a patents [sic] issuance. This tactic will be even more common if 18 month publication becomes law." *Id.*

126. *See id.* The author argues that patent applicants often have a great deal of uncertainty concerning their inventions and by adding to the length of the patent, the uncertainty is also extended. *See id.* This could be detrimental to innovation. *See id.*

127. *See id.* The only requirements for a provisional patent application are a specification, a cover sheet, and drawings. *See id.* However, the provisional patent application must be "enabling," such that a person of ordinary skill in the art could build or perform the invention/method from the detail specified in the application. *See id.*

128. *See* Wright, *supra* note 74.

129. *See id.* The one-year term of the provisional patent application is not figured into the twenty-year patent term if the inventor chooses to pursue the twenty-year patent. *See Frequently Asked Questions about Provisional Patent Applications,* Brown, Pinnisi & Michaels, PC, *available at* http://www.lightlink.com/bbm/provapp.html (Dec. 7, 1999)[hereinafter FAQ]. Reasons for seeking a provisional patent application include: (1) If there is no time to prepare a formal application and there is going to be a publication or sale of the invention. However,

Both GATT and the North American Free Trade Agreement (NAFTA) facilitated the amendment of 35 U.S.C. § 104.[130] The change meant that inventors who created an invention in NAFTA or World Trade Organization member countries would be entitled to the same rights of priority in establishing a date of invention in the United States as those inventors who actually created an invention within the United States. [131]

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in the area of biotechnology, USPTO examiners "hold the position that a disclosure which is non-enabling as a patent application is nevertheless enabling as a publication." *Id.* Thus, filing a provisional application here might not meet the inventor's desired protection. *See id.* (2) It allows time to study the market and work out uncertainty in the invention. *See id.* (3) Provisional patent applications provide an inventor with time to arrange financing. *See id.*

130. *See* Wright, *supra* note 74. The provision of the United States Code entitled "Invention Made Abroad" states:

I. In general
  A. Proceedings. In proceedings in the Patent and Trademark Office, in the courts, and before any other competent authority, an applicant for a patent, or a patentee, may not establish a date of invention by reference to knowledge or use thereof, or other activity with respect thereto, in a foreign country other than a NAFTA country or a WTO member country, except as provided in sections 119 and 365 of this title.
  B. Rights. If an invention was made by a person, civil or military --
    1. while domiciled in the United States, and serving in another country in connection with operations by or on behalf of the United States,
    2. while domiciled in a NAFTA country and serving in any other country in connection with operations by or on the behalf of that NAFTA country, or
    3. while domiciled in a WTO member country and serving in another country in connection with operations by or on behalf of that WTO member country, that person shall be entitled to the same rights of priority in the United States with respect to such invention as if such invention had been made in the United States, that NAFTA country, or that WTO member country, as the case may be.
      a. Use of Information. To the extent that any information in a NAFTA country or a WTO member country concerning knowledge, use, or other activity relevant to proving or disproving a date of invention has not been made available for use in a proceeding in the Patent and Trademark Office, a court, or any other competent authority to the same extent as such information could be made available in the United States, the Director, court, or such other authority shall draw appropriate inferences, or take other action permitted by statute, rule, or regulation, in favor of the party that requested the information in the proceeding.

II. Definitions. As used in this section—
  A. the term "NAFTA country" has the meaning given that term in section 2(4) of the North American Free Trade Agreement Implementation Act [19 USCS § 3301(4)]; and
  B. the term "WTO member country" has the meaning given that term in section 2(10) of the Uruguay Round Agreements Act [19 USCS § 3501(10)].

35 U.S.C. § 104 (2000).

131. *See* Wright, *supra* note 74.

While the GATT legislation provided significant modifications to the patent law system, no major changes have occurred since 1953, which was the first change since the creation of the patent law system in the 1700s.[132] However, new legislation, titled the American Inventors' Protection Act (AIPA)[133] has overhauled the patent system. One representative stated that the purpose of the AIPA is "[t]o advance American technology, strengthen our nation's global competitiveness, and to reward inventors on a more timely basis . . . ."[134] The AIPA has changed patent law in three major ways. One provision provides for optional limited contested reexamination, which ultimately allows for more third-party participation on reexamination of patents.[135] A second important change is the provision for publication of U.S. patent applications.[136] Another important feature guarantees the term of the patent to compensate for USPTO delays.[137]

Critics of the AIPA have suggested that it will reshape the U.S. Patent System in favor of big corporations who want quicker access to invention information.[138] Specifically, many fear that the requirement, which demands publication after eighteen months, may promote others to steal invention ideas before the inventions are protected by a patent.[139] However, these fears are combated by proponents of the AIPA who point out that this legislation could make patent laws more congruent with European and Japanese patent laws, increasing U.S. companies' ability to compete internationally.[140]

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132. *See* Cyndia Zwahlen, *Small Business; Mind to Market; Big Firms, Independents at Odds on Patent Plan*, L.A. TIMES, Oct. 13, 1999, at 8, *available in* LEXIS, Los Angeles Times File.

133. *See* H.R. 1907, 106th Cong. (1999) (enacted).

134. Rep. Coble made the statement. *See Summary of Patent Reform Legislation in the 106th Congress*, TECH. L.J., *available at* http://techlawjournal.com/cong106/patent/Default.htm (last visited Sept. 21, 2000).

135. *See Highlights the American Inventors' Protection Act of 1999*, Greenblum & Bernstein, P.L.C., *available at* http://www.gbpatent.com/announce/highlights.htm. Prior to AIPA, a third party could initiate a reexamination of a patent, but could not be involved with subsequent proceedings before UPSTO. *See id.* Because of AIPA, third parties can now be involved in these subsequent proceedings and also now have available appeal procedures to the Board of Appeals. *See id.*

136. *See id.* This provision is a significant change. *See id.* Previously, patent applications were held in confidence. *See id.* Now, if the inventor chooses foreign filing in addition to UPSTO filing, "all pending U.S. patent applications will be published at 18 months from the earliest convention or PCT filing date." *Id.* Provisional royalties will be rewarded to the applicant between the times of publication and patenting as long as the patent issued reflects the claims published. *See id.*

137. *See id.* This guarantee for the term of a patent compensates for UPSTO delays from "interferences, secrecy orders or appeals, as well as when the PTO fails to grant the patent within three years." *Id.*

138. *See* Zwahlen, *supra* note 132, at 8.

139. *See* John Schwartz, *Inventors Say Proposed Patent Law Will Lead to Stealing Ideas*, WASH. POST, Nov. 4, 1999, at A8, *available in* LEXIS, Washington Post File.

140. *See* Zwahlen, *supra* note 132, at 8.

B. *European Patent Law*

1. *Harmonisation of Patent Law in Europe*

European patent law functions on many levels. It is important to initially note that there is no unitary European patent law system.[141] Thus, a discussion of European patent law is inclusive of a combination of European countries' national patent systems that all contain their own administrative and judicial history.[142] However, European patent law also contains many efforts to *harmonise* these European countries' patent systems through treaty efforts like the Paris Convention (PC),[143] Patent Co-operation Treaty (PCT),[144] and the European Patent Convention (EPC).[145] The discussion below will focus

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141. *See* PHILIP LEITH, HARMONISATION OF INTELLECTUAL PROPERTY IN EUROPE x (Adrian Chandler ed. 1998).

142. *See id.* at xi.

143. *See* Paris Convention, 1883. The PC, which has been revised several times since its signing in 1883, established an International Union for the Protection of Industrial Property. *See Paris Convention for the Protection of Industrial Property*, 1 B.D.I.E.L. 677, *available in* LEXIS. The PC assists patent and trademark protection by establishing minimum standards of industrial property protection. *See id.* As of January 1, 1988, the following countries were parties to PC: Algeria, Argentina, Australia, Austria, Bahamas, Barbados, Belgium, Benin, Brazil, Bulgaria, Burkina Faso, Burundi, Cameroon, Canada, Central African Republic, Chad, China, Congo, Cote d'Ivioire, Cuba, Cyprus, Czechoslovakia, Democratic People's Republic of Korea, Denmark, Dominican Republic, Egypt, Finland, France, Gabon, German Democratic Republic, Germany (Federal Republic of), Iraq, Ireland, Israel, Italy, Japan, Jordan, Kenya, Lebanon, Libya, Liechtenstein, Luxembourg, Madagascar, Malawi, Mali, Malta, Mauritania, Mauritius, Mexico, Monaco, Mongolia, Morocco, Netherlands, New Zealand, Niger, Nigeria, Norway, Philippines, Poland, Portugal, Republic of Korea, Romania, Rwanda, San Marino, Senegal, South Africa, Soviet Union, Spain, Sri Lanka, Sudan, Suriname, Sweden, Switzerland, Syria, Togo, Trinidad and Tobago, Tunisia, United States, Uruguay, Viet Nam, Yugoslavia, Zaire, Zambia, and Zimbabwe. *See Id.*

144. *See* Patent Cooperation Treaty, June 19, 1970. The PCT allows applicants to file an international patent application signifying which member countries in which they seek protection. *See Patent Cooperation Treaty*, 1 B.D.I.E.L. 831, *available in* LEXIS. The application is filed within the applicant's own country. *See id.* As of January 1, 1988, the following countries were party to the treaty: Australia, Austria, Barbados, Belgium, Benin, Brazil, Bulgaria, Cameroon, Central African Republic, Chad, Congo, Democratic People's Republic of Korea, Denmark, Finland, France, Gabon, Germany (Federal Republic of), Hungary, Italy, Mali, Mauritania, Monaco, Netherlands, Norway, Republic of Korea, Romania, Senegal, Soviet union, Sri Lanka, Sudan, Sweden, Switzerland, Togo, United Kingdom, and United States. *See id.* Presently there are around seventy member states. *See* LEITH, *supra* note 140, at 46.

145. *See* European Patent Convention, October 7, 1977 [hereinafter EPC]. As of October 1987, there were thirteen member states: Austria, Belgium, France, Germany (Federal Republic of), Greece, Italy, Liechtenstein, Luxembourg, Netherlands, Spain, and Sweden. Presently, there are eighteen member states. *See* LEITH, *supra* note 141, at 25. *See generally* SINGER: THE EUROPEAN PATENT CONVENTION (Raph Lunzer ed. 1995) (discussing each provision of the

primarily on the EPC because it plays a definitive role in biotechnology business.

The EPC, a treaty among eighteen European nations, was created to promote European state collaboration regarding protection of patentable matter.[146] The EPC gave rise to the European Patent Office (EPO).[147] Essentially, the EPC allows an inventor to go through one office, the EPO, in order to obtain a bundle of national patents, which are subject to the corresponding national laws of the relevant EPC member states.[148] Ultimately, an inventor who wants to obtain a patent on an invention in multiple European nations should file with the EPO, whereas an inventor seeking a patent in only a few countries should file directly with those nations' patent offices.[149]

A positive result of the EPC has been the modification of some individual European nation's patent laws to correspond with neighboring nations.[150] While the EPC is not ensuring patent uniformity, it certainly is causing some positive movement towards supranational agreement.[151] This prevents forum-shopping among states and lends hope to the ultimate goal of patent law uniformity among developed countries worldwide.[152]

2. *Substantive Requirements for Patentable Material*

The substantive requirements for patentable subject matter under EPC are slightly different than the statutory requirements which must be met under U.S. law. The substantive requirements under the EPC are: (1) novelty,[153] (2)

EPC).

146. *See* LEITH, *supra* note 141, at ix.

147. *See What is the EPC (European Patent Convention)?*, Oppedahl & Larson LLP, *available at* http://www.patents.com/patents.htm#pct [hereinafter *What is the EPC?*].

148. *See* LEITH, *supra* note 141, at x.

149. *See What is the EPC?*, *supra* note 147.

150. *See* LEITH, *supra* note 141, at x.

151. *See id.* The vast majority of member states have made their domestic patent laws conform to the EPC. *See id.* For example, the United Kingdom passed the 1977 Patents Act to bring their domestic laws in line with the EPC. *See id.*

152. *See* LEITH, *supra* note 141, at vi.

153. *See* EPC, *supra* note 145, at art. 54. Article 54 states:

1. An invention shall be considered to be new if it does not form a part of the state of art.
2. The state of the art shall be held to compromise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.
3. Additionally, the content of European patent applications as filed, of which dates of filing are prior to the date referred to in paragraph 2 and which were published under Article 93 on or after that date, shall be considered as compromised in the state of the art.
4. Paragraph 3 shall be applied only in so far as a Contracting State designated in respect of the later application, was also designated in respect of the earlier

inventive step,[154] and (3) industrial application.[155] In addition, there are certain exceptions to patentability, which means that if an invention falls within the category of exceptions it cannot be patented.[156]

The exceptions to patentability are specifically important to the field of biotechnology. The exceptions illustrate the once conservative view[157] on Euro-Biotech patenting, as Article 53(a) leaves open an exception for those inventions that violate public policy or morality.[158] Further, Article 53(b) prohibits patents on biological methods for the production of animals or plants.[159] In order to better understand Article 53 and its relation to evolving biotechnology patent laws in Europe, an overview of conflicting case law must be discussed.

3. *EPC Article 53 Case Law: Harvard Mouse & Plant Genetic Systems v. Greenpeace*

Case law discussing Article 53 issues in the past has been somewhat contradictory and perhaps foreshadowed the need for European patent reform

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application as published.

5. The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

EPC, *supra*.

154. *See id.* at art. 56. Article 56 states: An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents are not to be considered in deciding whether there has been an inventive step. *Id.*

155. *See id.* at art. 57. Article 57 states: "An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture." *Id.*

156. *See id.* at art. 53. Article 53 states:

European patents shall not be granted in respect of:

1. inventions [sic] the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
2. plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

Id.

157. This can be considered a conservative viewpoint when compared to the United States, which does not have similar statutory exceptions.

158. *See* EPC, *supra* note 145, at art. 53(a).

159. *See id.* at art. 53(b).

to respond to an increasingly technological world.[160] This contradiction has been particularly apparent in the field of transgenics.[161] A comparison of the well-known *Harvard mouse* case,[162] a transgenic animal case, and *Plant Genetic Systems v. Greenpeace*,[163] a case concerning transgenic plants, illustrates the contradiction.

The *Harvard mouse* case concerned a transgenic mouse that was susceptible to cancer. The invention came about when Harvard researchers introduced the myc gene, which is an activated oncogene,[164] into the non-human mammalian genome of a mouse. The case proceeded through three phases of legal action. Initially, the EPO Patent Examining Division excluded Harvard's patent application by excluding it under 53(b), calling the invention an "animal variety."[165] The Examining Division referred to the EPO Board of Appeals when it was unable to decide whether or not the Harvard mouse should be excluded under 53(a) for violating public policy.[166]

In this second phase, the EPO Board of Appeals returned the case to the EPO Examining Division clarifying that it must determine whether the claim actually constituted an "animal variety."[167] The Board ordered that if the Examining Division came to the conclusion that the claim did not include an "animal variety," then the invention should not be barred from patentability.[168] In addition, the Board ordered the Division to determine whether Article 53(a)

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160. *See* Breffni Baggot, *Patenting Transgenics in the European Union*, BIOTECH PATENT NEWS, *available at* http://www.townweb.com/biotech/baggot_eu.html.

161. *See id.* Transgenics is an area of science that involves introducing DNA from foreign sources into plants or animals, to illicit a positive change. *See* ATLAS, *supra note* 4, at 862. Via this recombinant DNA technology, plants have been altered to make them more resistant to pests and pathogens and also enhancing their nutritional capacity to increase crop yields. *See id.* However, transgenics extends beyond plants. *See* WATSON, *supra* note 11, at 478. While it has been performed on mice for approximately a decade, scientists have recently successfully extended the study to larger livestock animals. *See id.* After learning about the transgenic mouse, scientists attempted to mirror the procedure in farm animals. *See id.* They used a technique known as differential interference contrast microscopy in order to visualize the location of the often opaque nuclei of the fertilized egg in the farm animal. *See id.* Early experiments showed positive results but low frequency of occurrence. *See id.* One early study showed that a transgenic animal would only occur 1 in 200 trials. *See id.* at 279. However, today the success rate has improved. *See id.* Particularly, scientists have introduced genes to allow for the expression of growth hormone. *See id.* This has produced leaner swine, which leads to a better meat product. *See id.*

162. *See* Case V 0006/92, Harvard (Apr. 3, 1992) [hereinafter V 0006/92].

163. *See* Case T 0356/93, Plant Genetic Systems v. Greenpeace, Ltd. (Feb. 21, 1995) [hereinafter PGS].

164. An oncogene is a gene that can lead to "malignant transformations of animal cells," or a cancer-causing gene. ATLAS, *supra* note 4, at 1224.

165. *See* Case V 0004/89, Harvard (July 14, 1989).

166. *See id.*

167. *See* T 0019/90, Harvard (Oct. 3, 1990).

168. *See id.*

barred the claim from patentability.[169] Accordingly, the Board suggested that the Division weigh the suffering of animals and possible risks to the environment against the usefulness to mankind.[170]

The Division, in the third phase, made a decision concerning the Board's orders.[171] In determining whether the invention, a mouse, actually constituted an "animal variety," the Division compared the term animal to "animal variety."[172] It noted that an "animal variety" constituted a "sub-unit of a species" and thus ranked lower than a species.[173] However, an animal, here a rodent, fell within a taxonomic classification unit much higher than a species.[174] Thus, 53(b) did not exclude the *Harvard mouse*.[175]

In deciding the issue of whether the mouse should be barred relative to 53(a) because of public policy, the Division employed the balancing test suggested by the Board.[176] The Division noted the high value of the interest to develop anticancer treatments.[177] It also pointed out that there would be no danger to the environment since skilled researchers under controlled conditions do the experimentation.[178] Finally, it hypothesized that animal suffering would actually decrease since fewer animals would be needed because of the wide availability of the patented mouse.[179] Ultimately, the Division granted the patent, making it the first patent on a transgenic non-human mammal.[180]

After the Harvard mouse ruling, Plant Genetic Systems filed a patent application for transgenic plants.[181] The EPO initially granted the patent, but Greenpeace opposed the patent.[182] The Board then reviewed the patent, analyzing separately the following three categories: (1) the plant cells and seeds, (2) the process for producing the transgenic plant, and (3) the transgenic plants.[183] Ultimately, the court held that the plant cells and seeds and the process for producing the transgenic plants were patentable.[184] However, the court found the transgenic plant not patentable because it fell under the realm

169. *See* Baggot, *supra* note 160.
170. *See id.*
171. *See*, V 0006/92, *supra* note 162.
172. *See id.*
173. *See id.*
174. *See id.*
175. *See id.*
176. *See id.*
177. *See id.*
178. *See id.*
179. *See id.*
180. *See id.*
181. *See* EPO Application No. 87400141.
182. *See* PGS, *supra* note 163.
183. *See id.*
184. *See id.*

of "plant variety" according to Article 53(b).[185]

Harvard mouse and *Plant Genetic Systems* raised questions as to how EPO viewed Article 53 since it had granted a patent for a transgenic animal, but not for a transgenic plant. The inconsistencies made investors cautious about seeking protection for intellectual property in the uncertain European patent legal system.[186]

4. *European Patent Directive on the Legal Protection of Biotechnological Inventions*

In May 1998, the European Parliament approved a European Patent Directive on Biotechnology ("Directive"),[187] a product of more than ten years of controversy over patenting life forms.[188] When the Directive went into effect in July 1998, it required that all European member states implement its rules accordingly.[189] At the time of the Directive's adoption, no other rules

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185. *See id.*

186. *See* Baggot, *supra* note 160.

187. Critics of the Directive, including Greenpeace, have labeled this Directive a "Biopiracy Directive." *See Bio-piracy Encouraged By EU biotechnology Patent Directive*, Genetic Engineering Press Releases, May 12, 1998 *available at* http://www.greenpeace.org/pressreleases/geneng/1998may12.html. One critic stated that biopiracy is the "unauthorized patenting of genetic resources taken form developing countries by mighty Western multinationals and institutions . . . ." Niccolo Sarno, *Biotechnology-Europe: Parliament Clears 'Biopiracy' Directive*, World News Inter Press Service, May 12, 1998 *available at* http://www.oneworld.org/ips2/may98/00_36_002.html. (statement made by Magda Aelvoet, co-president of the EP's Green group). Essentially, critics argue that the Directive will allow stealing of genetic resources in developing countries. *See id.* This could have many implications. *See id.* Specifically, it could force farmers, who once used freely available seeds, to pay royalties in the future if the genetic make-up of the seeds are changed and patented. *See id.*

188. *See* Dan Leskien, *The European Patent Directive on Biotechnology*, BIOTECH. DEV. MONITOR, No. 36, September/December. The European Parliament (EP) rejected the precursor of this Directive in March of 1995 because it did not exclude germ line therapies and only excluded human genes. *See id.* However, the new Directive differs only slightly from the 1995 rejected proposal. *See id.* The new Directive qualifies the treatment on any of the human body's elements to be patented, "even if the structure of that element is identical to that of a natural element." *Id.* Thus, the Directive requires that member states "grant patents for naturally-occurring genes isolated from the human genome, provided they have been properly characterized and are 'new' in the sense of having no previously recognized existence." *Id.* Despite taking a more liberal approach to biotechnology patenting, the Directive does exclude the following areas: (1) the human body and its elements; (2) processes from cloning human beings; (3) processes for modifying the genetic identity of human beings in the germ line; (4) the use of human embryos for industrial or commercial purposes; and (5) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to humans or animals, and also animals resulting from such processes. *See* European Directive on the Legal Protection of Biotechnological Inventions, May 1998 [hereinafter Directive].

189. *See* Leskien, *supra* note 188.

had established the scope of biotechnology patents.[190] The Directive explicitly set forth a broad scope for biotechnology patents involving: biological material,[191] biotechnological processes,[192] and products containing or consisting of genetic information.[193] The Directive also made a mark in European history by allowing an explicit legal right to plants and animals, while diverging from the EPO's interpretation of the EPC regarding Article 53 plant and animal varieties.[194] For example, under the Directive, the transgenic plant in *Plant Genetic Systems* would be patentable.[195] Upon the Directive's adoption, many of its rules were contrary to the more conservative view of biotechnology patents as seen in the EPC, yet it did not cause EPC member states to circumvent their obligations to the convention.[196]

On June 16, 1999, a decision from the Administrative Council of the *European Patent Organisation* amended the Implementing Regulations to the EPC, which reflected the initiative of the Directive.[197] For example, the decision added a Chapter entitled "Biotechnological Inventions" which included general definitions,[198] the scope of biotechnological inventions,[199]

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190. Neither the EPC nor patent laws within its member states specifically discuss the scope of biotechnology patents. *See id.*

191. *See* Directive, *supra* note 188, at Ch. II, Art. 8, § 1. Under the section entitled "Biological material," the Directive sets forth a broad scope for these kinds of inventions: "Patents on biological material possessing specific characteristics shall extend to any biological material derived from patented material, provided the patented material still possesses those same characteristics." *Id.*

192. *See id.* at Ch. II, Art. 8, § 2. The section entitled "Biotechnological Processes" states: "Likewise, patents on processes that enable a biological material to be produced possessing specific characteristics shall extend to all material directly and indirectly obtained through that process. Patent protection shall also cover all biological material directly derived from that material provided that the derived material possesses those same characteristics." *Id.*

193. *See id.* The section labeled "Products Containing or Consisting of Genetic Information" states: "Finally, patents on products containing or consisting of genetic information shall extend to all material (except human beings) in which the product is incorporated and in which the genetic information is contained and performs its function." *Id.*

194. *See id.*

195. *See id.*

196. *See* Leskien, *supra* note 188. Except in Cyprus, Liechtenstein, Monaco, and Switzerland, the EPC does not prevent its member nations from granting patents which are excluded under Article 53 of the EPC. *See id.*

197. *See Decision of the Administrative Council Amending the Implementing Regulations to the European Patent Convention*, Doc. OJ 7/1999 (June 16, 1999) [hereinafter *Decision*].

198. *See* EPC, *supra* note 145, at Ch. VI, Rule 23b. Rule 23b sets forth general definitions. *See id.* For example, "biotechnological inventions" are "inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used." *Id.* at (2). Plant variety means:any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be: (a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes, (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and (c) considered as a unit with regard to its suitability for being

clarifications of Article 53 exceptions,[200] and information on patenting the human body and its elements,[201] including genes. These additions to EPC reflect the initiative of the Directive and therefore demonstrate the reality of European patent law evolution.

5. *European Patent Reform on the Horizon*

The European Patent Law System continues to evolve. In fact, in late November 2000, a Diplomatic Conference took place with the overriding objective being the cautious modernization of the European Patent System through the EPC revisions.[202] One of the goals was to insure that the EPC remains parallel to technical and legal advancements that may occur in the

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propagated unchanged." *Id.* at (4). "'Microbiological process' means any process involving or performed upon or resulting in microbiological material." *Id.* at (6).

199. *See id.* at Rule 23c. Rule 23c, entitled "Patentable biotechnological inventions" states: Biotechnological inventions shall also be patentable if they concern:

1. biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;
2. plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;
3. a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

Id.

200. *See id.* at Rule 23d. Rule 23d, entitled "Exceptions to patentability" states: Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

1. processes for cloning human beings;
2. processes for modifying the germ line genetic identity of human beings;
3. use of human embryos for industrial or commercial purposes;
4. processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Id.

201. *See id.* at Rule 23e. Rule 23e, labeled "The human body and its elements," states:

1. The human body, at various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of the element is identical to that of a natural element.
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Id.

202. *See Diplomatic Conference to Revise the European Patent Convention*, Official Journal, Sept. 27, 2000, *available at* wysiwyg://78http://www.European-patent-office.org/news/pressrel/2000_09_27_e.htm.

future.[203] The desire to continually update the EPC is arguably a positive step for the biotechnology industry in Europe.

IV. ETHICAL CONCERNS V. ECONOMIC INCENTIVE

An analysis of biotechnology patent laws as they apply to disease research would be incomplete without noting related ethical issues in light of the incentives necessary to promote scientific innovation. It is important to begin by acknowledging that the ethical concerns surrounding this controversy extend far beyond the U.S. borders, while the majority of economic rewards for biotechnology advancements, secured by patents, are going to large research corporations here in the United States. The discussion below weighs major ethical issues against incentives for scientific advancement.

A. Ethical Concerns: Exploitation and Common Heritage

One of the major ethical concerns associated with gene patenting is the fear that third world individuals will be exploited by researchers who seek to patent their genes.[204] Patenting of genes from individuals of third world countries has cultural, moral, and social implications.[205] Because many third world countries are isolated from the rest of the world, individuals from these countries may be immune to diseases that plague individuals in developed countries.[206] This unique immunity makes these individuals' genes attractive to researchers.[207] Similarly, since researchers have now completed a draft of the human genome, interest in third world countries may intensify, as scientists seek to understand genetic diversity as it relates to disease.[208] Before the controversy over patenting third world genes can be discussed, the perspective these countries have on the HGP must be considered.

With the draft of the human genome now complete, the question arises as to whether this project was an affirmative universal decision. Because geneticists estimate that any two people are ninety-nine percent similar genetically, the draft, for all practical purposes, represents the genetic makeup of all humans.[209] With the United States contributing over three billion dollars to the effort,[210] and other developed countries substantially contributing big

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203. *See id.*

204. *See generally* Debra Harry, *Indigenous People Should Control Research That Could Affect Them*, ST. LOUIS POST, Sept. 24, 2000, at F3, *available at* LEXIS, St. Louis Post-Dispatch File.

205. *See id.*

206. *See* Sturges, *supra* note 49, at 244.

207. *See id.*

208. *See* Harry, *supra* note 204.

209. See Macer, *supra* note 3.

210. *See id.*

money, it seems that third world countries have little voice at all. Thus, those countries that did not wish to have the genome identified for conflicting religious, philosophical, or cultural reasons, never had the chance to "opt out" of the research. While this ethical stop sign may be countered by the proposition that the HGP may someday provide the medical aid these third world countries need, ethical questions surrounding related gene patenting must be considered.

Individuals in countries which are less developed than the United States and many of the European countries often have views on gene patenting that differ from developed countries.[211] Individuals from less developed countries often believe that intellectual property should belong to the public as a whole rather than to the private sector.[212] Moreover, they feel that gene patenting is interrupting nature and reducing life to a commodity.[213] Researchers justify their actions by pointing out that the individuals give consent and are compensated with royalties for their cell line donations.[214] However, this must be considered in light of third world poverty and the standard of education in these countries. One might expect individuals in third world countries to forego their cultural and moral beliefs if they do not have the educational foundation to comprehend what they are giving up. Moreover, even if these individuals understand that which they are giving the researchers, they may be so plagued by poverty that they will choose the royalties despite their belief system.

In addition to cultural and moral concerns, there may also be social implications to consider. As scientists seek out genes from individuals from third world countries to study diversity as it relates to disease,[215] several fears arise. For instance, Jonathan King, a professor at MIT and member of the board of Council for Responsible Genetics states,

> [w]e are concerned that the emphasis on gene sequences will be used to imply that genes are at the basis of a variety of human disease and conditions, when in fact the great body of evidence establishes that the majority of human ill health is not inherited but is due to external insult including pollution, infection, inadequate or inappropriate diet, physical accident, excess stress or social disruption such as wars. Preventing damage to human genes from carcinogens is a far more effective public health strategy than allowing the disease to develop and then attempting gene therapy.[216]

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211. *See* Sturges, *supra* note 49, at 244.
212. See *id.*
213. See *id.*
214. *See id.*
215. *See* Harry, *supra* note 204.
216. *Id.*

The Indigenous Peoples Council on Biocolonialism[217] has developed a model ordinance to assist tribal governments on these types of matters.[218]

Within this concern of exploitation of indigenous people lies an important topic also to be addressed, the Common Heritage Principal.[219] This ethical concern and the fear of exploitation of indigenous people are issues that should be considered before patent law is reformed.

One of the disputes over gene patenting arises from the question of how genetic property interests should be distributed.[220] Presently, the private sector in wealthy countries maintains control over much genetic material. Many argue that this is not appropriate because genetic material, in the case of the human genome, belongs to all of us through our ancestry.[221] Accordingly, the genome should be accessible to everyone under the international theory of the Common Heritage Principal.[222] If the Common Heritage Principal were applied to gene patenting, public consent would be mandatory before patents could be obtained.[223] It is important that all of the ethical concerns over gene patenting be weighed against the need for innovation and the corresponding necessary economic incentive.

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217. The Indigenous Peoples Council on Biocolonialism recently drafted an Act that is "intended to foster cooperation and set the stage for research that the Tribe sees as beneficial." *Indigenous Research Protection Act,* Indigenous Peoples Council on Biocolonialism, Sept. 30, 2000 *available at* http://www.ipcb.org/pub/irpaintro.html. The Act, entitled "Indigenous Research Protection Act," is a suggested format for legislation for Tribal countries that have yet to pass such an Act. *See id.* The Act provides that tribes may ban research altogether or regulate it on their own terms. *See id.* The Act sets forth its own purposes:

1. protect the people, culture and natural resources of the Tribe and the Tribe's future generations from unauthorized scientific research; and
2. to reduce the adverse effects of research and related activities on the Tribal community; and
3. to ensure that researchers recognize Tribal control of research activities and that the Tribe owns all data and information generated or produced by such research; and
4. to establish and provide a statutory basis for a process to review and govern any research, collection, database, or publication undertaken on the Reservation.

Indigenous Research Protection Act §2.1 (a-d).

218. *See* Harry, *supra* note 204.

219. "The Common Heritage of Mankind principle is an international legal concept which conveys equal property interests to all people." Sturges, *supra* note 49, at 245.

220. *See generally* Sturges, *supra* note 49 (applying the Common Heritage Principal to intellectual property rights).

221. *See id.* at 249.

222. *See id.*

223. *See id.* at 250.

B. *Incentive & Innovation*

Due to the efforts of the HGP, there seems to be increasing hope that this newly acquired knowledge will be applied positively to the field of medicine. However, the scientists who are attempting to find useful purposes for the HGP knowledge spend large amounts of time and money and therefore seek patents to protect their investment.[224] Because great medical benefits could arise through this research, and the known way to secure this research is via patents, one might argue that it is unethical to prohibit gene patents. Moreover, it seems fundamentally unfair to deprive hard-working researchers, who have the means to promote public health, from the possibility of receiving profits for their efforts.

While most would agree that scientific innovation should be promoted, the controversy on certain gene patents continues. The reward theory, an economic patent theory, proposes that without reward, inventors would have no incentive to invent.[225] Along the same line, if inventors do not have the benefit of patent protection, competition could cause prices to decrease, leaving little profit to the original inventor who invested time and money.[226] Such a discouraging market could ultimately decrease innovation since investors would no longer wish to expend energy to reach a low-profit outcome. This could be detrimental to biotechnology research.

V. BIOTECHNOLOGY PATENT LAWS AND DISEASE RESEARCH: BROAD PATENTS

As patent laws continue to evolve in the United States and Europe, becoming increasingly pro-patent, it is important to reflect upon the trends in the law and analyze their impact on disease research. One product of

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224. In the past, scientists have spent approximately seven billion dollars on research and development in the biotechnology industry. *See* Wright, *supra* note 74.

225. *See* Erramouspe, *supra* note 74, at 973. The author also discusses another economic patent theory known as rent dissipation theory. In discussing the rent dissipation process, the author argues:

> [s]ome patents will confer rewards that exceed the inventor's development costs. Where these excessive rewards are expected, inventors will often compete with each other to be the first and only inventor to win the patent. These competitions can be socially unproductive because they often duplicate inventive activity and divert resources into the inventive sphere even though society would be better served were these resources used elsewhere. At a limit, the total net social benefit derived from an invention can be depleted entirely in a race to develop the invention quickly, perhaps too quickly.

Id. at 976.

226. *See id.* at 973.

evolving patent laws is a broad patent.[227] This growing movement toward patent offices granting broad patents on biotechnology inventions is of great concern.[228] A broad patent is a patent that covers a wide scope of innovation, rather than just a sole invention.[229] Broad patents are often the goal of commercially-motivated companies since they can result in huge royalties from competing companies who seek licenses to use the patented inventions.[230] Many argue that this movement towards broad patents is having a detrimental effect on disease research.[231]

Broad patents can have negative consequences.[232] Because these patents are wide in scope, "stacking" of patent claims often occurs when multiple aspects of a biotechnology product are broadly patented.[233] This stacking means that researchers who do not hold the patent but who wish to use the information for further research must obtain corresponding "stacked" patent licenses.[234] Each of these licenses can cost huge dollars, often too much money for small corporations to afford.[235] The result for those who cannot afford the high costs means not entering this realm of research, simply hampering innovation.[236] For those who can afford the high costs, their dollars are spent on these expensive licenses or perhaps on legal counsel if they infringe upon the broad patent claims. Thus, in light of the changes in U.S. and European patent law, the ethical considerations of biotechnology patents, the necessity for incentive, and the desire for innovation, suggestions for legal reform can be discussed.

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227. *See* Jeroen van Wijk, *Broad Biotechnology Patents Hamper Innovation*, BIOTECH. & DEV. MONITOR, No. 25, 1995, *available at* http://www.gene.ch/www.pscw.uva.nl/monitor/2506.htm.

228. *See id.*

229. *See id.*

230. *See id.* "Deoxyribonucleic acid (DNA) for new genes, expression promoters, and enhancers, DNA probes, hybridomas, antibodies, plasmids, vectors, cell lines with high expression of certain genes or that display particular receptors, transgenic animals . . . are all examples of physical property which can be licensed." PETERSON, *supra* note 63, at 30.

231. *See* Wijk, *supra* note 227.

232. *See id.* The author also points out that not all broad patents are damaging. *See id.* For example, research carried out with a non-commercial objective, such as university or non-profit research projects, can receive a broad patent without hampering innovation. *See id.* However, those commercial corporations will use litigation to protect their broad patents, which can be expensive and draining on research. *See id.* The advantage cited for broad patents is that of high incentive, since broad patents can be a goldmine of royalties. *See id.*

233. *See* John Murray, *Owning Genes: Disputes Involving DNA Sequence Patents*, 75 CHI.-KENT. L. REV. 231, 254 (1999).

234. *See id.*

235. *See* Wijk, *supra* note 227.

236. *See id.*

VI. PROPOSAL FOR LEGAL REFORM: ACKNOWLEDGING ETHICAL CONCERNS, ENHANCING INCENTIVE, AND PROMOTING INNOVATION

Biotechnology patent law reform is difficult because it should involve a careful balancing of competing interests, including ethical concerns worldwide, research economic incentive, and public need for innovation in the arena of disease research. In an effort to address competing interests and with the fear that existing protocol within patent law in both the United States and Europe will hamper disease research, legal suggestions for reform can be presented:

Ethical Concerns: While Europe has already expressed its consideration of ethical issues by creating and maintaining Article 53 of the EPC, the United States does not seem to have a comparable legal safeguard.[237] While the United States may support organizations like the Indigenous Peoples Council on Biocolonialism, it does not have statutory safeguards that represent the portion of our nation who disagree with biotechnology patenting altogether. Thus, the legislature should enact a statutory ethical safeguard similar to Article 53(a) of the EPC so the patent and judicial system must appropriately consider and possibly adhere to public policy concerns before granting a controversial patent.

Economic Incentive: Although broad patents provide great economic incentive for companies, this must be considered alongside their alleged negative effect upon disease research. To resolve the dilemma between the simultaneous need for incentive and disease research, patent offices could replace broad patents with cross-licensing agreements.[238] For example, if a company had a specific patent on a gene or sequence, then that company would receive a portion of the profits when the specific gene or sequence they discovered was used in a mass-market drug.[239] This is a feasible alternative because future drugs are likely to work because they influence the behavior of many genes.[240] Cross-licensing agreements would still make profits attainable, and thus incentive high, while also allowing crucial information to be shared in order to promote disease research.

Promoting Innovation: In order to promote innovation, patent offices should develop a more sophisticated provisional patent application process.

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237. Differing from Europe, the United States generally promotes the commercialization of human elements (cells, tissues, genes). *See* Macer, *supra* note 3.

238. *See Gene Patent Reform Vital; The Patent Office's Current Approach Threatens to Impede Research. Gene Discoveries Must Be Shared For the Sake of Society*, L. A. TIMES, at 7, *available in* LEXIS, Los Angeles Times File. The suggestion is made by a legal scholar from the University of Michigan, Rebecca Eisenberg. *See id.* The article discusses the trend toward broad patents, expressing a fear that commercially-motivated companies will hide gene sequences like trade secrets, severely impeding disease research. *See id.*

239. *See id.*

240. *See id.*

Presently, provisional applications allow inventors to secure up to a year of provisional patent protection if they are unsure of the invention's marketability.[241] After that year expires, inventors can secure a twenty-year patent term if they so desire. A reform of this system, by providing more kinds of provisional patents, each varying in the number of years of protection proportionate to the invention's anticipated level of utility and likelihood of development or marketability, could help promote innovation.

For example, imagine a small company seeking a provisional patent on a particular biotechnology invention whose further development is uncertain, while it is projected to be of high utility. Because of the high costs of traditional twenty-year patents, a company may wish to seek a provisional patent application,[242] yet at the same time fear that the one-year provisional application period may not provide the time needed to decide if a twenty-year patent is warranted. At the end of the one-year, the company may prematurely enter into the twenty-year patent,[243] possibly contributing to patent "stacking" despite the invention's uncertainty.[244] With a reformed provisional patent system, UPSTO or EPO could establish a system objectively measuring predictable utility, then measure the inventions possible utility and assign an according specific term of years for this provisional patent. This would ultimately give uncertain companies the time they need to explore all avenues before prematurely seeking a twenty-year patent that could exclude others from the invention for a long period of time. Ultimately, this could decrease the number of twenty-year patents being granted to uncertain inventions, and hopefully decrease the monopolization of biotechnology so that innovation can be maximized.

VII. CONCLUSION

Disease research provides hope of escape from threatening illnesses for future generations and ourselves. Thus, biotechnology patent laws should be reformed to parallel the importance of this research. While many argue that cures for cancer, AIDS, and other life-threatening diseases are years away, worldwide patent law systems should take appropriate steps to make sure that time is sooner rather than later. This means finding the best way to provide all researchers with the incentive to explore and discover, while promoting innovation worldwide. This is difficult to juggle, particularly when competing legitimate ethical concerns must be considered to prevent exploitation of indigenous people.

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241. *See FAQ, supra* note 129.

242. *See* Wright, *supra* note 74.

243. *See Patent Term, supra* note 125. (noting the uncertainty inventors often have when seeking a patent or provisional patent application).

244. *See* Murray, *supra* note 233, at 254.

Legal patent reform is necessary to insure that disease research is maximized. Both the United States and Europe have recognized this need and are presently seeking a resolution. However, this resolution may be short-lived as technology advances quickly. Ultimately, in this constantly evolving process of attempting to establish a mirror between patent laws and technology, we must unite internationally to promote innovation, yet recognize the importance of all of our cultural, social, and religious value systems at the same time.

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