First-to-File: Promoting the Goals of the United States Patent System as Demonstrated Through the Biotechnology Industry

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The patent system added the fuel of interest to the fire of genius.
—Abraham Lincoln

THE UNITED STATES PATENT system provides inventors with an incentive to publicly disclose their inventions in order to effectively promote the innovation of new technology. The system was designed to address the tension that, although innovation is best promoted by bringing inventions into the public arena early to allow others to use and expand on the new idea, inventors will not be motivated to disclose their inventions to the public unless they receive a benefit for doing so.[1] The United States patent system provides a benefit by granting the inventor a period of market exclusivity for the invention.[2] Thus, the patent system promotes innovation by requiring public disclosure while compensating the inventor with certainty of protection against unauthorized use of the invention.

The current United States patent system does a fair job of encouraging innovation, but room for improvement still exists—specifically in the present manner of determining inventorship priority. The United States relies on a first-to-invent priority system, in which a patent is awarded to the party to show conception of an idea coupled

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1. Stephen G. Kunin et al., *Reach-Through Claims in the Age of Biotechnology*, 51 AM. U. L. REV. 609, 615–16 (2002) ("The Founding Fathers of this nation felt strongly that rewarding innovation in exchange for public disclosures would make the country prosper.").

2. *See* 35 U.S.C. § 154(a)(1) (2000) (granting the patentee the right to exclude others from "making, using, offering for sale, or selling the invention").

with reduction to practice of that idea before another.[3] This system does not adequately promote early public disclosure and certainty of protection and has proven particularly burdensome for the biotechnology industry, where scientists often work toward similar research goals.[4]

For example, many companies and institutions are currently working diligently to discover a cure for diabetes.[5] Imagine that, within a three month period, two separate institutions independently discover a critical step in the islet cell transplantation process,[6] making the procedure ninety percent effective in treating patients with Type One diabetes. Company *A* ("*A*") makes the discovery first, but delays in filing the patent application.[7] Company *B* ("*B*") makes the same discovery three months after *A* and immediately files in the United States and abroad for a patent on the process. *B* begins the rigorous process of prosecuting the patent, spending approximately $10,000 upfront in preparation for prosecution.[8] Upon learning that

3. 35 U.S.C. § 102(g)(1) (2000).

4. DAVID B. RESNIK, OWNING THE GENOME: A MORAL ANALYSIS OF DNA PATENTING 1 (2004). The National Institute of Health filed patents on thousands of gene fragments in 1994 attempting to undercut efforts by private parties to patent those sequences. *Id.*

5. The research institutions include: The Islet Foundation, Joslin Diabetes Center, and the Diabetes Institutes Foundation, among others. *See, e.g.*, The Islet Foundation, http://www.islet.org (last visited Feb. 18, 2007); Joslin Diabetes Center, http://joslin.org/Research_Index_1186.asp (last visited Feb. 18, 2007); Diabetes Institutes Foundation, http://www.dif.org/research/ (last visited Feb. 18, 2007).

6. "Islets are clusters of cells in the pancreas that make insulin." American Diabetes Association, Islet Transplantation, http://www.diabetes.org/type-1-diabetes/islet-transplants.jsp (last visited Feb. 18, 2007). The islet cells of a Type One diabetic no longer produce insulin, requiring the patient to take multiple insulin injections each day to process sugar. American Diabetes Association, Type One Diabetes, http://www.diabetes.org/type-1-diabetes.jsp (last visited Feb. 18, 2007). The islet transplantation process takes islet cells from a donor pancreas and implants the cells into a diabetic pancreas. American Diabetes Association, Islet Transplantation, *supra*. A successful implant allows the pancreas to make insulin using the new islet cells. *Id.*

7. An applicant may delay in filing an application in order to refine an invention, to determine the commercial viability of an invention, or just by spending time in preparation for filing. Under 35 U.S.C. § 102(b), an applicant has a grace period in which an invention may be in "public use or on sale" for up to one year before the applicant is barred from filing for a patent. *See* 35 U.S.C. § 102(b); *see also infra* note 8.

8. *See* Benjamin Hershkowitz, *Maximizing Your Patent Prosecution Dollars*, 4 L.J. NEWSLS. PAT. STRATEGY & MGMT. 1, Chart A (2003) *available at* http://www.kenyon.com/files/tbl_s47Details/FileUpload265/62/Dollars.pdf. The primary costs associated with obtaining a patent are the legal fees for preparing an application and filing it with the USPTO. *Id.* at 1. A company will also want to do a prior art search before filing to ensure that the invention is not anticipated by another patent or publication. *See* 35 U.S.C. § 102 (setting out the boundaries of prior art, including: knowledge or use of the invention in the United States before the date of invention, a patent on the invention or description of the invention in literature anywhere in the world, public use or sale of the invention in the

no known prior art exists to impede the issuance of the patent, *B* solicits its investor support for the development, approval, and implementation of the process. In the meantime, *A* files its own patent application for the same process. The examiner at the United States Patent and Trademark Office ("USPTO") rejects *A*'s application as anticipated by *B*'s. *A* then initiates an interference proceeding against *B*, asserting priority of inventorship.

Under the current first-to-invent patent system in the United States, if *A* could demonstrate that it created the identical cell transplantation process three months before *B*, *A* would gain priority as the first inventor, effectively making *B*'s discovery and timely public disclosure worthless.[9] It will be difficult for *B* to find investors to contribute to the development of a product with no economic value in the United States. While both companies made the same discovery independently of each other within a short period of time, *A* will reap the benefits of the invention in the United States because of prior discovery, despite the fact that *B* brought the information to the public earlier. This result runs counter to the goal of promoting progress through early public disclosure.

In June 2005, Congressperson Lamar Smith addressed these concerns with the introduction the Patent Reform Act of 2005 ("Patent Reform Act").[10] Smith introduced the Patent Reform Act as a means

United States for more than a year before the filing of the application in the United States, abandonment of the invention, the existence of a patent on the invention by the applicant in another country more than twelve months before the filing of the application in the United States, a failure of claimed inventor to actually invent the subject matter claimed in the application, or invention by another party before the applicant). A prior art search can cost up to $1000. *See* Bay Area Intellectual Property Group, http://www.bayareaip.com/Search_flat/Search_flat.htm (last visited Feb. 18, 2007); STO's Prior Art Search Services, http://www.bustpatents.com/prior.htm (last visited Feb. 18, 2007).

9. As all other countries operate under a first-to-file system, *B* would still have the patent on the cell transplantation process in other countries. Gerald J. Mossinghoff, *The U.S. First-To-Invent System Has Provided No Advantage To Small Entities*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 425, 425 n.1 (2002). This would result in *B*'s invention having no value in the United States, and *A* being unable to protect the patented cell transplantation system abroad. *See* Roland H. Schwillinski & Benjamin Hershkowitz, *Are Major Changes in Store for the U.S. Patent System?*, IP ADVISOR 1 (Oct. 2005), *available at* http://www.goodwinprocter.com/Publications.aspx (follow "Find a Publication" hyperlink, then search by date and publication type). The United States is currently the only country operating under a first-to-invent patent system. *Id.*

10. Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005). Co-sponsors include: Rep. Lamar Smith (TX-21), Rep. Howard Berman (CA-28), Rep. Rick Boucher (VA-9), Rep. Chris Cannon (UT-3), Rep. John Carter (TX-31), Rep. Howard Coble (NC-6), Rep. John Conyers, Jr. (MI-14), Rep. Bob Goodlatte (VA-6), Rep. Darrell Issa (CA-49), Rep. Zoe Lofgren (CA-16), Rep. Michael McCaul (TX-10), and Rep Adam Schiff (CA-29). THOMAS, H.R. 2795 Cosponsors, http://thomas.loc.gov/cgi-bin/bdquery/z?d109:HR

to "eliminate legal gamesmanship from the current system that rewards lawsuit abuses over creativity . . . [and] enhance the quality of patents and increase public confidence in their legal integrity."[11] The sponsors of the Patent Reform Act sought to address three concerns: the decrease in patent quality, the increase in litigation abuses, and the desire to further harmonize the United States patent laws with the patent laws of other countries.[12] The Patent Reform Act would make various reforms to the current United States patent system, including a shift from the current first-to-invent system to the more practical first-to-file system of patent priority.[13]

This Comment supports the proposal that the United States move to a first-to-file inventorship system, awarding a patent to the first party to file for a patent on the invention. Under a first-to-file system, inventors claiming the right to a patent in the United States would no longer need to undergo difficult and costly proceedings to determine who invented first. If adopted, the United States inventorship system would support the constitutional goal of the patent system—the promotion of progress through innovation—by awarding priority of inventorship to the first party to file a patent application for the invention, bringing the invention to the public earlier.[14]

This Comment will illustrate that moving to a first-to-file system of priority would greatly benefit the biotechnology industry and the United States patent system. A first-to-file system would promote the innovative goals of the patent system by encouraging early public disclosure and providing greater certainty of protection. Through the lens of the biotechnology industry, this Comment will show that the technological future of innovation hinges upon the benefits afforded

2795:@@@P; Bay Area Intellectual Property Group, http://www.bayareaip.com/Search_flat/Search_flat.htm (last visited Feb. 18, 2007).

11. *Amendment in the Nature of a Substitute to H.R. 2795, the "Patent Act of 2005": Hearing Before the Subcomm. on Cts., the Internet, and Intell. Prop. of the H. Comm. on the Judiciary*, 109th Cong. 1 (2005) (statement of Senator Lamar Smith), *available at* http://judiciary.house.gov/media/pdfs/printers/109th/21655.pdf.

12. *Id.* at 3 (statement of Senator Howard Berman).

13. These reforms include: changing the patent priority system from a first-to-invent to a first-to-file system, eliminating the best mode requirement, imposing a duty of candor and good faith on all persons involved in patent proceedings, limiting damages for infringement, limiting a patentee's ability to get an injunction, requiring increased regulation of continuation applications, instituting a post-grant opposition procedure, imposing an eighteen-month publication requirement that applicants cannot opt out of, and allowing third parties to submit prior art. Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005); *see also* Public Knowledge, H.R. 2795: The Patent Reform Act of 2005, http://www.publicknowledge.org/issues/hr2795.

14. *See* H.R. 2795 § 3; Schwillinski & Hershkowitz, *supra* note 9.

by the first-to-file system. It will dispel the concerns associated with the first-to-file system of priority and demonstrate that the purposes of early public disclosure and certainty are not effectuated through the current first-to-invent system.

Part I provides an overview of the biotechnology industry and the United States patent system, arguing that the first-to-file system will be more beneficial to this emerging and innovative field. Part II discusses the advantages a first-to-file system would provide for the United States patent system as a whole, identifying the promotion of early public disclosure and certainty and dispelling concerns about the first-to-file system. Part III concludes that the current system of priority provides inadequate patent protection for both the emerging field of biotechnology and all other patentable subject matter.

I. Biotechnology and the United States Patent System: The Emerging Fields of Innovation Are Incompatible with the First-to-Invent System of Issuing Patents

Intellectual property protection encompasses rights relating to literary, artistic, and scientific works, inventions, and designs.[15] The intellectual property doctrine, developed by philosophers and legal scholars in the seventeenth and eighteenth centuries, provides the foundation for these rights.[16] Under the doctrine, an inventor or author is entitled to the property rights of his intellectual creation.[17] The intellectual property doctrine influenced the founders of this country when they drafted Article One of the United States Constitution to provide the basis for the United States patent system.[18] The clause, which states, "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries,"[19] seeks to balance the public good served by early disclosure of scientific and artistic progression with the need to reward the innovator as an incentive for disclosing creations.[20]

Because an inventor must fully disclose an invention in order to obtain patent protection, the inventor may lose a competitive advan-

15. Peter A. Jackman, *Adoption of a First-to-File Patent System: A Proposal*, 26 U. BALT. L. REV. 67, 69 (1997).
16. *Id.*
17. *Id.*
18. U.S. CONST. art. I, § 8, cl. 8.
19. *Id.*
20. Kunin, *supra* note 1, at 616.

tage as a result of the disclosure.[21] Thus, the patent system provides the inventor with an incentive to disclose in the form of exclusivity. A patent grants the holder "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States."[22] In exchange, the government requires that the inventor provide a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same . . . ."[23] This exchange of exclusivity for disclosure is based on the belief that the public knowledge resulting from the disclosure of the invention will lead to future progress and innovation.

As one of the "fastest growing industrial sectors in the United States," the biotechnology industry relies heavily on strong patent protection for both investor support and sustainability.[24] The most valuable assets a biotechnology company holds are the ideas that turn into products; potential investors want to see forward-thinking product ideas that will evolve into profitable products.[25] Because biotechnology companies are built upon a foundation of ideas, the companies must protect their intellectual property as diligently as possible.[26] As patents provide the strongest form of intellectual property protec-

21. For some inventions, it may be more advantageous from a business perspective to not disclose an invention to the world. *See* IVER P. COOPER, BIOTECHNOLOGY AND THE PATENT SYSTEM § 1:7 (Thomson/West 2006) (1998). An inventor may choose to keep her invention a secret and receive protection under a state's trade secret laws. *See, e.g.*, CAL. CIV. CODE §§ 3426.1, 3426.2 (West 1997). The downside of opting for trade secret protection is that the protection lasts only as long as the invention remains a secret, and does not protect an inventor from others who independently create the same thing or reverse engineer the invention. COOPER, *supra*, § 1:7.

22. 35 U.S.C. § 154(a) (2000). The term of exclusivity provided by the patent grant is twenty years. *Id.* This limited monopoly allows the inventor to retain the sole rights to the invention and the financial gains associated with those rights for the term of the patent—a necessary tradeoff to promote innovation.

23. 35 U.S.C. § 112 (2000).

24. Christopher M. Holman, *Biotechnology's Prescription for Patent Reform*, 5 J. MARSHALL REV. INTELL. PROP. L. 318 (2006) (arguing against many of the reforms proposed by the Patent Reform Act); Kunin, *supra* note 1, at 615.

25. Kunin, *supra* note 1, at 615 ("In order to raise the necessary funds, companies need to be as forward thinking as possible during the research and development phase.").

26. *Id.* ("[C]ompanies need to leverage technological innovation to garner sustaining investments.").

tion,[27] biotechnology companies rely on the strength of their patents to attract investors and recoup investments.[28]

The nature of biotechnology innovation is such that it requires a significant investment of time and money with little guarantee that an invention will produce a capital return.[29] If and when an invention does produce useful results, the window of time for remaining patent protection is very small.[30] Thus, it is essential that companies producing viable inventions receive substantial protection from use of those inventions by others. Strong protection allows the inventing company to earn back the time and resources it invested in developing the innovation. The first-to-file priority system adds an element of certainty to a patent by eliminating the possibility of future invalidation, while maintaining the goals of the patent system by encouraging early disclosure.

A. The Biotechnology Industry

Biotechnology involves the use of biological processes to produce valuable medical and industrial materials.[31] The first instances of biotechnology occurred when humans learned to breed plants and animals with desirable characteristics to produce better crops and livestock.[32] Increased understanding of Mendelian genetics and the role of genetic mutation led to breakthroughs in the use of genetic engineering.[33]

Genetic engineering often involves the use of biological tools, such as a phage[34] or a plasmid,[35] to introduce foreign DNA into host

27. *Id.* at 610.

28. "Without patents . . . there would be no biotech industry and no innovative drug development." *Id.* at 610 n.4 (citing Charles Craig, *Current Public Policy Challenges*, CONVERGENCE, THE BIOTECHNOLOGY INDUSTRY REPORT, 2000, at 65).

29. The cost of bringing a new drug to market is approximately $500 million. John K. Borchardt, *The Business of Pharmacogenomics*, 4 MOD. DRUG DISCOVERY 35 (July 2001). The probability of an idea turning into a new drug, however, is very slim. *See* Kunin, *supra* note 1, at 614 ("For example, in the pharmaceutical industry, for every 5,000 to 10,000 compounds screened there are about 250 lead candidates in pre-clinical testing, and of these, only one is likely to become a Food and Drug Administration ["FDA"] approved drug.").

30. "It may take as long as thirteen years from initial screening to FDA approval, thereby hindering any quick return on investment." Kunin, *supra* note 1, at 614. Because a patent term is for twenty years from the date of filing, a company may have as little as seven years of protection after FDA approval. *See* 35 U.S.C. § 154(a)(2) (2000).

31. BLACK'S LAW DICTIONARY 179 (8th ed. 2004).

32. *See* COOPER, *supra* note 21, § 1:1.

33. *Id.*

34. A phage is a type of virus that specifically infects bacteria. A temperate phage is useful in genetic engineering because it will not always kill its host. Instead, the genetic

cells.[36] The introduction of the foreign DNA guarantees that, under the right circumstances, the host cells will cause the foreign DNA to replicate, allowing for the expression of that DNA.[37] The genetically-engineered organism then becomes unique, expressing characteristics that would not exist in the organism without the engineering.[38]

Although many public-policy debates have arisen concerning genetic engineering—some critics fear the creation of new pathogens, while others express concern over the application of genetic-engineering techniques to humans[39]—the benefits of the research significantly outweigh the potential harms.[40] One example of the benefit provided by life-altering innovation in the biotechnology industry is the conversion of bacteria into a metabolic factory to make human insulin.[41] This was the first product Genetech created as an emerging biotechnology firm in the early 1980s.[42] Genetech licensed the technology to Eli Lilly and Company for manufacturing, revolutionizing the treatment of diabetes, and making the use of the less effective animal insulin obsolete.[43]

material of the temperate phage will become integrated into the host's genome. This allows for the creation of organisms with the desired characteristics. *Id.* § 1:3.

35. A plasmid is a small genetic component existing outside of a chromosome. Plasmids often carry genes that control the production of toxins, antibiotic resistance, or unusual metabolic ability. Conjugative plasmids are useful in genetic engineering because they can transfer DNA by conjugation. Thus, plasmids with desirable characteristics can insert those characteristics into select organisms. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.* § 1:7.

40. *Id.* Some concerns associated with the use of genetic technology include: the existence of new allergens in food resulting from transgenic crops, the production of new toxins by genetically engineered organisms, and the imposition of environmental harms associated with the possible transfer of introduced genes between plants. *See* Union of Concerned Scientists, Risks of Genetic Engineering, http://www.ucsusa.org/food_and_environment/genetic_engineering/risks-of-genetic-engineering.html (last visited Feb. 18, 2007). Some of the beneficial results of genetic technology include: the production of environmental clean-up products that use pollution-eating microbes to clean up hazardous waste more effectively than chemical pesticides; the use of DNA finger printing in criminal investigations, forensic medicine, anthropology, and wildlife management; and a reduced reliance on chemical pesticides. *See* Biotechnology Industry Organization, Biotechnology Industry Facts, http://www.bio.org/speeches/pubs/er/statistics.asp?p=yes (last visited Feb. 18, 2007).

41. *See* U.S. Patent No. 4,421,685 (filed May 11, 1981) (issued Dec. 20, 1983).

42. Robert L. McCown & George L. Coffman, *Development of Biotechnology Curriculum for the Biomanufacturing Industry*, 22 PHARMACEUTICAL ENGINEERING 1 (2002), *available at* http://www.ispe.org/galleries/campusconnection-files/02MJ-Coffman.pdf.

43. *Id.*

Breakthrough research in the field of biotechnology comes at substantial financial cost; the industry spends tens of billions of dollars on research and development each year.[44] The innovation resulting from this research is often considered a significant contribution to the field, providing a product or process that can be widely used throughout the industry.[45] The industry has developed and marketed more than 350 medicines used to treat or cure hundreds of millions of patients.[46] In 2002 alone, the USPTO granted 7763 patents to the biotechnology industry.[47] In addition, the biotechnology sector filed over 40,000 new biotechnology patent applications in the 2003 fiscal year.[48] Because the cost of biotechnology innovation is so high, the need for adequate and efficient patent protection is essential to encourage investment in life-changing research.

In 1980, the biotechnology industry experienced a breakthrough in patent protection for genetically-engineered inventions. In a landmark decision, *Diamond v. Chakrabarty*,[49] the Supreme Court allowed for the patenting of living things.[50] Chakrabarty genetically modified a strain of bacteria to efficiently break down oil, useful in remedying the harmful effects of an oil spill.[51] The patent office denied the application, stating that the bacteria fell under the "product

44. *See* Biotechnology Industry Organization, Biotechnology Industry Facts, *supra* note 40. The biotechnology industry is one of the most research-intensive industries in the world, spending $17.9 billion on research and development in 2003. *Id.*

45. It is not uncommon for licensing agreements to exist between companies in the same industry to allow for easier use of advanced technology. *See* HERBERT HOVENKAMP, MARK D. JANIS & MARK A. LEMLEY, IP AND ANTITRUST § 34.2a (2006).

46. A. Scott Whitaker, Biotechnology Industry Organization Letter on Patent Reform (May 12, 2005), http://www.bio.org/ip/action/20050513.pdf. For example, nine million children that would have died in 1974 from vaccine-preventable diseases do not die today due to the increased number and availability of vaccines. *See* Robert Bazell et al., 21stC Biotechnology Forum, *Biotechnology in 2018: How will genetic science and technology change the world?*, http://www.columbia.edu/cu/21stC/issue-3.3/forum_all.html (last visited Nov. 15, 2006).

47. Biotechnology Industry Organization, Biotechnology Industry Facts, *supra* note 40. The USPTO issued 167,334 foreign and United States patents in 2002. U.S. Patent and Trademark Office, Calendar Year 2002 Patent Counts by Patent Type and by State and Country of Origin, http://www.uspto.gov/go/taf/st_co_02.htm.

48. *Amendment in the Nature of a Substitute to H.R. 2795 the "Patent Act of 2005": Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 109th Cong. 27 (Sept. 15, 2005) (statement of Robert B. Chess, Executive Chairman, Necktar Therapeutics, Testifying on Behalf of the Biotechnology Industry Organization), *available at* http://judiciary.house.gov/media/pdfs/printers/109th/23434.pdf [hereinafter Chess, *Hearing*].

49. 447 U.S. 303 (1980).

50. *Id.* at 310.

51. *Id.* at 305.

of nature" exception to patentability.[52] The Supreme Court reversed, declaring that a "manufacture" under 35 U.S.C. § 101 includes "anything under the sun that is made by man," including a microorganism.[53] Since *Chakrabarty*, living-organism patentability has been extended from single-celled organisms to multicellular organisms.[54] In fact, the only living organism that appears beyond the reach of a patent is a human being.[55]

Chakrabarty marked the beginning of the biotechnology patent boom.[56] In the ensuing years, biotechnology has changed rapidly as an industry, exhibiting tremendous innovative potential.[57] Biotechnology inventions require a significant amount of time and expense upfront,[58] and most companies do not have the unlimited resources necessary to continuously develop new inventions without the security of a return. The exclusivity offered by a patent helps compensate the patent holder for the time and effort invested in the inventing process.[59] Without exclusive rights, non-inventors could freely make, use, and sell the invention at a significantly lower price than the inventor.[60] While the inventor must price the item or license the invention to cover the costs of research and development as well as the costs of manufacture, the non-inventor must only cover the costs of manufacture.[61] Without exclusivity, inventors and companies would be in the

52. *Id.* at 306. A product of nature is not patentable subject matter under 35 U.S.C. § 101 because it does not constitute a machine, composition of matter, or manufacture. 35 U.S.C. § 101 (2000). DONALD S. CHISUM, CHISUM ON PATENTS § 1:1.02[7] (Matthew Bender & Co. 2006) (1998).

53. *Chakrabarty*, 447 U.S. at 309.

54. Transgenic Non-Human Mammals, U.S. Patent No. 4,736,866 (filed June 22, 1984) (patent granted for a genetically-altered mouse).

55. In December 1997, Dr. Stuart Newman filed a patent application claiming human-animal chimeras. The Patent Office rejected the claims because they encompassed human beings. Warren D. Woessner, *Patenting Transgenic Animals—From the Harvard Mouse to "Hello Dolly,"* 1999, http://www.slwk.com/CM/IPPapers/IPPapers12.asp.

56. Chess, *Hearing*, *supra* note 48, at 25. "It is safe to say that most, if not all, of the revolutionary medical advances developed by the biotechnology industry would not exist had the U.S. Supreme Court not ruled in 1980 that biotechnology inventions were entitled to patent protection." *Id.*

57. *See id.*

58. ROBERT P. MERGES, ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 11 (3d ed. 2003). *See also* Kunin, *supra* note 1, at 610 ("Companies are investing approximately $400–$500 million in researching, developing, and bringing to market new technologies that will raise people's standard of living, improve quality of life, reduce suffering, and promote longevity.").

59. MERGES, *supra* note 58, at 610.

60. *Id.* at 11–12.

61. *Id.*

undesirable position of being unable to recoup the expenses of their investment.[62]

A patent's grant of exclusivity is meaningless unless a patent owner can be certain that another party will not challenge ownership.[63] The current first-to-invent system of patent priority does not adequately protect the innovations arising out of the biotechnology industry. Under the current priority system, ownership is never certain because a prior inventor could theoretically always exist, having invented first but not filed accordingly. This level of uncertainty is dangerous for the biotechnology industry, as the industry relies heavily on their intellectual property for existence.[64] Due to the nature of the industry, the strongest possible patent protection is essential to keep up with the innovative and industrial demands of biotechnology. A patent holder needs certainty that its intellectual property will be protected so investors will continue to invest and the necessary research and development can go forward.[65] Biotechnology companies invest so much into an invention that they cannot risk that a patent will be invalidated years after it is granted due to a priority of inventorship dispute. Overall, the first-to-file system provides better protection for the patent holder, thus supporting the innovative purpose of the patent system.

B. Determining Priority Under the Current Patent Act and the Patent Reform Act

Under the current United States patent laws, inventorship is awarded to the party able to prove the earliest date of invention.[66] Inventive priority is typically awarded to the inventor who first reduces an embodiment of the invention to practice.[67]

62. "Patents provide the needed assurance for investors to risk the capital necessary in the long development process; e.g. that his/her investment cannot only be recouped but also generate a profit." Biotechnology Industry Organization, Intellectual Property Overview, http://www.bio.org/ip/ (last visited Nov. 18, 2006).

63. Chess, *Hearing*, *supra* note 48, at 25 ("[P]erhaps no other industry is as dependent upon patents as is the biotechnology industry.").

64. See *supra* notes 56–62, for a discussion of the importance of patent protection in the biotechnology industry.

65. "Without the certainty that comes from knowing that an invention discovered 10–15 years prior to coming to market can be protected, there would be little incentive for investors to fund high risk biotechnology products." Chess, *Hearing*, *supra* note 48, at 26.

66. 35 U.S.C. § 102(g)(1) (2000).

67. *See* CHISUM, *supra* note 52, § 10.03[1]; JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 163 (2003). Reduction to practice can be actual or constructive. MUELLER, *supra*, at 163. "Actual reduction to practice occurs when a physical embodiment of the invention has been constructed that works for its intended purpose." *Id.* The filing of a

Two exceptions to this general rule exist. The first exception allows an inventor to claim priority over another if he conceived first but reduced to practice last only if he exercised reasonable diligence between conception and reduction to practice.[68] A showing of reasonable diligence requires inventors to demonstrate that they diligently pursued the invention from the time of the first party's reduction to practice to the inventor's own reduction to practice.[69] Since the patent system favors early public disclosure, and this exception awards priority to the inventor who delayed in disclosing the invention, reasonable diligence is a difficult standard to meet.[70]

The second exception to the general priority rule allows an inventor who reduced an invention to practice *after* another inventor to claim priority if the first inventor abandoned, suppressed, or concealed his invention.[71] Abandonment, suppression, and concealment is determined by examination of three areas: the length of the delay period, the existence and nature of any activity during the period of delay, and the cause for resumption of activity.[72] This exception supports the public disclosure purpose of the patent system; patent protection is designed not only to encourage innovation, but also to allow the public to enjoy the benefits of the technology.[73]

Priority under the current patent system is challenged through an interference proceeding.[74] An interference proceeding has seven parts: "(a) declaration of the interference; (b) a motion period and filing of preliminary statements; (c) discovery; (d) a testimony period or periods; (e) a hearing; (f) judgment; and (g) court review."[75] In order to show priority of inventorship, parties are required to present evidence as to conception, reduction to practice, and diligence.[76] Due

patent application in compliance with 35 U.S.C. § 112 acts as constructive reduction to practice of an invention. *Id.*

68. 35 U.S.C. § 102(g)(1); *see also* CHISUM, *supra* note 52, § 10.03[1].

69. Hunter v. Beissbarth, 230 U.S.P.Q. 365, 368 (B.P.A.I. 1986).

70. *Id.*

71. 35 U.S.C. § 102(g)(1).

72. CHISUM, *supra* note 52, § 10.08[1].

73. *Id.* § 10.08[1].

74. *Id.* § 10.09[1][a]. "The purpose of an interference proceeding is to resolve the question of priority of invention when more than one applicant seeks a patent on substantially the same invention." *Id.*

75. *See* 35 U.S.C. § 102(g); CHISUM, *supra* note 52, § 10.09[1][c].

76. CHISUM, *supra* note 52, § 10.09[1][a]. Evidence of conception may be shown by "written descriptions, drawings, or a model." *Id.* § 10.04[2][b]. Sometimes, "oral testimony by the inventor and corroborating witnesses without supporting documentary or tangible evidence may be sufficient to establish prior conception." *Id.* To show actual reduction to practice, "an inventor must not only construct an embodiment of the invention (or per-

to the many factors involved, a challenge to determine priority of inventorship under the current system requires parties to provide a significant amount of data to show their relative dates of conception and reduction to practice.[77]

The movement to a first-to-file priority system, as suggested in the Patent Reform Act, would eliminate the cumbersome inventorship requirements, specifically, the production of evidence to establish timing of conception and reduction to practice, by awarding a patent to the first to file an application for an invention.[78] Specifically, the Patent Reform Act would change the priority system by making an earlier filed patent prior art,[79] effectively barring the issuance of any subsequently filed patent.[80] The Patent Reform Act would amend 35 U.S.C. § 102 to state:

> A patent for a claimed invention may not be obtained if . . . the claimed invention was patented . . . *before the effective filing date of the claimed invention* . . . or . . . the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was *effectively filed before the effective filing date of the claimed invention.*[81]

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form the steps of a process) but must also test the device or process so as to establish its capacity to perform successfully its intended purpose." *Id.* § 10.06[2][a]. To establish diligence, "the inventor must account for the entire critical period by showing either activity aimed at reduction to practice or legally adequate excuses for inactivity." *Id.* § 10.07.

77. *Id.* § 10.09[1][c].

> For those subject to challenge under first-to-invent, the proceeding is costly and often very protracted; frequently it moves from a USPTO administrative proceeding to full court litigation. In both venues it is not only evidence of who first reduced the invention to practice that is at issue but also questions of proof of conception, diligence, abandonment, suppression, and concealment, some of them requiring inquiry into what an inventor through and when the inventor thought it.

COMM. ON INTELLECTUAL PROP. RIGHTS IN THE KNOWLEDGE-BASED ECON., NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY, 125–26 (Stephen A. Merrill, et al. eds. 2004) [hereinafter A PATENT SYSTEM FOR THE 21ST CENTURY].

78. H.R. 2795, 109th Cong. § 3(b) (2005).

79. Prior art is "the legally available technology and information with which the claimed invention will be compared, in order to determine whether that invention is patentable." MUELLER, *supra* note 67, at 139.

80. H.R. 2795, 109th Cong. § 3(b) (2005).

81. *Id.* (emphasis added). The current first-to-invent rule is embodied in 35 U.S.C. § 102(g) (2000), which states:

> A person shall be entitled to a patent unless . . . (g)(1) during the course of an interference conduct under section 135 or section 291, another inventor involved therein establishes . . . that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this

The authors of the Patent Reform Act included this provision in response to frustration associated with the unpredictability inherent in a priority determination under the current first-to-invent system, which creates uncertainty in patent ownership.[82] The first-to-file system would eliminate this unpredictability by increasing the reliability of the priority process thus increasing the quality of issued patents and encouraging investment in the patented product or research. As Senator Berman stated during the House Committee hearing on the bill, "[h]igh-quality patents are essential to a healthy patent system. Poor-quality patents tend to spawn litigation; [sic] which in turn creates uncertainty in markets that depend on patent rights. As a result, investors hesitate to invest; innovators hesitate to invent."[83] The Patent Reform Act addresses these concerns by embracing the first-to-file movement, thereby increasing certainty in the patent system while upholding the innovative purpose of the patent system.

The purpose of the patent system is to promote early public disclosure, allowing the public to enjoy the benefit of the innovation in exchange for the grant of exclusivity. However, the current first-to-invent rule makes the process cumbersome and expensive, directly conflicting with the system's intentions. Adopting the proposed first-to-file rule would better promote the ultimate public-benefit purpose of the United States patent system while increasing certainty in patent protection. The greater certainty regarding the true owner of a patent would lead to stronger patent protection and thus encourage innovation and investment in essential industries, such as biotechnology.

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country by another inventor who had not abandoned, suppressed, or concealed it.

Id.

82. The current system . . . frequently does *not* award patents to the first to invent. . . . [A]n inventor can be the first to make the invention and first to file a patent application, but still forfeit the right to a patent because the inventor cannot sustain the cost of the "proof of invention" system.

Amendment in the Nature of a Substitute to H.R. 2795 the "Patent Reform Act of 2005": Hearing on H.R. 2795, Before the Subcomm. on Courts, the Internet, and Intellectual Property, 109th Cong. 10 (2005) (statement of Gary L. Griswold, President and Chief Intellectual Property Counsel, 3M Innovative Properties Company, on behalf of the American Intellectual Property Law Association), *available at* http://judiciary.house.gov/media/pdfs/printers/109th/21655.pdf.

83. *Id.* at 3 (statement of Senator Howard Berman).

II. A First-to-File System Promotes the Goals of the United States Patent System, Positively Impacting the Biotechnology Industry

Moving to a first-to-file system has been a topic of discussion among patent reformists for a number of years. The first proposal occurred in 1966, as a series of changes recommended by the President's Commission on the Patent System.[84] Despite support at that time from the USPTO for a first-to-file movement, the proposal was rejected due to "widespread opposition from representatives of industry, small business, individual inventors, and legal associations."[85] The discussion arose again in the early 1990s as part of obligatory trade negotiations under the General Agreement on Trade and Tariffs ("GATT").[86] While other reforms to the patent system resulted from the negotiations,[87] the United States remains the only country in the world with a first-to-invent system.[88]

In order to further the constitutional purpose of the patent system—promotion of innovation—patent laws must allow for early public disclosure as well as certainty of protection for inventors and their creations. A movement to a first-to-file system of priority upholds the purpose of the patent system by responding to each of these necessities. The system encourages early disclosure, by rewarding the first inventor to disclose the innovation with exclusivity, and allows for greater certainty, by eliminating cumbersome interference proceedings.

84. Ned L. Conley, *First-to-Invent: A Superior System for the United States*, 22 ST. MARY'S L.J. 779, 781 (1991).

85. *Id.*

86. MERGES, *supra* note 58, at 171.

87. The reforms were the result of the GATT agreement called "Trade-Related Aspects of Intellectual Property." *Id.* The reforms included: changing the patent term from seventeen years from the date of issuance to twenty years from filing under 35 U.S.C. § 154 (2000); allowing inventive activity occurring in a World Trade Organization member country to be admitted to determine priority of inventorship under 35 U.S.C. § 104 (2000); expanding the definition of infringement to include unauthorized offering for sale and importing under 35 U.S.C. § 271 (2000); and introducing a provisional application system under 35 U.S.C. § 111 (2000). *Id.*

88. Mossinghoff, *supra* note 9, at n.1. At the time of the GATT negotiations, only the United States and the Philippines operated under a first-to-invent system. *Id.* The Philippines switched to a first-to-file system on January 1, 1998. *Id.* Canada operated under a first-to-invent system similar to the United States' until 1989. *See* Robin Coster, *From First-to-Invent to First-to-File: The Canadian Experience*, 2, 7, *available at* http://www.torys.com/publications/pdf/ARTech-19T.pdf (last visited Nov. 18, 2006). At that time there was little controversy in Canada over switching to a first-to-file system. *Id.* at 9.

"Strong intellectual property protection is essential to the success, and in some instances to the survival, of the over 1,200 biotechnology companies in this country."[89] The nature of the biotechnology industry makes it dependent on its intellectual property. It may take a company ten or twenty years to develop a product that proves profitable.[90] For this reason, when a product is finally ready to go to market, the company must be allowed an opportunity to recoup its long-term investment.[91] The exclusivity provided by the patent system provides this opportunity. The system would work better, however, if there is more certainty in the patent process so investors are confident in the strength of their intellectual property.

A. The Certainty Afforded by the First-to-File System Promotes Innovation

Under the current first-to-invent system, a patent holder can never be completely safe in ownership of the patent because another can always potentially invalidate the patent by showing priority of invention under 35 U.S.C. § 102(g).[92] The efficiency of the first-to-file system remedies this problem by allowing for an immediate determination of priority.[93] This change benefits both the patent office and inventors, allowing the parties to simply look at the dates of filing to determine priority, thus preventing long delays associated with costly interference proceedings.[94] These changes reduce administrative tasks for the patent office and costly uncertainty for applicants.[95] In the biotechnology industry, certainty is especially important because investors rely on the viability of the product when investing; part of the product's viability depends on whether the patent holder can ex-

89. Biotechnology Industry Organization, Intellectual Property Overview, *supra* note 62.

90. Chess, *Hearing*, *supra* note 48, at 25.

91. *See supra* notes 58–62 and accompanying text (discussing a biotechnology company's ability to recoup investments).

92. "No United States patent is totally immune from a challenge that it claims an invention that another in fact invented earlier and therefore is invalid under 35 U.S.C. Section 102(g)." William S. Thompson, *Reforming the Patent System for the 21st Century*, 21 AIPLA Q.J. 171, 181 (1993).

93. Charles R.B. Macedo, *First-to-File: Is American Adoption of the International Standard in Patent Law Worth the Price?*, 18 AIPLA Q.J. 193, 221 (1989).

94. *See id.*

95. *See id.*

clude others from the invention and thereby recoup investments in development.[96]

Most of the money raised by biotechnology companies is spent on research and development.[97] Thus, the companies diligently protect their intellectual property in order to gain a return on their investments.[98] The biotechnology drug discovery process can take anywhere from two to sixteen years.[99] Without the certainty that comes from knowing that an invention discovered ten to fifteen years prior to coming to market can be protected, there would be little incentive for investors to fund high-risk biotechnology products.[100]

In *Amgen, Inc. v. Chugai Pharmaceutical Co.*,[101] the Federal Circuit Court upheld the validity of United States Patent Number 4,703,008 ("the '008 patent") on isolated sequences of deoxyribonucleic acid ("DNA") coding for Erythropoietin ("EPO"), a protein that stimulates the production of red blood cells.[102] This breakthrough case upheld the patentability of isolated DNA sequences, prompting a race in the

96. *See supra* notes 58–62 and accompanying text (discussing a biotechnology company's ability to recoup investments).

97. Chess, *Hearing*, *supra* note 48, at 26. Specifically:

> The vast majority of biotech companies spend more than 50 percent of their operating expenses on research and development. This is due to the huge investments required to bring a product through the discovery and lead optimization phase, preclinical testing, and the clinical trials required to gain market approval. The total amount of spending to bring a successful product through commercialization is typically several hundred million dollars.

Id.

98. *See id.* As an example of invention returns relating to patents, Nektar Therapeutics, in collaboration with Pfizer, developed Exubera®, an inhaled insulin powder, which was truly innovative as the first non-injectable insulin for diabetics. *Id.* "Upon word of the issuance of the patent covering inhaled insulin in dry powder form, Nektar's stock valuation increased by 20%." *Id.* The market increase helped attract the investment capital necessary to bring the product to the FDA advisory committee approval. *Id.* Today, Exubera® is approved for use by both Type One and Type Two diabetics in both the United States and the European Union. *See* Nektar, Exubera®, http://www.nektar.com/wt/page/exubera (last visited Nov. 15, 2006). According to Robert Chess, Nektar's "story is similar to the story of the hundreds of U.S. biotechnology companies in the United States." Chess, *Hearing*, *supra* note 48, at 26.

99. Biotechnology Industry Organization, Biotechnology Industry Facts, *supra* note 40.

100. *See* Chess, *Hearing*, *supra* note 48, at 26.

101. 927 F.2d 1200 (Fed. Cir. 1991).

102. *Id.* at 1219. The defendants in *Amgen* also challenged the validity of the '008 patent based on priority of inventorship asserting that another scientist conceived of the strategy used by Amgen's scientist to isolate the EPO gene. *Id.* at 1205. The Federal Circuit judges had to review the priority determination of the district court, ultimately affirming and finding that Amgen's scientist invented first. *Id.* at 1206–07. This is just a small example of the inefficiency of priority challenges under the current first-to-invent system.

genomic industry to quickly sequence and patent as many isolated strands of DNA as possible.[103] During this time, it is probable that many parties applied for patents for the same DNA sequences.[104] Between 1976 and 2002, the USPTO issued over 16,000 patents on isolated and purified DNA sequences or on processes used to identify, isolate, copy, sequence, or analyze DNA sequences.[105] This large number of patents was due in part to the race to sequence the human genome.[106] It is unknown how many parties have claimed duplicate DNA sequences, but, because of the high number of applications on DNA sequences, it is likely that multiple parties claimed inventorship of the same sequence. These patents may be subject to priority proceedings under the current first-to-invent system, with evidence being submitted on diligence in research, dates of conception and reduction to practice, and arguments of abandonment, suppression and concealment. These costly interference proceedings will further strain the USPTO's already tight resources.[107]

Under the first-to-file system, however, a priority determination could be made in a matter of minutes solely by referencing the applicants's filing dates, thereby saving the USPTO's and the applicants's time and money. In the example above, priority of inventorship for the sequenced DNA applications would be relatively simple to establish, and parties could quickly ascertain whether their issued patent would be subject to an inventorship challenge in the future. Under the first-to-invent system, however, patents are subject to an inventorship dispute at any time, thus making the patent validity uncertain for the duration of the patent.[108]

The uncertainty associated with the determination of priority can be very costly, with legal fees from interference proceedings draining millions of dollars from the biotechnology industry each year.[109] Inter-

103. Tom Abate, *Biotech Firms Rushing to Patent Gene Fragments*, S.F. CHRON., Oct. 18, 1999, at B14, *available at* http://www.sfgate.com/cgi-bin/article.cgi?file=/Chronicle/archive/1999/10/18/BU17692.DTL.

104. Byron Spice, *Genes May Become Big Business*, PITTSBURG POST-GAZETTE, July 16, 2000, at A10. "[S]o many patent applications have been filed that researchers joke that 800 percent of the human genome has been patented." *Id.*

105. DAVID B. RESNIK, OWNING THE GENOME, A MORAL ANALYSIS OF DNA PATENTING 1 (2004).

106. *See id.* at 3.

107. *See* Schwillinski & Hershkowitz, *supra* note 9, at 1; *Chess*, Hearing, *supra* note 48, at 27.

108. Thompson, *supra* note 92, at 182 ("The potential for challenge based on inventorship hangs over a patent throughout its life under the first to invent system.").

109. Jon F. Merz & Michelle R. Henry, *The Prevalence of Patent Interferences in Gene Technology*, 22 NATURE BIOTECH. 153 (2004).

ference proceedings in gene discovery and biotechnology are more prevalent than other areas of technology.[110] Between 1998 and 2002, the rate of interference declaration in the biotechnology/organic chemistry sector of the patent office was "at least 2.5 times higher" than the next leading industry; in fact, the average rate amounted to 6.5 times that of the other industries for that five-year period.[111] Seventy-five percent of these interference proceedings involved biotechnology applications.[112] The high interference rate is likely attributable to the strong competition, and often outright races, among companies working toward the same genetic discoveries.[113] While certain types of interference proceedings will remain in a first-to-file system,[114] the overall decrease in the number of proceedings will lead to a higher degree of certainty under the first-to-file system and lower the costs to the industry, allowing companies to invest more money into research. The net effect of this change would be an increase in the life-saving innovation researchers in biotechnology work toward everyday.

The patent system would benefit as a whole from a first-to-file system because inventors could ascertain with more certainty whether their invention has been anticipated.[115] It is easier to determine if another party has filed earlier rather than invented earlier, since the filing date is clear, while the date of invention is not always known. Innovators will likely be highly discouraged if they are issued a patent that is subsequently deemed invalid for inventorship reasons when the inventor had no way of knowing prior art existed. The first-to-file system would avoid this costly and discouraging problem because a potential applicant would be able to determine that no prior art exists before filing a patent application. Armed with the knowledge that an application for the same invention was not on file at the time of the

110. *Id.*

111. *Id.*

112. *Id.*

113. *See id.*

114. Interferences that will remain in a first-to-file system: (1) derivation cases, (2) inventorship disputes among former colleagues, (3) interfering cases naming the same inventive entity but filed by different parties, (4) interleaving priorities, (5) improvidently issued patents, and (6) cases having the same effective filing date. Charles L. Gholz, *How the U.S. Currently Handles the Interference Issues that Will Remain in a First-to-File World*, 18 AIPLA Q.J. 1, 2–13 (1990).

115. Thompson, *supra* note 92, at 182 ("The potential [for challenge based on inventorship] is removed at the outset under the first to file system, giving clear title, which is vital in the birth stage of product introduction.").

first inventor's filing, the inventor is assured invested efforts will be protected by the patent grant.

B. The First-to-File System Encourages Innovation by Rewarding Inventors for Early Public Disclosure

The constitutional purpose of the patent system is the promotion of "Progress in Science and useful Arts."[116] A first-to-file system promotes the goals of the system by rewarding early filing and thus ensures earlier public disclosure of the invention.[117] Such early public disclosure is a vital step in promoting the constitutional goals of the patent system. It facilitates further innovation, allowing other inventors to create something new from the patented invention.[118] Under a first-to-file system of patent priority, the reward of a patent would always go to the inventor who first initiated the process of bringing the invention into the public domain by filing a patent on the invention, thereby fulfilling his or her role in promoting progress in the science and useful arts.[119]

Early public disclosure is essential to innovation because the earlier a patent is disclosed, the sooner others can build on the technology. A company should not be able to conceal its invention from the public and then challenge the priority of another patent that discloses an independent discovery of the same product or process and allows the public to benefit from it.

In *United States v. Duiblier Condensor Corp.*,[120] the Supreme Court distinguished between an inventor's right to keep an invention secret and an inventor's ability to receive a reward for disclosing the invention to the public.[121] The Supreme Court artfully described the public benefit encouraged by the patent system in *Dubilier*: "An inventor deprives the public of nothing which it enjoyed before his discovery, but gives something of value to the community by adding to the sum of human knowledge. . . . In consideration of its disclosure and the consequent benefit to the community, the patent is granted."[122] The quid pro quo nature of the United States patent system reflects the tension

116. U.S. CONST. art. I, § 8, cl. 8.

117. Charles L. Gholz, *First-to-File or First-to-Invent?*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 891, 895 (2000) [hereinafter Gholz, *First-to-File*].

118. Kunin, *supra* note 1, at 616 ("Each new discovery builds on the foundation laid by those who came before it.").

119. *See* Gholz, *First-to-File*, *supra* note 117, at 895.

120. 289 U.S. 178 (1933).

121. *Id.* at 186.

122. *Id.*

inherent in facilitating the public purpose it was intended to serve—that society will benefit if innovation is made available for public use, but that inventors must be rewarded for disclosing innovation to the public. A first-to-file system would support the means of early public disclosure; because the first inventor to file is awarded the patent, the system encourages inventors to file earlier, thus reinforcing the innovative purpose of the patent system. The earlier an invention is filed with the USPTO, the earlier the invention is disclosed and released to the public.[123]

Early public disclosure is especially beneficial in the biotechnology industry where many companies spend considerable time and resources in pursuit of common research goals.[124] Because the first-to-file system promotes early filing and thus early public disclosure, researchers working toward a common goal will be able to use and expand upon technology developed by competitors, which will encourage innovation and discourage duplicative efforts.[125] If a biotechnology company becomes aware that a problem has been solved, the company can stop investing time and resources into research that will not provide the company with a return on its investment. The company may then choose to redirect its efforts into another innovation or begin building upon the new technology to create an even greater invention.

For example, in Company *A* and Company *B*'s hypothetical race toward a cure for diabetes, *B* would get the patent grant under a first-to-file system because *B* was the first to bring the invention to the public. While *A* did not have an obligation to patent its invention, it should not be able to reap the benefits of a patent if it decides to file for patent protection after another has already disclosed the invention to the public. *A*'s delay in filing does not facilitate innovation through public disclosure because *B* already disclosed the invention. Rewarding *A* with a patent in this situation does not encourage public

123. Today, an invention is published within eighteen months of the application's earlier effective filing date, unless the inventor is applying for a patent in a foreign country and opts out of patenting in the United States. 35 U.S.C. § 122(b) (2000). Because the first-to-file system would promote early filing, inventions would be disclosed to the public eighteen months after that early filing. The Patent Reform Act also has a provision proposing the removal of the opt-out publication exception. *See* Patent Reform Act of 2005, H.R. 2795 § 9, 109th Cong. (2005). If this provision of the bill is adopted, then the publication requirement would be an even stronger tool in the promotion of innovation.

124. *See supra* note 5 and accompanying text (providing an example of institutions working toward a cure for diabetes).

125. *See supra* note 45 (discussing the common practice of licensing technology among companies in an industry).

disclosure; rather, it facilitates interferences and discourages *B*'s future innovation. Some may argue that this is an unfair result because the first inventor to make a discovery was not rewarded for the invention. However, in light of the policies that the patent system seeks to promote, this concern is misguided because, if the purpose of the patent system is to "promote scientific and technological progress by providing incentives for inventors, then it is not unfair to reward genuine inventors for coming forward with their inventions by granting the patent to the first inventor to do so."[126]

The promotion of early public disclosure, essential to innovation, is best accomplished by the first-to-file system of priority. A first-to-file system rewards those inventors who disclose their inventions, providing the public with notice of the technology and allowing them an opportunity to expand upon it. Whereas the complexities involved in the current first-to-invent system are a hindrance to the public policy goals of the patent system, the simplicity of the first-to-invent system supports those goals.

C. Dispelling the Myths of the First-to-File System

While a first-to-file system will undoubtedly create more certainty in patent validity and bring inventions to the public earlier, a number of concerns remain regarding its implementation. Those concerns, however, are both outdated and unfounded. The first-to-file opponents take their arguments largely from the first-to-file debates that occurred during the GATT negotiations.[127] In the years following those debates, reforms to the patent procedures have mitigated many of those concerns.

1. Myth #1: The First-to-File System Will Cause a Race to the Patent Office

Many first-to-file opponents fear that a first-to-file system will cause a race to the patent office so that an inventor may be on record as the first to file an application.[128] The race to the patent office concern centers around the idea that sloppy patents will be filed on in-

126. Robin Coster, *From First-to-Invent to First-To-File: The Canadian Experience*, 13–14, *available at* http://www.torys.com/publications/pdf/ARTech-19T.pdf (last visited Nov. 18, 2006).

127. *See supra* note 87–88 and accompanying text (discussing the United States' rejection of the first-to-file system in the 1999 GATT negotiations).

128. Schwillinski & Hershkowitz, *supra* note 9, at 1 ("Opponents of a first-to-file system often label it as a 'race-to-the-Patent Office' system.").

complete or frivolous ideas.[129] According to those wary of a race to the patent office, such a race will lead to a flood of incomplete applications.[130] Opponents of the first-to-file system base this fear on an assumption that people will quickly file patent applications to protect their ideas, without fully considering or supporting the patentability of the idea as an invention.[131] Because patent applications must "particularly point[ ] out and distinctly claim[ ] the subject matter" regarded as the invention,[132] the fear is that applicants will rush to file patents that do not meet the patentability requirements. The first-to-file opponents argue that an application filed too quickly will not have an adequate disclosure for patentability purposes.[133] The concern that a race to the patent office will lead to sloppy applications is significantly weakened by recent changes to the patent-filing procedures.[134]

The first policy to address the concern over sloppiness was the implementation of a procedure by which a party may file a provisional patent application at the patent office.[135] The provisional application requires only a specification, one claim, and a drawing.[136] It allows an applicant to guarantee a filing date without submitting a full utility application.[137] The security provided by a provisional application allows the applicant more quality time to draft the full utility application in accordance with the patentability requirements without feeling pressure to rush in order to secure a filing date. This one-year window thus decreases the likelihood that an applicant will file a sloppy application.[138] Giving an applicant up to one year to perfect the utility application does not affect the time of public disclosure because the eighteen-month publication rule applies to the earliest effective filing date, which would be the filing date of the provisional application.[139]

129. *See* Bob DeMatteis, Article, Professional Inventor's Alliance, http://www.piausa.org/patent_reform/articles/bob_dematteis_08_31_2005.

130. *Id.*

131. *Id.*

132. *See* 35 U.S.C. § 112, ¶ 2 (2000).

133. DeMatteis, *supra* note 129; *see also* A PATENT SYSTEM FOR THE 21ST CENTURY, *supra* note 77, at 126.

134. *See* Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 1 (proposed Jan. 3, 2006) (to be codified at 37 C.F.R. pt. 1).

135. 35 U.S.C. § 111(b) (2000).

136. *Id.*

137. *Id.*

138. *Id.*

139. 35 U.S.C. § 122(b) (2000); *see also supra* note 125 and accompanying text (discussing the benefits of early publication).

The second policy to address concerns over sloppiness is the USPTO's changes to the practice of filing continuances on a patent application.[140] Under a continued examination practice, applicants may continue the examination of a patent after an examiner rejects it, allowing the applicant to prolong the application process and gain additional time to craft the claims for issuance.[141]

Opponents of a first-to-file system fear that the applicants who file too soon will tie up proceedings in the patent office with continuous attempts to amend weak applications in order to meet patentability standards, prolonging the process with multiple continuations.[142] The concern raised by this approach is that multiple continuations under a first-to-file system would not only make any issued patent weaker, due to the constraints imposed by the initial application,[143] but would make potential patent protection for another inventor of the same or similar invention dependant upon the outcome of the proceedings of the inventor who filed too quickly.

On January 3, 2006, the USPTO issued changes to the practice of continuation filings in patent applications.[144] Under continued examination practice, applicants may continue the examination of a patent after an examiner rejects it, allowing the applicant additional time to craft the claims for issuance.[145] Due to the additional time a continuation adds to the examination of a patent application, the USPTO revised the rules to require that an applicant support a second or subsequent continued examination filing with a showing as to why the amendment, argument, or evidence presented could not have been submitted with the original filing.[146] This change is critical because in the patent application process, an applicant has two opportunities to amend the patent claims for issuance.[147] Under the USPTO's former practice, an applicant could prolong the application process by filing

140. *See* Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 1 (proposed Jan. 3, 2006) (to be codified at 37 C.F.R. pt. 1).

141. MUELLER, *supra* note 67, at 163.

142. DeMatteis, *supra* note 129.

143. An applicant is prohibited from adding new matter to an application without receiving a new filing date for that new matter. Thus, if an applicant files an incomplete application at the outset, the final application may be less complete because it would lack essential matter not included in the original filing. *See* 37 C.F.R. § 1.121(f) (2005).

144. *See* Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 1 (proposed Jan. 3, 2006) (to be codified at 37 C.F.R. pt. 1).

145. *Id.*

146. *Id.*

147. *See* 37 C.F.R. § 1.112 (2005).

multiple continuations, thus receiving numerous opportunities to amend claims to the level of patentability. Under the reformed guidelines, a patent applicant has only two chances to amend an application absent an adequate reason to allow the examination to continue.[148] Thus, the initially filed application must be as close to patentability as possible. The fear that the first-to-file system would elicit an onslaught of poorly drafted patent applications in an attempt to be the first in line is mitigated by the fact that a poorly drafted patent application would be less likely to be issued under the new guidelines.

2. Myth #2: The First-to-File System Will Harm Independent Inventors

Opponents of the first-to-file system argue that it will harm independent inventors.[149] Independent inventors often have limited resources compared to large companies, and it is argued that, under a first-to-file system, independent inventors will be at a disadvantage because they lack the necessary capital to quickly file a patent application.[150] In spite of these arguments, the perceived advantage of the first-to-invent system—and the perceived inequity of the first-to-file system—cannot be reconciled with statistical evidence indicating that independent inventors are, in fact, not benefited by the current system.

Contrary to the arguments of small entities, scholars have hailed the current first-to-invent system as unfair to independent inventors and small entities due to its costs and complexities.[151] Under the first-to-invent system, a challenge to priority may result in a costly interference proceeding, where the party challenging inventorship must show by clear and convincing evidence that they are the first inventor.[152] Due to the complex rules governing the current priority determina-

148. *See* Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 1 (proposed Jan. 3, 2006) (to be codified at 37 C.F.R. pt. 1).

149. DeMatteis, *supra* note 129. Those in favor of maintaining the first-to-invent system include parties considered to be small entities: individual inventors, small businesses, and non-profit organizations. 35 C.F.R. § 1.27(a) (2000) (defining small entities).

150. A PATENT SYSTEM FOR THE 21ST CENTURY, *supra* note 77, at 126 (recognizing the concern that small inventors may be disadvantaged); DeMatteis, *supra* note 129 (discussing the limited resources of small inventors).

151. *Hearing Before the Subcommittee on Courts, the Internet and Intellectual Property United States House of Representatives Washington, D.C. on H.R. 2795 "Patent Act of 2005,"* 109th Cong. 10 (2005) [hereinafter Griswold, *Hearing*] (statement of Gary Griswold, past President of the American Intellectual Property Law Association).

152. *See* Enzo BioChem, Inc. v. Gen-Probe, Inc., 424 F.3d 1276, 1281 (Fed. Cir. 2005).

tions, inventors must present proof of inventorship. This proof requires detailed data from previous years regarding conception and reduction to practice.[153] Small entities without knowledge of the patent laws at the time of inventorship often do not have the records to support their inventorship dates.[154] The limited resources of small inventors pose a hindrance under the current priority system given the costly litigation associated with interference proceedings. The median cost for the discovery phase of an interference proceeding alone was $113,000 in 2005.[155] Many small entities do not have the financial resources or sophisticated understanding of patent law to adequately protect themselves.[156] For this reason, large companies will use the interference proceeding as a sword to challenge the priority of small entities.[157] Since an entire interference proceeding can cost upwards of $500,000, many small entities are forced to license their patents to large companies capable of supporting the costs of defending inventorship.[158]

Due to the difficulty in overcoming a patent's presumption of validity, priority proceedings under the first-to-invent system do not necessarily grant priority to the first party to invent.[159] The difficulty is a result of both the cost of proceedings and the high level of proof required to show inventorship. Furthermore, the party asserting inventorship against a patent holder must show by clear and convincing evidence that they are the first party to invent.[160] Since many small entities do not have adequate records supporting their inventorship dates, meeting the standard of clear and convincing evidence is very difficult.[161] Thus, a small entity challenging inventorship may actually be the first to invent, but still be denied priority due to the difficulty of overcoming the presumption of validity.[162]

Furthermore, interference proceedings may actually stifle the innovation that the patent system seeks to promote.[163] During an interference proceeding, inventors are called away from their work to

153. *See* 35 U.S.C. § 102(g) (2000).
154. Jackman, *supra* note 15, at 83.
155. Griswold, *Hearing*, *supra* note 151, at 10.
156. Jackman, *supra* note 15, at 83.
157. Griswold, *Hearing*, *supra* note 151, at 10 (citing to Mark A. Lemley & Colleen V. Chien, *Are the U.S. Patent Priority Rules Really Necessary?*, 54 HASTINGS L.J. 1299 (2003)).
158. Merz & Henry, *supra* note 109, at 154.
159. *See* 35 U.S.C. § 282 (2000); Griswold, *Hearing*, *supra* note 151, at 10.
160. *See* Enzo BioChem, Inc. v. Gen-Probe, Inc., 424 F.3d 1276, 1281 (Fed. Cir. 2005).
161. *See* Jackman, *supra* note 15, at 83.
162. 35 U.S.C. § 282. "A patent shall be presumed valid." *Id.*
163. Gholz, *First-to-File*, *supra* note 117, at 894–95.

spend time trying to recall historical information regarding dates of conception and reduction to practice.[164] While these inventors are trying to recall dates from years past, they are not working toward the innovation encouraged by the United States patent system. Charles Gholz provides a compelling example of this problem from personal experience:

> A couple of years ago I was handling a big ticket interference in which my side's inventors were named the Inventors of the Year by the Intellectual Property Owners Association. At about the same time, my client assigned the lead inventor to us full time. That is, it told him that it was more important for him to work with us to win the interference than it was for him to work at his laboratory bench making more inventions!
>
> My client's decision was good for us, but it was grotesquely bad for the nation. While the inventor spent his time racking his brain trying to remember what he had done and when he had done it years before (and more importantly, trying to find documents to substantiate his hazy memory), he could have been back at his bench making *more* important inventions.[165]

Removing an inventor from work for interference discovery could be more harmful to small entities that have a smaller research and development department than a large company. Taking away even one inventor for interference litigation would deplete the resources of a small entity more than the removal of a single inventor on the daily operations of a large company. In the biotechnology industry, many new drugs are discovered by start-up companies.[166] At the same time, mergers among existing biotechnology firms are taking place, creating large companies with large research and development programs.[167] The detrimental effects of removing an inventor from a start-up company are even more pronounced when the potential competition is a company able to sacrifice the efforts of a single inventor without losing considerable research time.

If the United States moves to a first-to-file system, the problems associated with interference proceedings will be eliminated, and small

164. *Id.*

165. *Id.* at 894–95.

166. John K. Borchardt, *The Business of Pharmacogenomics*, 4 MOD. DRUG DISCOVERY 35 (2001), *available at* http://pubs.acs.org/subscribe/journals/mdd/v04/i07/html/07borchardt.html ("Of the 50 firms with a single new drug approval during the 1990s, for 41 firms, this was their first-ever new drug approval. Many of these are startup firms, often biotechnology companies. . . . [A]dvances in biomedical science may have fostered less concentration of new drug development among existing firms and stimulated new entry to the industry.").

167. *Id.*

inventors will not have to worry about losing time and money in an interference proceeding. It is natural for concerns to arise when changes are proposed to a system that has been in place for over a century. The concerns pronounced by first-to-file opponents, however, are ultimately unpersuasive in light of the benefits offered by a first-to-file system.

IV. Conclusion

The constitutional purpose of the United States patent system is the promotion of progress in the useful arts. The most effective means of accomplishing this goal is to ensure a high level of certainty of protection coupled with the encouragement of early public disclosure. Certainty ensures that inventors will have the strongest protection and will be encouraged to patent future inventions, while early public disclosure allows the public to build on innovations.

The first-to-file system of patent priority fulfills the constitutional goals of the patent system by promoting early public disclosure and providing for greater certainty in patent protection. The first-to-file system would positively impact the biotechnology industry, as the nature of the industry is such that certainty in patent protection is essential. Biotechnology companies rely almost entirely on their patent protection to gain investor support and remain viable. The first-to-file system ensures certainty in priority of inventorship, protecting patent holders from challenges to patent validity by unknown prior inventors who failed to disclose their invention to the public.

The concerns surrounding a movement to a first-to-file system are outdated and unfounded because other changes to the patent procedures have adequately addressed the concerns. Furthermore, the belief that independent inventors will be harmed under a first-to-file system is sharply contrasted against the reality that independent inventors currently suffer under the first-to-invent system of priority.

The first-to-file priority system conforms to the patent goals as set forth in the United States Constitution and greatly benefits the biotechnology industry. As one of the fastest growing and most innovative industries in existence, the biotechnology sector requires strong patent protection to maximize innovation.