

**A CLEARINGHOUSE: THE SOLUTION TO CLEARING UP
CONFUSION IN GENE PATENT LICENSING**

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I. INTRODUCTION

ALL THE MEANS OF ACTION —
THE SHAPELESS MASSES, THE MATERIALS —
LIE EVERYWHERE ABOUT US. WHAT WE NEED
IS THE CELESTIAL FIRE TO CHANGE THE FLINT
INTO TRANSPARENT CRYSTAL, BRIGHT AND CLEAR.
THAT FIRE IS GENIUS!¹
—HENRY WADSWORTH LONGFELLOW

Although it is safe to assume that Longfellow was not writing about the patent crisis plaguing the biotechnology industry, his words are appropriate to the current situation. Over the past half-century, innovations within the genetic diagnostics sector have increased by leaps and bounds. We now have the ability — “[a]ll the means of action” — to detect whether a person has inherited the genes associated with a certain disease well in advance of the onset of any symptoms. Patients who choose to undergo these genetic tests can subsequently take preventive measures that might stave off a disease that they are likely to develop. However, patient access to such tests has been limited due to the intellectual property protection granted to diagnostic tests and the underlying genes — creating a barrier between patent holders and laboratories that would otherwise offer these genetic tests.² We have “the shapeless masses, the materials” to diagnose patients with these diseases, but “What we [still] need Is the . . . transparent crystal” — the solution to increasing patient access to genetic testing.

A gene patent can be one of three distinct types: (1) a diagnostic patent, (2) a composition of matter patent, or (3) a patent on functional uses.³ Diagnostic patents typically cover all known methods of testing for a disease based on differences from a normal gene sequence.⁴ Composition of matter patents cover a specific isolated and purified gene as well as any derivative products such as recombinant proteins or drugs.⁵ Functional use patents typically claim methods or small-molecule drugs that are capable of up- or down-regulating the expression of a gene within a cell — ultimately affecting the gene’s functioning.⁶

1. HENRY WADSWORTH LONGFELLOW, *THE LONGFELLOW BIRTHDAY-BOOK* 18 (Charlotte Fiske Bates ed., 1881).

2. Richard Gold et al., *Gene Patents and the Standard of Care*, 167 *CAN. MED. ASS’N J.* 256, 256 (2002).

3. Jon F. Merz & Mildred K. Cho, *What Are Gene Patents and Why Are People Worried About Them?*, 8 *COMMUNITY GENETICS* 203, 204 (2005).

4. *Id.*

5. *Id.* at 205.

6. *Id.* at 206.

In the United States, there are approximately 40,000 patents related to human genes.⁷ Although only 20% of the human genome is patented,⁸ existing patents cover important genes such as those associated with hereditary breast and ovarian cancer, Huntington's disease, and muscular dystrophy.⁹ The 40,000 gene patents also include methods and devices used in the diagnosis of genetic diseases. Innovations in diagnostic testing have led to the recent implementation of multiplex testing, which allows clinicians to screen a wide array of genes all at once, saving both time and money. However, the arrays of multiplex testing typically analyze hundreds or thousands of genes¹⁰ — many of which a typical lab is not licensed to use.¹¹ Consequently, labs will decide to take one of two routes. Either they will forego the use of such tests, even though the technology is available, or they will complete the tests anyway and avoid reporting results on the genes they are not licensed to use.¹²

Gene patents may also be interfering with innovation in multiplex testing technology, as innovators may find it daunting to obtain licenses from all of the many different patent holders of genes that can be simultaneously screened. A quarter of clinical laboratories in the United States that perform genetic testing have stopped employing a certain type of genetic test because of a gene patent, and over half of U.S. laboratories have decided not to develop a test on a certain disease due to patent or licensing issues.¹³ As patent holders have exclusive rights over a gene or genetic test, they have the ability to set licensing prices as high as they like. Some clinical laboratories will be unable to pay a high licensing fee and will decide to forego offering that genetic test. This will decrease patient access to these tests. The quality of these tests also often decreases, as genetic testing manufacturers do not need to be concerned with competition from other tests. Thus, their tests do not need to be of the best quality to survive in the marketplace. These problems exist because there is a fundamental

7. Harriet A. Washington, *Gene Patenting Produces Profits, Not Cures*, THE HUFFINGTON POST (July 14, 2010, 12:07 PM), http://www.huffingtonpost.com/harriet-a-washington/gene-patenting-produces-p_b_645862.html.

8. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239, 239 (2005).

9. Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 6 (2003).

10. *Microarrays Fact Sheet*, NAT'L CENTER FOR BIOTECHNOLOGY INFO., <http://www.ncbi.nlm.nih.gov/About/primer/microarrays.html> (last updated Jul. 27, 2007).

11. Cho et al., *supra* note 9, at 5.

12. The latter route constitutes infringement of the patented gene, but since results are not reported, many labs believe it is unlikely that a patent holder would ever find out. SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY, DEP'T OF HEALTH & HUMAN SERVS., *GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS* 41 (2010) [hereinafter SACGHS], available at http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf.

13. Cho et al., *supra* note 9, at 3.

disconnect between the innovators of genetic technologies and the developers of downstream products that incorporate the inventions. Two barriers contribute to this disconnect: (1) a lack of clarity in gene patent terminology, resulting in confusion over whether a patent needs to be licensed for a particular test; and (2) the difficulty faced by potential licensees in pinpointing exactly what patents they need to license leads to high transaction costs, often preventing gene patent holders and product developers from effectively communicating about the licensing of gene patents. Both of these barriers stem from the same basic problem: there is a widespread lack of transparency in the field of gene patents that is creating legal uncertainty amongst the players in this field.

This Note argues for the implementation of a gene patent clearinghouse — an institution to resolve the confusion currently surrounding gene patents and facilitate interactions and the transfer of information between gene patent licensors and potential licensees. Although some scholars and critics advocate for the banning of gene patents as a solution to this crisis, Part II of this Note argues that this remedy would be neither effective nor adequate. Part III will discuss an initial step that must be taken in order to clear up the confusion with gene patent licensing: resolving unclear terminology in gene patent claims. Part IV details how the gene patent clearinghouse should be structured, as well as how and why it is likely to solve the problems in the industry. It is crucial that all or nearly all holders of gene patents join the clearinghouse for it to be an effective solution. Similarly, the more potential licensees registered with the clearinghouse, the more useful the institution will be. Part V discusses potential ways to motivate patent holders and potential licensees to join the clearinghouse. Part VI concludes.

II. WHY GENE PATENTS SHOULD NOT BE BANNED

In Committee Reports accompanying the 1952 Patent Act, Congress stated that patentable subject matter includes “anything under the sun that is made by man.”¹⁴ In 1980, the Supreme Court further clarified: “[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity.”¹⁵ In addition to these qualifications, any patentable material must meet the standards of utility,¹⁶ novelty,¹⁷

14. S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952).

15. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

16. 35 U.S.C. § 101 (2006).

17. *Id.* § 102.

and nonobviousness.¹⁸ Substances that have been extracted from the human body and purified have been patented since the early twentieth century.¹⁹ These substances are considered to be patentable because the process of purification renders them “man-made.”²⁰ The first extracted chemical to be patented, adrenaline, was patentable on the basis that it was commercially and therapeutically distinct from its non-purified version.²¹ Just like adrenaline, isolated genes are deemed to be patentable material because they have increased commercial and therapeutic utility compared to genes in the human body.²² Without being isolated from the human body, gene sequences could not be used for such things as the diagnosis of disease or the manufacture of therapeutic proteins.²³

The main motivation for granting patents on discoveries is to provide incentives for innovation.²⁴ If potential innovators know that they will be rewarded with exclusive rights to an invention, they will be more likely to put in the time, effort, and money required for the innovation process. However, some critics argue that patents are unnecessary to stimulate innovation in the genetic diagnostics sector.²⁵ These critics reason that there are plenty of motivations for researchers to pursue discoveries and new technologies in this field even without the promise of a patent.²⁶ Researchers in biotechnology are typically academics who are motivated principally by the desire to advance understanding in the field.²⁷ These researchers will likely enhance their own reputation and standing within the field by isolating a new gene or inventing a new diagnostic method; these rewards supposedly provide plenty of incentive to innovate.²⁸ In one study, scientists “stated that they would have pursued their research even if their discoveries were not patent-eligible.”²⁹ Instead, they indicated that they were motivated more by their association with a discovery and improved reputation within the field.³⁰

18. *Id.* § 103.

19. See Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 RUTGERS COMPUTER & TECH. L.J. 1, 28 (1991).

20. See *id.*

21. *Id.*

22. See Teresa M. Summers, Note, *The Scope of Utility in the Twenty-First Century: New Guidance for Gene-Related Patents*, 91 GEO. L.J. 475, 478–79 (2003).

23. See, e.g., *id.*

24. See, e.g., Nancy T. Gallini, *The Economics of Patents: Lessons from Recent U.S. Patent Reform*, 16 J. ECON. PERSP. 131, 136 (2002).

25. SACGHS, *supra* note 12, at 20.

26. See *id.*

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.* at 20–21.

Critics also argue that disclosure of biotechnology inventions would not decrease if these inventions were not patented.³¹ Another of the primary functions of patent law is to provide for the disclosure of discoveries to the public.³² When an inventor files a patent application, it will typically be published within eighteen months.³³ This disclosure allows the public to learn of new technologies and use that knowledge as a springboard for further innovation.³⁴ Furthermore, this disclosure prevents the public from wasting resources developing something that has already been invented.³⁵ Without patenting and the disclosure that comes along with it, it is likely that inventors would hold on to their inventions as trade secrets, preventing widespread disclosure from occurring.³⁶ However, the critics of gene patents argue that even if a genetic diagnostic invention were not patented, a researcher would still disclose the invention to the public.³⁷ Researchers often seek to publish the results of their studies and findings in academic journals, which elevates the researchers' prestige within their given fields.³⁸ Furthermore, academic prizes are typically awarded to the first person who makes a groundbreaking discovery, providing incentives for prompt disclosure of results.³⁹

However, critics of gene patents overlook one key element in the chain of the discovery process: funding for research discoveries. Researchers cannot complete their studies "without considerable capital and resources."⁴⁰ Initial discoveries must be followed up with replication and validation studies, the costs of which can be prohibitive.⁴¹ Patents provide the incentive for private investors to fund such research.⁴² Although the federal government is a key funder of basic research, many researchers and their labs seek private funds to support their work.⁴³ Private investors typically require some sort of licensing privileges on the resultant patents in exchange for funding the research.⁴⁴ For example, Eli Lilly funded Myriad Genetics' research into the genes associated with breast cancer (BRCA genes) on the assumption that Myriad would be the first to discover and patent the

31. *Id.* at 26.

32. *See id.*

33. MPEP § 1120 (8th ed. Rev. 6, Sept. 2007).

34. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974).

35. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1062 (1989).

36. *Id.* at 1030.

37. *See, e.g.*, SACGHS, *supra* note 12, at 26–27.

38. *See id.*

39. *Id.* at 27.

40. *Id.* at 23.

41. *Id.*

42. *Id.*

43. *Id.* at 25.

44. *Id.* at 23.

genes.⁴⁵ Eli Lilly would then receive “licensing privileges for diagnostic kits and therapeutic products” associated with the genes in return for their investment.⁴⁶ The costs of developing a diagnostic test are typically high enough that patent protection is sought to fund development.⁴⁷ In addition, genetic sequences are often the basis for many pharmaceutical and biological therapies, which require expensive clinical trials, and patent protection is key for the development of commercial products.⁴⁸ When a genetic diagnostic invention is patented and exclusively owned, the patent holder will have a strong incentive to educate physicians and patients about the test and market it to patients.⁴⁹

Legal concerns about gene patents center on the problems with patient access to genetic testing services. Scholars are concerned that a patent thicket will develop because many different patent holders own the rights to many different genes.⁵⁰ A patent thicket occurs when there is “a dense web of overlapping intellectual property rights that . . . must [be] hack[ed] . . . through in order to actually commercialize new technology.”⁵¹ As more and more rights holders emerge, it is feared that the development of useful diagnostic technologies that incorporate the use of several patented genes will be stymied. Critics of gene patents urge that the banning of composition of matter gene patents would provide a useful solution.⁵² However, only 3% of gene patent claims on the composition of matter itself can be classified as “blocking.”⁵³ Blocking patents are patents that have claims that overlap, so that one patent cannot be practiced without infringing another patent.⁵⁴ The existence of blocking patents can be a direct indication of a patent thicket.⁵⁵ As not many blocking gene patents exist, it does

45. *Id.*

46. E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS MED. S39, S41 (2010).

47. SACGHS, *supra* note 12, at 34.

48. Frederic M. Scherer, *The Economics of Human Gene Patents*, 77 ACAD. MED. 1348, 1352 (2002).

49. SACGHS, *supra* note 12, at 36.

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

51. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam B. Jaffe et al. eds., 2001).

52. See, e.g., SACGHS, *supra* note 12, at 91.

53. Isabelle Huys et al., *Legal Uncertainty in the Area of Genetic Diagnostic Testing*, 27 NATURE BIOTECHNOLOGY 903, 906–08 (2009) (explaining that although there is not a thicket of patents on gene sequences, there may be a patent thicket on method and functional use claims).

54. JEANNE CLARK ET AL., U.S. PATENT AND TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? 8 (2000), available at <http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf>.

55. See, e.g., Huys et al., *supra* note 53, at 908.

not appear that banning patents on genes would provide a useful solution to the alleged patent thicket problem.⁵⁶

Many critics of gene patents feel that the problems associated with such patents far outweigh any benefits and that gene patents should therefore be banned.⁵⁷ Recent legal cases have highlighted the critics' efforts. In 2010, Judge Robert Sweet, in the Southern District of New York, invalidated composition of matter and method claims associated with Myriad Genetics' patent on breast cancer genes.⁵⁸ Judge Sweet explained that isolated genes are not distinct enough from their natural counterparts and that patentable subject matter must be markedly different from a product of nature.⁵⁹ Judge Sweet also cited the views of amici who believed the use of patents to deprive patients of medical tests was unethical.⁶⁰ Siding with Judge Sweet, some scholars reason that gene patents should be banned on ethical grounds, as it appears immoral to allow individuals to own genes found in another human being.⁶¹ However, as illustrated above, it is not the genes as found within the human body that are patentable, but rather the isolated and purified genes. Furthermore, all humans share 99.9% of the same genetic code.⁶² Patent holders do not have ownership in the genes of any particular individual but instead have property rights in gene sequences that are found in the population as a whole.

We also should be wary of treating one area of innovation and research differently from all others. Banning a particular type of patent may be an overreaction to the threats posed by those patents.⁶³ Claims on DNA sequences protect inventions involving therapeutic proteins, monoclonal antibodies, and transgenic plants in addition to genetic diagnostics.⁶⁴ Attempts to ban patents on this type of technology threaten the proper functioning of the entire biotechnology industry.⁶⁵ Instead of trying to solve the problem of gene patents from within the basic framework of patent law, we should find an alternate means to enable gene patents to better serve the goals of our intellectual property laws.

56. *Id.* at 909.

57. *See, e.g.,* SACGHS, *supra* note 12, at 91.

58. Ass'n. for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

59. *Id.* at 229.

60. *Id.* at 209.

61. Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 69 (2002).

62. WILLIAM GOODWIN ET AL., AN INTRODUCTION TO FORENSIC GENETICS 11 (2007).

63. David B. Resnik, *A Biotechnology Patent Pool: An Idea Whose Time Has Come?*, J. PHIL., SCI. & L. (January 2003), <http://www6.miami.edu/ethics/jpsl/archives/papers/biotechPatent.html>.

64. Geoffrey Kamy, *In Defense of Gene Patenting*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS, Apr. 1, 2007, at 6, available at <http://www.genengnews.com/gen-articles/in-defense-of-gene-patenting/2052/>.

65. *Id.*

III. STEPPING STONE TO CLARITY: RESOLVING CONFUSION IN PATENT TERMINOLOGY AS APPLIED TO BIOTECHNOLOGY

Although a patent thicket may not exist on claimed genes, there do seem to be problems with method claims on genetic diagnostics.⁶⁶ Many test developers are deciding that further innovation is not worth the effort because of high transaction costs and the existence of many patent holders.⁶⁷ This is especially true for multiplex and whole genome sequencing tests where many genes are involved.⁶⁸ This problem is commonly known as “the tragedy of the anticommons.” In the context of patent law, the tragedy of the anticommons is a situation in which there are so many property rights held by so many different owners that it is difficult for parties to successfully negotiate licensing rights on the patented inventions.⁶⁹ As it becomes increasingly difficult for clinical laboratories to discover who the patent holders are on specific gene patents and whether those patents are licensed for others to use, laboratories often decide to forego the use of some genetic tests.⁷⁰ Consequently, patients cannot receive access to potentially life-saving tests because only a few labs across the United States own licensing rights to perform these tests.

What is the solution to this increasingly complex problem? If the banning of gene patents is neither an effective nor a plausible solution, and it is problematic to treat one sector of technology differently from all others within our patent law framework, it is necessary to look for external solutions — outside ways to improve communication between patent holders and potential licensees. This preserves the integrity of our patent system while correcting many of the problems associated with gene patents, ultimately bringing diagnostic tests to the patients who need them.

The lack of transparency that exists between patent holders and potential licensees needs to be resolved in order to enable the widespread use of genetic diagnostics. Confusing patent terminology creates a disconnect between these two types of parties. It is important to clarify gene patent terminology rather than alter the patent system itself. Biotechnology, with its close association with living and breathing organisms, is distinct from all other technology fields. Because of this, the scope of common patent terms is not always clear in this context.

The Patent Act sets forth the requirement that all inventors must provide as part of their application a sufficient written description of

66. Huys et al., *supra* note 53, at 908.

67. SACGHS, *supra* note 12, at 3.

68. *Id.*

69. Heller & Eisenberg, *supra* note 50, at 698.

70. Cho et al., *supra* note 9, at 7.

their invention that enables one skilled in the art to make and use that invention.⁷¹ However, unclear terminology in gene patent claims sometimes makes it difficult for those skilled in the art to understand exactly what has been patented and what acts would constitute infringement of the patent. Most gene claims are on complementary DNA (“cDNA”) sequences, as opposed to DNA sequences.⁷² However, most protocols and guidelines for genetic diagnostic testing do not detail the use of cDNA as starting material for tests.⁷³ Typical protocols recommend starting from human blood samples to isolate genomic DNA sequences.⁷⁴ Thus, it is unclear whether the use of genomic DNA in a blood sample as a template for a genetic test would infringe on a cDNA claim.⁷⁵ And with nucleic acids forming the basic structure of DNA, cDNA, RNA, primers, *and* probes, it is sometimes difficult to determine the exact scope of gene claims.⁷⁶ With all of these nucleotide structures, made from the same building blocks, it can be ambiguous what the terms “product” and “use” mean in the context of genetic tests and whether infringement of claims has occurred.⁷⁷ Many gene patent claims appear vulnerable to changing interpretations.⁷⁸

The patent examination guidelines provide that genetic sequences can only be patented if some sort of human intervention occurs, such as isolation from the human body.⁷⁹ However, the context of the term “isolation” can be far from clear when used in a patent claim. A study conducted on patents for twenty-two molecular diagnostic tests found that the term “isolated” was rarely clarified within the patent description; when it was elaborated upon, it was obscured by other unclear language or broad terms.⁸⁰ An example of this appears in the Myriad patent on a BRCA gene, in which the meaning and scope of the term “isolated” is far from clear.⁸¹

71. 35 U.S.C. § 112 (2006).

72. Huys et al., *supra* note 53, at 908. Patents are sought on cDNA, as these sequences contain only the coding regions found in genomic DNA. See Lori Andrews, *Michael Crichton Is Right About Gene Patents*, TCS DAILY (Jan. 23, 2007, 12:00 AM), http://www.ideasinactiontv.com/tcs_daily/2007/01/michael-crichton-is-right-about-gene-patents.html.

73. Huys et al., *supra* note 53, at 908.

74. *Id.*

75. *Id.*

76. *Id.*

77. *Id.*

78. Subhashini Chandrasekharan & Robert Cook-Deegan, *Gene Patents and Personalized Medicine — What Lies Ahead?*, 1 GENOME MED. 1 (2009).

79. MPEP § 2105 (8th ed. Rev. 6, Sept. 2007).

80. Huys et al., *supra* note 53, at 908.

81. *See Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 216 (S.D.N.Y. 2010).

This confusion creates legal uncertainty within the field of patents on genetic diagnostics.⁸² Neither the courts nor Congress has resolved this confusion.⁸³ To effectively resolve this significant uncertainty, experts skilled in this particular art should clearly define these commonly-used terms, possibly from within the United States Patent and Trademark Office (“USPTO”). Although the USPTO does not currently have substantive rule-making power, with the implementation of something like a clearinghouse, as discussed in Part IV, one can imagine the USPTO one day having this capability. The USPTO could create model or standard definitions for patent applications. These definitions could then be assumed for all biotech patents unless the patentee defines them otherwise.⁸⁴ Since patent examiners are grouped into art units, it seems plausible that the examiners assigned to the applications for patents on genetic diagnostic tests would be the best equipped to define the terms that patent applicants most commonly use. They could work in coordination with the staff of the Manual of Patent Examining Procedure (“MPEP”) to update the MPEP with clearer guidelines in this particular sector. If disputes arise, appeals through the courts will result in further refinement of the definitions. But with the amount of uncertainty that is currently in place, it seems that some effort from within the USPTO will be necessary, as any efforts from the courts or Congress will likely be slow to occur. Resolving these definitional issues will sharply decrease terminology disagreements between parties to infringement suits. How can a clinical laboratory know if it will be infringing a patent unless it has been given an adequate description of all the terms used within the patent? A lab might forego the use of a diagnostic test if it cannot effectively negotiate with the patent holder and incorrectly believes it would be infringing the patent otherwise.⁸⁵ Resolving these issues will go a long way toward keeping both parties on a level playing field.

IV. THE SOLUTION: A BIOTECHNOLOGY CLEARINGHOUSE

The second step necessary to resolve the lack of transparency in the market between gene patent holders and potential licensees is to create a well-functioning market for these biotechnology patents. A well-functioning market must be (1) thick with many buyers and sellers, (2) uncongested so that a party can easily deal with many other parties on the opposite side of the market, and (3) safe such that

82. Huys et al., *supra* note 53, at 908.

83. *See id.* at 909.

84. MPEP § 2111.01 (8th ed. Rev. 6, Sept. 2007).

85. *See* John P. Walsh et al., *View from the Bench: Patents, Research and Material Transfers*, 309 SCIENCE 2002, 2002 (2005).

strategizing or bargaining outside of the market is not profitable.⁸⁶ The current market for technology, including biotechnology patents, possesses none of these attributes.⁸⁷

Currently, transaction costs are too high for gene patent holders and potential licensees to communicate effectively about patent licensing.⁸⁸ Because of these high transaction costs, many gene patent holders and potential licensees decide that trying to transact with parties on the other side of the market is not worth it.⁸⁹ Consequently, current licensing practices of gene patents are not optimal for the wide distribution of this technology, and patient access is hindered. A recent study found that “out of 100 licensable technologies, in only 25 cases a potential licensee is found, in six to seven cases, negotiations are started, and three to four deals are eventually concluded.”⁹⁰ The most commonly offered explanations for such a small number of licensing deals include the high costs of searching for potential licensees, wariness over opportunism in licensing deals, and lack of sufficient monitoring capabilities to ensure the valid enforcement of intellectual property rights.⁹¹ To optimize the licensing of gene patents for patient access, each of these issues needs to be resolved.

A. A Patent Pool: Not the Best Solution

One frequently proposed solution is the formation of a biotechnology patent pool.⁹² A patent pool is formed when a group of individuals holding patents on similar technologies come together to cross-license their patents as a package amongst themselves or to third parties.⁹³ This will occur when members decide that it is more profitable for all of them to work together in licensing their technologies as a group to prevent issues surrounding blocking patents.⁹⁴ The patent pool is typically managed either by one of its members on behalf of the rest or by a third-party management organization.⁹⁵ Examples of

86. Ashish Arora & Alfonso Gambardella, *Ideas for Rent: An Overview of Markets for Technology*, 19 INDUS. & CORP. CHANGE 775, 778 (2010).

87. *Id.*

88. See Walsh et al., *supra* note 85, at 2002.

89. See *id.*

90. *Id.* at 787.

91. *Id.*

92. Resnik, *supra* note 63.

93. Reiko Aoki & Aaron Schiff, *Promoting Access to Intellectual Property: Patent Pools, Copyright Collectives, and Clearinghouses*, 38 R&D MGMT. 189, 194 (2008) [hereinafter Aoki & Schiff, *Promoting Access to Intellectual Property*].

94. Bradley J. Levang, *Evaluating the Use of Patent Pools for Biotechnology: A Refutation to the USPTO White Paper Concerning Biotechnology Patent Pools*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 229, 236 (2002).

95. Aoki & Schiff, *Promoting Access to Intellectual Property*, *supra* note 93, at 195.

effective patent pools may be found in the mobile communications and video encoding industries.⁹⁶

However, there are several obstacles to the implementation of a patent pool in the biotechnology industry.⁹⁷ First, the costs of initially forming and subsequently maintaining a patent pool are very high.⁹⁸ Companies in the video encoding and consumer electronics industries worked together to finance their pools in anticipation of the profits of mass-produced consumer devices.⁹⁹ It does not seem plausible that gene patent holders will be quite as willing to invest such money into a pool that does not have as wide a consumer base as these other industries.¹⁰⁰ Furthermore, patent pools are often prone to antitrust issues.¹⁰¹ As the patent pool works on behalf of its member patent holders, it is easy for patent holders to collude to fix prices.¹⁰² Finally, a single patent pool is only effective as long as all of the patents within it are complementary to each other and none are substitutes.¹⁰³ If substitutes are present in the pool, it would no longer be efficiency-enhancing, as pool members would try to increase profits at the expense of patent users.¹⁰⁴ Since most gene patent claims are on methods,¹⁰⁵ it seems likely that substitute technologies will be patented.¹⁰⁶ This could lead to the formation of multiple biotechnology patent pools to avoid substitute technologies within a single pool. Multiple patent pools would cause fragmentation rather than centralization of biotechnology, leading to further confusion instead of transparency for potential licensees. Although a biotechnology patent pool has some appeal, it does not appear to be the most promising solution.

B. A Clearinghouse: Higher Probability of Success

An often-overlooked solution is to create a third-party biotechnology clearinghouse. Clearinghouses were first used in the banking industry as a means for banks to transfer only net balances in cash but have expanded to encompass any means of matching providers and

96. *Id.*

97. *See* Levang, *supra* note 94, at 240–51.

98. *Id.* at 242.

99. *Id.*

100. *See id.*

101. *Id.* at 244.

102. *Id.*

103. Aoki & Schiff, *Promoting Access to Intellectual Property*, *supra* note 93, at 199. Substitutes are technologies that can be replaced by one another.

104. *Id.* at 194.

105. Huys et al., *supra* note 53, at 908.

106. Since most gene patents claim methods, it seems likely that there would be substitutes, as one can imagine multiple methods for diagnosing the same disease.

users of goods or information.¹⁰⁷ In the realm of intellectual property, clearinghouses facilitate the matching of patent holders and potential licensees, either for the transfer of information about patented technologies or, more importantly, for the arrangement of potential licensing deals. Unlike a patent pool, a third-party clearinghouse is a two-sided platform that would seek to maximize its own profits instead of those of the patent holders.¹⁰⁸ It works on behalf of parties on both sides of the platform as opposed to just patent holders.

A clearinghouse is much more likely to resolve the issue of lack of transparency between patent holders and potential licensees than is a patent pool, as it can successfully tackle each of the three problems that stand in the way of successful licensing deals. First, a clearinghouse can minimize the high transaction costs that prevent patent holders and potential licensees from communicating effectively by aggregating information about the technology needs of parties on both sides into a single database.¹⁰⁹ If many parties use this database, it could become the best and easiest source for gathering information about potential parties to a transaction. Second, as a third-party player in the deals between patent holders and licensees, the clearinghouse can eliminate the problem of opportunism in licensing deals by using standardized licensing practices and legal expertise to monitor fair deals.¹¹⁰ Third, the clearinghouse can use legal experts to monitor the enforcement of intellectual property rights to ensure that any patent infringement or other violation of licensing deals is detected, providing incentives for licensees to exercise only those privileges provided for in their licenses.¹¹¹

Throughout history, patent agents and lawyers have played a significant role in matching inventors with parties who are eager to develop and commercialize inventions.¹¹² By the late nineteenth century, buyers of new technology would often consult with patent agents or patent lawyers about the merits of an invention prior to purchase.¹¹³ Patent lawyers in various cities across the country would often use networking connections to market patents to potential buyers.¹¹⁴ Acting as intermediaries in the market for technology, patent agents and

107. Esther van Zimmeren et al., *A Clearinghouse for Diagnostic Testing: The Solution to Ensure Access to and Use of Patented Genetic Inventions?*, 84 BULL. WORLD HEALTH ORG. 352, 353 (2006).

108. Aoki & Schiff, *Promoting Access to Intellectual Property*, *supra* note 93, at 200.

109. *Id.* at 197.

110. *See* Aoki & Schiff, *Promoting Access to Intellectual Property*, *supra* note 93, at 196.

111. *See id.*

112. Naomi R. Lamoreaux & Kenneth L. Sokoloff, *Intermediaries in the U.S. Market for Technology*, in FINANCE, INTERMEDIARIES AND ECONOMIC DEVELOPMENT 209, 211 (Stanley L. Engerman et al. eds., 2003).

113. *Id.* at 218.

114. *Id.* at 219.

lawyers helped improve the efficiency of patent trading.¹¹⁵ With the specialized knowledge they acquired about inventors and potential buyers, they were able to match interested parties appropriately and expeditiously.¹¹⁶ Now, as then, patent agents and lawyers with specialized knowledge in the biotechnology field have the potential to use their expertise to resolve the lack of transparency currently hindering the matching of patent holders and potential licensees in licensing deals. One can imagine that with a bit of revision, the USPTO, working in concert with patent agents and attorneys from across the country, could centrally manage a third-party clearinghouse.

A third-party clearinghouse provides two advantages over a patent pool or a clearinghouse that is managed by its members: (1) a third-party clearinghouse has the ability to centralize information and decision-making; and (2) it has independence, freeing it from bias in licensing deals and improving its economic efficiency.¹¹⁷ As an offshoot of the USPTO, a biotechnology clearinghouse would act as an independent, third-party player in licensing deals. As a non-profit government entity, it would work to promote transparency and further innovation in the biotechnology sector rather than seek a profit. Additionally, with the expertise of patent examiners, patent agents, and patent lawyers, it would have the ability to centralize information efficiently and maximize congruency in the matching of patent holders and potential licensees.

1. Providing an Online Searchable Database

One example of a third-party patent clearinghouse currently in place is Google's patent search function.¹¹⁸ Though Google does not coordinate licensing deals, it centralizes information about patents into a single database and provides this information to potential licensees along with the rest of the public.¹¹⁹ This centralized system is more effective at distributing information about patents than individual investigations undertaken by small-scale licensees. The centralization of searching into a single database allows for the use of more sophisticated and extensive search capabilities and the distribution of costs over a wide number of users.¹²⁰ Similarly to Google Patents, the third-party biotechnology clearinghouse could present to the public

115. *Id.* at 221.

116. *Id.*

117. Reiko Aoki & Aaron Schiff, Third-Party Clearinghouses and Intellectual Property Licensing 3 (Feb. 25, 2008) (unpublished article) [hereinafter Aoki & Schiff, Third-Party Clearinghouses], available at <http://ssrn.com/abstract=1018578>.

118. GOOGLE PATENTS, <http://www.google.com/patents> (last visited May 6, 2011).

119. *About Google Patent Search*, GOOGLE PATENTS, <http://www.google.com/googlepatents/about.html> (last visited May 6, 2011).

120. Aoki & Schiff, *Promoting Access to Intellectual Property*, *supra* note 93, at 197.

and potential licensees an online searchable database that collects information on biotechnology patents. The database can also collect information from potential licensees on their technology needs, allowing patent holders to search the database as well. This could be likened to a dating site for patent holders and interested licensees, each looking for its perfect match.

2. Overseeing Licensing Deals

Going a step further than Google Patents, the proposed biotechnology clearinghouse could also arrange and determine the details of licensing deals. First, with information collected on many patent holders, the clearinghouse could bundle various licenses into packages for licensees to purchase as a group. This would be particularly helpful for licensees seeking to develop technologies that utilize several different genes in one device, like technologies for multiplex testing or whole genome sequencing.¹²¹ These licensees would no longer have to contact each patent holder individually and negotiate licensing terms. The clearinghouse can use its expertise to bundle licenses for particular multiplex tests in advance. Then a potential licensee could use a simple search function to find the bundled package of licenses that she needs and purchase licensing rights with a simple click of her mouse. It would, of course, be necessary to have experts within the clearinghouse review the patent bundles to ensure that all licensing rights are essential for the downstream technology, especially where a licensee is unable to make this assessment herself.¹²²

3. Standardizing Licensing

The clearinghouse would also provide for standardized licensing, eliminating much of the confusion currently present in licensing deals and minimizing the chance for opportunism. Standardized licenses would also reduce transaction costs between the parties and reduce the time spent negotiating licensing deals.¹²³ Each license provided through the clearinghouse would have a set of essential clauses present in every license agreement.¹²⁴ These would include such terms as the licensed subject matter, field of use, license rate, and term of the license.¹²⁵ The license would also include non-essential clauses as

121. SACGHS, *supra* note 12, at 26.

122. See Aoki & Schiff, *Third-Party Clearinghouses*, *supra* note 117, at 26.

123. Lynda Covello & David Newman, *Standardizing Patent License Agreements: A Method of Evaluating What May Be Standardized*, 2010 LICENSING EXECUTIVES SOC'Y 1, available at <http://www.gtlaw.com/NewsEvents/Publications/PublishedArticles?find=146924>.

124. *Id.*

125. *Id.* at 2.

needed, such as patent marking, effects of termination, and dispute resolution, which could be standardized as much as possible.¹²⁶ Categorizing license agreements into these essential and non-essential clauses will allow for a consistent methodology across all licenses, allowing potential licensees to follow all licensing deals within the clearinghouse easily. This standardization will sharply reduce the legal fees that go into licensing negotiations and will streamline much of the license drafting process.¹²⁷ After the clearinghouse has set a standard licensing format, patentees can then fill in the blanks in the licensing deals without much independent drafting.

4. Setting Licensing Prices

The clearinghouse will also have the ability to set licensing prices more accurately. Currently, final licensing prices are typically set around an opening bid.¹²⁸ Whatever a potential licensee suggests as its opening bid, that number will anchor all subsequent negotiations that a patent holder has with any potential licensees.¹²⁹ Furthermore, most potential licensees fear that they will end up paying more than what a technology is actually worth.¹³⁰ Thus, they tend to hedge their bets and bid less than the value they actually expect the technology to return, sometimes reducing the value of their bids by up to 65%.¹³¹ Unlike physical commodities, the price of a technology or innovation cannot easily be anchored to a particular valuation measure.¹³² Imprecise valuations by patent holders and potential licensees can often lead to impasses in negotiations, preventing efficient licensing from occurring.¹³³ Thus, it might be beneficial if the prices of licensing deals were determined by experts. The patent examiners, agents, and attorneys from within the clearinghouse at the USPTO, in conjunction with economists and finance professionals, could use their expertise in the field to resolve uncertainty concerning the value of innovations.¹³⁴ Lawyers with experience in this field can be consulted to determine the appropriate value of these deals. This is similar to what patent agents and lawyers did at the turn of the twentieth century, when technology buyers would consult them on the value of new technologies.¹³⁵

126. *Id.*

127. *Id.* at 3.

128. See Arora & Gambardella, *supra* note 86, at 791.

129. *Id.*

130. *Id.* at 790.

131. *Id.*

132. *Id.* at 791.

133. *Id.*

134. See Aoki & Schiff, Third-Party Clearinghouses, *supra* note 117, at 8–9.

135. *Id.* at 9.

5. Incorporating Know-How Licensing

Another aspect of technology transfer that the clearinghouse will have to manage is licenses for know-how. Know-how concerns the practical knowledge that is needed to complete a certain activity or task.¹³⁶ It consists of any unpatented inventions or methods along with accumulated skills or experiences that are necessary to make and use the patented invention. Know-how is typically kept confidential. Its transfer is sometimes necessary along with the licensing of a patent when a patent holder has developed special techniques that are required to successfully develop the patented product, though the techniques themselves are not or cannot be patented.¹³⁷ For the licensee to manufacture and subsequently sell a product that incorporates the patented technology, he must also gain the patent holder's confidential know-how. Thus, patent holders will often license know-how alongside patented inventions. A recent study of representative patent-filing firms in Europe and Japan found that over 40% of European licensors indicated that the transfer of know-how was involved in more than 20% of their licensing deals, while 25% of Japanese firms reported the same.¹³⁸

6. Monitoring and Enforcing Licensing Deals

To ensure the effective transfer of technology between patent holders and licensees, the biotechnology clearinghouse can go one step further in the licensing process and monitor the use of the licenses to detect any patent infringement. Such a mechanism would be extremely valuable to licensors as the cost for a clearinghouse to monitor and enforce licensing deals is likely much less than the total cost for all licensors to monitor licensing deals individually.¹³⁹ Best practices for monitoring licensing deals include maintaining contact lists of all licensees, which should not be difficult if each licensee must register with the clearinghouse before entering into any licensing deals, and managing a filing system including data on royalty payments, receipts, and reporting updates from licensees.¹⁴⁰ It would also be valuable to solicit periodic updates from licensors so that the clearinghouse can be aware of any potential infringement that patent hold-

136. Joanne Roberts, *From Know-How to Show-How? Questioning the Role of Information and Communication Technologies in Knowledge Transfer*, 12 *TECH. ANALYSIS & STRATEGIC MGMT.* 429, 431 (2000).

137. *See id.*

138. Arora & Gambardella, *supra* note 86, at 780.

139. *Id.* at 11.

140. Anatole Krattiger et al., *Monitoring, Enforcement, and Resolving Disputes*, in *EXECUTIVE GUIDE TO INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES* 163, 164 (Anatole Krattiger et al. eds., 2007), available at <http://www.iphandbook.org/handbook/ch15/summary/>.

ers may have learned about.¹⁴¹ Furthermore, experts within the clearinghouse can regularly review media coverage of technology news to seek out potential infringers.¹⁴²

7. Establishing an Alternative Dispute Resolution System

In conjunction with the monitoring and enforcement of licensing deals, the clearinghouse can maintain an alternative dispute resolution system. This may include methods such as mediation and arbitration, specialized for the biotechnology patents licensed from the clearinghouse. Both patent holders and licensees will find this attractive, as the costs and risks associated with litigation can be high.¹⁴³ Licenses granted from the clearinghouse could include an essential clause that all disputes will first be handled through such alternative dispute mechanisms provided by the clearinghouse. Thus, an agreed upon system of dispute resolution could be set up between parties before any difficulties even arise.¹⁴⁴

8. Divvying Royalty Payments

An important consideration for the clearinghouse will be how to divvy up the royalty payments to the patent holders or licensors of the clearinghouse. The clearinghouse can either divide royalty payments equally among all the patent holders in the clearinghouse, or there can be an unequal royalty payment scheme where each patent holder receives royalties in direct proportion to the number of licensing deals it has made and the licensing payments from those deals. The latter method is likely preferable as compared to the equal royalty scheme because the unequal scheme can improve welfare in all licensing situations.¹⁴⁵ Furthermore, the unequal scheme will incentivize the full participation of all biotechnology inventors within the clearinghouse, as discussed in the next section.

V. ESTABLISHING THE CLEARINGHOUSE

A. Membership Fee Schemes

Both patent holders and potential licensees may initially be skeptical of this new system's potential for success and may be reluctant to

141. *See id.*

142. *Id.*

143. *Id.* at 165.

144. *Id.*

145. Reiko Aoki & Aaron Schiff, Intellectual Property Clearinghouses and Investment in R&D 3 (Jan. 30, 2008) (unpublished article), available at <http://ssrn.com/abstract=1097489>.

join the clearinghouse.¹⁴⁶ However, it is crucial that many parties from both sides of the platform join for the clearinghouse to be successful.¹⁴⁷ Guaranteeing large membership may “require[] some kind of intervention by the clearinghouse.”¹⁴⁸ First, the clearinghouse must determine how membership fees will be collected so as to fund the work of the clearinghouse. Either one or both sides of the platform could pay membership fees upon joining the clearinghouse. However, fees simply to join the clearinghouse might dissuade many parties from joining. If a patent holder is unsure that the clearinghouse will be of any worth to him, especially if he must pay fees simply to allow other parties to find his patent and licenses within the database, he may not join it. Similarly, potential licensees, who already must struggle with fees once they have settled a licensing deal, might be deterred from the clearinghouse once they have realized that they must pay another fee to simply search for licenses within the database. A search for alternative schemes to fund the clearinghouse seems necessary.

1. Unequal Fee Scheme

One type of membership fee scheme is an unequal scheme between the two sides of the platform, where only one type of party pays to join the clearinghouse, while the other is granted free access. Success of a clearinghouse depends on whether a critical mass of membership has been reached. However, with a two-sided platform, it is only necessary to achieve critical mass on one side of the platform, as the existence of many members on one side will induce members on the other side to join. Here, it makes the most sense to provide free membership to the side of the market that is otherwise least likely to join the clearinghouse, while making the other side of the market pay membership fees. The side of the market that is less likely to join the clearinghouse is the patent holder side.¹⁴⁹ Patent holders could easily decide to develop the technology on their own or to license the patent outside of the market at a very high rate to only one or a few licensees to avoid the extra costs associated with the clearinghouse. If patent holders do not have to pay a fee to use the clearinghouse, they will be much more likely to join even if they have pessimistic expectations about the success of such a mechanism.¹⁵⁰ Potential licensees, on the other hand, will be more willing to pay a fee to use the clearinghouse

146. Aoki & Schiff, *Promoting Access to Intellectual Property*, *supra* note 93, at 200.

147. See Aoki & Schiff, *Third-Party Clearinghouses*, *supra* note 117, at 12.

148. Aoki & Schiff, *Promoting Access to Intellectual Property*, *supra* note 93, at 201.

149. See Aoki & Schiff, *Third-Party Clearinghouses*, *supra* note 117, at 14.

150. *Id.* at 13.

since they know they will receive access to much information that they could not find otherwise.¹⁵¹

2. Success-Based Fee Scheme

Another type of fee that might be better suited for the clearinghouse is a success-based fee. This type of fee would only be paid upon the conclusion of a successful licensing deal between two parties of the clearinghouse.¹⁵² Therefore, two parties do not pay simply to join the clearinghouse, but pay whenever a deal is consummated. However, this type of scheme will require close monitoring by the clearinghouse to ensure that all deals made using the clearinghouse's system are accounted for and paid.¹⁵³ Instead, we could try to integrate this model with that of the unequal membership fee scheme, such that only licensees would pay a fee upon the successful completion of a licensing deal. As opposed to the unequal fee scheme, where one party must bear all the costs to see the information, this scheme increases transparency within the clearinghouse by not imposing financial barriers for simply accessing information. The success-based fee scheme might resolve this problem, as all parties will be able to see information for free. Further economic research should be conducted to determine the scheme that is best suited for a well-functioning biotechnology clearinghouse.

3. Advertisement-Based Funding

Another way to fund the clearinghouse would not require any membership fees. Instead, the clearinghouse could obtain advertisement-based fees. As the clearinghouse would be a searchable online database, the use of advertisements might be particularly appropriate. A model for this approach is Google's online patent search database, which generates advertising revenue. Users of the clearinghouse could also submit advertisements. For instance, downstream technology developers could advertise their products for others' diagnostics or laboratory needs.

B. Patent Holder Membership Is Key

As discussed above, the patent holder side of the market is less likely to join the clearinghouse.¹⁵⁴ Patent holders do have other alternatives. They can develop the technology encompassed by their patent

151. *See id.*

152. *Id.* at 15.

153. *Id.*

154. *See id.* at 14.

themselves and avoid licensing to competitors, or they can charge a very high price for licensing and only license to a few technology developers. Yet for the clearinghouse to be of much use to potential licensees, most, if not all, biotechnology patent holders must join the clearinghouse.¹⁵⁵ There should be incentives in place to induce patent holders to join. As previously discussed, patent holders could be allowed to join the clearinghouse free of charge, providing great incentives and very few drawbacks to involvement in the clearinghouse.¹⁵⁶

Some patent holders may decide that it is in their best interests not to license their patents and instead to develop the technology themselves, avoiding competition with licensees. These patent holders will not join the clearinghouse even if membership were free to all licensors. To overcome this problem, we must convince patent holders that licensing is advantageous for them. Studies have shown that internal research and development and licensing should be considered as complements rather than substitutes — meaning that patent holders, even if they themselves are developing the technology in their patents, would find it advantageous to license as well.¹⁵⁷ Dispersing this information to patent holders would allow them to realize that licensing through the clearinghouse can bring monetary benefits.

Another potential incentive to attract patent holders to the clearinghouse would be to expedite the patent prosecution process on all biotechnology patents whose holders agree to license the patent through the clearinghouse once it is granted. The sooner a patent is granted, the sooner a patent holder can start receiving revenue on its technology. Patent holders can sometimes start licensing or developing products during the patent application process, but this technology is typically worth more once a patent has been granted.¹⁵⁸ However, such a scheme must be carefully designed to not run afoul of the patent statute. In the patent examination process, the USPTO currently permits “petitions to make special,” which allow for accelerated examination of a patent application. Section 708.02(b) of the MPEP provides that “[a]pplications wherein the inventions are deemed of peculiar importance to some branch of the public service . . . may be advanced for examination.”¹⁵⁹ As the diagnostic technologies encompassed by these patents have life-saving potential for some patients, it is reasonable to believe that these inventions could be deemed to be of “peculiar” importance. Furthermore, the USPTO already grants expedited patent examination to applications involving recombinant DNA

155. *See id.* at 13.

156. *Id.*

157. Arora & Gambardella, *supra* note 86, at 786.

158. Gili Greenberg, Small Firms, Big Patents? Estimating Patent Value Using Data on Start-Ups’ Financing Rounds 21 (Dec. 2009) (unpublished manuscript), available at <http://www2.druid.dk/conferences/viewpaper.php?id=500704&cf=44>.

159. MPEP § 708.02(b) (8th ed. Rev. 6, Sept. 2007).

and biotechnology applications from small entities.¹⁶⁰ It is not difficult to imagine that expedited examination could be extended to all biotechnology applications, on the condition that the applicants agree to license their patents through the USPTO's clearinghouse.

VI. CONCLUSION

To develop such a clearinghouse, the project must attract widespread policy support. Education and awareness of the benefits of a clearinghouse in the biotechnology sector need to be promoted. A clearinghouse also requires financial capital to get off the ground. If such an expansive clearinghouse does succeed within the biotechnology sector, there is potential for other similar clearinghouses to be established in other technology sectors where needed. The establishment of a clearinghouse in this field shines as the "transparent crystal, bright and clear" as Longfellow suggested in the opening quote. We have all the elements to alter the "flint Into transparent crystal" — the patents, patent holders, licenses, licensees, etc. — and the steps that must be undertaken for the "celestial fire" of genius to transform those flints are clear. Now we must undertake the most difficult step of all by sparking that fire and initiating the process.

160. *Id.* § 708.02.