TO THE FRONT OF THE LINE: SPURRING BIOTECH COLLABORATION THROUGH PATENT FAST-TRACK EXAMINATION VOUCHERS

I. INTRODUCTION

The current incentive behind patent law with respect to biotechnology research may be falling short of its constitutional basis.[1] The possibility of data secrecy and upstream over-patenting may be creating an "anticommons" that strangles downstream research and development. [2] Instead of focusing on statutory changes to the patent law, an incentive program by the United States Patent and TradeOffice ("USPTO") that encourages voluntary data sharing and open use of research tools by granting fast-track examination and reexamination vouchers might be a novel solution to combat the possible anticommons and help "promote the Progress of Science and the useful Arts" in the realm of biotechnology research.[3] The Alzheimer's Disease Neuroimaging Initiative ("ADNI") will be reviewed as a model for the benefits of data sharing and collaboration.

This Comment will elaborate on this proposal by first introducing the ADNI as a foundation for the benefits, goals and necessities of data sharing in biotechnology research in Part II.[4] Part III of this Comment will give an overview of patent law and purposes.[5] Part IV will discuss the Bayh-Dole Act and its influence on university research and patent practices.[6] Part V will discuss the "Theory of the Anticommons," investigating its possible existence and impact on biotechnology research.[7] Part VI reviews past proposed solutions to reduce the occurrence and impact of an anticommons on biotechnology research.[8] Part VII gives an overview and criticisms of the FDA priority review voucher system.[9] Part VIII reviews the USPTO proposal of a humanitarian reexamination voucher program and will propose

1. U.S. CONST. art. I, § 8, cl. 8.

2. Under an anticommons, multiple owners hold exclusionary rights in a scarce resource to such a degree that others cannot effectively use the resource. *See infra* Part V.A.

3. U.S. CONST. art. I, § 8, cl. 8.

4. See infra Part II.

5. See infra Part III.

6. See infra Part IV.

7. See infra Part V.

8. See infra Part VI.

9. See infra Part VII.

expansion of this proposal to include patent incentives for entering into data and research collaboration efforts.[10] Finally, Part IX concludes that a fast-track examination voucher awarded to qualifying researchers who participate in an open data and research tool collaboration could be an efficient incentive mechanism to overcome a possible biotechnology anticommons through voluntary participation.[11]

II. ALZHEIMER'S DISEASE NEUROIMAGING INITIATIVE (ADNI) AND DATA SHARING

In August of 2010 the beneficial results of a new way of conducting large scale biomedical research came to light.[12] Seven years prior, in 2003, scientists and high-level officials from the National Institutes of Health, the Food and Drug Administration, universities and non-profit organizations, along with the pharmaceutical and medical imaging industries joined forces in an unprecedented, "collaborative effort to find the biological markers that show the progression of Alzheimer's disease in the human brain."[13] Thus the ADNI was born.[14]

What made the collaboration so unique and ambitious was not only its goal of tackling Alzheimer's but also the agreement to "share all the data, making every single finding public immediately, available to anyone with a computer anywhere in the world."[15] Since no other research is conducted under a similar premise, the fact that no single entity could own the data or file patent applications was "worrisome" to some scientists.[16] Many feared that with open, public ownership of the data, less experienced researchers could "misinterpret it and publish information that was wrong."[17] However, as stated by Dr. John Q. Trojanowski, one collaborative researcher from the University of Pennsylvania, "we all realized that we would never get biomarkers unless all of us parked our egos and intellectual-property noses outside the door and agreed that all of our data would be public immediately."[18] While the data would be shared, the profit incentive remained through the ability of private entities to file patent applications on any resulting drugs or diagnostic tests.[19]

10. See infra Part VIII.
11. See infra Part IX.
12. Gina Kolata, Rare Sharing of Data Led to Results on Alzheimer's, N.Y. TIMES, Aug. 13, 2010, at A1.
13. *Id.*
14. *Id.*
15. *Id.*
16. *Id.*
17. Kolata, *supra* note 12.
18. *Id.* (internal quotations omitted).
19. *Id.*

The collaboration offered a win-win situation to all involved parties. Prior to the initiative, researchers and pharmaceuticals were trapped in a "prisoner's dilemma";[20] everyone "wanted to move the field forward, but no one wanted to take the risks of doing it."[21] With large data sets requiring 800 subjects, the task was too large for any single entity to tackle.[22] Furthermore, developing robust and valid tests for the disease offered "such limited returns on the investment that it was in no one company's interest to pursue it."[23]

The ADNI has already been the model for a similar research initiative sponsored by the Michael J. Fox Foundation in the search for Parkinson's biomarkers.[24] However, some argue that freely published scientific data, resources, and "technological prospect[s]" will lead to "'chaotic, duplicative, and wasteful' effort."[25] A counter viewpoint suggests that an absence of openness will lead researchers to "unknowingly build on something less than the total accumulation of scientific knowledge or work on problems already solved."[26] While there are differing opinions on both sides regarding data sharing and openness, this Comment recognizes the widespread benefits of such a voluntary research model. This Comment proposes the ADNI model as a method of attack for many large scale human diseases. By pooling resources and disclaiming intellectual property rights in the collaborative results, the investment risks can be reduced. The downstream costs of using open, freely available data and research methods are essentially eliminated. This Comment expands upon a recent USPO proposal discussed in Part VIII to include fast-track patent examination vouchers for collaborating partners as an incentive to share data and advance scientific research. It is advanced that such a pull mechanism, operating on the voluntary participation of collaborating researchers is a more balanced approach to possible stagnation or anticommons in the biotechnology field than some of the more radical proposed solutions.[27]

20. *Id.* (internal quotations omitted).

21. *Id*. (internal quotations omitted).

22. Kolata, *supra* note 12.

23. *Id.* (internal quotations omitted).

24. *Id.*

25. Peter Lee, *Patents, Paradigm Shifts, and Progress in Biomedical Science*, 114 YALE L.J. 659, 670 (2004).

26. Eric G. Campbell et al., *Data Withholding in Academic Genetics: Evidence from a National Survey*, 287 JAMA 473, 473 (2002).

27. *See infra* Part VI.

III. OVERVIEW OF UNITED STATES PATENT LAW AND IMPACTS ON BIOTECHNOLOGY RESEARCH

Patent protection in the United States finds its roots in the U.S. Constitution.[28] Article 1, Section 8, Clause 8 states that Congress shall have the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[29] In the absence of patent law, "copyists may easily free-ride on the efforts of inventors" leading to a market failure with a dearth of invention.[30] Therefore patent law incentivizes inventive activity and disclosure by giving patent holders, or patentees, the right to exclude others from practicing, making, selling or offering to sell, and importing the patented invention.[31] This limited monopoly currently extends for twenty years from the filing date,[32] making the time between filing and patent issue critical to the length of protection and the amount of investment return.[33] Theoretically, the patent law would be the "most efficient mechanism to incentivize invention . . . while at the same time ensuring the existence of a public domain upon which additional inventions may be built."[34] In practice, however, the current patent system "may create roadblocks to the development of commercial applications, particularly when applied to a new technology, such as biotechnology."[35]

To receive patent protection an invention must be novel,[36] have some utility[37] and must be non-obvious.[38] Further, the law grants protection to a "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[39] Absent from the realm of patentable subject matter are "laws of nature, physical phenomena, and abstract ideas."[40] The law views such principles as "part of the storehouse of knowledge of all

28. U.S. CONST. art. I, § 8, cl. 8.

29. U.S. CONST. art. I, § 8, cl. 8.

30. Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 144 (2004).

31. *Id.*

32. 35 U.S.C. § 154 (2006).

33. Caroline A. Crenshaw, *Patents and Patients: Who Is the Tragedy of the Anticommons Impacting and Who Is Bearing the Cost of High-Priced Biotechnological Research?*, 9 MINN. J. L. SCI. & TECH. 913, 916 (2008) (citing Brian T. Yeh, Cong. Research Serv., RL33159, Influenza Antiviral Drugs and Patent Law Issue 6 (2005)).

34. Mireles, *supra* note 30, at 144.

35. *Id*.

36. 35 U.S.C. § 102 (2006).

37. *Id.* § 101.

38. *Id.* § 103.

39. *Id.* § 101.

40. Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) (internal quotations omitted).

men . . . free to all men and reserved exclusively to none."[41] However, such inputs, including raw data, to patentable subject matter are closely guarded[42] and it is the intent of this Comment to encourage the sharing of such inputs.

In the 1980s, the courts took a major step in advancing the biotechnology research and development field by pushing for "privatization of medical research and patent protection of new discoveries and treatment methods."[43] With the 1980 Supreme Court decision in *Diamond v. Chakrabarty*, living matter was held to be patentable subject matter within the ambit of §101.[44] The Court granted protection to the respondent's micro-organism because it was a "nonnaturally occurring manufacture of composition of matter – a product of human ingenuity 'having a distinctive name, character [and] use.'"[45] Reading the patent statutes broadly,[46] the Court recognized that "Congress intended statutory subject matter to include anything under the sun that is made by man."[47] This decision, along with the passage of the Bayh-Dole Act (discussed in Part III) laid the foundation for the biotechnology industry.[48]

In the thirty years since *Chakrabarty* was decided, the biotechnology research and development industry has taken off. However, an early 2010 United States District Court of New York decision[49] appeared to put on the brakes in the realm of gene patenting. In *Association for Molecular Pathology v. United States Patent & Trademark Office* (also known as the *Myriad* case), the Court held that the breast cancer gene sequences, BRCA1 and BRCA2, are unpatentable subject matter since the

> [The] DNA's existence in an "isolated" form alters neither [the physical embodiment of biological information] of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to "isolated DNA" containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. § 101.[50]

On July 29, 2011 the United States Court of Appeals for the Federal Circuit overruled in part the District Court *Myriad* ruling, holding that such

41. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).
42. *See infra* Part V.B.
43. Crenshaw, *supra* note 33, at 917.
44. Diamond v. Chakrabarty, 447 U.S. 303, 309-10 (1979).
45. *Id.*
46. *Id*. at 308.
47. *Id*. at 309 (internal quotations omitted).
48. Mireles, *supra* note 30, at 143.
49. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *aff'd in part*, *rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011).
50. *Id*. at 185.

isolated gene sequences are in fact patentable subject matter under § 101.[51] Since the isolated DNA sequences at issue "have a distinctive chemical identity and nature" that is "markedly different" from naturally occurring molecules, they should be afforded patent protection.[52] Falling in line with *Chakrabarty's* "anything under the sun that is made by man" language, the Federal Circuit found that the method of "cleaving or synthesizing a portion of native chromosomal DNA imparts" a new and distinct identity wholly different from the native DNA.[53]

Interestingly, the Department of Justice ("DOJ") reversed its long held position on the patentability of isolated gene sequences in its amicus brief filing for the *Myriad* case on October 29, 2010 with the Court of Appeals for the Federal Circuit.[54] In that brief, the Government stated that "isolated but otherwise unaltered" genes should not be patentable because they are elements of nature, thus falling outside the scope of 35 U.S.C. § 101.[55] This position runs counter to the decade's old policy within the USPTO of granting patents, in addition to the synthetic DNA sequences seen in *Chakrabarty*, to isolated, naturally occurring gene sequences.[56] Such gene sequences are "genomic material excised from an organism's genome and isolated from the cellular environment in which it normally occurs, but without material change to its naturally occurring chemical structure and function."[57] The filing notes that the USPTO sees even isolated genes as non-naturally occurring since they are not found to exist in such an isolated manner in nature.[58] Proponents of attaching patent rights to isolated gene sequences, falling in line with current USPTO policy, disagree with the new policy statement.[59] Opponents of patentability, arguing in line with the DOJ, state that "locking up basic genetic information in patents actually impedes medical progress."[60] The government states that this change will

51. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1350 (Fed. Cir. 2011), *vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, No. 11-725, 2012 WL 986819, at *1 (U.S. Mar. 26, 2012).

52. *Id.* at 1351.

53. *Id.* at 1352.

54. Brief for the United States as Amicus Curiae in Support of Neither Party at 18, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 09-CV-4515) [hereinafter Brief for the United States].

55. *Id.*

56. *Id.* at 4.

57. *Id.*

58. *Id.* at 5-6.

59. Andrew Pollack, *In a Policy Reversal, U.S. Says Genes Should Not Be Eligible for Patenting,* N.Y. TIMES, Oct. 30, 2010, at B1.

60. *Id.*

have little impact on the genetic sciences, since human manipulations of genetic sequences will still be afforded patent protection.[61]

If the Federal Circuit had followed the reasoning of the United States and upheld the District Court's ruling the biotechnology research and development industry could have been seriously damaged. With the biotechnology field encompassing a large area of the national economy, a sweeping invalidation of many patents that form its foundation would have been highly detrimental to the economy as a whole. However if the District Court ruling had been upheld, it could be argued that putting isolated genes within the public domain could overcome an anticommons problem in the biotechnology industry.[62] The question of patenting genetic materials remains unanswered because on March 26, 2012, the Supreme Court vacated the Federal Circuit holding in *Myriad* in light of its 9-0 decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*.[63]

IV. PASSAGE OF BAYH-DOLE ACT

Between the late 1970s and early 1980s, the federal government realized that commercialization of government-funded innovations would require massive investment; however "private firms were unwilling to invest in commercializing innovations unless those firms received a proprietary interest in the end product."[64] Therefore to increase commercialization, "the government determined that technology developed with government funds should be transferred to the private sector for further research, development, and investment . . . ."[65] In 1980, Congress passed the Bayh-Dole Act as an amendment to the Patent and Trademark Amendments Act of 1980, which allowed universities and small companies to retain intellectual property rights in the inventions developed through the infusion of government funds.[66] Prior to the passage of the Bayh-Dole Act, the biotechnology sector operated under a commons model, with the federal government funding "upstream" research that "encouraged broad dissemination of results in the public domain."[67] These unpatented discoveries could be incorporated by

61. *Id.*; Brief for the United States, *supra* note 54, at 11.

62. *See infra* Part V.A.

63. Ass'n for Molecular Pathology v. Myriad Genetics, No. 11-725, 2012 WL 986819, at *1 (U.S. Mar. 26, 2012).

64. Mireles, *supra* note 30, at 158.

65. *Id.* at 158-59.

66. Crenshaw, *supra* note 33, at 917; *see generally* Bayh-Dole Act, 35 U.S.C. §§ 200-211 (2006).

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

any developer into "downstream" diagnostic and treatment methods at a low transaction cost.[68]

As a result of the passage of Bayh-Dole, collaboration between the public and private sectors in biotechnology research and development has flourished.[69] Since the federal government is the largest funding entity for university research and development in the United States, the passage of the Bayh-Dole Act has had "a tremendous effect on the appropriation of technology."[70] Government funds currently account for roughly twenty-six percent of all research and development funding in the United States.[71] Further, the government funds nearly sixty percent of all university research and development.[72] Prior to Bayh-Dole, the rate of commercialization of government-funded technologies was only four percent.[73] Biotechnology patent applications by qualifying entities "increased by more than 300 percent in the first five years after the enactment of the legislation, as compared with the five years prior to the passage of the Act."[74]

By looking at the above numbers, it appears that the Bayh-Dole Act has achieved the government's goals of: avoiding stagnating commercial development of government-funded projects by increasing the efficiency of transfer "of discoveries that would otherwise languish in government and university archives"; reviving U.S. industry through new technology infusions "that would enhance productivity and create new jobs"; and keeping federally-funded research advances in the U.S. for development by U.S. firms.[75] However, many critics believe that the emphasis on private commercialization of research runs counter to the ultimate knowledge seeking purposes of university research.[76] Others fear that university researchers will be "unduly influence[d]" in their decisions on research projects and paths.[77] Scientists may have become more competitive and less willing to share data that would otherwise spur academic progress out of fear of losing intellectual property (IP) rights.[78] In essence, the private sector may discourage disclosure and publication of research until

68. *Id.*
69. Mireles, *supra* note 30, at 155.
70. *Id.* at 155-56.
71. *Id.* at 156.
72. *Id.*
73. *Id.*
74. Mireles, *supra* note 30, at 160-61.
75. *Id.* at 159.
76. *Id.* at 157.
77. *Id.*
78. Michael Tomasson, *Legal, Ethical, and Conceptual Bottlenecks to the Development of Useful Genomic Tests*, 18 ANNALS HEALTH L. 231, 244 (2009).

intellectual property rights are secured.[79] What may result is a lack of foundational research that other researchers can use as a starting point.[80] Under the auspices of increasing collaboration between private industry and non-profit organizations, the Bayh-Dole Act has "encouraged an alternative university culture which focuses attention on entrepreneurial activities."[81] Several critics have stated that the Bayh-Dole Act has pushed university science too far into a "private competitive model."[82]

V. THEORY OF THE ANTICOMMONS IN BIOTECHNOLOGY

A. Defining the Anticommons

To understand the tragedy of the anticommons, one must first look to the tragedy of the commons. First theorized by Garrett Hardin in 1968, under the "tragedy of the commons" commonly held resources are over-exploited because no single person has any incentive to conserve the property that they alone do not own.[83] Michael Heller and Rebecca Eisenberg suggest that while such a theory bolsters the argument for private property rights, it turns a blind eye to resource underuse when the government grants the property right of exclusion to too many.[84] What then results is an anticommons; where "multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use."[85]

Following the passage of the Bayh-Dole Act, the privatization of biomedical discoveries, Heller and Eisenberg argue, has led to a "proliferation of intellectual property rights upstream [that] may be stifling life-saving innovations further downstream in the course of research and product development."[86] Accordingly, aggregating the various privately held rights in order to advance the science under an anticommons "is often brutal and slow."[87]

The anticommons results in "obstacles to future research" because privatization has put the rights to prior discoveries in the hands of too

79. Mireles, *supra* note 30, at 157.

80. *Id.*

81. Tomasson, *supra* note 77, at 244.

82. David E. Winickoff et al., *Opening Stem Cell Research and Development: A Policy Proposal for the Management of Data, Intellectual Property, and Ethics*, 9 YALE J. HEALTH POL'Y L. & ETHICS 52, 56 (2009).

83. Heller & Eisenberg, *supra* note 66, at 698.

84. *Id*.

85. *Id*.

86. *Id.*

87. *Id.*

many.[88] This has resulted in a "spiral of overlapping patent claims in the hands of different owners, reaching ever further upstream in the course of biomedical research."[89] These overlapping claims have increased the cost of doing business in the biotechnology field because an individual researcher "needs access to multiple patented inputs to create a single useful product."[90] With each required upstream patent comes a toll that the individual patent owner can charge the subsequent researcher "slowing the pace of downstream biomedical innovation."[91] Beyond slowing the speed of biomedical development, this "patent thicket" can give rise to an "innovation malaise born of unwillingness on the part of investors to put money behind projects because of the uncertainty over whether a cost-viable path to market will be found for the new, unproven technology."[92]

Heller and Eisenberg suggest that the government has fostered the growth of the anticommons by "creating too many concurrent fragments of intellectual property rights" in downstream products or by allowing upstream patentees to "stack licenses on top of the future discoveries of downstream users."[93]

The market of concurrent fragments began in 1991 when the National Institutes of Health ("NIH") began filing patent applications on "expressed sequence tags (ESTs)."[94] While the NIH has since ceased this controversial path, private entities have picked up the baton with patent filings on DNA sequences and gene fragments prior to "identifying a corresponding gene protein, biological function, or potential commercial product."[95] If the USPTO grants such claims, a wealth of raw inputs into the biotechnology research field will be privatized. Essentially, as more patentees hold rights to each gene fragment or cell line, later researchers will be required to pay each patentee for access to the elements needed for further drug and therapy development. As researchers encounter more "tollbooth[s] on the road to product development" they may find it difficult and time consuming to gather the required licenses and are forced to "choose between diverting resources to less promising projects with fewer licensing obstacles or proceeding to animal and then clinical testing on the basis of incomplete information."[96] As a way of navigating the morass of pending rights on fragments, research firms and universities enter licensing agreements at a

88. Heller & Eisenberg, *supra* note 66, at 698.
89. *Id.*
90. *Id.* at 699.
91. *Id.*
92. Winickoff et al., *supra* note 81, at 73.
93. Heller & Eisenberg, *supra* note 66, at 699.
94. *Id.*
95. *Id.*
96. *Id.*

time when "there is substantial uncertainty as to the scope of patent rights that will ultimately issue."[97] The patent filing party may have the upper hand by contractually securing broader rights than the rights recognized once the patent, if ever, is issued, thus "compound[ing] the obstacles to developing new products."[98]

Another possible source of a biotech anticommons are stacking licenses found in reach through licensing agreements ("RTLAs").[99] The RTLA grants the upstream patentee rights to downstream developments, usually in the form of royalties on sales, "exclusive or non-exclusive license[s] on future discoveries, or an option to acquire such a license."[100] While RTLAs may be beneficial to researchers, who can gain immediate access to the patented research tools with little upfront cost, they give patentees the upper hand through a "continuing right to be present at the bargaining table as a research project moves downstream toward product development."[101]

Licensing patents provide financial incentives to patentees; while they may not "eliminate downstream appropriation," they can "retard it through the friction of transaction costs."[102] An inefficient market might result due to administrative red tape, looming deadlines, and scientists' relative unfamiliarity of patent licensing practices.[103] Not only can transaction costs significantly increase under an anticommons, there is also a greater potential for holdout situations when licenses from multiple patentees have to be independently negotiated in order for scientists to move forward down a particular research path.[104] Under such holdout situations, cognitive biases can take hold, leading upstream patentees to overinflate the value of their individual patent.[105]

97. *Id.*
98. Heller & Eisenberg, *supra* note 66, at 699.
99. *Id.*
100. *Id.*
101. *Id.*
102. Lee, *supra* note 25, at 674-75.
103. *Id.* at 675.
104. *Id.*
105. Heller & Eisenberg, *supra* note 66, at 701. Heller and Eisenberg explain the issue as such: "Imagine that one of a set of 50 upstream inventions will likely be the key to identifying an important new drug, the rest of the set will have no practical use, and a downstream product developer is willing to pay $10 million for the set. Given the assumption that no owner knows ex ante which invention will be the key, a rational owner should be willing to sell her patent for the probabilistic value of $200,000. However, if each owner overestimates the likelihood that her patent will be the key, then each will demand more than the probabilistic value, the upstream owners collectively will demand more than the aggregate market value of their inputs, the downstream user will decline the offers, and the new drug will not be developed." *Id.*

B. *Evidence of Anticommons at Work in Biotechnology Research and Development*

Paralleling the theory of the anticommons with regard to biotechnology patents is a 2002 study that found that data withholding is prevalent in academic genetics.[106] Study respondents participating in genetics research indicated that they had requested information, data or materials pertaining to published research on average of 8.8 times over the previous three years, with ten percent of all the requests being denied.[107] Forty-seven percent of research academics reported that at least one of their requests was denied by a fellow academic.[108] The top reasons respondents gave for denying information, data or material requests were the effort required to produce the requested information and the necessity of protecting the researcher's ability to publish.[109] Furthermore, researchers stated that engaging in commercial endeavors was a key reason for denying a request.[110] Nearly thirty percent of all geneticists stated that their inability to replicate published results was a "direct result of another academic scientist's unwillingness to share information, data, or materials."[111] Data sharing is important within the scientific community considering that the same number of respondents ended collaborative research because of data withholding.[112] A large majority feel that such practices are detracting "somewhat or greatly" from the level of scientific communication and "slowing the rate of progress in their field of science."[113] The study authors comment on the level of withholdings, stating

> Data withholding may paradoxically occur most commonly during extremely rapid progress, since scientists are generating large numbers of new findings that stimulate much jockeying for scientific priority. The commercial applications of genetics research, along with increasing dependence on industry funding and the rise of commercial norms in the academy, may be partially responsible as well for data withholding.[114]

The study recognizes a drag on genetic research progress that closed data creates, yet there are pushes within the field toward making data sharing more prevalent.[115]

106. Campbell et al., *supra* note 26, at 477.
107. *Id.*
108. *Id.*
109. *Id.* at 478.
110. *Id.*
111. Campbell, *supra* note 26, at 478.
112. *Id.*
113. *Id.*
114. *Id.* at 479.
115. *Id.*

To accomplish data openness and continued progress in the biotechnology fields, the National Human Genome Research Institute encourages "rapid release and dissemination of new sequence data by its funded investigators."[116] Several journals have also stepped up by making publication contingent on the placement of data and materials in public depositories or some other broad dissemination mechanism.[117] While these are promising starts to overcome the anticommons theory and the hurdles presented by closed data, the proposed examination voucher program could provide the needed incentive to bring forth widespread sharing of research data and methods.

C. Questioning the Existence of an Anticommons

By incentivizing researchers to share data and patented research tools in recognized collaborations, the obstacles of license aggregation, reach through costs and speculative valuations can be reduced or eliminated, thereby fostering research and development of treatments for complex diseases. However, some commentators question the existence of an anticommons in the biotechnology field, or the detriment to innovation should one exist.[118] Searching for the tragedy of the anticommons is a difficult prospect because "the researcher is attempting to prove a counterfactual: if something had not happened, then something else would have resulted."[119] Those warning of the impacts of the anticommons call for drastic solutions to a possible nonexistent problem, such as: strengthening the utility requirement, increasing the use of patent pools, granting a more generous experimental use defense to patent infringement, and most radically recognizing a fair use exception to patent infringement.[120] With no clear conclusion on whether an anticommons exists, such sweeping changes to the patent law could "undermine the incentives provided by patents to invent, disclose, and innovate."[121] Since the patent system caters to many different technical fields, changing the rules to correct for possible deficiencies in one sector could have unintended consequences in myriad others. The biotechnology industry, as with all industries where capital investment is critical, "requires stable and strong property rights to justify investment in research and development."[122]

116. Campbell, *supra* note 26, at 479.

117. *Id.*

118. David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1680 (2007).

119. Mireles, *supra* note 30, at 145.

120. *Id.* at 146.

121. *Id.*

122. *Id.*

After a thorough empirical study of the biotechnology landscape in the United States, David Adelman found that there is "little evidence that recent growth in biotechnology patenting is threatening innovation."[123] The study comprised 52,000 United States granted biotechnology patents from January 1990 through December 2004.[124] While Heller and Eisenberg suggest that concurrent fragment ownership is a cause of an anticommons,[125] this study found that biotechnology patent ownership is diffuse, with the largest companies obtaining fewer than thirty biotechnology patents per year on average.[126] Further, there has been a steady increase in the number of entities obtaining patents in the biotechnology field.[127] Such a "continuous record of new market entrants" and the absence of concentrated control lend weight to the argument that "biotechnology patenting is not adversely affecting innovation."[128] The Adelman study posits that the current debate has "morphed the anticommons theory into one that associates rising patent numbers almost inexorably with patent anticommons, transforming Heller and Eisenberg's contextually delimited theory into a generalized model premised on a relatively simple relationship existing between patent counts and transaction costs."[129] The study questions the "assumption that upstream patents will inevitably restrict access to essential research tools for which no alternatives exist," and finds the "generalized anticommons theory" to be "empirically elusive."[130]

The Adelman study looks to the rise and fall of patent applications as one factor to determine the presence of an anticommons.[131] The study found that in 1998 biotechnology patent issuances per year peaked at 5,977 and by 2004 that rate had decreased by twenty-nine percent to 4,324 per year.[132] The study suggests that such a decrease could be seen as the generalized anticommons theory at work; "a drop in innovative output [after 1999] brought about by the fragmenting effects of thousands of patents . . . on research and development" could be seen as the point where "spiraling licensing costs" tipped the scales against the incentives to patent.[133] However, the study looks deeper, noting that the number of patent applications filed (versus patents issued) for "biotechnology patents

123. Adelman & DeAngelis, *supra* note 117, at 1680.
124. *Id.*
125. Heller & Eisenberg, *supra* note 66, at 698.
126. Adelman & DeAngelis, *supra* note 117, at 1681.
127. *Id.*
128. *Id.*
129. *Id.* at 1682.
130. *Id.* at 1686.
131. Adelman & DeAngelis, *supra* note 117, at 1687.
132. *Id.*
133. *Id.* at 1688.

rose substantially post 1999."[134] This observation pierces a hole in the anticommons theory.[135]

While the study looks to economic factors,[136] it finds more influence in the USPTO changes.[137] First, the study acknowledges a move within the patent office to a stronger utility requirement as an explanation of the "dramatic leveling off of biotechnology patenting."[138] Such a change could account for the lengthened prosecution time and the increase of denials after 1999.[139] Suggesting not an anticommons at work, but a more fine toothed comb, "the number of biotechnology patent applications filed with the PTO increased by about forty percent while the number of . . . patents issued declined by almost thirty percent."[140]

The study further weakens the anticommons theory by evaluating two strong transient influences on the declining patent rates. The first identified factor is the June 1995 change in patent term from seventeen years from issue to twenty years from filing that caused a spike in biotechnology patent applications, with 4,602 filings in 1994, 7,626 in 1995, and 4,045 in 1996.[141] The second, and more revealing, transient factor regarding the "falloff in the number of biotechnology patents issued likely reflects a saturation of examiner resources."[142] With only a finite number of patent examiners dedicated to the growing biotechnology field, "the rate-limiting step in issuing patents is no longer inventive output but the PTO itself."[143] The study determined that the USPTO's "maximum review capacity lags current application rates by hundreds of patents" across all biotechnology categories.[144] This finding is crucial to the proposal of this Comment regarding fast-track examination vouchers. With a lack of examiner resources, a voucher that would allow an inventor to get to the front of the examination line could be highly prized in an open market. Such a lucrative commodity, transferrable to any willing purchaser in any industry, could be pivotal in incentivizing data and research tool sharing in the biotechnology field.

Further strengthening the Adelman argument against the existence of an anticommons is the aforementioned diffuse ownership of biotechnology

134. *Id.*
135. *Id.*
136. *See* Adelman & DeAngelis, *supra* note 117, at 1688-89.
137. *Id.* at 1689.
138. *Id.*
139. *Id.* at 1690.
140. *Id.*
141. Adelman & DeAngelis, *supra* note 117, at 1691.
142. *Id.*
143. *Id.*
144. *Id.*

patents, as evidenced by the "low averages for the number of patents received annually per assignee."[145] Over the fifteen year study, the average number of total biotechnology patents issued per assignee was roughly twelve, less than one patent per year, and approximately "fifty percent of assignees obtained no more than twenty-five patents . . . ."[146] With this modest data in hand, it is plausible to "suggest that no single entity has the patent capital necessary to dominate biotechnology research and development."[147] While diffuse ownership would tend to require increased numbers of licenses to conduct research and development, Adelman suggests an anticommons does not play a role, as empirical studies show that no more than a "handful" of patents need to be licensed.[148]

Adelman surmises that scientists cannot keep pace with the "explosion of new information" in the biotechnology field, suggesting that the opportunities "far exceed the capacities of the scientific community."[149] Research scientists note that the need to license patents can be eliminated by following a parallel research path. This parallel research path is what Peter Lee finds to be particularly beneficial to biotechnology progress even under an anticommons.[150]

D. Benefits of an Anticommons in Biotechnology Research and Development

Lee shifts his focus from applied science to patents' effect on the "advancement of *scientific theory*, the scientific community's conceptual understanding of the basic structure and properties of natural phenomena."[151] Lee finds benefits in the ability of patents to induce "paradigm shifts"; the "creation of a novel theoretical framework that better explains a particular set of natural phenomena . . . ."[152] Shifting research frameworks may be a key to success in certain areas of disease research and treatment development, lending support to the argument that an anticommons is actually beneficial. A strong field of patents can open the door to new avenues, "encouraging scientists to experiment outside the realm of mainstream research tools, encourag[ing] them to generate and test new theories."[153] An anticommons landscape may incentivize

145. *Id.* at 1695.
146. Adelman & DeAngelis, *supra* note 117, at 1695.
147. *Id.* at 1697.
148. *Id.*
149. *Id.* at 1699.
150. Lee, *supra* note 25, at 663.
151. *Id.* at 662.
152. *Id.* at 662-63.
153. *Id.* at 664.

researchers to "reconceptualize familiar natural processes" from a different reference frame that avoids prior art.[154] The typical patent incentive shifts from receiving payments to an "incentive to innovate in order to avoid paying someone else and accepting exogenous constraints on one's research."[155] It is suggested that this may be key to Alzheimer's research.[156] "For a neuroscientist working on a treatment for Alzheimer's disease, the exclusive patents on human embryonic stem cells provide an incentive not only to investigate alternate mechanisms for neurogenesis but also to test alternate theories of brain structure, physiology, and the pathology of Alzheimer's itself."[157]

Patents can be seen as a "fulcrum defining the balance between two kinds of valuable scientific activity: hypothesis validation and exploration (comprising the main business of normal science) and hypothesis generation (leading to paradigm shifts)."[158] Without evaluating this balance, discussion about changes to patent doctrine are "uniformed and incomplete."[159]

VI. PAST PROPOSED SOLUTIONS TO THE POSSIBLE ANTICOMMONS IN BIOTECHNOLOGY

In order to overcome issues of a possible anticommons in biotechnology research, commentators have proposed various solutions. However, many of the proposals could be too far-reaching, resulting in many unintended outcomes in industries outside of the biotechnology realm. Protection under the patent law should be uniform for all technology sectors, yet several of the proposals could implement different rules for different technologies.

A. Mandatory Data Release for Publicly-Funded Research

Prior to publication of the Heller and Eisenberg article outlining the anticommons theory, the U.S. House of Representatives, meeting in July 1997, proposed an appropriations bill amendment that would require researchers operating with government grants to make available to the public all of their raw medical and scientific data within ninety days of the first publication of any study results.[160] Exempt from such disclosure requirements would be defense research and research where required disclosure would result in "economic harm to commercial proprietary

154. *Id.* at 686 (internal citations omitted).
155. Lee, *supra* note 25, at 687.
156. *Id.*
157. *Id.*
158. *Id.* at 665.
159. *Id.*
160. George D. Thurston, *Mandating the Release of Health Research Data: Issues and Implications*, 11 TUL. ENVTL. L.J. 331, 331 (1997).

interests."[161] The initial proposal was in response to industry calls for data on air pollution studies;[162] however the broad mandate would have had a major impact on biotechnology research, publication and patent strategies. The proposal was defeated but raised questions about the forced publication of government-funded research.[163]

The foundation of the proposal, running against Bayh-Dole, was that the research was paid for by taxpayer-funded government grants and should therefore be placed in the public domain for any and all to critique and evaluate.[164] While there could be benefits of increased validity through broader scrutiny, ethical and practical concerns were also raised.[165] Forced data release could have an adverse effect on "(1) the scientific credibility of the research involved, (2) the confidentiality of research participants' medical records, (3) the intellectual ownership of research ideas and their results, and (4) the speed of research progress in the medical and public health fields."[166]

While a mandatory data release program could "represent a major loss, professionally and financially" to researchers and organizations,[167] this Comment's proposed voluntary program of data sharing coupled with USPTO vouchers could overcome such financial loss. Furthermore, the government views that its grants are simply that; they are not contracts that purchase the product of the grantee's work, but are instead mechanisms to "support or stimulate activity which serves the public good."[168] This view aligns with Bayh-Dole and runs counter to the mandated data release proposal. The proposed data release mandate could result in an overall slowing of biotechnological and medical research.[169] Study participants could be less likely to apply for fear that their personal health information would be publicly available.[170] The ninety day data release imposition would incentivize researchers to *not* publish study results until all research avenues are pursued, leading to a dearth of scientific publication in a particular field for years.[171] The mandated data release proposal would

161. *Id.* at 332. (internal quotations omitted).
162. *Id*.
163. *Id.*
164. *Id.*
165. Thurston, *supra* note 159, at 333.
166. *Id.*
167. *Id.* at 347.
168. *Id.* at 348.
169. *Id.*
170. Thurston, *supra* note 159, at 348.
171. *Id.* at 331, 349.

effectively stall scientific advancement by closing researchers off from the public and their colleagues in the scientific community.[172]

However, a voluntary program incentivized by the USPTO, as proposed, could overcome some of these issues. Working under a voluntary data release model, participants from the outset could be informed on how their personally-identifiable information, if any would be released. Up-front voluntary agreements to openly share data could have the opposite effect as the mandated data release schedule. Following ADNI, data would be released as soon as possible, giving all researchers access to larger data pools, spurring activity down alternate research paths.

B. Mandatory Experimental Use Phase After Patent Issuance

Leveraging the experimental use defense to patent infringement, some commentators see an expansion of that defense as a tool to overcome a possible anticommons in biotechnological research.[173] Justice Story first hinted at an experimental use defense in his 1813 opinion in *Whittemore v. Cutter*.[174] He stated that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[175] Successive courts have recognized the experimental use defense in the theoretical realm; however they have rarely been swayed to follow it in practice.[176]

Lee calls for strengthening the experimental use defense into an operating, "robust" exception.[177] The proposed exception would apply to any material or process that is defined by the National Institutes of Health (NIH) as a research tool.[178] Such conforming technology would be granted a "research tool patent" where immediately after patent issue and for a finite period of time a "robust experimental use exception" would be in force.[179] During this finite period, any "noncommercial experimental use of the patented research tool would be permitted."[180] This broad definition of

172. *Id.* at 349.

173. Lee, *supra* note 25, at 691.

174. *See* Whittemore v. Cutter, 29 F. Cas. 1120, 1120 (D. Mass. 1813) (No. 17,600). Justice Story decided this case while sitting as a United States Supreme Court Justice. MEMBERS OF THE SUPREME COURT OF US, SUPREME COURT OF THE U.S., http://www.supremecourt.gov/about/members_text.aspx (last visited on Feb. 12, 2011).

175. *Whittemore*, 29 F. Cas. at 1121.

176. *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1023 (1989).

177. Lee, *supra* note 25, at 691.

178. *Id.*

179. *Id.*

180. *Id.*

experimental use would give safe haven to any use of a research tool that was not "intended to produce, or that did not actually produce, a commercial application."[181] Lee suggests that this finite time last for five years to allow for a balancing of time scientists need to perform and publish experiments using the patented tools, and the ability of the patentees to recoup their costs.[182] After five years, the exception would expire and "any nonlicensed use of the patented material, even for experimentation with no direct commercial application, would constitute infringement."[183]

Such a proposal would foster similar goals as a voluntary data sharing collaboration by allowing "[f]ree access to research tools closely associated with an insurgent theory of natural causation . . . enabl[ing] members of the scientific community to engage in the crucial process of testing, refuting, and perhaps validating that theory."[184] However, this system would create a separate patent system for a separate technological group and as Lee admits, would "invert current legal frameworks of intellectual property."[185] Lee's proposal would grant open access to the patented research tool right from the beginning, close access once the exception expires and, following normal patent law, allow for unrestricted open use after the patent has expired.[186]

While it is suggested that such a model would still incentivize innovation,[187] it is expected that it would do just the opposite. With patent term length being so important to patentees, such a proposal removes patent protection from at least the first quarter of the patent term.[188] With the fast changes in biotechnology, by the time the patent protection "reattaches" to the patent, there may be little or no commercial value left in the patented technology. While positing a default five year exception, Lee places the burden on Congress for determining the "optimal length" of the experimental use exception by exploring the "cost structure of creating new research tools, rates of research tool invention and obsolescence, and the

181. *Id.* at 691 n.158.

182. Lee, *supra* note 25, at 691.

183. *Id.* at 691-92.

184. *Id.* at 692.

185. *Id.*

186. *Id.*

187. *See* Lee, *supra* note 25, at 692.

188. This assumes the impossible: that the patent issues immediately. With current patent term being twenty years from filing and the time from application to issuance (average total pendency) being 34.6 months in FY 2009, a five-year experimental use exception could eliminate just over a third of the actual effective patent term. *See* U.S. PATENT & TRADEMARK OFFICE, 2010-2015 STRATEGIC PLAN 10, *available at* http://www.uspto.gov/about/stratplan/USPTO_2010-2015_Strategic_Plan.pdf [hereinafter USPTO STRATEGIC PLAN].

time horizon for conducting biomedical experiments."[189] However, such a detailed analysis of biotechnological research landscapes seem better suited for determination by the market and a traditional patent system without an experimental use exception. By placing the final determination on whether a particular technology would receive a "research tool patent" in the hands of the USPTO, with possible input from the NIH,[190] it is assumed that such a "research tool patent" would be mandatory for any qualifying application. Without mandatory participation, there would be few — if any— patent applicants who would chose to have an unenforceable patent for the first five years or more. Overall, such a proposal seems inefficient at spurring biotechnological research growth by artificially weakening the patent through Congressional, rather than market, valuation of the research tool.

C. *Patent Prizes*

In an effort to overcome a detriment to distribution that the patent monopoly can present, some have called for the awarding of patent prizes.[191] Patent prizes are most effective in the pharmaceutical realm where "a single successful patent is closest to being a successful product."[192] Through direct investment in a patented technology, the patent prize operates as a pull mechanism on research[193] by ensuring a market for a patented technology.[194] The prize could further innovation by placing the intellectual property in the public domain or could operate as a subsidy of a particular patented technology or treatment.[195] However, such a system carries issues of determining which patent deserves the prize, calculating the amount to be paid and determining the best "delivery method to stimulate innovation."[196] One author has suggested that the patent prize can be effective at bringing malaria treatments to market through aid organizations providing payment-per dose.[197] The estimated payment commitment would be $3.1 billion and bestows the prize on the vaccine developer and increases the incentive to produce through the payment for every dose

189. Lee, *supra* note 25, at 691 n.157.
190. *Id.* at 691 n.156.
191. Kyle *See* Kyle Wamstad, *Priority Review Vouchers – A Piece of the Incentive Puzzle*, 14 VA. J.L. & TECH. 126, 139 (2009).
192. *Id.*
193. *Id.* at 138-39.
194. *Id*. at 139.
195. *Id.*
196. Wamstad, *supra* note 190, at 139.
197. *Id*.

delivered.[198] Such an amount would be sufficient to provide research and development incentive while maintaining public health cost effectiveness.[199]

D. Open Source Approaches to Biotechnology Research and Development

Moving closer to the foundation of the proposed voluntary data sharing and patent voucher proposal of this Comment, is the call for applying open source ideals from the software industry to the biotechnology field. Returning to the most fundamental view of science, some view patent enforcement of scientific discoveries as being diametrically opposed to the "traditional scientific norms [that] call . . . for free dedication of new knowledge to the scientific community."[200] Moving away from a discourse on whether an anticommons exists and instead focusing on "identify[ing] and promot[ing] the wealth of intrinsic benefits associated" with an open source biotechnology model may be more productive.[201]

A main issue of the current closed research system is the absence of motivation to replicate prior scientific experiments.[202] There is little to be gained by scientists who wish to scrutinize work through replication; funding, recognition and publication are unlikely to result from such activities,[203] however beneficial they may be in confirming or altering biotechnological discoveries. Especially during the paradigmatic shifts that may be required to solve the most complex diseases, open access to research data and discoveries can be key in order to challenge prior theories or offer alternative explanations.[204] An open source model therefore facilitates scrutiny[205] and helps to eliminate errors.[206] With more eyes focused on the openly available research data and methods, higher quality research may result.[207]

With greater scrutiny, open access "promotes scientific progress by permitting other scientists to use prior discoveries in subsequent research."[208] By allowing the free flow of data between collaborative researchers, an open source model will also likely bring about a "more

198. *Id*.
199. *Id*.
200. Eisenberg, *supra* note 175, at 1046.
201. Yann Joly, *Open Source Approaches in Biotechnology: Utopia Revisited*, 59 ME. L. REV. 385, 387 (2007).
202. Eisenberg, *supra* note 175, at 1050.
203. *Id.*
204. *Id.* at 1053.
205. *Id.*
206. Joly, *supra* note 200, at 398.
207. *Id.*
208. Eisenberg, *supra* note 175, at 1055.

modular and effective coordination of research projects."[209] Within an open source research project, every user is a "potential source of new ideas for future directions in the product, and the workload for implementing change is shared between an expanded group of developers."[210] Expanding the pool of researchers is especially important for large-scale research efforts such as the ADNI and its Parkinson's follower. The value of the massive amounts of data that these experiments generate is increased when "shared between various research groups, because sharing enables researchers to identify networks of genes or proteins that function in concert."[211] The successful human genome project, conducted through collaboration between sequencing centers located around the globe is a testament to how collaboration benefits the progress of science.[212]

While some see an anticommons or patent thicket increasing transaction costs through RTLAs, open source research collaborations can reduce such costs.[213] With data openly available, complex licensing agreements are not necessary, eliminating the costs of paying for the license and the time intensive negotiations involved in hashing out specifics.[214] By dedicating data and research to the public domain, downstream negotiations and associated costs of internal and external IP access and patent protection are averted.[215] Through placing data into community databases, scientists are given the tools to "quickly explore the links among genes, proteins, mRNAs, phenotypic data, RNAi data, microarray data," and other biomarkers that are research critical.[216] Such open, collaborative databases can spur innovation by reducing the time and associated costs that researchers spend on gathering information.[217] Therefore, placing such patentable research in the public domain can avert an anticommons altogether.[218]

The aforementioned open source collaborations built upon voluntary participation would likely perform much better than the previously noted robust experimental use exception or other compulsory licensing agreements. Such compulsive measures require the government to carry out the difficult job of determining the proper compensation and can

209. Joly, *supra* note 200, at 399.

210. *Id.* (internal quotations omitted).

211. Katherine M. Nolan-Stevaux, *Open Source Biology: A Means to Address the Access & Research Gaps?*, 23 SANTA CLARA COMPUTER & HIGH TECH L.J. 271, 282 (2007).

212. *Id.*

213. *Id.* at 282-83.

214. Joly, *supra* note 200, at 401-02.

215. *Id.* at 402.

216. Nolan-Stevaux, *supra* note 210, at 294.

217. *Id.* at 294-95.

218. *Id.* at 283.

contravene the "goals of the patent system to reward innovation."[219] Therefore, the expansion of the USPTO proposed reexamination voucher program would provide an incentive to enter into voluntary open source research collaborations: leaving the value determinations to the research scientists interested in participating.

VII. FDA PRIORITY REVIEW VOUCHER SYSTEM AND CRITICISMS

While the debate on whether an anticommons exists in the biotechnology research and development field, a method of incentivizing research in the area of neglected diseases provides a foundation for the proposal of this Comment.

To overcome a lack of financial incentive for pharmaceutical companies to invest money in developing neglected diseases that plague low-income countries, David Ridley, Henry Grabowski and Jeffrey Moe proposed a novel solution[220] that was quickly adopted by the FDA.[221] This solution comprised of a "priority-review voucher" granted to drug companies that developed drug therapies for diseases affecting low-income countries.[222] To qualify for the proposed voucher the therapy was required to:

> (1) treat neglected diseases such as African trypanosomiasis, Chagas disease, leishmaniasis, or dengue fever; (2) receive approval by the U.S. Food and Drug Administration (FDA) or the European Agency for the Evaluation of Medicinal Products; (3) be clinically superior to existing treatments, (4) forgo patent rights; and (5) find at least one manufacturer for the product.[223]

What provided the incentive was that upon meeting the above requirements, the granted voucher entitled the grantee to "priority FDA review for another drug (or possibly multiple drugs) and orphan tax credits."[224] Furthermore, the voucher would be completely transferrable on the open market.[225]

Such a voucher could have the dual benefit of bringing successful drug therapies to neglected diseases while speeding access to "blockbuster" drug therapies in the developed world.[226] Through the nexus of these two benefits, the drugs which could be most benefited by priority review will be

219. *Id*. at 310.

220. David B. Ridley et al., *Developing Drugs for Developing Countries*, 25 HEALTH AFF. 313, 313 (2006).

221. Wamstad, *supra* note 190, at 140.

222. Ridley et al., *supra* note 219, at 313.

223. *Id*. at 313-14.

224. *Id*. at 314.

225. *Id*. at 313, 314.

226. *Id*. at 315.

highlighted through the voucher market.[227] The authors estimate that the value of an individual voucher could be worth upwards of $300 million for a blockbuster drug, in that it could decrease FDA review time by two-thirds, from an average of eighteen months to six months.[228] While the priority review does not lower the safety and efficacy standards necessary to gain FDA approval, the proposed system would require more FDA resources and an increased cost of $1 million over a standard review.[229] The authors proposed a user fee on the voucher that would cover such costs.[230]

Another variant of the proposed FDA program would include a government-facilitated auction of the priority-review voucher to a drug manufacturer.[231] This second option would eliminate the direct transfers from drug developer to manufacturer, but would still provide a payment incentive to the developer of a neglected disease treatment.[232]

Both proposals include push and pull mechanisms to stimulate neglected areas of science and can easily be applied to areas of possible stagnation. Push strategies can subsidize research inputs by decreasing research and development costs, while pull strategies work to incentivize research output through increasing financial returns.[233]

On September 27, 2007, shortly after the above priority review voucher proposal, President George W. Bush signed into law the Food and Drug Administration Amendments of 2007 ("FDAAA").[234] The bill added section 524 to section 1102 of the Food, Drug, and Cosmetic Act which authorized the FDA to award priority review vouchers to developers of therapies for specific enumerated tropical diseases.[235] The bill also gives the Commissioner of the FDA power to make eligible for the voucher program "[a]ny other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations."[236] Included in the bill was the market incentive of transferable priority review vouchers first proposed by Ridley, Grabowski and Moe.[237]

227. Ridley et al., *supra* note 219, at 315.
228. *Id.*
229. *Id.*
230. *Id.*
231. *Id.*
232. Ridley et al., *supra* note 219, at 315.
233. *Id.* at 316.
234. Wamstad, *supra* note 190, at 140.
235. *Id.*; Food and Drug Administration Amendments Act (FDAAA) of 2007, Pub. L. No. 110-85, § 1102, 121 Stat. 823, 972 (to be codified at 21 U.S.C. § 360n).
236. FDAAA § 1102, 121 Stat. at 973.
237. Wamstad, *supra* note 190, at 140.

Not included in the bill was a proposed pull mechanism of a "transferable patent exclusivity right."[238] Such transferable right would have granted a right to an extended patent term on a different product in return for licensing a product for a neglected disease.[239] Senator Brownback (R-Kansas) was pleased to see that such a provision for patent extensions for pharmaceuticals was not included, averting the "political divisiveness" that is appurtenant with such extensions.[240] Previous proposed patent extensions on pharmaceuticals tended to limit the "rewards for innovation to those companies that possessed existing valuable patents and played havoc with generic manufacturers."[241] The proposed and adopted priority review voucher program overcomes this issue by giving any holder two valuable paths independent of prior patent ownership: using the voucher for internally developed treatments, or selling it to the highest bidder.[242] "Allowing transferability of the vouchers and limiting the commitment of the innovators are the most significant features of the voucher program."[243]

A. Responses and Criticisms

Despite avoiding the political mine field of patent extensions, the priority review voucher system is not immune to criticisms. Considering the novelty of the system and the attendant uncertainties of the actual process, many large pharmaceutical firms are wary of participating until more specifics of the process are determined.[244] Thus, those with the most to gain, the largest players with the deepest pockets, are waiting on the sidelines questioning "how the FDA will fit a standard application into a priority review voucher slot."[245]

Furthermore, others criticize the plan for not requiring the pharmaceutical company to make available the drug therapy as a contingency for obtaining the voucher.[246] The proposed patent voucher program in this Comment would require dissemination of research data and discoveries in order to obtain the voucher.

Until the market for the FDA vouchers is established and a confident value assigned to such vouchers, large pharmaceutical companies may not reallocate research capital to underserved and otherwise low-profit

238. Ridley et al., *supra* note 219, at 317.
239. *Id.*
240. Wamstad, *supra* note 190, at 140.
241. *Id.* at 141.
242. *Id.*
243. *Id.* at 143.
244. *Id.*
245. Wamstad, *supra* note 190, at 143.
246. *Id.* at 144.

diseases.[247] The value of the voucher is wholly dependent upon the speculative value of a potential blockbuster drug.[248] Therefore, some point to a disconnect between the incentive and innovation, which could result in an "inefficient and potentially dangerous way of encouraging research into tropical diseases."[249] The majority of pharmaceutical firms that develop drugs for tropical diseases tend to hold smaller drug portfolios and are unlikely to use their own vouchers.[250] While this can facilitate the sale of the vouchers to large firms, such transfers could bring only marginal innovation.[251] Furthermore, such transactions may be devoid of transparency whereby intellectual property transfers may result that increase costs and restrict access to subsequent therapies.[252] Such outcomes may be detrimental to the entire goal of the FDA voucher program. Some fear that the priority review voucher program may lead to fast-track approval of drugs with "little or no clinical urgency" that are subjected to inadequate levels of FDA review.[253]

VIII. USPTO HUMANITARIAN REEXAMINATION VOUCHER SYSTEM

With the FDA priority review voucher as a baseline, the USPTO proposed a similar voucher system on September 20, 2010 as a "pro-business strateg[y] for incentivizing the development and widespread distribution of technologies that address humanitarian needs."[254] Seeing that "patents under reexamination are often the most commercially significant patents," the USPTO proposed a fast-track ex parte reexamination voucher.[255] Such a voucher would be a valuable incentive to investigate or make patented technologies available for humanitarian use since it would enable patent owners to reaffirm the validity of their patents in a more efficient and cost effect manner.[256] Paralleling the FDA program, the proposed USPTO reexamination voucher could be used for any patent owned by the voucher grantee or could be sold on the open market.[257] Qualifying technologies need not be originally developed for humanitarian

247. *Id.*

248. Aaron S. Kesselheim, *Drug Development for Neglected Diseases – The Trouble with FDA Review Vouchers*, 359 NEW ENG. J. MED. 1981, 1981 (2008).

249. *Id.*

250. *Id.*

251. *Id.*

252. *Id.*

253. Kesselheim, *supra* note 247, at 1982.

254. Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System, 75 Fed. Reg. 57,261, 57,261 (Sept. 20, 2010).

255. *Id.*

256. *Id.*

257. *Id.*

needs; patent owners can broadly show "humanitarian uses [or research] of patented technologies" or "licensing [behavior] that address humanitarian needs."[258]

Reexaminations to which the fast-track voucher apply, would be elevated to the highest priority, wherein an examiner would process the reexamination as if it were next in the queue.[259] Furthermore, the USPTO proposes a goal of accelerating reexamination time for fast-track reexaminations to six months.[260] Shortening of the process is where the true value of the voucher may lay considering that the current timeframe for reexamination proceedings is nineteen to twenty months.[261] A patent holder who wishes to use a fast-track voucher would not forfeit any "statutory and procedural rights, and would have the same time periods for filing responses and other communications as those under the existing procedure."[262]

A. Proposed Expansions to Incentivize Open Data Collaboration and Research Tool Sharing

While the USPTO tracks closely to the FDA priority review voucher program, this Comment calls for an expansion of their proposal on several fronts. First, looking to the success that ADNI has achieved in publicly sharing all of its gathered data, the proposal should include a provision for collaborative research and development efforts focused on challenging health issues (Alzheimer's, cancer, Parkinson's, Multiple Sclerosis, etc.) that are not restricted to neglected or humanitarian diseases. However, the free and open exchange of research data and methods must be a key component of the research collaboration. Further paralleling the ADNI, those entering the collaboration must give up all intellectual property rights on processes, methods, products, etc. that were developed during research. This would include any research data, cell lines, novel processes to develop cell lines, novel data extraction and analysis techniques, or any other patentable subject matter that resulted from the search for a particular biomarker or biological process that was the aim of the collaboration. However, the collaborators and wholly outside developers could still maintain an intellectual property right in any drug or therapy that resulted from the identified biomarkers, cell lines or processes. The voucher would be an integral part in incentivizing researchers to give up their patent rights.

258. *Id.* at 57,261-62.

259. Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System, 75 Fed. Reg. at 57,261.

260. *Id.* at 57,261-62.

261. *Id.* at 57,262.

262. *Id.*

Second, the priority review voucher program should be expanded to vouchers for examination proceedings; going beyond the proposed reexamination proceedings. Therefore, scientists or research organizations involved in qualified research collaborations (who gave up their initial right to file a patent on behalf of their work) would be able to apply the voucher to any drug or therapy that resulted from their research, independent of whether such was the result of the collaborative effort or other closed research. Essentially, researchers would lose out on patent protection on early discoveries by entering the collaboration, but would obtain the right to jump to the front of the queue in any subsequent patent filing. Since the United States patent term of twenty years begins at time of filing,[263] the faster a patent application becomes an issued patent, the longer the effective patent monopoly the patent holder would be entitled. Expanding the program to include fast-track examinations may require significant workforce expansions within the patent office. This would be required to overcome the previously discussed issue of examiner saturation.[264] However, the USPTO is currently engaged in an effort to increase examination capacity and efficiency.[265] One step to achieving this goal is through workforce expansions of 1000 examiners in FY 2011 and FY 2012.[266] With the signing into law of the America Invents Act (AIA), the USPTO now has the ability to determine its own fee structures[267] which should help the Office in attaining its goal of workforce expansion.

While allowing applicants to get to the front of the examination queue could be seen as more radical than a fast-tracked reexamination voucher, the USPTO already provides applicants options for prioritized examinations.[268] A longstanding procedure, Section 708.02 of the Manual of Patent Examining Procedures allows for applicants to file a Petition to

263. 35 U.S.C. § 154 (2006).

264. *See* Adelman & DeAngelis., *supra* note 117, at 1691.

265. USPTO STRATEGIC PLAN, *supra* note 187, at 8.

266. *Id.* at 12.

267. Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, § 10, 125 Stat. 284, 316 (2011) (to be codified at 35 U.S.C. § 41). More significantly, the AIA changes the United States patent regime from a first-to-invent system to a first-to-file system by overhauling 35 U.S.C. § 102. *Id.* § 3; *see also* 35 U.S.C. § 102 (2006). Even with this change to first-to-file, the proposed fast-track examination vouchers would still be beneficial as the term of effective patent protection remains at 20 years from filing. *See* 35 U.S.C. § 154; AIA § 3(j).

268. *See USPTO Patent Examination Acceleration Programs and Proposals*, U.S. PATENT & TRADEMARK OFF., http://www.uspto.gov/patents/process/file/accelerated/comp_chart_dom_accel.pdf (last visited Jan. 15, 2012); *see also Accelerated Examination*, U.S. PATENT & TRADEMARK OFF., http://www.uspto.gov/patents/process/file/accelerated/index.jsp (last visited Jan. 15, 2012); *Patent Prosecution Highway (PPH) – Fast Track Examination of Applications*, U.S. PATENT & TRADEMARK OFF., http://www.uspto.gov/patents/init_events/pph/index.jsp (last visited Jan 15, 2012).

Make Special asking for priority review of the patent application.[269] Currently there is a small entity petition available for biotechnology patents, however a fee is required.[270] Under this proposed expansion of the USPTO reexamination voucher, an examination voucher would achieve a result similar to the biotech exception; however the voucher could be used by any entity, small or large, and would waive the associated fee. Similarly, a prioritized examination procedure has been implemented in the USPTO.[271] The goal of the Prioritized Examination track (Track 1) is to "provide final disposition within twelve months of prioritized status being granted."[272] For the fiscal year of 2011, prioritized examination requests are limited to 10,000; however the USPTO intends to reevaluate this number to determine future appropriate limits.[273] Applicants wishing to have their applications processed through Track 1 must pay a $4000 fee, in addition to normal USPTO fees, for a total cost of $5,520 ($4,892 for small entities).[274] Under this Comment's proposed fast-track examination voucher system, a voucher holder would be able to waive the $4000 Track 1 Prioritized Examination fee, thus providing another incentive to enter into a data collaboration initiative. Furthermore, the proposed program could exempt voucher-holders from the 10,000 applicant limit or any future limits set by the USPTO, enhancing the market value for such vouchers.

Similar to the USPTO proposal and the FDA program, the expanded examination voucher program would allow for sale of the vouchers on the open market. The program could allow for purchasers of the voucher to be outside the realm of biotechnology. Theoretically, an IBM, Boeing, or GE could purchase a fast-track examination voucher and apply it to a non-biotechnology patent application. Broadening the program to include examination vouchers could strengthen the market more than simply restricting it to reexamination vouchers. There may be patent holders with few-if any-patents in reexamination proceedings that would otherwise benefit

269. U.S. PATENT & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 708.02 (8th ed., 8th rev. 2010).

270. *Id.*

271. Changes to Implement the Prioritized Examination Track (Track 1) of the Enhanced Examination Timing Control Procedures, 76 Fed. Reg. 18,399, 18,399-18,400 (Apr. 4, 2011) (to be codified at 37 C.F.R. pt. 1). Prioritized examination has also received backing from the newly passed American Invents Act. AIA § 25 (amending 35 U.S.C. § 2(b)(2)) (stating that prioritized examination should be available for "applications for products, processes, or technologies that are important to the national economy or national competitiveness.").

272. Changes to Implement the Prioritized Examination Track (Track 1) of the Enhanced Examination Timing Control Procedures, 76 Fed. Reg. at 18,400.

273. *Id.*

274. *Id.*; 37 C.F.R. § 1.102(e) (2011).

from the line-cutting during the application phase that the examination voucher would provide. A problem that could arise through broadening the market to non-biotechnology related firms and applications is that it may introduce uncertainty into the voucher market due to variations in voucher valuations. The value of the voucher would most likely depend on what the patent applicant believes is the potential worth of their application and the value in having such application proceed through prosecution at a faster rate. Patents from different industries would most definitely hold varied values, unlike the typical blockbuster drug that the FDA voucher is marketed toward. Such uncertainty may stall the voucher market and the overall level of collaboration.

The fast-track examination voucher could also become a defensive tool, especially in the pharmaceutical industry. A pharmaceutical maker with a blockbuster drug that is nearing the end of its patent term may purchase a voucher simply to stall a competitor from entering the market. By purchasing the voucher at a price the competitor cannot pay, the winning pharmaceutical maker will effectively force the losing competitor to either seek a fast-track voucher from another holder or proceed through patent prosecution at the normal rate. Large, profitable pharmaceutical companies may make an effort to purchase many vouchers, with no intention of using them, simply to hold competitors at a disadvantage. While this may appear to be a failure of the voucher system, the goal of the program is still being met. With voucher prices increased by companies looking for a competitive advantage, research collaborations become more enticing, resulting in more raw data and research tools available to the greater scientific community.

By creating an incentive program based on voluntary participation, the patent system would not differ in its treatment of patent applications based on technology area like the mandatory experimental use exception stated above.[275] Essentially, an issued patent that was prosecuted with a fast-track examination voucher would grant the patentee the same level of right of exclusion that any regularly prosecuted patent would afford. Maintaining such uniformity would most likely eliminate any extra costs that might be associated with a government-mandated scheme or government backed patent prizes.

Furthermore, granting a fast-track examination voucher would most likely introduce less controversy than the aforementioned patent term extensions. If the voucher were instead used to extend the patent term, and could still be sold on the open market to any patentee in any industry, serious questions would most likely arise. Should the extended term voucher

275. *See supra* Part VI.B.

be applied with the initial patent application? It should be considered whether the voucher be applied to a patent near the end of its term, so as to add additional time in the eleventh hour. In addition, we must examine how the public could (or should) be notified of extended time applied to the patent. Other issues include the length of the extension and whether the extended time should be proportional to the amount of data collaboration under which the voucher was first awarded. By applying the voucher to the front of the process during the initial examination, these questions would not be raised. A patent processed with a fast-track examination voucher would still be enforceable for a term of twenty years from application date.

Finally, this proposed voucher system could help to avoid increased transaction costs. With researchers voluntarily entering into data collaborations there would be no need for RTLAs as the data and research tools would be openly available. With instant access to the latest research data, collaborators and outside scientists would not have to wait for license negotiations to be hammered out and could instead focus on efficiently moving their research forward. Open data sharing would eliminate research and development tollbooths and help to eliminate the aforementioned cognitive biases that overinflate the value of research data.[276]

IX. CONCLUSION

Looking to the Alzheimer's Disease Neuroimaging Initiative as an example, incentivizing collaboration and data and resource sharing among research organizations can be an effective way to further the search for solutions to humanity's most vexing diseases. By utilizing a pull mechanism of a fast-track examination voucher to incentivize collaboration, the USPTO can play a vital role in such searches and can further fulfill its constitutional mandate of "promot[ing] the Progress of Science and the useful Arts."[277] Such an expansion of the proposed USPTO voucher program could operate more efficiently at alleviating an anticommons in biotechnology research and development, should one exist. With participation being completely voluntary, the program could more closely attain the goals of an open source system than the previously proposed solutions. The voluntary nature of the program would not require differing patent protection based on the technology area of the application; maintaining a uniform patent system for all applications. This proposed fast-track examination voucher would dovetail well with current USPTO initiatives that allow the USPTO to better prioritize workload and accelerate examination times.[278] The NIH is even

276. *See supra* Part V.A.
277. U.S. CONST. art. I, § 8, cl. 8.
278. USPTO STRATEGIC PLAN, *supra* note 187.

recognizing the need for programs like the proposed fast-track examination voucher. Seeing that pharmaceutical companies "have neither the will nor the resources" to forge ahead with research in many areas, the NIH is injecting $1 billion into the new National Center for Advancing Translational Sciences.[279] The goal of the new center is to complete as much research as necessary to entice pharmaceutical company investment.[280] The activities could range from the initial screening of chemicals that might factor into a drug or cure to performing animal and human tests.[281] Once the research achieves the requisite commercial appeal, the activities would be transferred from the "academic support line and into the private sector."[282] Thus, a fast-track patent examination voucher can be an integral part of a concerted effort to ensure the continued search for the keys to human health and well being.

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279. Gardiner Harris, *A New Federal Research Center Will Help to Develop Medicines*, N.Y. TIMES, Jan. 23, 2011, at A1.

280. *Id.*

281. *Id.*

282. *Id.* (internal quotations omitted).

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