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By Robin Feldman[*] and Kris Nelson[**]

One of the most hotly contested issues in the field of intellectual property law concerns the existence, or non-existence, of patent thickets and the extent to which any such bottlenecks may be interfering with research. For decades, scholars warned that problems related to the over proliferation of patent rights would interfere with innovation. In contrast, a growing body of commentary argues that patent thickets are not a problem in modern industries. Either patent thickets do not exist, or if they do, patent thickets do not interfere with the progress of research.

The rhetoric is particularly heated these days because of dramatic changes underway in patent law. Research bottlenecks, or lack thereof, are invoked either in support of or in opposition to such changes, and it is difficult to have a rational discussion when so much seems to be at stake.

Stepping back from the rhetoric a bit, this Article suggests that one can sometimes indirectly observe effects, even if one cannot directly measure the extent of a phenomenon. With this in mind, the Article describes three approaches appearing in modern patent markets that are directed at mitigating the effects of patent thickets. These approaches can be described as Open Source, Open Access, and Open Transfer. From our vantage point, we may not be able to see or to measure the depth of the thicket. We can, however, observe the altered growth patterns that give us some indication of where the problems lie.

¶1 One of the most hotly contested issues in the field of intellectual property law is the extent to which legally created rights may be inhibiting, rather than promoting, scientific research. Although intellectual property rights are designed to encourage scientific progress, over proliferation or distortion of an optimal arrangement of rights could create bottlenecks that obstruct the flow of research. The debate plays out in themes related to the ways in which both patent and copyright law may be obstructing scientific research at commercial and academic institutions.

¶2 On the patent front, a key debate concerns the existence, or non-existence, of bottlenecks such as patent thickets and the extent to which any patent thickets may be interfering with research. For decades, scholars warned that problems related to the over proliferation of patent rights would interfere with innovation.[1] In theory, multiple

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[1] *See, e.g.*, Rebecca S. Eisenberg, *Bargaining over the Transfer of Proprietary Research Tools: Is This*

overlapping patent rights can hamper innovation by creating high transactions costs as researchers try to navigate the tangle of existing rights. These costs can discourage investment in research or distort the paths that researchers take due to the difficulty of identifying and negotiating all of the underlying rights necessary to begin researching. This leads to inefficiencies and underutilization of intellectual resources. Across the years, patent mavens traded stories of research deterred or research deferred due to patent thickets.[2] Innovation costs also may rise as rational enterprises factor in the risk that their inventions will be plagued by suits from patent holders who emerge from the shadows of the patent thicket to claim a share as soon as the invention is successful.[3]

¶3 The sheer number of rights for any individual piece of research can be staggering. The simple act of researching ways to genetically improve plants cultivated for food can involve identifying and obtaining licenses to dozens of separate rights.[4]

¶4 Problems that flow from the number of patents in existence are exacerbated by the difficulty of determining what an individual patent actually covers. The scope of rights inherent in any given patent is not immediately clear upon inspection of the patent and is

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Market Failing or Emerging, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY 223, 225 (Rochelle Cooper Dreyfuss et al. eds., 2001); NATIONAL RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY (1997); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, *in* INNOVATION POLICY AND THE ECONOMY 1, 1–2 (Adam Jaffe et al. eds., 2001), *available at* http://faculty.haas.berkeley.edu/shapiro/thicket.pdf; Robin Feldman, *The Open Source Biotechnology Movement: Is It Patent Misuse?*, 6 MINN. J.L. SCI. & TECH. 117, 123–25 (2004); Michael Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998); Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239, 239–40 (2004); *cf*I COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN RESEARCH AND INNOVATION, NATIONAL RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH (2006), *available at* http://fermat.nap.edu/catalog/11487.html?onpi_newsdoc11172005 (concluding that intellectual property restrictions rarely impose significant burdens on biomedical research but that there are reasons to be apprehensive about their future impact on scientific advances in this area); COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE-BASED ECONOMY, NATIONAL RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY (Stephen A. Merrill et al. eds., 2004) *available at* http://lab.nap.edu/nap-cgi/discover.cgi?term=a%20patent%20system&restric=NAP (concluding that although the patent system does not require fundamental change, economic and legal changes, including those resulting from the sheer volume of patents, are putting strains on the patent system); FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf (finding that poor patent quality and inadequate legal standards and PTO procedures can hamper competition that would otherwise stimulate innovation); Lori Andrews et al., *When Patents Threaten Science*, 314 SCIENCE 1395, 1395–96 (2006) (arguing that recent judicial and administrative precedents raise questions about the delicate balance between a common body of knowledge and the exclusive rights over scientific information embodied in a patent); Lita Nelsen, *The Rise of Intellectual Property Protection in the American University*, 279 SCIENCE 1460, 1461 (1998) (noting that the rise in partnership between academia and industry is increasing the inherent tension between academia's goal of disseminating knowledge and industry's goal of controlling and keeping confidential any intellectual property); *see also* Interview by Pamela Jones with Dan Ravicher, Executive Director, Public Patent Foundations (Dec. 23, 2003), *available at* http://lwn.net/Articles/64378/ (referring to "markets crippled by patent thickets").

[2] *See*, *e.g.*, Eisenberg, *supra* note 1, at 225 (explaining that scientists must wait months or years as their institutions wade through licensing agreements to gain access to research tools); Nelson, *supra* note 1, at 1461 (noting research delays at universities).

[3] *See*, *e.g.*, John R. Allison et al., *Valuable Patents*, 92 GEO. L. J. 435, 477 (2004); R. Polk Wagner & Gideon Parchomovsky, *Patent Portfolios*, 154 U. PA. L. REV. 1 (2005).

[4] *See* CAMBIA BIOS Initiative: Biological Innovation for Open Society (Mar. 29, 2004) (unpublished manuscript, on file with author).

likely to emerge only after extended litigation. For example, claim construction is the term used in patent law for the process of determining what a patent actually claims. The indeterminacy of claim construction in the modern courts is well-documented.[5] Even when construction of the claims has been resolved, the question of whether those claims will be interpreted to encompass the activity of the accused infringer, either directly or through the doctrine of equivalents, is a complex and difficult one. It can be hard to predict at the start of litigation, let alone in the initial phases of a research project, whether an activity will be judged to fall within the sphere of a particular patent.

¶5 Despite these concerns, a growing body of commentary argues that patent thickets are not a problem in modern industries. Such commentary suggests that either patent thickets do not exist, or if they do, patent thickets do not interfere with the progress of research. In particular, two widely-cited empirical studies by John Walsh and his colleagues conclude that, although the number of patents on research tools has increased dramatically, drug discovery has not been substantially harmed. Using voluntary surveys, the authors conclude that research is not impeded in the majority of cases because patent holders can cope through strategies including inventing around patented technology, obtaining licenses, or simply ignoring the existence of patent rights with the expectation that patent holders will not come after them.[6] The studies are cited as evidence that the dreaded patent thicket is no more than an illusion. They have also been criticized for using subjective data and for relying on a small pool.[7]

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[5] *See, e.g.*, Joseph Scott Miller, *Enhancing Patent Disclosure for Faithful Claim Construction*, 9 LEWIS & CLARK L. REV. 177, 177 (2005) (arguing that claim construction jurisprudence is in disarray and noting that the Federal Circuit reverses trial court claim construction decisions at a worryingly high rate); Kimberly A. Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?*, 9 LEWIS & CLARK L. REV. 231, 231–33 (2005) (documenting a concern among the bench and bar that the Federal Circuit's *de novo* review of district court claim construction decisions and lack of guidance have caused considerable unpredictability); *see also* Christian A. Chu, *Empirical Analysis of the Federal Circuit's Claim Construction Trends*, 16 BERKELEY TECH. L.J. 1075, 1104 (2001); Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 HARV. J.L. & TECH. 1, 8–10 (2001); R. Polk Wagner & Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 U. PA. L. REV 1105 (2004); Andrew T. Zidel, *Patent Claim Construction in the Trial Courts: A Study Showing the Need for Clear Guidance from the Federal Circuit*, 33 SETON HALL L. REV. 711 (2003). *But see* Jeffrey Lefstin, *The Measure of the Doubt: Dissent, Indeterminacy, and Interpretation at the Federal Circuit*, 58 HASTINGS L.J. 1025, 1027, 1094 (2007) (arguing that despite the nearly seamless consensus of problems related to *de novo* review of patent claim construction, it is the indeterminacy of patent law, rather than the application of patent law by the district courts or the Federal Circuit's review of the district courts, that is responsible for the current circumstances of patent litigation).

[6] *See* John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002 (2005); John P. Walsh et al., *Working Through the Patent Problem*, 299 SCIENCE 1021, 1021 (2003); *see also* John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 340 (Wesley M. Cohen & Stephen Merrill eds., 2003).

[7] *See* F. Scott Kieff, *IP Transactions: On the Theory & Practice of Commercializing Innovation*, 42 HOUS. L. REV. 727, 752 (2005) (noting the limitations of the Walsh study due to the small sample set of only seventy interviews with IP attorneys, business managers, and scientists from ten pharmaceutical firms and fifteen biotech firms, as well as university researchers and technology transfer officers from six universities, patent lawyers, and government and trade association personnel); Paul A. David, *The Economic Logic of "Open Science" and the Balance Between Private Property Rights and the Public Domain in Scientific Data and Information: A Primer* 13–16 (Stanford Inst. for Econ. Pol'y Res., SIEPR Discussion Paper No. 02-30, 2003), *available at* http://siepr.stanford.edu/papers/pdf/02-30.pdf (criticizing the value of the earlier Walsh study); Yann Joly, *Open Source Approaches in Biotechnology: Utopia Revisited*, 59 ME. L. REV. 385, 397 (2007) (noting that the Walsh study authors themselves recognized an important limitation to their study design concerning the difficulty of measuring the extent to which

¶6 If patent thickets exist, the concern is that they will substantially impair research and development because the tools of invention cannot flow freely through the research and development community. Similar charges have been made about the flow of information among researchers, particularly at academic institutions. With the passage of the Bayh-Dole Act in 1980,[8] Congress granted universities the right to elect ownership of inventions made with federal funds and encouraged them to participate in licensing and commercialization of those inventions. The Act was intended to bring to the public the benefits of federal research dollars by giving universities an incentive to patent and commercialize those products. Prior to passage of the Act, legislators were concerned that for a variety of reasons, the government had proved ineffective as a shepherd of the inventions created with federal research dollars.

¶7 Bayh-Dole has been a wild success when analyzed in terms of the number of patents granted to universities and the number of products created. Looking back on the first twenty years of Bayh-Dole, The Council on Government Relations reported that academic institutions had filed tens of thousands of patents which had led to the creation of more than 1000 products actually on the market. In addition, 2200 new companies were formed based on licensing of university patents. Another study showed that the number of patents granted to universities each year jumped from 264 in 1974 to 3200 in 2001.[9] Patent licensing brought $959,000,000 to universities in 2002 alone, although much of the revenue went to about a dozen research universities.[10]

¶8 Concerns have surfaced across time that, among other problems, the partnership between government, industry, and academia may have the unintended consequence of impeding the flow of information among researchers. Industry cosponsors of research may delay or suppress the results of data.[11] Researchers may be reluctant to publish data until patent rights are secure. Moreover, researchers have complained that copyright and cost restrictions in the academic publishing industry hamper the use of published information for teaching and research. These problems play out in the field of copyright law as well as patent law.

¶9 The rhetoric concerning research bottlenecks is particularly heated these days because of dramatic changes underway in patent law. Congress continues to debate a massive bill that would make substantial changes in patent statutes, including changing damage calculations, creating a post-grant opposition proceeding, shifting to a first-to-file system, and placing limitations on patent venue.[12] Although receiving less serious consideration, another bill would ban patenting of a "nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies."[13] The latter bill has been

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projects were not started or had been redirected because of patent concerns).

[8] *See* The Patent and Trademark Law Amendments Act, Pub. L. No. 96-517 (1980) [hereinafter Bayh-Dole Act].

[9] JENNIFER WASHBURN, UNIVERSITY, INC: THE CORPORATE CORRUPTION OF HIGHER EDUCATION 70 (2005).

[10] *Id.* at 169.

[11] *See, e.g.*, Charles Cathey, *The Bayh-Dole Act and the Development of Organizations like Stevens Institute for Technology Commercialization and Alfred E. Mann Institute for Biomedical Engineering at USC* 4–6 (2008) (unpublished paper on file with author) (detailing publication delays and other troubling influences exerted by commercial entities on university research).

[12] *See* Patent Reform Act of 2007, S. 1145, 110th Cong. (2007); Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007).

[13] *See* Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007).

supported in the popular press with dramatic statements such as "YOU, or someone you love, may die because of a gene patent."[14] If passed, the bill could have a sweeping impact on the biotechnology industry.

¶10 Case law also is evolving quickly. The Supreme Court has reviewed an unusually high number of patent cases in the last few terms. The decisions generally have narrowed patent rights or made it more difficult to obtain patents.[15] Moreover, a battle rages in the courts concerning invalidation of the Patent and Trademark Office's extensive new rules on continuation of patent applications.[16]

¶11 Research bottlenecks, or lack thereof, are invoked either in support of such changes or in opposition to them.[17] It is difficult to have a rational discussion when so much seems to be at stake. Stepping back from the rhetoric a bit, this Article offers a different approach to the question of whether research bottlenecks, such as patent thickets, exist and whether they have an effect on modern markets. Given the complex nature of the patent landscape, it is challenging to identify in a robust manner the extent to which patent thickets may, or may not, exist. Nonetheless, one can sometimes indirectly observe effects, even if one cannot directly measure the extent of a phenomenon. With these concerns in mind, the Article describes three approaches appearing in modern patent markets that are directed at mitigating the effects of patent thickets. These approaches can be described as Open Source, Open Access, and Open Transfer.

¶12 As a general matter, markets tend to respond to real problems. There are costs associated with shifting market positions, and one would ordinarily expect to see an avoidance of those costs if the expenditures were not necessary. Information distortions certainly can get in the way. In other words, it is possible that if people believe patent thickets exist they may engage in behaviors to avoid the effects, even if the perception is inaccurate. In addition, the analysis is complicated by the fact that universities are key players in the market for patent research. Universities play a dual role as both commercial actors reaping tremendous rewards from capitalization of their patented inventions and educational institutions viewing themselves as keepers of the intellectual

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[14] Michael Crichton, Op-Ed., *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, at A2; *see also* Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295 (2007) (discussing and opposing the bill).

[15] *See, e.g.*, Ill. Toolworks Inc. v. Indep. Ink, Inc., 547 U.S. 28 (2006) (finding no presumption of market power for patent holders in antitrust actions). Other patent cases that were granted *writ of certiorari* by the Supreme Court include Microsoft Corp. v. AT&T Corp., 127 S. Ct. 1746 (2007) (limiting extraterritorial reach of patent protection); KSR Int'l Co. v. Teleflex, Inc., 127 S. Ct. 1727 (2007) (strengthening the nonobviousness standard for obtaining a patent); MedImmune v. Genentech, Inc., 127 S. Ct. 764 (2007) (granting standing to licensees to challenge validity of patents); eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006) (rejecting rule that patent infringement should always be enjoined); Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124 (2006) (*cert. dismissed*, improvidently granted with dissenting opinion) (considering whether a medical correlation is patentable); Merck KGaA v. Integra LifeSciences I, Ltd., 545 U.S. 193 (2005) (concerning scope of research exemption to patent infringement for research related to government submissions).

[16] *See* Tafas v. Dudas, 541 F. Supp. 2d 805 (E.D. Va. 2008) (invalidating continuation rules).

[17] *Compare* Ann Mills & Patti Tereskerz, *Proposed Patent Reform Legislation: Limitations of Empirical Data Used to Inform the Public Policy Debate* (Biotechnology Industry Organization White Paper, Jan. 30, 2008), *available at* http://bio.org/ip/domestic/UVA_Limitations_of_Empirical_Data.pdf (opposing patent reform legislation) [hereinafter BIO White Paper] *with* NATIONAL RESEARCH COUNCIL, *supra* note 1 (proposing patent reform legislation) *and* COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE-BASED ECONOMY, *supra* note 1 (same) *and* FEDERAL TRADE COMMISSION, *supra* note 1 (same).

flame. For example, a group of University Tech Transfer officers recently put forward a white paper on points that their fellow officers should consider in licensing university technology. The paper noted universities must "be mindful of their primary mission to use patents to promote technology development for the benefit of society."[18] The dual role may also affect their behaviors in what we would describe as the patent market.

¶13 Nevertheless, the costs of creating alternative market pathways should be a deterrent, if the need for alternative pathways is less than such costs. Moreover, as a general matter, the actual contours of market transactions should be a more reliable indicator of what is happening in those markets than any academic speculation.

¶14 Thus, although currently one may not be able to prove anything definitive about the extent of bottlenecks and thickets, the creation of avoidance behaviors may be useful in confirming their existence. Most important, market responses may give us an indication of where the problems lie and may suggests paths that the law should encourage—or at least not stifle.

¶15 In short, from our vantage point, we may not be able to see or to measure the depth of the thickets. We can, however, observe the altered growth patterns that give us some indication of where the problems lie.

I. OPEN TRANSFER

¶16 One of the great shocks to the academic system in recent years was the Federal Circuit's decision in *Madey v. Duke*.[19] Professor Madey was a tenured research professor in the physics department at Duke University and the sole owner of two patents in use at Duke's free electron laser lab. After a falling out with University officials, the University removed Madey as director of the lab, and Madey resigned. The lab continued to use the lab equipment, however, and Madey sued for infringement. Among other defenses, Duke claimed that any activity in the lab was covered by the experimental use exception. The experimental use exception is a common law creation that can be traced back to cases in the 1800s.[20]

¶17 Although the trial court had upheld the University's experimental use defense, the Federal Circuit reversed, keeping faithful to a formulation from the early cases in which the exception is available only for activities having the sole purpose of gratifying a philosophical taste, satisfying curiosity, or amusement.[21] Most important, the Federal Circuit suggested that universities would have a very difficult time *ever* asserting the experimental use defense. The court specifically noted that the experimental use exception does not apply when an entity is engaged in commercial activity that furthers its legitimate business objectives.[22] According to the Federal Circuit, a university's legitimate business objectives include educating and enlightening students and faculty, as well as increasing the status of the university, luring lucrative research grants, and

[18] In the Public Interest: Nine Points to Consider in Licensing University Technology 6 (March 6, 2007) (on file with author) [hereinafter University White Paper].

[19] 307 F.3d 1351 (Fed. Cir. 2002).

[20] Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 19 (2001).

[21] *Id.* at 1361 (noting that the experimental use defense is quite narrow and is limited to actions performed "for amusement, to satisfy idle curiosity or for strictly philosophical inquiry").

[22] *Id.* at 1362.

attracting faculty and students.[23] This definition effectively eliminates any research exception for universities.

¶18 Prior to the *Madey* decision, academic researchers routinely ignored patent rights in conducting their teaching and experiments.[24] Although they may have comforted themselves with thoughts of a research exception, *Madey* made it clear that no such exemption exists. Without any hope of asserting a research exception, university researchers in theory would be forced to navigate the maze of patent licensing or face infringement suits. An informal poll of research institutions at a meeting in 2002 revealed that a number of institutions were receiving more infringement notification letters in the wake of the *Madey* decision.[25] Other reports suggested that academic researchers were continuing to ignore patent rights with the tacit acquiescence of patent holders,[26] a decidedly risky strategy for an institution.

¶19 Academic institutions, however, have not simply waited to see whether the tide will shift and patent holders will start suing for infringement. Rather, the institutions have attempted to alter the market rights, to the extent possible, through their technology transfer agreements. For example, a group of prominent research universities issued a white paper outlining nine important issues for universities to consider in technology transfer agreements.[27] The group includes Cal-Tech, Cornell, Harvard, MIT, Stanford, University of California, University of Illinois, University of Washington, Wisconsin Alumni Research Foundation, Yale, and The Association of American Medical Colleges.[28]

¶20 In particular, the University White Paper recommends that universities reserve the right to practice licensed inventions.

> Universities should consider reserving rights in all fields of use, even if the invention is licensed exclusively to a commercial entity, for themselves and other non-profit and governmental organizations: to practice inventions and to use associated information and data for research and educational purposes, including research sponsored by commercial entities; and to transfer tangible research materials (e.g., biological materials and chemical compounds) and intangible materials (e.g., computer software, databases and know-how) to others in the non-profit and governmental sectors.[29]

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[23] *Id.*

[24] The Walsh surveys were conducted as the *Madey* decision was making its way through the courts. The Federal Circuit reversed and remanded in 2002, and the district court rendered its final opinion in 2004. *Id.*; Madey v. Duke 336 F. Supp. 2d 583 (M.D.N.C. 2004). The Walsh studies were published in 2003 and 2005. *See* the studies cited, *supra* note 6. Although some commentators have speculated that university researchers were unaware of the *Madey* decision in its immediate aftermath and that researchers and private industry would alter their behavior across time, others dispute this interpretation. *See* BIO White Paper, *supra* note 17, at 22 (noting the controversy and citing the FTC, NAS, NCR and Walsh reports, *supra* notes 1 and 6, as disputing the notion that lack of anti-commons effect can be attributed to lack of knowledge about *Madey*).

[25] *See* BIO White Paper, *supra* note 17, at 22.

[26] *See* Walsh studies, *supra* note 6.

[27] University White Paper, *supra* note 18.

[28] *Id.* at 1.

[29] *Id.* at 2.

In other words, rights should be reserved, not just for the university itself, but on behalf of all non-profit and governmental organizations. We call such provisions Open Transfer Agreements.

¶21 The University White Paper notes further that clear articulation of the reserved rights is critical and offers examples of retained rights clauses.[30] One of the examples in the University White Paper comes from license agreements used by Stanford University's Office of Technology Transfer.[31] The provision reserves use rights "for any non-profit purpose, including sponsored research and collaborations."[32]

¶22 A Stanford technology transfer officer noted that the university previously used a clause that retained the right to use technology for "non-commercial purposes."[33] While the University believed that industry-sponsored research at the university should be included in the notion of "non-commercial" purposes, some companies disagreed.[34] Thus, Stanford moved to more explicit language.[35] The dispute highlights the difficulty of defining what constitutes non-commercial or academic research, particularly in an environment in which academic and commercial entities collaborate.

¶23 The University White Paper also mentions this issue, noting the importance of defining the notion of non-commercial purposes. The commentary in the paper explains that "to address the *Madey* issue in recent agreements, we have attempted to make clear that . . . activities held under *Madey* to be the 'business' activities of universities are within the scope of our reserved rights."[36] The commentary provides an example of a definitional clause to clarify the meaning of non-commercial purposes.[37]

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[30] *Id.* at 2, 10–12.

[31] *Id.* at 10; E-mail from Katherine Ku, Stanford University Office of Technology Transfer (Nov. 13, 2007) (on file with author).

[32] University White Paper, *supra* note 18, at 10. The full provision reads:

> Institution retains the right, on behalf of itself and all other non-profit academic research institutions, to practice the Licensed Patent and use Technology for any non-profit purpose, including sponsored research and collaborations. Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution. Institution and any such other institution has the right to publish any information included in the Technology or a Licensed Patent.

[33] Ku E-mail, *supra* note 31.

[34] *Id.*

[35] *See id.*

[36] University White Paper, *supra* note 18, at 11.

[37] "Non-commercial Research Purposes" means:

> Use or practice of *Licensed Patent Rights* for academic research and other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not involve the production or manufacture of products for sale or the performance of services for a fee. Without limiting the foregoing: (i) "academic research and other not-for-profit or scholarly purposes" includes, in non-limiting fashion, research that leads, or may lead, to patentable or unpatentable inventions that may be licensed or otherwise transferred, either directly or indirectly, to third parties; and (ii) neither (A) receipt of license revenues on account of such inventions or receipt of reimbursements for the costs of preparation and shipping of samples of materials provided to third parties as a professional courtesy, in response to post-publication requests or otherwise in accordance with academic custom nor (B) receipt of funding to cover the direct and/or indirect costs of research, shall constitute sale of products or performance of service for a fee.

University White Paper, *supra* note 18, at 11.

¶24 In conversations with the authors of this Article, one university technology transfer officer commented that companies are not happy about including the Open Transfer language in their agreements, but that the University takes the position that failure to include the language is a deal-killer. Interestingly, the University White Paper and examples of such clauses in university technology transfer agreements do not seem to have made their way into the academic literature yet, although they have been operative for several years. The February 2008 Biotech Industry Organization (BIO) White Paper notes that the American Association for the Advancement of Science (AAAS) planned in 2002 to monitor universities' experiences with the research exception, but that BIO is unaware of any follow-up by the AAAS or other organizations.[38]

¶25 In general, Open Transfer clauses are designed to create a market space of free experimentation that will be available for all non-profit research institutions. The attempt is less than perfect in its coverage. The clauses will apply only to technology created by universities themselves, not to the vast amount of technology created in the private sector, and they will only apply to technology that is licensed going forward. In addition, the University White Paper suggests only issues to consider and does not bind any of its signatories. Finally, although the signatories represent many of the major players in the fields of scientific research, they do not represent all of them. Thus, to the extent that a patent thicket exists, the Open Transfer initiative offers only a partial solution. Nevertheless, Open Transfer is a creative attempt to mitigate difficulties with access to research rights, and one that indicates the existence of a significant problem for research universities.

II. OPEN SOURCE BIOTECHNOLOGY

¶26 The notion of open source systems developed first in the world of information technology and computer software through efforts by programming leaders such as Richard Stallman. Understanding so-called Open Source Biotechnology requires some understanding of its predecessor in the software world.

¶27 Software developers write software in a variety of programming languages, all designed to make it easier for humans to tell computers what to do as effectively as possible. This human-comprehensible format is known as "source code" and is relatively easy for a trained programmer to use and understand.[39] Computers, on the other hand, rely on "object code," produced by a computer program known as a "compiler," which takes human-friendly source code and produces machine-comprehensible object code.[40] With access to the source code, programmers can change the software, what it does, how it looks, and how it operates. They can customize it, repackage it, change its name, or do almost anything they wish.

¶28 For exactly this reason, most companies that sell software have relied on a "closed-source" or proprietary software development and distribution model.[41] Source code written by programmers is kept secret, and is kept under tight control by the companies

[38] *See* BIO White Paper, *supra* note 17, at 22.

[39] *See* Christian H. Nadan, *Open Source Licensing: Virus or Virtue?*, 10 TEX. INTELL. PROP. L.J. 349, 350–51 (2002).

[40] MARK A. LEMLEY ET AL., SOFTWARE AND INTERNET LAW 25 (3rd ed. 2000).

[41] Nadan, *supra* note 39, at 350–51.

that own it.[42] In addition to keeping the source code secret, proprietary software makers usually release their object code under tight licensing restrictions that supplement technical protections, as well as patent and copyright restrictions, with additional contractual protections restricting end users rights to modify, copy or distribute the software.[43]

¶29 The Open Source Software movement,[44] on the other hand, utilizes a different model in which source code is freely distributed along with object code.[45] To Open Source Software advocates, "free" refers to "liberty, not price."[46] A common and colorful analogy in the Open Source Software movement is that free software is "'free' as in 'free speech,' not as in 'free beer.'"[47] Essentially, to be a true Open Source license, a licensee must be permitted to at any time and for any purpose copy, change, and distribute the source code of the software.[48] Typically, Open Source Software development is highly collaborative, with frequent, iterative releases that fix bugs and introduce changes much more rapidly than traditional proprietary software development.[49] A group of developers often operate loosely as project managers and guide the incorporation of new code written by many others into the core software.[50] This peer-production model allows for effective utilization of available materials more efficiently than for individuals operating in a traditional market approach.[51] A broad goal of Open Source is to foster the reuse of available resources instead of a constant necessity to "reinvent the wheel."[52]

¶30 While critics have attacked Open Source as undermining copyright, hampering innovation, and providing a limited public good,[53] many companies have nevertheless adopted Open Source as a key part of their business strategy, either as contributors to Open Source development or as users of Open Source products.[54] Red Hat, Inc., for

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[42] *Id.* at 351–52. *See also* Mathias Strasser, *A New Paradigm in Intellectual Property Law?: The Case Against Open Source*, 2001 STAN. TECH. L. REV. 4, 10 (2001).

[43] *See* Joseph Scott Miller, *Allchin's Folly: Exploding Some Myths About Open Source Software*, 20 CARDOZO ARTS & ENT. L.J. 491, 496 (2002).

[44] For detailed discussions of the open source software movement, see generally RICHARD STALLMAN, FREE SOFTWARE, FREE SOCIETY: SELECTED ESSAYS OF RICHARD STALLMAN (Joshua Gay ed., 2002).

[45] *Id.* at 16.

[46] GNU Project, The Free Software Definition, http://www.gnu.org/philosophy/free-sw.html (last visited Nov. 6, 2008).

[47] *Id.*

[48] *See* Larry Rosen et al., *Live from Silicon Valley, Views of Open Source Practitioners*, *in* LEGAL ISSUES RELATING TO FREE AND OPEN SOURCE SOFTWARE 37, 39 (B. Fitzgerald & G. Basset eds., 2003). *See also* J.T. Westermeier, *Open Source Software*, 801 PLI/PAT 421, 428 (2004).

[49] *See* Eric S. Raymond, *The Revenge of the Hackers*, *in* OPEN SOURCES: VOICES FROM THE OPEN SOURCE REVOLUTION (Chris DiBona et al. eds., 1999); *see also* ERIC S. RAYMOND, THE CATHEDRAL AND THE BAZAAR: MUSINGS ON LINUX AND OPEN SOURCE BY AN ACCIDENTAL REVOLUTIONARY (2001).

[50] Nadan, *supra* note 39, at 353.

[51] *See* Yochai Benkler, *Coase's Penguin, or Linux and the Nature of the Firm*, 112 YALE L.J. 369, 376–77 (2002) ("Transaction costs associated with property and contract limit the access of people to each other, to resources, and to projects when production is organized on a market or firm model, but not when it is organized on a peer production model.").

[52] Raymond, *supra* note 49.

[53] *See, e.g.*, Strasser, *supra* note 42.

[54] *See, e.g.*, P.G. Capek et al., *A History of IBM's Open-Source Involvement and Strategy*, 44 IBM SYS. J. 249 (2005), *available at* http://www.research.ibm.com/journal/sj/442/capek.pdf.

example, provides software support services and bundles of the Linux operating system, which is developed under an Open Source model.[55] Red Hat does not control Linux development, but it both contributes to and profits from it.[56] In fact, Red Hat has generated enough business to "win the approval of financial markets and maintain [significant] market capitalization."[57]

¶31 Open Source Biotechnology tries to borrow from elements of the Open Source Software movement, orienting those elements around the scientific development of biotechnology. It is described using different names, including Open Source Biotechnology, recognizing its roots in Open Source Software, and Open Science, recognizing the elements that differ from the computer world.[58]

¶32 There are two main divisions within the broad category of Open Source Biotechnology. The first category primarily involves bioinformatics—the application of computer software and methodologies to solve biological problems. With its focus on software, this category is a direct beneficiary of Open Source Software and Open Source approaches. Three examples of Open Source in the bioinformatics world are BioPerl, BioJava, and BioPython. All of them are now organized together under the auspices of the Open Bioinformatics Foundation.[59]

¶33 These projects all make their work available under standard Open Source licenses, such as the GNU Lesser General Public License, version 2.1.[60] According to Lincoln Stein, a researcher at the Cold Springs Harbor Laboratory who works with the human genome project, BioPerl resources "saved the human genome project" by allowing the development of quick and useful tools to facilitate the interchange of data amongst laboratories who kept their research in dissimilar formats.[61] The Bioinformatics Organization takes an even broader approach to encouraging collaboration and participation in bioinformatics development, maintaining computational resources and promoting open access to materials and methods for bioinformatics research and education throughout the world.[62]

¶34 The second category of Open Source Biotechnology is much broader, and is more loosely connected with the approaches used by Open Source Software. As the subjects of the projects move further from the software interface, they may be better described as "Open Science." Although difficult to characterize as a whole, these Open Science

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[55] *See* David McGowan, *Legal Implications of Open-Source Software*, 2001 U. ILL. L. REV. 241, 242–43 (2001).

[56] *Id.* at 242.

[57] *See id.*

[58] *Compare* Lee Petherbridge, *Road Map to Revolution: Patent Based Open Science*, 59 ME. L. REV. 339 (2007) *with* Robin C. Feldman, *The Open Source Biotechnology Movement: Is It Patent Misuse?*, 6 MINN J. L. SCI. & TECH. 117 (2004) *and* David W. Opderbeck, *The Penguin's Genome or Coase and Open Source Biotechnology*, 18 HARV. J.L. & TECH. 167, 198–201 (2004). *See also* Katherine M. Nolan-Stevaux, *Open Source Biology: A Means to Address the Access & Research Gaps?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 271 (2007) (using the term Open Source Biology).

[59] *See* Open Bioinformatics Foundation, http://www.open-bio.org (last visited Nov. 6, 2008).

[60] *See, e.g.*, BioJava Project, http://www.biojava.org (last visited Nov. 6, 2008); *see also* GNU Lesser General Public License, version 2.1, http://www.gnu.org/licenses/old-licenses/lgpl-2.1.html (last visited Nov. 6, 2008).

[61] Lincoln Stein, *How Perl Saved the Human Genome Project*, THE PERL JOURNAL (Sept. 1996), *available at* http://www.bioperl.org/wiki/How_Perl_saved_human_genome.

[62] *See* Bioinformatics Organization, http://wiki.bioinformatics.org/Bioinformatics_Organization (last visited Nov. 6, 2008).

projects try to ensure that the biotechnology tools required for research and innovation are openly available.[63] Some are aimed at solving problems in underserved communities,[64] given that the non-profit researchers who focus on those communities may not have the financial capacity to navigate the maze of patent rights and licensing necessary to engage in the targeted research. Many of the projects cite cutting through patent thickets as an important goal.

¶35 Open Science Projects share some characteristics with their Open Software predecessors. Open Science tends to involve collaborative projects that pool the work of many participants and makes advances available to a broad community. Most important, a number of Open Science projects copied the Open Source Software licensing approach, using the power of the patent system to ensure that the core technology of the project and any innovations remain openly available.[65] For these projects, participants agree to either grant licenses or enforce their rights in a way that maintains the availability of the inventions and improvements in the future.

¶36 Open Science projects differ significantly, however, from Open Source Software projects. Open Source Software allows a broad range of researchers to see information that remains hidden in the program. The Open Science world is quite different. Although information flow may be hampered if individuals choose not to patent their research, much of Open Science is premised on patent rights, which presupposes that the information has been revealed in a patent application. Such information will most likely become public at some point. In addition, any individual with a computer and the proper programming skills can participate in Open Source Software. In contrast, Open Science projects may require the use of sophisticated laboratory equipment. Given the resources required for such endeavors, participants are likely to be at large academic or commercial research organizations, which complicates efforts to enroll participants and shape their rights. Finally, the rights system underlying Open Source Software is copyright, while the rights system underlying Open Science is patent. Differences between these rights systems guarantee that the rights, licensing structures and enforcement potentials will differ.[66]

¶37 Examples of Open Science include the HapMap Project, CAMBIA and the Biological Innovation for Open Society Initiative (BiOS), and the Public Patent Foundation.[67] The HapMap Project is a multi-country effort to identify and catalog genetic differences in humans.[68] The project, funded with both public and private funds, started in 2002 and includes researchers from six countries.[69] HapMap's goal is a specialized map of the human genome particularly containing information about cites in

[63] *See* Feldman, *supra* note 1, at 118. For a more detailed description of the Open Source Biotechnology projects introduced below, see *id.*

[64] *See, e.g.*, Stephen M. Maurer et al., *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, *in* BIOTECHNOLOGY: ESSAYS FROM ITS HEARTLAND 33 (Lynn Yarris ed. 2004) (advocating a tropical disease initiative).

[65] *See id.*

[66] Opderbeck, *supra* note 58, at 198–201.

[67] For a more detailed description of these and other Open Science projects, see Feldman, *supra* note 1.

[68] *See* About the HapMap, http://www.hapmap.org/thehapmap.html.en (last visited Nov. 6, 2008).

[69] *See* News Release, National Institutes of Health, National Human Genome Research Institute, International HapMap Consortium Expands Mapping Effort (Feb. 7, 2005), *available at* http://www.genome.gov/13014173.

the human genome where the DNA sequences vary among individuals. These variations are called single nucleotide polymorphisms, or SNPs.

¶38 Originally, HapMap users agreed to take certain steps to maintain the open availability of information in the database. The click-wrap license stated that patents filed for particular uses of SNPs in the database must be licensed on terms that would maintain free access to the information in the database for other purposes.[70] HapMap's licensing strategy was short-lived. Among other reasons, the stringency of the license terms prevented HapMap data from being incorporated into other public genomic databases.[71] In addition, developments in the scientific arena led HapMap to conclude that the SNPs probably were not patentable.[72] Data from the HapMap project is now completely available to the public.[73]

¶39 CAMBIA is another Open Science Project. CAMBIA, and its child project, the BiOS Initiative, are focused on expanding access to biological research, especially for disadvantaged communities.[74] The goal is to increase democratic innovation through "astute use of intellectual property informatics and analysis" and to allow for the cooperative development of technology.[75] In other words, BiOS tries to develop and bundle groups of technologies that can be used for scientific research related to underprivileged communities. The stated objective of the BiOS Initiative is "to create a public-spirited and public-good based initiative with respect to biological innovations."[76] BiOS has developed a system to increase understanding of patents and to foster "patent transparency,"[77] created licenses to foster open research,[78] and created an online community for biological innovation, known as "BioForge."[79]

¶40 The Public Patent Foundation was yet another form of Open Science project. Public Patent was aimed not specifically at underprivileged communities, but more broadly at market areas hampered by so many patents that even those holding some of the patents could not efficiently navigate the licensing. The Foundation hoped to establish patent pools in which the technology would be openly available to other pool participants.[80]

¶41 Open Science systems have not always matched the initial expectations. The HapMap Project has assembled a tremendous data base, but it has had to shift from a

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[70] *See* Feldman, *supra* note 1, at 125–26.

[71] News Release, National Institutes of Health, National Human Genome Research Institute, International HapMap Consortium Widens Data Access, (Dec. 10, 2004, *available at* http://www.genome.gov/12514423; *see also* Opderbeck, *supra* note 58, at 198–201 (predicting other problems with the HapMap licensing approach).

[72] International HapMap Consortium Widens Data Access, *supra* note 71.

[73] *See id.*

[74] *See* BiOS Initiative, http://www.bios.net/daisy/bios/about/3.html (last visited Nov. 6, 2008).

[75] What Is BiOs?, http://www.bios.net/daisy/bios/g1/2442/24.html (last visited Nov. 6, 2008).

[76] *Id.*

[77] *See* The Patent Lens, http://www.patentlens.net/daisy/patentlens/patentlens.html (last visited Nov. 6, 2008).

[78] *See* About BiOS Licenses and MTAs, http://www.bios.net/daisy/bios/licenses/398.html (last visited Nov. 6, 2008).

[79] *See* Bioforge: An Online Community for Biological Innovation, http://www.bioforge.net/forge/index.jspa (last visited Nov. 6, 2008).

[80] *See* Interview by Pamela Jones with Dan Ravicher, *supra* note 1; E-mail from Dan Ravicher, Executive Director, Public Patent Foundation, to Robin Feldman, Assistant Professor of Law, University of California Hastings College of the Law (Jan. 13, 2004, 11:34 PST) (on file with author).

GNU-style licensing scheme to a system that places the data into the public domain. Public Patent foundation has not moved forward with its pooling project and continues as an advocacy group.[81] Nevertheless, Open Science initiatives continue in various forms and with various degrees of progress.

III. OPEN ACCESS

¶42 Open Transfer and Open Source are attempts to allow the tools of invention to flow more freely among researchers. Open Access is somewhat different. The goal of Open Access is to allow *information* to flow more freely among researches, as well as to the public at large.

¶43 For problems relating to the flow of information, copyright law, rather than patent, is the vehicle through which barriers are erected. Nevertheless, the pace of scientific inventions, including those that are likely to become the subject of patents, may be affected by impediments in the flow of information.

¶44 Such Open Access systems have developed in response to concerns that articles published in scientific journals are too restricted in their availability. Academic scientists, who must publish or perish, have no choice but to offer their papers to scientific journals. The amount of scientific information is staggering. Each year, 2.5 million articles are published in refereed journals, across all disciplines, languages and nations."[82]

¶45 The wealth of information available in those papers then becomes difficult to access for a variety of reasons. The sheer number of articles creates a challenge to the efficient flow of information in the scientific community. In addition, two barriers create particular problems for information dissemination. The first problem is "price barriers," given that access to journals may require hefty subscriptions, licensing fees, or pay-per-view fees. [83] The second is "permission barriers," given that restrictions on all uses including research and teaching may be limited by copyright and by licensing restrictions. [84] The prestige factor of existing journals, combined with the importance of prestige publication for a science career, serve as entry barriers for individual journals that might compete on price and terms.

¶46 Individual efforts are difficult, but coordinated projects in the scientific community have led to the development of Open Access systems for scientific research. The scientific open-access movement began to gain momentum in 1998 through the efforts of the Scholarly Publishing and Academic Resources Coalition.[85] The coalition's efforts led to the founding of the Public Library of Science (PLoS), and the eventual launch in 2003 of a group of open-access journals, primarily focused on medicine and biology.[86] Other notable open-access efforts include ArXiv, the Social Science Research Network,

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[81] *See* About PUBPAT, http://www.pubpat.org/About.htm (last visited Apr. 3, 2008) (describing the current activities of the Foundation).

[82] D-LIB MAGAZINE (Mar. 2005), *available at* http://dlib.org/dlib/march05/03contents.html.

[83] *See* Peter Suber, Open Access Overview, http://www.earlham.edu/~peters/fos/overview.htm (last visited Nov. 6, 2008).

[84] *See id.*

[85] David W. Opderbeck, *The Penguin's Paradox: The Political Economy of International Intellectual Property and the Paradox of Open Intellectual Property Models*, 18 STAN. L. & POL'Y REV. 101 (2007).

[86] *Id.*

Biomed Central, and Berkeley Electronic Press.[87] These efforts are all informed by a broader international movement towards open-access scholarship generally, including the Budapest Open Access Initiative,[88] the Bethesda Statement on Open Access Publishing,[89] and the Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities.[90]

¶47 One example of "open access" comes from the charter of the PLoS, which allows "all users a free, irrevocable, worldwide, perpetual right of access to, and a license to copy, use, distribute, transmit and display the work" and requires a "complete version of the work and all supplemental materials . . . [to be] deposited immediately upon initial publication in at least one online repository."[91] This standard is also known as the Creative Commons Attribution License (CCAL):[92] "Under the CCAL, authors retain ownership of the copyright for their article, but authors allow anyone to download, reuse, reprint, modify, distribute, and/or copy articles in PLoS journals, so long as the original authors and source are cited. No permission is required from the authors or the publishers."[93]

¶48 Other funding organizations, such as the Howard Hughes Medical Institute and the Wellcome Trust, have also recently moved to require scientists to deposit such electronic copies in a publicly-accessible repository.[94]

¶49 There are a range of approaches within the Open Access movement. Pure Open Access would remove both price barriers and use barriers.[95] Some systems, however, provide variations on the theme, for example, removing price barriers but not permission barriers.[96] Such public availability is sometimes referred to as Public Access, rather than Open Access.

¶50 It is important to understand that Open Access and Public Access are not the same thing as placing an article into the public domain. Although some scholars advocate that works generated by publicly financed research should enter the public domain and have no rights attached,[97] the Open Access movement and its Public Access cousin follow a different concept. Like Open Source, they use the power of an Intellectual Property regime, here copyright, to control the article once it is published in a way that ensures a free flow of information.

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[87] Chris Armbruster, *Open Access in Social and Cultural Science: Innovative Moves to Enhance Access, Inclusion and Impact in Scholarly Communication*, 6 POL'Y FUTURES IN EDUC. 424 (2008), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=849305.

[88] Budapest Open Access Initiative (Feb. 14, 2002), http://www.soros.org/openaccess/read.shtml.

[89] Bethesda Statement on Open Access Publishing (June 20, 2003), http://www.earlham.edu/~peters/fos/bethesda.htm.

[90] Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities (Oct. 22, 2003), http://www.zim.mpg.de/openaccess-berlin/berlindeclaration.html.

[91] PloS Definition of Open Access, http://www.plos.org/oa/definition.html (last visited Nov. 6, 2008).

[92] Creative Commons Legal Code, http://creativecommons.org/licenses/by/2.5/legalcode (last visited Nov. 6, 2008).

[93] PLos Medicine, Open-Access License No Permission Required, http://journals.plos.org/plosmedicine/license.php (last visited Nov. 6, 2008).

[94] Ted Agres, *Open Access Opening Wider*, THE SCIENTIST, July 5, 2007, *available at* http://www.the-scientist.com/news/display/53366/.

[95] Suber, *supra* note 83.

[96] *Id.*

[97] *See* Samuel Trosow, *Copyright Protection for Federally Funded Research: Necessary Incentive or Double Subsidy?*, 22 CARDOZO ARTS & ENT. L.J. 613 (2004).

¶51 What is most interesting about the Open Access movement is that the Federal Government, taking the lead from private organizations, has joined the effort. With Open Access, legal policy has, at least to some extent, followed the path blazed by participants in the relevant industry.

¶52 Specifically, in recently-passed legislation, Congress has directed the National Institutes of Health (NIH) to require that research papers developed as a result of NIH funding should be made publicly available through PubMed Central. Similar to the contractual provisions that universities are using in Open Transfer, the process will be accomplished through contractual language in publishing contracts. Earlier legislation had spawned NIH provisions requesting that researchers who receive NIH funding *voluntarily* submit final versions of manuscripts accepted for publication for inclusion in a public database. Only four percent of eligible articles were submitted to the database under that language.[98]

¶53 The NIH Open Access system is a compromise. It is less open than a pure Open Access standard and somewhat less open than even a true Public Access system. NIH primarily addresses price barriers (subscription fees, for example), not permission barriers (licensing restrictions and other aspects of copyright). In addition, public access can be delayed up to twelve months, giving publishers some time to earn a return on initial publication of the information.[99]

¶54 Unlike the licensing used by the PLoS, the NIH imposes no requirement that the author or copyright owner change or modify the copyright of the work deposited with PubMed Central, *except* that a NIH-funded author must reserve the right to deposit the article for viewing by the public. With this limited reserved access, the public can read the full-text article, cite to it, and exercise general "fair use" exceptions to copyright, but cannot, for example, print the article out and make photocopies of it for an entire class, as would be permissible under most open-access approaches.

¶55 To accomplish this, the NIH asks authors to insert language such as the following into the copyright agreements authors sign with publishers: "Journal acknowledges that Author retains the right to provide a copy of the final peer-reviewed manuscript to NIH upon acceptance for Journal publication, or thereafter, for public archiving in PubMed Central as soon as possible but no later than twelve months after publication by Journal."[100]

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[98] *See* Enhanced Public Access to NIH Research Information, 69 Fed. Reg. 56,074 (Sept. 17, 2004), *available at* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-064.html; NAT'L INST. OF HEALTH, DEP'T OF HEALTH AND HUM. SERVS., REPORT ON THE NIH PUBLIC ACCESS POLICY (2006); *see also* Opderbeck, *supra* note 85, at 111–14, 118–19 (describing the history of the voluntary provision and its lack of success).

[99] The Consolidated Appropriations Act 2008, Pub.L. No. 110-161, Div. G, Title II, § 218, reads as follows:

> The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: *Provided*, That the NIH shall implement the public access policy in a manner consistent with copyright law.

[100] National Institutes of Health Public Access, Public Access Frequently Asked Questions, http://publicaccess.nih.gov/FAQ.htm#c2 (last visited Nov. 6, 2008).

¶56 The goal is to provide the public the ability to access federally-funded research after a reasonable period without expensive subscription fees and without fundamentally altering the economics of the publishing industry. Congress sought to: (1) allow publishers to financially benefit from public investment, while encouraging them to keep investing in improved publishing methods; and (2) lower the costs of public access and quicken the pace at which the public is allowed to directly benefit from federal research spending.[101]

¶57 Before passage of the bill, the Bush Administration had identified three areas of concern with legislation making public access mandatory for NIH-funded research, although the Administration indicated that these concerns should be balanced against "the benefit of public access to taxpayer supported research."[102] Those areas were: (1) the impact on scientific research publishing, (2) the impact on scientific peer review, and (3) "the United States' longstanding leadership in upholding strong standards of protection for intellectual property."[103]

¶58 The traditional publishing industry argues that Public Access will increase their costs and make them less profitable. This, they argue, will increase the costs of access to their journals, reduce innovation in the publishing realm, and hamper the business of scientific publishing, the free market, and the progress of science. Critics of the even broader approach taken by Open Access initiatives believe Open Access undermines the traditional scientific publishing model even more than the limited public access mandated by the 110th Congress. As the congressional mandate moves forward, it will be interesting to see whether the balance is appropriate or whether problems predicted by the publishing industry materialize.

¶59 Although much more limited than Open Access advocates would like, the congressional/NIH program is remarkable in several ways. First, it marks a legislative effort to follow private voluntary initiatives that attempt to increase the flow of research information. More important, the effort uses the NIH and the massive power of its federal funding to encourage terms that will promote greater exchanges in the scientific community. To the extent that coordinated action may be important for easing research

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[101] *See* The Public Access Policy of the National Institutes of Health: Before the Subcomm. on Courts, the Internet, and Intell. Prop. of the H. Comm. on the Judiciary, 110th Cong. 6–7 (2008) (statement of Elias A. Zerhouni, Director, National Institutes of Health), *available at* http://judiciary.house.gov/hearings/pdf/Zerhouni080911.pdf; Hearing on H.R 6845 Before the Subcomm. on Courts, the Internet, and Intell. Prop. of the H. Comm. on the Judiciary, 110th Cong. 3–7 (2008) (statement of Heather Daltiero Joseph on behalf of Scholarly Publishing and Academic Resources Coalition, Alliance for Taxpayer Access, and Association of Research Libraries), *available at* http://judiciary.house.gov/hearings/pdf/Joseph080911.pdf. *See also* NIH PUBLIC ACCESS WORKING GROUP OF THE NLM BOARD OF REGENTS MEETING SUMMARY (2005), *available at* http://www.nlm.nih.gov/od/bor/PublicAccessWG-11-15-05.pdf (meeting on Nov. 15, 2005, discussing what recommendations the NIH should make to Congress in regards to public access); Lila Guterman, *Advocates of Open Access Hope to Strengthen the NIH's Policy on Making Research Results Available Online*, CHRON. OF HIGHER EDUC., May 19, 2006.

[102] *See* Mark Graczynski & Lynn Moses, *Open Access Publishing—Panacea or Trojan Horse?*, 1 MED. SCI. MONITOR 1, 1–3 (2004) (criticizing the idea that taxpayer funding should result in either public or open access).

[103] OFFICE OF MGMT. & BUDGET, EXECUTIVE OFFICE OF THE PRESIDENT, STATEMENT OF ADMINISTRATION POLICY, (Oct. 17, 2007), *available at* http://www.whitehouse.gov/omb/legislative/sap/110-1/s1710sap-s.pdf.

bottlenecks, the NIH certainly sits at the center of American scientific research activity, a position that provides the opportunity for significant coordination.

¶60 This is not the first time the NIH has used its power to encourage licensing terms that it believes will be in the public interest. For example, NIH guidelines for grant recipients who use or develop research tools discourage recipients from engaging in certain types of licensing provisions, on the grounds that such royalties lead to unreasonable restraints on publication and academic freedom as well as impeding scientific progress.[104] In addition, the NIH has been quite explicit in expressing its hope that influencing NIH funding recipients will encourage other organizations to adopt similar policies.[105] Binding requirements like the recently enacted publication provisions have a much greater impact than guidelines, however, even when those guidelines are accompanied by soaring language.

IV. OBSERVATIONS

¶61 Open Source, Open Access, and Open Transfer indicate ways that those in the markets for scientific research have tried to develop strategies to address research bottlenecks. These approaches suggest that relevant market participants perceive impediments to their activities and are sufficiently motivated to develop avoidance behaviors.

¶62 The implications one can draw from the observations above are quite modest. The observations cannot resolve whether damage calculations should be apportioned differently nor can they resolve any of the other hotly contested issues in the pending patent reform legislation. Nor can they suggest whether the pending massive continuation rules should be voided or left to stand. In general, as academics, we would be wise to avoid sweeping generalizations from modest observations as well as the temptation to use limited data in support of broad policy strategies.[106] Moreover, the three open system approaches described above are unlikely to indicate the only places in which research bottlenecks are occurring. Nevertheless, they do suggest that research bottlenecks, in fact, create significant problems—problems substantial enough that the research community itself has tried to develop mitigation pathways.

¶63 One could argue that the development of these pathways suggests that research bottlenecks are not a problem with which courts and legislatures should be concerned. Perhaps those in the relevant field have proven perfectly capable of adapting to any thickets or bottlenecks that occur. The solutions described above, however, are limited at best. They cannot cover all participants, they provide only partial solutions to the problems that they identify, and in some cases, they have met with only limited success. Thus, they are more useful for confirming the existence of a problem in scientific

[104] *See* Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090, 72,093 (Dec. 23, 1999) (Final Notice) (discouraging the use of reach-through royalties for research tools).

[105] *See id.* (noting in the research-through royalty provisions that "[w]hile these Principles are directly applicable only to recipients of NIH funding, it is hoped that other not-for-profit and for-profit organizations will adopt similar policies and refrain from seeking unreasonable restrictions or conditions when sharing materials").

[106] *See generally* ROBIN FELDMAN, THE ROLE OF SCIENCE IN LAW (forthcoming 2009).

research than they are for demonstrating the ability of those engaged in scientific research to solve the problem.

¶64 It is particularly interesting to note that all three approaches involve coordinated efforts. In other words, evidence of coordination of efforts could suggest that the problems are intractable on an individual level. This is precisely the type of problem that would benefit from governmental efforts. Again, we should not use the existence of research bottlenecks to support all manner of broad changes in the patent system. Nor should we ignore them.