PROTECTING THE PUBLIC DOMAIN OF SCIENCE: HAS THE TIME FOR AN EXPERIMENTAL USE DEFENSE ARRIVED?

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Today I will be addressing questions about the public domain of science, whether it needs protecting, and whether patent law requires a new experimental use defense to maintain a robust, creative environment for modern science and biotechnology. I am going to start my talk with some background on these issues; suggest why there is a problem and why it is being raised now; and then move on to consider strategies for preserving a rich sphere of public science.

I would like to thank the symposium for choosing a topic very close to my heart. I worked as a bench chemist in medical academia and in a large pharmaceutical company. As a lawyer, I served on the National Academies' Board on Science, Technology, and Economic Policy's Committee on Intellectual Property Rights in the Knowledge-Based Economy and as a consultant for the Federal Trade Commission while it was holding hearings on promoting innovation.[1]

I. BACKGROUND

Until a short while ago, no one would have thought there was a need to focus on the question whether the scientific community needed the help of an experimental use defense to patent infringement. By 1890, the issue of whether experimentation amounted to patent infringement seemed to have been clearly

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* Pauline Newman Professor of Law, New York University School of Law. I would like to thank Graeme Austin for his generous introduction and for inviting me here. Thanks also to Quarles & Brady Streich Lang for sponsoring this event, and for doing so at a time when it is a blessing to be away from New York. It is wonderful to be here in Arizona, and a special treat to have the judge that I clerked for, Wilfred Feinberg, of the United States Court of Appeals for the Second Circuit, in the audience.

1. See Nat'l Res. Council of the Nat'l Acads., A Patent System for the 21st Century (Stephen A. Merrill et al. eds., National Academies Press) (containing reports, forthcoming 2004), available at http://www.nap.edu/books/0309089107/html/ [hereinafter NAS Patent Report]; Fed. Trade Comm'n, 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 [hereinafter FTC Report].

resolved by a series of cases authored by the legendary Justice Joseph Story. As William Robinson summarized their holdings in his treatise:

> [W]here [the patented invention] is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of intellectual character . . . . But if the products of the experiment are sold...the acts of making or of use are violations of the rights of the inventor and infringements of his patent.[2]

In other words, to early jurists, a clear distinction could be made between using patented material to learn about the patented invention and using patented material for business or for commerce—between using the patent to satisfy curiosity or using it to turn a profit.

The intuition that there was a significant difference between uses of an intellectual character and uses for sale persisted well into this century. For example, when I worked in pharmacology in the late 1970s, the pharmaceutical company that I worked for had a relaxed attitude towards academic researchers. Indeed, one of my responsibilities as a bench chemist was to furnish researchers with the metabolites I generated in the course of my work. This was something I really enjoyed, seeing that the metabolites that I had found were of interest not only to the firm I worked for, but also to scholars; I thought that by sending out my samples, I was helping to foster basic science.

To be sure, there were cases that raised hard questions. In the 1980s, during the previous iteration of health-care reform, laws were enacted to support the generic drug industry, and those efforts raised the question whether the activities necessary for FDA approval of generic drugs would be considered infringing. Such activity was clearly commercial—it was for business, and not idle curiosity. But the argument was made that unless premarket-clearance testing was considered within the experimental use exception to patent infringement, there would be a long delay between patent expiration and the public's access to generic substitutes. In *Roche Products v. Bolar*,[3] however, the United States Court of Appeals for the Federal Circuit refused to see things that way. In the court's view, premarket clearance activity was motivated by commercial interests. Accordingly, it was not entitled to the common law experimental use defense.

Significantly, however, in the Hatch-Waxman Act of 1984, Congress quickly overturned that decision.[4] The legislature in effect cut a deal. It recognized that if *Bolar* had gone the other way—had the generic manufacturer been allowed to experiment during the patent period and enter the market on the day that the patent on the proprietary analogue expired—the holder of the patent would have suffered considerable financial loss. After all, it also had to satisfy FDA premarket

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2. WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898 (1890); Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17600); Sawin v. Guild, 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12391).

3. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984).

4. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e)).

clearance procedures, and it had been required to use a part of its patent period to do so. Thus, in a way, it deserved to enjoy exclusivity beyond the patent term, during the time when generic competitors conducted their safety and efficacy studies. Recognizing this tradeoff as inherent to the *Bolar* decision, Congress decided to reverse it: in exchange for a new statutory experimental use defense, proprietary manufacturers were given patent extensions to cover delays caused by their own testing obligations. The new provision created a statutory experimental use defense "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . ."[5]

The bottom line is that, by the end of the 1980s, there were two experimental use defenses: the common law defense articulated by Robinson and the statutory defense created by the Hatch-Waxman Act. In an important and prescient article in 1989, Rebecca Eisenberg examined the interaction between these two and asked whether, taken together, they went far enough in facilitating the sort of fundamental research that is key to basic science, and whether they created a domain of materials that could be shared in a way that fostered a vibrant innovation environment.[6] At that time, Eisenberg thought a broader defense was needed: she suggested a fairly complicated scheme that would recognize situations where the patented technology could be utilized without authorization and without payment, as well as spheres where compulsory licensing would be required. However, her approach was not implemented, the general perception being that the statutory and common law defenses were adequate to meet researchers' needs. At least, such was the case until the last few years, when several developments created new interest in the question of experimental use.

The first set of provocations is anecdotal—a series of incidents that suggest that the tolerance for experimental use that I saw when I worked in pharmacology had ended. Several are mentioned in the Report of the National Academies of Sciences' Committee on Intellectual Property Rights in the Knowledge-Based Economy; two examples drawn from that Report will suffice for these purposes.[7] The first involves Myriad Pharmaceuticals, which owns patent rights in a test for the gene BRCA 1, which is associated with a certain breast cancer. Clearly, any unauthorized use of Myriad's test to determine whether a patient is vulnerable to this form of cancer is infringing. However, it is not as clear that research on *other* genetic causes of breast cancer should come within the scope of the patent. To conduct such research on breast tumors, BRCA 1 causation must first be excluded. Thus, Myriad's patented information is necessarily utilized. But it is used not to test patients; instead, it accomplishes a different (and socially valuable) goal: to learn more about breast cancer and to find tests to detect other genetic vulnerabilities to it. And yet Myriad has taken the position that its permission is needed to conduct these experiments. It has asserted rights against

5. 35 U.S.C.A. § 271(e)(1) (West 2004).

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

7. *See* NAS PATENT REPORT, *supra* note 1, at 62–63.

medical researchers (as opposed to treating physicians) and has insisted on the payment of stiff fees (albeit lower fees than it charges for clinical applications).

In some ways, the Myriad story had a happy ending: after all, Myriad does permit researchers to do this work so long as it is paid that stiff—but still reasonable—fee. The second incident, involving Cell Pro, is more troubling. Cell Pro developed a method of using stem cells for cancer therapy. It developed the system entirely on its own, although its work apparently infringed a patent claiming all antibodies recognizing CD34, an antigen found on stem cells. The patent was awarded to Johns Hopkins University, which had granted an exclusive license to Baxter Healthcare. Cell Pro asked Baxter for a sublicense and was offered one—but at a rate so high Cell Pro did not feel it could continue with its work. Even that might have been acceptable were Baxter itself developing similar therapies, but it was not. In other words, the patent was used in a manner that blocked a potentially fruitful avenue of medical research.[8]

Admittedly, these are just stories and anecdotes and are not (and probably should not be) enough to spur legislative change. Further, when the National Academies' Intellectual Property Rights Committee commissioned an empirical study to measure the true extent of the problem, the study found hints that blockages could emerge, but the authors concluded that they could not detect anything approaching a crisis worthy of congressional intervention.[9] Since that time, however, there have been three cases for the Federal Circuit that throw this conclusion into significant doubt.

The first case is *Embrex, Inc. v. Service Engineering*,[10] which held that a patent on a method for inoculating chicks against diseases *in ovo* was infringed by university researchers who were, essentially, trying to find a way to work around the patent. According to the court, the common law defense was inapplicable even though university scientists conducted the work because the ultimate intent was commercialization. Indeed, Judge Rader, in a separate opinion, would have gone even further.[11] He thought a rule based on intent was too hard to administer. He suggested that the common law defense be eliminated entirely.

In the second case, *Madey v. Duke University*,[12] the court arguably did exactly as Judge Rader suggested. In that case, Duke University was using patented laser technology in its teaching and research laboratory. Duke did not have a license from the patentee because it thought it was entitled to the common law defense: it was, after all, a university and its work was fundamental scientific research and not designed for commercial purposes. But the Federal Circuit disagreed. It rejected the traditional version of the curiosity/profit distinction and instead looked at whether the conduct at issue was "in keeping with the alleged

8. *See* Avital Bar-Shalom & Robert Cook-Deegan, *Patents and Innovation in Cancer Therapies: Lessons from CellPro*, 80 MILBANK QUARTERLY 637 (2002).

9. John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation, in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen et al. eds., 2003).

10. Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343 (Fed. Cir. 2000).

11. *Id.* at 1352 (Rader, J., concurring).

12. Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002).

infringer's legitimate business, regardless of commercial implications."[13] Since Duke's objectives—to educate and enlighten—increased its status and lured lucrative research grants, renown faculty, and exceptional students, the court concluded, "[i]t does not qualify for the very narrow and strictly limited experimental use defense."[14] If *Duke* is rightly decided—and the Supreme Court denied the university's petition for certiorari[15]—it may mean that most university-based scientific research will now require licensing from patentees. Universities will, in short, be treated just like any other commercial actor.[16] The upshot of these two cases, then, is that the common law experimental use defense is now quite limited.

The third case, *Integra Lifesciences v. Merck*,[17] concerned the statutory defense. There, the defendant found that the plaintiff's patented invention, which the plaintiff knew to promote wound healing, might also be used to screen drugs that halt tumor growth. Although the work was not aimed directly at acquiring premarket clearance from the FDA, Merck relied on a series of prior cases that had expanded the "solely for uses reasonably related" language to include mixed usages.[18] It thus argued that its use of the technology qualified for the statutory defense because any new tumor treatment identified would ultimately require FDA approval. But, as with the common law defense, the *Integra* court took a hard and limiting line. According to the court, the term "solely for uses reasonably related," to development and submission to the FDA means "solely."[19] Any work with uses aimed at finding new—and commercializable—products fails to qualify.

The bottom line may be this: a rather small defense for generic drug approval processes, and otherwise, virtually no experimental use defense at all. To my mind, these events raise three questions: First, is basic science in trouble? Second, if it is, what should be done? And, finally, why is this problem rearing its head now?

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13. *Id.* at 1362.

14. *Id.*

15. Duke Univ. v. Madey, 539 U.S. 958 (2003).

16. There is a small irony here, as the study commissioned by the Intellectual Property Committee was partially conducted by Wes Cohen, who now teaches at Duke.

17. Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003).

18. *See, e.g.*, Amgen, Inc. v. Hoechst Marion Roussel, Inc., 3 F. Supp. 2d 104, 107–08 (D. Mass. 1998) (holding that the phrase "solely for uses reasonably related" is less restrictive than other phrases Congress could have chosen, such as "use is solely for purposes reasonably related"); Abtox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997) (finding that the statute "does not look to the underlying purposes or attendant consequences of the activity"); Telectronics Pacing Sys. v. Ventritex, Inc., 982 F.2d 1520 (Fed. Cir. 1992) (holding that § 271(e)(1)'s safe harbor is not lost because a party makes use of the patented invention other than for FDA-related data gathering, specifically by displaying the device at medical conferences and referring to the device in fund-raising efforts). *See generally* Nicholas Groombridge & Sheryl Calabro, Integra Lifesciences v. Merck—*Good for Research or Just Good for Research Tool Patent Owners?*, 22 BIOTECHNOLOGY L. REP. 462 (2003).

19. *Integra Lifesciences*, 331 F.3d at 866.

II. WHY NOW

The last question, "why now" might seem the least of the problems, but I am going to start there because the answer to that question sheds light on the other two issues. I attribute this development to three factors: the first has to do with the characteristics of modern science, especially biotechnology; the second, with transformations in the organization of science, again particularly in the biotech industry; and the third concerns broader changes in the political economy of information production.

By the nature of modern science, what I mean is this: there was a time when science was regarded as distinct from technology. For example, Vannevar Bush, who was President Franklin Delano Roosevelt's science advisor, conceptualized a linear progression from basic science, to applied science, to commercializable technology, to consumer end-products.[20] That conception was essentially hardwired into the law. The developments at the end of that progression were patentable, the developments along the rest of the trail were not. Thus, *O'Reilly v. Morse* held that the abstract idea of using "the motive power of the electric or galvanic current" to communicate was not patentable (although at the same time, the Court upheld claims to a specific telegraph).[21] *Funk Brothers v. Kalo Inoculant* struck a claim directed at the idea of combining strains of nitrogen fixing bacteria for enriching farm soil (as distinguished from a claim to a specific combination tailored to particular farming needs).[22] Further, in *Brenner v. Manson*,[23] the Supreme Court emphasized that only end-products are patentable. Other inventions—such as the method at issue in the case, which produced a steroid that interested only researchers—stay in the public domain. A patent, the Court said, "is not a hunting license . . . not a reward for the search, but compensation for its successful conclusion."[24]

In these three cases, the Supreme Court articulated a clear dichotomy that greatly facilitated scientific research. On the one hand, these were end-products that could be patented. While they created something of a monopoly in a product market, the product market was, in most cases, literally the end of the trail. It was the culmination of research, not the fountain from which it sprung. Moreover, end products could usually be invented around, so even if they were needed in research and the patentee refused to license, alternative paths could be found to accomplish the same result. In contrast, foundational developments—principles of nature as in *Morse*, features of nature as in *Funk*, and research tools as in *Brenner*—stayed in the public domain, where they were free for all to use. Under such a system, it is easy to see why a narrow experimental use defense would suffice. Most material of research significance was in the public domain anyway.

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20. VANNEVAR BUSH, OFFICE OF SCIENTIFIC RESEARCH AND DEVELOPMENT, SCIENCE THE ENDLESS FRONTIER: A REPORT TO THE PRESIDENT (1945), *available at* http://www.nsf.gov/od/lpa/nsf50/vbush1945.htm.

21. O'Reilly v. Morse, 56 U.S. 62 (1853).

22. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

23. Brenner v. Manson, 383 U.S. 519 (1966).

24. *Id.* at 536.

And that is where the nature of modern science comes in. The fruits of biotechnology are a perfect example. They are different from the kinds of inventions at issue in *Morse*, *Funk*, and *Brenner* because they blur that core dichotomy between fundamental and end-use work.[25] Inventions in this field—genomics and proteomics, for example—have immediate, commercial applications as diagnostics or treatments and thus they qualify for patent protection. At the same time, they are of crucial importance to researchers, and as such, they have enormous power. These "upstream" patents cover not just product markets but also innovation markets—as we saw in the Cell Pro and the Myriad cases, the ability to carry out fundamental research. They cannot be invented around: for instance, any scientist who wants to study the genetics of breast cancer needs to utilize the BRCA 1 test.

One might have thought that upstream patenting would lead the courts to expand the experimental use defense, but the Federal Circuit has actually narrowed it. So another question is: why is the court being so stingy? For an answer, two of the other changes I mentioned are relevant: the organization of science and the political economy of information production.

The organization of science has changed in several ways. For example, when Woody Powell was a sociology professor here at the University of Arizona, he conducted an interesting study of firms in the pharmaceutical sector. He showed that the large and vertically integrated firm structure that characterizes classic pharmaceutical research does not describe the firms at the forefront of modern biotechnology research. In that subsector, expertise is acquired not through successive hiring (as with classic pharmaceutical research), but rather through serial collaboration.[26] The fluidity involved in these collaborations—which Powell calls "networks of learning"—puts a great deal of pressure on patenting, for firms that want to be involved in the networks need a means to signal both their technical and business prowess. It is no wonder that courts support strong patents because one of their core functions is to fulfill exactly that role.[27]

But as interesting as this development is, my main focus today is not on the biotech industry, but rather on universities. I focus there because at one time, a distinctive feature of scholarly output was its spillover effects. Scholarship generated important research prospects for both academic and commercial scientists because it was freely published. It was, indeed, placed into the public

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25. *See, e.g.*, Francis Narin & Dominic Olivastro, *Status Report: Linkage Between Technology and Science*, 21 RESEARCH POL'Y 237 (1992) (using citation measures to demonstrate that the tie between science and technology is becoming closer over time and is more pronounced in drugs, medicine, chemistry, and computing than in fields such as machinery and transportation).

26. *See* Walter W. Powell, *Networks of Learning in Biotechnology: Opportunities & Constraints Associated with Relational Contracting in a Knowledge-Intensive Field*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 251, 258 (Rochelle Dreyfuss et al. eds. 2001) [hereinafter EXPANDING THE BOUNDARIES]; Walter W. Powell, *Inter-Organizational Collaboration in the Biotechnology Industry*, 152 J. INSTITUTIONAL AND THEORETICAL ECON. 197, 205 (1996).

27. *See, e.g.*, Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625 (2002).

domain under what is known as the Mertonian ethos,[28] a commitment to a system of open science, where results are shared, criticized and, ultimately, utilized to push forward the frontiers of knowledge. Arguably, this commitment did more than open research conducted in universities to broad public use. It also generated reciprocal behavior from commercial firms. Thus, one of the reasons I could so freely share metabolites when I worked for the biotech industry is that my employer had also absorbed the Mertonian norm—perhaps feeling responsibility to put something back in exchange for the spillover benefits it had previously captured; perhaps, more prosaically, thinking it would be in a good position to utilize the research prospects generated by academic experimentation with my metabolites.

But now universities are themselves deep in the intellectual property business. In part, it began with trademarks, when universities discovered how lucrative it was to license their logos for use on such products as t-shirts, sweatshirts, and jockey shorts. But interest in intellectual property really took off with the Bayh-Dole Act of 1980,[29] which permits universities to own patent rights in the fruits of their federally funded research. Bayh-Dole was enacted to promote technology transfer through licensing, and not specifically to enrich universities.[30] It also made the university's decision to acquire patent rights voluntary. However, the Act soon took on a life of its own. Many universities now appear to regard themselves as under an obligation to obtain patents to reduce tuition costs, decrease the burden on alumni, and—for state universities—to reduce the financial obligations of taxpayers. Universities have also begun to regard their technology transfer offices as the academic equivalent of their football teams: even if the offices aren't winning, there is cachet in fielding them. And the technology transfer offices want to win, just like the football teams do. They are judged by the number of patents granted and the value of the licenses negotiated. And so they have tremendous incentives to obtain every patent that they can get and to argue for more protection for the work that universities do, which is to say, for developments that are far upstream.

In fact, there is kind of a vicious cycle taking hold. Once universities acquired incentives to push for patents, they began to look like commercial actors. Once they began to look like commercial actors, the *Duke* court decided to treat them like commercial actors. Since commercial actors do not enjoy the experimental use defense, universities lost its benefits too. But that means that research costs universities more. To earn additional funding, universities have begun to reach further upstream for patents and to take a harder line on licensing,

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28. *See* Robert Merton, *The Normative Structure of Science*, *in* THE SOCIOLOGY OF SCIENCE 274–75 (1973). *See also* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 190–94 (1987).

29. Pub. Law No. 96–517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–12).

30. *See generally* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996).

which makes them look even more commercial—and even less sympathetic to the Federal Circuit.[31]

So that is the organizational change. But of course, that organizational change just prompts another question. Why are universities permitting this to get out of hand? Why are they allowing the Mertonian ethos to erode? For that, I turn to change number three: the political economy of information production.

Rob Merges put it this way: "One massive construct, the principle of the competitive baseline, has started to give way." Under this notion, IP rights were envisioned as a rare exception. "The general rule—the law's deep default—was open and free competition," in other words, a strong public domain.[32] But now, everyone has what might be called "Locke Jaw," a belief in John Locke's theory that labor deserves reward. When seen from that perspective, that "the proper baseline is to protect all manifestations of creativity," everything suddenly becomes the subject of intellectual property rights.[33]

We see this shift in many arenas, including new claims to copyright and trademark protection,[34] as well as attempts to propertize databases,[35] business method plans,[36] and even personal information.[37] It should, in short, not surprise us that faculty and universities seek protection for their creative labor: that is now the norm under which they find themselves operating. The result is significant. As Professor Jerry Reichman has so graphically put it, the classical patent and copyright systems were once islands of protection in a sea of competition. Now what we have is a sea of protection in which intrepid entrepreneurs encounter remote islands of free competition.[38]

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31. *Cf.* Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916 (Fed. Cir. 2004); Griffith v. Kanamaru, 816 F.2d 624 (Fed. Cir. 1987) (refusing to extend special treatment to universities in other contexts as well).

32. Robert P. Merges, *One Hundred Years of Solicitude: Intellectual Property Law, 1900–2000*, 88 CAL. L. REV. 2187, 2239 (2000).

33. *Id.*

34. An example in copyright law includes the Digital Millennium Copyright Act, Pub. L. No. 105–304, 112 Stat. 2860 (1998) (codified at 17 U.S.C. §1201 (2000)). An example in trademark law includes the Federal Trademark Dilution Act, Pub. L. No. 104–98, 109 Stat. 985 (1996) (codified at 15 U.S.C. §§ 1125(c), 1127).

35. *See, e.g.*, Council Directive 96/9/EC, 1996 O.J. (L 77) 20 (establishing a database directive for the European Union).

36. *See, e.g.*, State St. Bank & Trust Co. v. Signature Fin. Group, 149 F.3d 1368 (Fed. Cir. 1998).

37. *See, e.g.*, Jerry Kang, *Information Privacy in Cyberspace Transactions*, 50 STAN. L. REV. 1193 (1998) (proposing commodification of personal information in cyberspace as a way to protect privacy). For a critique of this approach, see Jessica Litman, *Information Privacy/Information Property*, 52 STAN. L. REV. 1283 (2000). For a general critique of privatizing information, see Jacqueline Lipton, *Information Property: Rights and Responsibilities*, 56 FLA. L. REV. 135 (2004).

38. J.H. Reichman, *Charting the Collapse of the Patent-Copyright Dichotomy: Premises for a Restructured International Intellectual Property System*, 13 CARDOZO ARTS & ENT. L.J. 475, 517 (1995). *See also* J. H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VAND. L. REV. 1743 (2000).

Put these developments together and it is clear why the issues of protecting the public domain of science and creating room to experiment have become so compelling. Patentees can now own—and many think they deserve to own—entire research opportunities, rights not only in product markets, the traditional markets that patents dominate, but rights in innovation markets as well. Patentees can exploit these innovation markets by doing research. They can license others to exploit them if they so choose. But they can also leave them unexplored. They are free to decide that the best way to earn a reward is to block further work in their fields. And yet, knowledge is cumulative. Newton saw further because he stood on the shoulders of giants.[39] If the giants can now deny the opportunity to use their shoulders, all our horizons are severely restricted.

III. STRATEGIES FOR PRESERVING A PUBLIC SPHERE

If one takes the position that fundamental research is fundamental and that its output cannot be easily invented around, the next question is whether a strategy can be devised for protecting public access in the name of promoting a robust innovation environment. In this regard, it is worth noting that many of the inventions that are of concern are essentially information products. For example, genetic and protein sequences are valued for what they say and not, as with the typical consumer product, primarily for what they do. It is thus highly significant that copyright law, which has long protected information products, contains a complex array of provisions that are specifically targeted at the problem of cumulative development. These provisions support the argument that patent law needs an infusion of similar principles.

To be sure, there are those who argue otherwise. There are some who claim that patentees deserve maximal returns on investment because it is the hope of such a return that leads inventors to work in inherently risky fields.[40] Besides, they say, no rational pioneer inventor would deny a license to researchers because any improvement made would spur sales and provide more of a return to the pioneer.[41] I am not so optimistic. I can imagine circumstances where patentees would rationally refuse to license.

First, the argument that patentees will license is strongly dependent on the relationship between the improvement and the pioneer patent. Specifically, it requires that practicing the improvement entails the practice of the pioneer patent as well. In some fields—biotech is a prime example—this relationship is not necessarily present, even in cases where the pioneer patentee is in the same

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39. *See* ROBERT K. MERTON, ON THE SHOULDERS OF GIANTS: A SHANDEAN POSTSCRIPT 31 (1965) (quoting a letter by Sir Isaac Newton).

40. *See, e.g.*, F. M. Scherer, *The Innovation Lottery*, *in* EXPANDING THE BOUNDARIES, *supra* note 26, at 3–21.

41. *See, e.g.*, F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697 (2001). I have called these observers "transactional optimists." *See* Rochelle C. Dreyfuss, *Games Economists Play*, 53 VAND. L. REV. 1821 (2000) (citing as examples, Robert P. Merges, *Of Property Rules, Coase, and Intellectual Property*, 94 COLUM. L. REV. 2655 (1994)); Suzanne Scotchmer, *Protecting Early Innovators: Should Second-Generation Products Be Patentable?*, 27 RAND J. ECON. 322 (1996).

business as the so-called improver. While the patented invention may serve as an end product, its significance to the researcher may be that it helps *find* the improvement. Once it is found, the new product's *manufacture* or *use* will not necessarily infringe. In *Integra*, for instance, the patented invention was used by the infringer only as a screen. Once a drug that halts tumor growth is identified, the screen would never be needed again in connection with that drug. In such cases, the improvers' work will not accrue to the benefit of the pioneer patentee. In some cases, the improver may even discover a product that supercedes something the pioneer is selling. Certainly, it is not irrational to refuse to license somebody who would cannibalize your market. Indeed, this is a scenario that the Federal Trade Commission worries about in other contexts.[42]

Second, a rational patentee might decide to climb the innovation ladder (that is, develop products) slowly, milking each market before progressing to the next one. Licensing others could interfere with this plan. Again, this concern is familiar. It has surfaced in patent cases from time to time.[43] Finally, as Eisenberg has argued, when an invention's potentials are difficult to evaluate, risk-averse patentees may prefer to wait to license until the significance of the patented invention is clarified.[44]

There are also some who would argue against a rule that creates special benefits for academia on the theory that the Federal Circuit is right to treat universities like commercial actors. Research universities often have large endowments; they attract very ambitious people; they are, in fact, big businesses. Again, I do not agree. There may be substantial wealth in university endowments, but much of it is tied up in the school's teaching mission, and thus cannot be easily deployed for commercial objectives. Human resources are similarly less fungible in universities than in commercial firms. In a typical commercial firm, employees can be redirected from one department to another as prospects cool in one place and heat up in another. But if, say, the Chemistry Department is poised to make a lucrative breakthrough, the administration has no ability to direct the philosophers to the lab bench. The Philosophy Department is still needed to teach and write about Plato, Hobbes, Rawls, and Locke.

Patenting strategies may also differ. At universities, promotions (such as tenure) depend on making big conceptual leaps. Because faculty cannot afford to waste time on incremental improvements, universities are not likely to hold a host of closely-related patents within particular fields. Compare that to the strategy of commercial enterprises. These enterprises do engage in incremental research

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42. *See* U.S. DEPARTMENT OF JUSTICE AND FEDERAL TRADE COMMISSION, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 3.2.3 (Apr. 6, 1995); *see generally* Richard M. Brunnel, *Symposium: A Critical Appraisal of the "Innovation Market" Approach*, 64 ANTITRUST L.J. 1 (1995).

43. For example, in both *Special Equip. Co. v. Coe*, 324 U.S. 370 (1945), and *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538 (Fed. Cir. 1995), the concern was that the patentee would incorporate his invention into only one type of product, failing to give customers a choice between a fully- and partly-automated machine.

44. Rebecca S. Eisenberg, *Bargaining Over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?*, *in* EXPANDING THE BOUNDARIES, *supra* note 26, at 223–49.

because they are trying to find an edge over their competitors. They will accumulate patents on these incremental improvements—partly to maintain exclusivity at the edge, but also on a theory of mutually assured destruction. That is, if every competitor in a field knows that the others are also obtaining patents, there is less of a tendency to engage in patent warfare. Assertions may not be made at all; when they do occur, disputes are settled by cross licensing.[45] Lacking deep patent portfolios, universities cannot participate in this game. When universities are sued, there is a risk that they will be required to pay real money.

So, while it is certainly true that universities can be treated like commercial actors, doing so ignores crucial differences and could, ultimately kill the traditional role that universities play in teaching, training, and creating the spillover benefits that are ultimately reaped by private enterprise.

Several ideas have been proposed to preserve the creative environment. Not all of them involve an experimental use defense, but as I list them, it becomes clear why many observers find the idea of expanding the scope of permissible experimentation the most appealing approach.

One set of changes would focus on the requirements for getting a patent. The definition of patentable subject matter could be changed to statutorily reinstate the carve-out for fundamental principles of science and for products of nature—upstream inventions generally. Alternatively, specific problem areas, such as genomics or proteomics, could be removed from the ambit of protectable works.[46]

The problem with this approach is that changing the law will not change the dual character of the fruits of modern science. Deciding what should be carved out of the protective regime will be as difficult as drawing the kinds of dichotomies envisioned by *Morse, Funk,* and *Brenner.* The carve-outs that are made may provide too little incentive to the end-use dimension of the subject matter excluded, leading to under-dissemination and utilization.[47] Furthermore, it would be difficult to decide whether a field needs to be excluded until after inventions in the field emerge. But a pattern of retroactively legislating carve outs highly destabilizes patent value. Investors who are considering funding inventive activities in new fields will have to discount the benefits they expect by the risk that the field will become subject to a carve out.

A second idea is to make patents more difficult to acquire. For example, the requirements for utility and nonobviousness could be significantly strengthened, thereby eliminating some of the patents that could now cause blockages. To some extent, such an approach is already underway. The Patent and

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45. *See, e.g.*, Bronwyn H. Hall & Rosemary H. Ziedonis, *The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconducter Industry, 1979–1975*, 32 RAND J. ECON. 101 (2001).

46. *See, e.g.*, Richard A. Epstein, *Steady the Course: Property Rights in Genetic Material, in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 168–88 (F. Scott Kieff ed., 2003); John H. Barton, *United States Law of Genomic and Post-Genomic Patents*, 33 INT'L REV. OF INDUS. PROP. & COPYRIGHT L. (IIC) 779 (2002).

47. In this regard, it is worth remembering that the Bayh-Dole Act was actually aimed at the problem of commercial underutilization of university-based research.

Trademark Office has instituted new utility guidelines[48] and now takes a "second look" at issuances in certain critical areas.[49] Further, there are moves afoot to change other operations within the PTO.[50] Indeed, there are so many reasons to think that a fresh look at these requirements is warranted that both the Reports of the National Academies and the FTC recommended this action.[51]

I doubt, however, that this approach will add significant protections to the scientific environment. Because of the dual nature of modern developments, changing the utility requirement can never be fully effective. There may be somewhat more potential in the nonobviouness requirement, where there is an increasing recognition of problems.[52] To take one example, although nonobviousness is measured by the level of skill in the art at the time the invention was made,[53] the Federal Circuit has not updated its understanding of what the average biotechnologist knows for many years.[54] But while revising the standard or implementation of the nonobviousness test would aid the patent system, the impact on scientific research will not be large. These steps will eliminate patents only on obvious inventions. However, much of the information that scientists need to push forward to the frontiers of knowledge is essential precisely because it is inventive—which is to say nonobvious under virtually any reasonable standard.

A third set of ideas would change the test for infringement. Scope could be narrowed to the level of disclosure; the doctrine of equivalents could be eliminated or substantially reduced. That is essentially the Federal Circuit's own approach to the problem. The court is making patents narrower, apparently on the theory that they will then be less powerful.[55] But I actually see this development as counterproductive. Narrowing patents will only lead people to apply for more of

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48. *See* 35 U.S.C.A. § 101 (West 2004); *see also*, UNITED STATES PATENT OFFICE, SYNOPSIS OF APPLICATION OF UTILITY GUIDELINES WITH EXAMPLES, www.uspto.gov/web/offices/com/sol/notices/utility-synopsis.html (last visited Sept. 9, 2004).

49. *See, e.g.*, Linda E. Alcorn, *Pursuing Business Method Patents in the US Patent and Trademark Office*, 20 COMPUTER & INTERNET L. 27, 30 (2003) (noting large reduction in business method patents issues after institution of a second look procedure within the PTO).

50. *See, e.g.*, UNITED STATES PATENT AND TRADEMARK OFFICE, THE 21ST CENTURY STRATEGIC PLAN, *at* http://www.uspto.gov/web/offices/com/strat21/ (last modified Nov. 23, 2003).

51. *See* NAS PATENT REPORT, *supra* note 1, at 72–78; FTC REPORT, *supra* note 1, at Ch. 4.

52. These are documented in the NAS PATENT REPORT, *supra* note 1, at 72–78.

53. 35 U.S.C.A. § 103.

54. In biotechnology cases, the court applies the standard of skill in the art that was first articulated in *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), and *In re Bell*, 991 F.2d 781, 784 (Fed. Cir. 1993).

55. *See, e.g.*, ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1090–91 (Fed. Cir. 2003); Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512 (Fed. Cir. 1995), *reversed by* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997); *see* Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998); Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997); Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 1995), *vacated by* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002).

them. That raises transaction costs, increasing the workload of the PTO, and creates room for the examiners to make more mistakes.

To the extent that universities are the core of the problem, a fourth strategy would be to amend the Bayh-Dole Act. At this point, it has to be assumed that many reliance interests have grown up around university patenting. Accordingly, it is unlikely that the core thrust of the Act could be reversed. But Rebecca Eisenberg and Arti Rai suggest that it could be modified to make it easier for public funders to retain patent rights for the government, or to march in and retrieve rights when exploitation is inadequate.[56] This approach would deal quite nicely with the Cell Pro situation because it was by virtue of the Bayh-Dole Act that Johns Hopkins owned the patent right that Baxter refused to license to Cell Pro. However, it will not reach all of the problems confronting fundamental research because not all of the patents scientists need stem from research subject to the Act.

To my mind, that basically leaves some version of an invigorated experimental use defense. There are several alternatives to choose from. Maureen O'Rourke, Janice Mueller, Donna Gitter, and others have made proposals along the lines of what Eisenberg was suggesting in 1989.[57] They would add defenses similar in effect to the fair use defense of copyright law, utilizing multi-factored analyses to identify spheres where work could be accomplished freely, as well as areas where payment (but not authorization) would be required.[58] These proposals are quite interesting from a theoretical point of view. However, they demand difficult pricing decisions. More important, they require hard line drawing—in some cases, exactly the type of scrutiny that Judge Rader was so concerned about in his separate opinion in *Embrex*.[59]

In a recent article, Katherine Strandburg suggested implementing a different approach, one close to that used in Europe, which is to distinguish between experimenting on a patented invention and experimenting with the patented invention.[60] The free right to experiment on the invention would permit peer review, and would also fulfill one of the key purposes of the patent system, one that Judge Newman pointed out in her separate opinion in *Integra*: it "facilitates further knowledge and understanding of what was done by the patentee

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56. Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2002).

57. Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument For Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1637 (2001); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 17 (2001); Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1205 (2000).

58. *Cf.* 17 U.S.C.A. § 107.

59. Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1352 (Fed Cir. 2002) (Rader, J. Concurring). *See also supra* text accompanying note 11.

60. Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81 (2004).

and may lead to further technologic advance."[61] Of course, experimenting with the patented invention could also advance understanding, but in Strandburg's view, an "experimenting with" defense would cut too deeply into the market of those whose business it is to develop research tools. Thus, it would erode incentives to innovate in what has become an important area of biotechnology.[62]

I find the Strandburg approach quite provocative. I fear, however, that it too, requires difficult line drawing.[63] Furthermore, to the extent there is a sharp line, it puts some of the uses of greatest concern—such as medical researchers' use of Myriad's BRCA 1 patent—on the wrong (the patentee's) side of the line.

Finally, there is a solution that I have proposed.[64] Under this plan, a university or other nonprofit research institution that wants to use patented material and cannot obtain a license from the patentee on reasonable terms could use the technology without permission if it is willing to sign a waiver. The waiver would require the institution to promptly publish the results of work conducted with the patented technology and to refrain from patenting discoveries made in the course of that work. For example, researchers who wanted to use Myriad's BRCA 1 patent to identify other genetic causes of tumors could have their institution sign such a waiver and then they could use the test without authorization and without paying royalties. However, should the researchers then discover another gene involved in breast cancer, that work would be immediately published and nothing associated with that discovery could be patented. Richard Nelson, an economist at Columbia, would modify my proposal, and I take his suggestion as a friendly amendment. He would allow the researchers to patent their work, but require them to agree to license on a nonexclusive basis for reasonable royalties.[65]

I proposed the waiver idea because I think it has several benefits. It eliminates the need for *courts* to characterize research as aimed as satisfying intellectual curiosity or for commercial purposes. Judge Rader's concern in *Embrex* would be assuaged because the *researchers* would reveal their own motivation through their decision to file a waiver. By providing this special right to university and nonprofit researchers, the proposal also recognizes the differences in resources between universities and genuine commercial actors. At the same time, it eliminates the problem of creating a comparative advantage for universities

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61. Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 873 (Fed. Cir. 2003) (Newman, J., concurring).

62. Since this speech was given, the American Intellectual Property Lawyers Association (AIPLA) proposed an experimental use exemption taking an approach similar to Strandburg's.

63. Indeed, a recent European report on the relationship between patents and science has suggested as much. *See* THE ROYAL SOCIETY, KEEPING SCIENCE OPEN: THE EFFECTS OF INTELLECTUAL PROPERTY POLICY ON THE CONDUCT OF SCIENCE, § 3.23, http://www.royalsoc.ac.uk/files/statfiles/document-221.pdf.

64. For a detailed discussion of this proposal, see Rochelle C. Dreyfuss, *Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT (F. Scott Kieff ed. 2003).

65. Richard R. Nelson, *The Market Economy, and the Scientific Commons*, 33 RES. POL'Y 455, 467 (2004).

over commercial enterprises when the university is, in fact, engaged in commercial work. Most important, the waiver serves to enrich the public domain because all resulting work is published and not patented (or licensed nonexclusively). In a sense, this would soften the adverse effect of the Bayh-Dole Act by allowing universities to monetize and internalize the benefits of agreeing to refrain from patenting. It would also restore some of that Mertonian ethos that has been lost, and it may even reinvigorate commercial norms of sharing with academia.

Of course, my approach also has problems. Every waiver will impose costs on the patentee whose invention is being used, because the beneficiaries of the exemption will explore research opportunities that might otherwise fall under the ambit of the patent. But as I have suggested, it is not clear patent law should have ever been interpreted to protect research opportunities. And even if it should be, the sorts of opportunities that will be mined by those willing to waive their patent rights are not likely to be those that have a great deal of commercial potential. Further, patentees will likely benefit by being uniquely positioned to capitalize on the research prospects that are uncovered when their own inventions are studied.

Another question is whether anyone would ever file a waiver. Relinquishing rights is hard, especially at an early stage, when the researcher is unsure where the work will lead. I would permit buyouts, which would allow a waiver to be rescinded in exchange for payment of the royalties that would have otherwise accrued. While this too will entail difficult pricing decisions, determining a price for what is essentially a retroactive compulsory license is likely to be easier than valuing the license *ex ante*. Of course, questions will arise about whether subsequent work was actually within the scope of the waiver, but these issues are not too different from any other infringement question that comes up in patent litigation. The university setting will also create some difficulties. Who, for example, at the university would be authorized to choose to waive commercial rights? Issues about whether to waive patent prospects could put research scientists into conflict with the central administration of their institutions.

In sum, mine is far from a perfect plan. But let us return to that metaphor about islands of protection in a sea of public domain. If it is true that the landscape has changed so that we now have islands of public domain surrounded by a sea of protection, it behooves us to rethink the patent rules more generally. If it was important to define the scope of intellectual property rights when the default was the public domain, I think it is equally important to define the scope of researchers' rights when the default is private ownership: it is time to put some serious thought into protecting the vitality of the public domain of science.