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EVOLVING SCIENTIFIC NORMS AND INTELLECTUAL PROPERTY RIGHTS: A REPLY TO KIEFF

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In *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*,[1] Scott Kieff critiques my Article entitled *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, which appeared in the Fall 1999 volume of the *Northwestern University Law Review*.[2] According to Kieff, my Article sets up the period before 1980 as the benchmark against which the current patent system should be judged,[3] paints the research community that existed before 1980 as a scientific utopia,[4] and rejects any view of the patent law that emphasizes the role for patents in commercial development.[5] If my Article had made these arguments, it would deserve Kieff's criticism. Unfortunately for Kieff, however, he sets up a straw man.

Regulating Scientific Research is organized to have both a historical-descriptive component and a normative component. In the historical-descriptive portion of my Article—Parts I and II—I lay out the central tenets of law-and-norms theory and argue that the evolution of academic research norms from the period before 1980 to the present day illustrates these tenets.[6] Specifically, as the background law has changed to encourage patenting by academic researchers, norms have evolved to encourage such

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[1] F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Reply to Rai and Eisenberg*, 95 NW. U. L. REV. 691 (2001).

[2] Arti Kaur Rai, *Regulating Scientific Research: Rights and the Norms of Science in Biotechnology Research*, 94 NW. U. L. REV. 77 (1999).

[3] Kieff, *supra* note 1, at 692 ("Rai begins her argument by painting a portrait of the basic biological research community before 1980 as a benchmark against which to measure the relative performance of that same community today.").

[4] *Id.* at 697 ("The benchmark offered by Rai is a utopian vision characterized by specific prescriptive norms against intellectual property generally and patents in particular, but devoid of descriptive norms such as selfish behavior, which enjoys no frustration of the consensus set of abstract prescriptive norms.").

[5] *Id.* at 701 ("Rai criticizes any theory of the patent system that focuses on the development of nascent inventions, like the commercialization theory.").

[6] Rai, *supra* note 2, at 81-115.

patenting as well.[7] This portion of my Article also notes that although norms have changed significantly since 1980, such that major research universities are now engaging in extensive patenting, these institutions have refrained from patenting the most early-stage research.[8] Parts III and IV, constituting the remainder of my Article, argue that the approach currently adopted by major research universities should be encouraged because it preserves the limited public domain that is necessary for development and commercialization of biological invention.

In asserting that I set up the pre-1980 period as the proper benchmark, Kieff thus misunderstands the thrust of my Article. My analysis of the pre-1980 norms is conducted as an historical analysis, and I offer it as a prelude to my discussion of how norms changed in response to the post-1980 legal change. Moreover, I hardly endorse a return to the pre-1980 regime. To the contrary, the norm regime that I endorse is the *current* regime, which is quite different from the regime that existed prior to 1980. As my Article repeatedly points out, the current regime encompasses very significant patenting activity by major research universities.[9] Where many of these major universities do draw the line, however, and where I would similarly draw the line, is in claiming property rights in the most upstream research, such as research involving gene fragments (ESTs) of unknown function.[10] As I stress in my Article, university technology transfer officers do not believe that patenting such research promotes the development of commercial products. In endorsing such enlightened self-interest—as contrasted with what appears to be purely strategic behavior by those who are currently seeking patents on ESTs of unknown function[11]—I am hardly calling for the "imposition of new prescriptive norms and laws."[12]

In addition, contrary to Kieff's assertions, my historical account of academic research prior to 1980 does not portray the pre-1980 scientific community as a utopia devoid of competition for intellectual kudos. Rather, as I discuss, aggressively competitive behavior was and still is tolerated in the name of the powerful invention norm, which is satisfied by establishing invention priority.[13] My assertion that academic scientists did not seek patents before 1980—a statement that is clearly supported by the

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[7] *Id.* at 109 ("As might be predicted by law-and-norms theory . . . universities and individual researchers soon began to respond to the financial incentives of Bayh-Dole by rejecting communalism and increasing efforts to seek patents.").

[8] *Id.* at 112-13.

[9] *See id.* at 109 (noting that universities are seeking thousands of patents per year); *see also id.* at 115 ("[T]he post-1980 move towards greater intellectual property rights has clearly had a significant impact on the traditional norms of research science.").

[10] *Id.* at 112-15. Gene fragments are also known as expressed sequence tags, or ESTs.

[11] *Id.* at 147.

[12] Kieff, *supra* note 1, at 705.

[13] Rai, *supra* note 2, at 92 ("[A]ggressively competitive behavior that seems contrary to the norms of communalism may be tolerated when invention is at stake.").

data[14]—is not a claim that scientists were, or are, altruistic and selfless human beings. The combination of descriptive and prescriptive norms that existed before 1980[15] encouraged vigorous competition. The prize, however, was not patents.[16] Kieff also makes the argument that academic scientists may have wanted to seek patents before 1980, but were restrained by the applicable law. The primary type of law restricting patenting, however, was technology transfer law, which typically did not allow the patenting of publicly funded inventions, no matter how clearly those inventions met the ordinary requirements of patentability.[17] Presumably, if academic scientists had truly wanted to seek patents, they would have left the academic sector. Kieff's argument also indicates a misunderstanding of the complex relationship between law and norms. As the rich literature on law and norms has demonstrated,[18] norms do not exist independently of law. Just as norms that currently encourage patenting in many situations are linked to laws that encourage such patenting, pre-1980 norms that discouraged patenting were intimately linked to pre-1980 law.

In any event, no matter what regime existed prior to 1980, I hardly urge a return to it. The comparison I *do* make is not with the pre-1980 regime, but rather between a patent regime that maintains some role for a public domain and a regime, apparently advocated by Kieff,[19] that would essentially eliminate the public domain by allowing the patenting of any invention that could be considered new, no matter how easy it would be to invent or how removed it would be from commercial application.[20] In my view, current research norms have an important role to play in maintaining an "efficient" public domain. Moreover, my discussion of an efficient public domain squarely addresses the importance of development. The balance

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[14] *See Patent Issues in Federally Funded Research: Hearings Before the Senate Judiciary Subcomm. on Patents, Copyrights, and Trademarks*, 103d Cong. 11 (1994) (statement of Birch Bayh) (testifying that the number of patents granted per year to universities had increased from fewer than 250 in 1980 to almost 2700 in 1992).

[15] Contrary to Kieff's assertion, *see* Kieff, *supra* note 1, at 693-96, I do not focus on prescriptive norms to the exclusion of descriptive norms. Indeed, if a norm community is functioning properly, descriptive norms should, in large part, comport with prescriptive norms. Moreover, departures from prescriptive norms should be punished.

[16] Rai, *supra* note 2, at 92 (noting that the norm of invention led "scientists to compete vigorously to be the first to present an invention or discovery to the scientific community").

[17] *Id.* at 95 (discussing the "cumbersome and complex" process for seeking patents on publicly-funded research prior to 1980).

[18] *Id.* at 81-88 (surveying this literature).

[19] *See generally* Kieff, *supra* note 1, at 698-705. The approach advocated by Kieff draws upon the work of Edmund Kitch. *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977) (arguing for strong patent rights early in the development process in order to stimulate and coordinate such development).

[20] Rai, *supra* note 2, at 80 & n.17 (noting that the Article will compare current research norms with "full-blown intellectual property rights"—that is, "property rights on all invention that could be considered new, no matter how far removed from commercial application or easy to invent").

of costs that I consider in determining how the public domain should be constructed explicitly includes development costs.[21]

Indeed, I critique a regime of "full-blown" patent rights primarily on the grounds that such rights may create transaction costs that *hinder* rather than promote development.[22] While monopoly rights can incentivize development, this incentive effect has to be balanced against the transaction costs that these rights create for future researchers. The more upstream the research, the greater the likelihood of these transaction costs.[23] Although Kieff acknowledges the possible confounding role of transaction costs, he dismisses their role as relatively trivial.[24] In contrast to those aspects of my Article that Kieff has simply misconstrued, the issue of the magnitude and significance of transaction costs is a major area of genuine dispute between us. In fact, it is our central disagreement. The remainder of this reply, therefore, focuses on the question of transaction costs.

Significant transaction costs would be likely to arise if rights were granted in such upstream biological research as ESTs and single nucleotide polymorphisms (SNPs)[25] of unknown function.[26] If such rights were granted, a researcher investigating a disease associated with a particular gene or genes would have to seek licenses from each of the entities that held patents on ESTs or SNPs found within the gene(s). Under conventional patent law doctrine, even if the researcher had independently patented the gene(s), she might have to seek a license. Kieff argues that because of the current judicial tendency to construe biotechnology patent claims narrowly, the researcher would not need a license.[27] He flatly asserts that a patent on

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[21] *Id.* at 136-37 (noting that the public domain should reflect a balance that includes development costs).

[22] *Id.* at 120-35. A concern with transaction costs also lies at the heart of the critique of patent rights put forward by Michael Heller and Rebecca Eisenberg. *See* Michael Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998). Molly Holman and Stephen Munzer have recently made the interesting argument that granting patents on ESTs of unknown function can create not only transaction cost difficulties, but also can distort research priorities and increase downstream development costs in a manner that causes a deviation from social welfare. *See* Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735, 774-92 (2000).

[23] I follow the conventional account in defining transaction costs broadly, so as to include the costs associated with identifying potential buyers and sellers, negotiating deals, measuring performance, and enforcing agreements. *See* THRÁINN EGGERTSSON, ECONOMIC BEHAVIOR AND INSTITUTIONS 14-16 (1990).

[24] Kieff, *supra* note 1, at 693-704 (arguing that "the basic biology research process, like any process, can be viewed as one that requires inputs and generates outputs, and experience shows that patents on inputs generally do not prevent the production of outputs").

[25] SNPs represent those areas in which human genomes differ by only one base pair from one another. SNPs can be found in the coding or noncoding regions of DNA. SNPs in the coding regions are known as cSNPs. The discussion in the text focuses on SNPs of the cSNP variety.

[26] It is important to distinguish between ESTs and SNPs of known function and those of unknown function. To determine the function of an EST or SNP, the researcher has to make a significant research investment. Thus, ESTs and SNPs of known function are not properly considered upstream research.

[27] Kieff, *supra* note 1, at 699-700.

a gene fragment that was restricted to the fragment itself could not block use of the full gene. However, the question is not that clear. John Doll, the Director of Biotechnology Examination at the Patent and Trademark Office (PTO), has explicitly stated that patents on a gene fragment may block use of the corresponding full-length gene, even though the full-length gene can be patented independently. According to Doll,

> The USPTO views this situation as analogous to having a patent on a picture tube. The picture tube patent does not preclude someone else from obtaining a patent on a television set. However, the holder of the picture tube patent could sue the television set makers for patent infringement if they use the patented picture tube without obtaining a license.[28]

To be sure, Doll's mechanical analogy may be in tension with the Federal Circuit's view of DNA as a subset of chemical technology. However, this does not mean that mechanical cases regarding blocking patents have no relevance in the gene fragment context. The Federal Circuit has simply not had occasion to consider the issue squarely.

Kieff argues that, even in the absence of patents, transaction cost-type difficulties can hinder development. Thus, for example, the competitive tendencies of a senior scientist may lead her to disparage follow-on research by a junior scientist.[29] Kieff's point is correct as far as it goes. Kieff's scenario would be far worse, however, if patents were available and the senior researcher had such a patent. In that case, the senior scientist not only could disparage the follow-on research, but also would have a legally enforceable right to *enjoin* that research. Kieff additionally makes the puzzling point that unpatented early-stage research is just as difficult to value as patented early-stage research.[30] However, if research is in the public domain, there is no need for *agreement* on valuation. Because a follow-on researcher does not need to obtain a license from the original inventor, she can use the research even if she values it quite differently than does the original inventor.

As detailed in my Article, scientists at leading research universities and within the federal government were among the first to sound the call about transaction cost problems that might be caused by granting property rights in the fruits of the most upstream genomics research.[31] These research sci-

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[28] John Doll, *The Patenting of DNA*, 280 SCIENCE 689, 690 (1998).

[29] Kieff, *supra* note 1, at 702-03.

[30] *Id.* at 703.

[31] Although norm communities are typically made up of private actors, scientists within the National Institutes of Health and other research agencies should probably be considered to inhabit the same norm community as their academic counterparts. These federal scientists interact closely with the academic research community. Indeed, many of them come from this community. Expanding the norm community to include federal scientists, however, raises thorny questions about the distinction between norms and law. This is particularly true because federal scientists can make policy, even if they have limited legal authority to enforce that policy. *See* Rai, *supra* note 2, at 147-49 (discussing policy decisions by Dr. Francis Collins, Director of the National Human Genome Research Institute, to encourage public release of early-stage genome research). I thank Rebecca Eisenberg for pressing me on this point.

entists have played a major role in ensuring that raw genomic information, as well as information about ESTs and SNPs of unknown function, is placed in the public domain. Even the PTO recently responded to the concern expressed by scientists by issuing new patentability guidelines.[32] These guidelines indicate that genetic sequences and protein structures of unknown function lack utility under § 101 of the patent statute and are, therefore, not patentable.[33] As a consequence, many EST applications will, according to John Doll, "have a difficult time" meeting the utility requirement.[34]

A skeptic might argue that the alarm of research scientists, who are unfamiliar with the ingenuity of the marketplace, is undue. But research scientists are not the only ones concerned. To the contrary, most of the major pharmaceutical companies have contributed half of the budget for a public-private venture that is putting SNP research into the public domain.[35] By putting this information into the public domain, the companies hope to preempt patent applications on this research. Apparently, these companies are not as sanguine as some market theorists are about surmounting the transaction cost difficulties associated with licensing.[36]

Once Kieff's various misunderstandings regarding my Article are put to one side, it becomes clear that the major disagreement between us involves how efficient development and commercialization of invention can best be achieved. Kieff believes that efficient commercialization is best achieved through virtual elimination of the public domain. In other words, the pendulum should swing all the way towards privatization of any inven-

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[32] *See* Peter G. Gosselin & Paul Jacobs, *Patent Office Now at Heart of Debate*, L.A. TIMES, Feb. 7, 2000, at A1 (noting that PTO was responding to a "drumbeat of concern" by scientists from the National Human Genome Research Institute as well as university scientists).

[33] *See* REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIAL 50-53 (2000). This handbook for PTO examiners interprets 35 U.S.C. § 101 (2000).

[34] Martin Enserink, *Patent Office May Raise the Bar on Gene Claims*, 287 SCIENCE 1196, 1197 (2000).

[35] *See* Nicholas Wade, *10 Drug Makers Join to Find Genetic Roots of Disease*, N.Y. TIMES, Apr. 15, 1999, at A27. The major research universities that took the lead in the public human genome project are also taking the lead in generating the data for the SNP consortium. Technically, the SNP consortium is filing provisional patent applications and then releasing the information into the public domain. So long as the consortium files a provisional application before another entity files a patent application, the consortium can preempt the subsequent patent application. For a discussion of preemptive publication as a competitive strategy for private sector firms, see Gideon Parmochovsky, *Publish or Perish*, 98 MICH. L. REV. 926 (2000).

[36] Unlike the interests of the biotechnology industry as a whole, the interests of large pharmaceutical companies do converge sufficiently for a cooperative strategy such as the consortium to be possible. However, even the consortium itself might not have been possible absent the facilitative role played by the Wellcome Trust, the U.S. National Human Genome Research Institute's partner in the public genome sequencing project. *See* Wade, *supra* note 35, at A27. A similar public-private initiative to sequence the mouse genome, and to release the results of that sequencing into the public domain, was recently announced by the National Institutes of Health, several pharmaceutical companies, and the DNA chip maker Affymetrix. The sequencing will be done at Washington University in St. Louis, the Whitehead Institute at MIT, and the Sanger Centre in the United Kingdom. *Public-Private Project to Deliver Mouse Genome in 6 Months*, 290 SCIENCE 242 (2000).

tion that is even arguably novel. In *Regulating Scientific Research*, I argue that there is a real danger in having the pendulum towards privatization swing too far, as efficient commercialization requires a role for the public domain. As detailed in my Article,[37] the weight of historical and economic evidence indicates that we should not privatize the most early-stage genomics research. Then, there is the real world test. The pharmaceutical companies' commitment of money to support a public domain in early-stage genomics research vindicates a hard-headed, commercialization-oriented stance in favor of the public domain.

[37] Rai, *supra* note 2, at 120-35.