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PATENTING SCIENCE: PROTECTING THE DOMAIN OF ACCESSIBLE KNOWLEDGE

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For the most part, the contributions to this Volume examine commodification as it applies to cultural products. In this Chapter, we look at the effect of commodification on scientific and technological activity. Differences between cultural and scientific production and within the intellectual property laws applicable to these enterprises alter the debate on the relationship between commodification and what (for reasons set out below) we prefer to call the "domain of accessible knowledge." Some issues are less contentious in the context of technological production while others take on new dimensions. Furthermore, the role that patents play in the organization of scientific research and the nature of international obligations applicable to patenting combine to impose significant constraints on the strategies available to those who would expand public access at the inventive frontier.

Our paper proceeds as follows: after discussing the nature of the commodification debate and the constraints unique to scientific and technological production, we explore ways in which the domain of accessible knowledge could be reconstituted. In our discussion of these strategies, we draw on previous work in which we analyzed various substantive methods for curbing perceived encroachments on the public domain to see how each would fare if challenged under the TRIPS Agreement;[3] we then investigated the relationship between the dynamics of domestic legislative procedures and TRIPS dispute resolution outcomes.[4] In this piece, we continue our examination of the domestic efficacy and TRIPS compatibility of substantive alterations to the patent system: strengthening the nonobviousness (inventive step) requirement; narrowing the scope of patent claims; and recognizing new occasions in which the government may use patented inventions without authorization (but with payment).

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[3] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments–Results of the Uruguay Round, vol. 31, 33 I.L.M. 81 (1994)[hereinafter TRIPS Agreement]. See Graeme B. Dinwoodie and Rochelle Cooper Dreyfuss, *WTO Dispute Resolution and the Preservation of the Public Domain of Science under International Law*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME (Keith E. Maskus & J. H. Reichman eds., Cambridge U. Press, forthcoming 2005); Graeme B. Dinwoodie and Rochelle Cooper Dreyfuss, *International Intellectual Property Law and the Public Domain of Science*, 7 J. Int'l Econ. L. 431 (2004)[hereinafter JIEL]. The approaches were excluding certain fields or subfields from the subject matter eligible for patent protection; recognizing a new experimental use (or fair use) defense to infringement; and curbing the right to seek relief from those who agree to make the fruits of their own work publicly available.
[4] Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *TRIPS and the Dynamics of Intellectual Property Lawmaking*, 36 Case. West Res. J. Int'l L. ___ (2005) (forthcoming)[hereinafter CWRU].

As in our other pieces, our purpose is not to predict the outcome of future disputes—there are far too few WTO precedents for that. Rather, our goal is to explore how the interpretive approaches pursued at the international level affect the ability of TRIPS members to keep their laws attuned to the developments and needs of science. Taking our four articles together, we argue that under certain interpretations of TRIPS, a variety of prophylactic substantive steps to protect the domain of accessible scientific knowledge could be taken, that each has a different pay-off as a matter of domestic policy, but that the there is little relationship between the strength of the obstacle posed by TRIPS and the impact of the approach on innovation. Furthermore, we see reason to worry that the analytical tools utilized to date carry a strong potential for altering the political economies of member states in ways that create a one-way ratchet in favor of increased commodification.

We conclude that a map of the public domain of the type charted by Pam Samuelson must do more than consider the effects of various domestic laws and policies because the international system (as currently administered) shapes the legal landscape on which individual nations are operating.[5] To alter that landscape, patent strategists should consider a variety of approaches. But we suggest that it may be particularly fruitful to adapt the rhetoric of scholars seeking to promote the public domain in domestic copyright law. The differences we see in the commodification debate may not, after all, reflect genuine differences between cultural and technological production. Rather, it may be that copyright scholars better appreciate the value in framing the public's interest as a right to access.

I. The nature of the debate

As noted above, the debate on commodification and the public domain is largely shaped by copyright scholarship. In that literature, there is general agreement that the public domain is shrinking. To a large extent, the arguments center on what should be counted as within the public domain and whether access to it matters. On the patent side, the situation appears somewhat different. There is little debate on what counts as public, nor is the claim of a need for access contested. Rather, the discussion focuses on whether the domain of public knowledge is actually shrinking, and—since there are significant constraints imposed on would-be reformers—considerable controversy on what could be done to reverse the trend.

a. What counts as public?

As Pam Samuelson's contribution demonstrates, charting a public domain map is not easy in copyright because there is little consensus on whether material subject to expired copyrights, uncopyrightable material, and information available through the fair use or other defenses to infringement are equally entitled to be considered part of the public domain. For patent lawyers, the need to make this distinction is almost

[5] Pamela Samuelson, Mapping the Digital Domain, 66 Law & Contemp. Probs 147 (2003); [**Cross cite to this volume]**

incomprehensible. The quid pro quo for receiving a patent—indeed, one of the core goals of patent law—is disclosure.[6] The same document that reserves rights in a new technology also reveals that new information to the public. While some of the material revealed will be subject to claims of exclusivity, the essence of the patent trade-off is that not all of that information is privatized. Underlying principles of nature disclosed in the patent have traditionally become available for immediate use. So do any applications of these principles that the patentee revealed but failed to "distinctly" claim.[7]

Of course, one could certainly quibble about whether unauthorized use of patented material that is subject to a defense against infringement is in or out of the public domain. There are, however, few such defenses. Post-TRIPS, most defenses are designed to deter bad conduct by the patentee (such as bad faith dealings with the patent office or anticompetitive use of the patent). Defenses to protect the public's interests are almost nonexistent.[8] To be sure, there is an experimental use defense that could ensure access.[9] But it is increasingly seen as there only to permit the public to test the validity of the patent (for example, to verify its claimed utility)—that is, to make sure that the advance was appropriately privatized in the first place.[10]

With disclosure considered so integral to the patenting system, it is no wonder that there is little quarrel over finer distinctions. What matters is whether the information a second comer needs is available for use—whether it is in a domain that might be called "the domain of accessible knowledge."

b. Does access matter?

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[6] See, e.g., Eldred v. Ashcroft, 537 US. 186, 190 (2003). We mainly draw our examples from U.S. law. Partly, this is a matter of convenience, partly because the problems we later describe appear to be more acute in the United States right now, but may be harbingers and provocateurs of similar developments elsewhere.

In U.S. patent law, the duality of claiming and disclosing is captured in a single provision of the Patent Act, 35 U.S.C. § 112. This provision requires that the inventor "point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention." It also requires the patentee to provide "a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms to enable any person skilled in the art to .. make and use the same…" Patentees must also disclosure their subjective views of the best mode for practicing their inventions. With the exception of the last requirement, these disclosures are also mandated by the TRIPS Agreement, see art. 29.

[7] 35 U.S.C. § 112.

[8] TRIPS, for example, bars general compulsory licensing provisions, art. 31, or local working requirements, art. 27.

[9] See, e.g., 35 U.S.C. § 271(e)(permitting experimentation on patented drugs "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"); WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898 (1890); Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813); Sawin v. Guild, 21 Fed. Cas. 554, F. Cas. No. 12391 (C.C.D. Mass. 1813)(permitting experimentation to gratify "scientific tastes").

[10] See, e.g., Katherine Strandburg. What Does the Public Get? Experimental Use and the Patent Bargain, 2004 Wis. L. Rev. 81, 89.

Several of the pieces in this Volume and elsewhere put forward theories for why access is important. This is a difficult issue in copyright law because only copying gives rise to claims of infringement. Thus, it could be argued that cultural progress does not require utilization of protected material, a position that would allow the law to safely ignore public access issues.

Theorists offer many reasons to believe, as Jessica Litman put it, that "[t]he public domain should be understood not as the realm of material that is undeserving of protection, but as a device that permits the rest of the system to work by leaving the raw material of authorship available for authors to use."[11] Richard Posner and William Landes emphasize economic aspects, arguing that optimal production cannot occur if the cost of inputs exceeds the profits obtainable from outputs; to keep costs in line, some access to protected works is necessary.[12] Wendy Gordon stresses market failure problems and has also argues that works "themselves become facts with which their audiences have to deal."[13] Pam Samuelson and Suzanne Scotchmer consider access in the context of interoperability.[14] In Julie Cohen's contribution to this Volume, she explores the sociology of creativity and the constitution of culture; Michael Birnhack's Chapter deals with access as an aspect of fundamental human rights. Whether it is necessary, or desirable, to find a "true" theory is difficult to say; it is sufficient to note that the different theories are likely to create different prescriptions for protecting access interests.

On the patent side, there is virtually no debate of this nature. To be sure, there is more than one way to think about access. There is a substantial literature on the distributive consequences of patenting, particularly as applied to pharmaceutical products.[15] However, the core value in access is undisputedly seen as utilitarian, stemming from a shared and unquestioned understanding that knowledge in science is cumulative—that access is integral to progress. Numerous examples of progress-through-access have been demonstrated by historians of science and epistomologists. A recent example is Peter Galison's book on the theory of relativity, which provides new

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[11] Jessica Litman, The Public Domain, 39 Emory L.J. 965, 968 (1990).

[12] William M. Landes and Richard A. Posner, An Economic Analysis of Copyright Law, 18 J Legal Stud 325, 332-33; 360-61 (1989).

[13] Wendy J. Gordon, Fair Use as Market Failure: A Structural And Economic Analysis of the Betamax Case and its Predecessors., 82 Colum. L. Rev. 1600 (1982); Wendy J. Gordon, Reality As Artifact: From Feist To Fair Use, 55 Law & Contemp. Probls. 93, 96 (1992).

[14] Pamela Samuelson and Suzanne Scotchmer, The Law and Economics of Reverse Engineering, 111 Yale L.J. 1575, 1612-1637 (2002)

[15] For example, patents on pharmaceuticals raise difficult questions on who may benefit from the fruits of society's investment in medical research: questions on the terms on which essential medicines are made accessible to citizens of less developed countries; on ways to assure that all developed countries pay a fair share of the costs of medical research; and on whether it is appropriate for the patent system to require taxpayers to make transfer payments to those whose inventions were made with government support. See, e.g., Gardiner Harris, Price of AIDS Drug Intensifies Debate On Legal Imports, New York Times, April 14, 2004, Sec. A, p.1, col. 1 (describing the pricing of Norvir, an AIDS drug, in the United States and Europe); Shubha Ghosh, Pills, Patents, and Power: State Creation of Gray Markets as a Limit on Patent Rights, 53 Fla. L Rev. 789 (2001); Note, Samantha Shoell, Why Can't the Poor Access Lifesaving Medicines? An Exploration of Solving the Patent Issue, 4 Minn. Intell. Prop. Rev. 151 (2002); Mary T. Griffin, AIDs Drugs and the Pharmaceutical Industry: A Need for Reform, 17 Am. J. L. and Med. 363 (1991).

insights into the relationship between Einstein's theories and his work in the Swiss patent office examining applications on inventions related to the synchronization of railway clocks.[16]

The crucial importance of access to prior knowledge is also readily admitted by scientists. Thus, Newton famously wrote to Robert Hooke "If I have seen further [than certain other men] it is by standing upon the shoulders of giants."[17] Scientists' own understanding can also be perceived in the Mertonian norms of communalism, universalism, disinterestedness, originality, and skepticism,[18] which create an environment of open science where new work is shared and refined—and, indeed, regarded by scientists as refined because it is shared through, for example, funding and publication processes dependent on peer review.

Patent law reflects the same perspective. Inventiveness (nonobviousness) is measured by comparing an invention to the knowledge that preceded it.[19] As Robert Merges has argued, the main work of this requirement and the novelty requirement, which bar patents on work that is already known, used, or described in the literature (including, significantly, the patent literature), is to force inventors to consult the prior art—that is, to do library research before they conduct bench research.[20] Indeed, the law can be understood as going further—as taking the position that duplicating work is contrary to public policy. Thus, there are features of patent law that are designed to ensure that inventors patent their work quickly, and to punish them if their delay leads others to waste laboratory resources on rediscovery.[21]

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[16] Peter Galison, Einstein's Clocks, Poincaré's Maps Empires of Time (Norton 2003). In his contribution, Eli Salzburger suggests that Thomas Kuhn's theory of revolutions within science is inconsistent with this claim. While it may well be true that there are paradigm shifts in scientific thinking, these shifts occur when enough facts accumulate to make old theories untenable. Since the continuing viability of a theory cannot be verified without the right to use accumulated facts and test them against the theory, access is clearly important even to revolutionary science. Admittedly, Kuhn states that revolutionary science is inconsistent with "cumulative development," but what he seems to mean is that science proceeds discontinuously and nonlinearly, see Thomas Kuhn, The Structure of Scientific Revolutions 108 (U.Chicago Press 3d ed. 1996). In many places throughout his book, Kuhn discusses the use of known facts to discard old theories and develop new ones. Access is also important to the acceptance of new paradigms. For example, Einstein's theory of relativity was (relatively) quickly accepted because his physics reduces to Newtonian mechanics for slow moving bodies, see, e.g., Heinz R. Pagels, The Cosmic Code (Simon & Schuster 1982).

[17] The Columbia World of Quotations No. 41418 (1996)(quoting Isaac Newton's Feb. 5, 1675 letter to Robert Hooke).

[18] See, e.g., Robert K. Merton, The Normative Structure of Science, in The Sociology of Science: Theoretical and Empirical Investigations 267, 273 (Norman W. Storer ed., 1973).

[19] See 35 U.S.C. §§ 103 (nonobviousness) and 102(a) (novelty).

[20] Robert Patrick Merges and John Fitzgerald Duffy, Patent Law and Policy: Cases and Materials 419-21 (3d ed. Matthew Bender and Co. 2002).

[21] See, e.g., 35 U.S.C. § 102(b)(setting up a bar to patenting an invention exploited by the patentee for more than a year before the application date); § 102 (g)(awarding priority to the first to conceive, unless that person delayed to the point where a second comer entered the race and reduced to practice first). For an interesting discussion of the relationship between priority and access within science, see Robert K. Merton, Priorities in Scientific Discovery: A Chapter in the Sociology of Science, 22 Am. Sociological Rev. 635 (1957).

With little disagreement on the need for access, the trick in patent law is to create the right level of access, given that patent rights (unlike copyrights) allow the patentee to exclude everyone—including independent inventors—from practicing claimed inventions.[22] As the discussion on the public domain just demonstrated, patent law's disclosure rules are intended to make sure that science can progress despite patenting; the issue is whether there is a commodification movement on the patent side that is rendering existing provisions less effective.

c. Is the domain of accessible knowledge shrinking?

On this issue, the shoe is on the other foot. Thus, recent changes in copyright-related law, such as legal protections for technological measures,[23] expansions of the categories of protectable subject matter,[24] extensions of rights to new participants in the creative enterprise,[25] enlargements on the scope of protection,[26] lengthening of the copyright term,[27] and recognition of new forms of self-help,[28] make it clear that commodification is proceeding apace in the cultural dimension. The same clarity does not quite exist for patenting. While concern has recently been expressed in several quarters that changes in patent policy are beginning to interfere with open science,[29] the evidence is decidedly mixed.[30]

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[22] 35 U.S.C. § 271(a). There is a limited "prior user right" to protect usages that predated the patent, § 273(b).

[23] 17 U.S.C. §§ 1201-1202.

[24] See, e.g., rights to sound recordings, 17 U.S.C. § 102(a)(7), and architecture, 17 U.S.C. § 102(a)(8). The Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases, Official Journal L 077, 27/03/1996, is another example.

[25] For example, in 1994, the United States granted rights to the performers of live musical works, 17 U.S.C § 1101. Such rights might be characterized as neighboring or related rights which have traditionally been protected under other national laws. However, TRIPS art. 14 required the grant of such rights as a matter of international law.

[26] See, e.g., the expansion of rights in sound recordings, 17 U.S.C. § 106(6).

[27] See, e.g., 17 U.S.C. § 302. See also Luke's Music Library Inc. v. Ashcroft (DDC 6/10/04)(upholding the constitutionality of a provision that restores copyright protection for works that already became part of the public domain in the United States under 17 U.S.C. § 514).

[28] See, e.g., Rochelle Cooper Dreyfuss, Do You Want to Know a Trade Secret? Licensing Under Article 2B of the Uniform Commercial Code, 87 Cal. L. Rev. 1193 (1999)(describing the Uniform Computer Information Transactions Act, then called Article 2B); ProCD, Inc. v. Zeidenberg, 86 F.3d 1447 (7th Cir. 1996).

[29] National Research Council of the National Academies of Sciences, A Patent System for the 21st Century (2004)(hereinafter NAS Patent Report); Federal Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, http://www.ftc.gov/os/2003/10/innovationrpt.pdf (2003)(hereinafter FTC Report). A group in the United Kingdom has issued a report expressing similar concerns, see The Royal Society, Keeping Science Open: the effects of intellectual property policy on the conduct of science, http://www.royalsoc.ac.uk/policy/. In the main, our paper focuses on the changes noted by the NAS Patent Report as of such substance that they deserve continued national scrutiny, see NAS Patent Report, at 15-31. One of the authors (Dreyfuss) was a member of the NAS Committee that worked on this Report.

[30] See, e.g., John P. Walsh, Ashish Arora, and Wesley M. Cohen, Effects of Research Tool Patents and Licensing on Biomedical Innovation, in Patents in the Knowledge Based Economy (National Academies Press (2003)(Wesley M. Cohen and Stephen A. Merrill, eds); Ronald J. Mann, The Myth of the Software Patent Thicket: An Empirical Investigation of the Relationship Between Intellectual Property and Innovation in Software Firms, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=510103 (2004).

As an empirical matter, it is certainly true that the number of patents has been rising substantially each year[31] and that increasing numbers of lawyers are entering into intellectual property practices.[32] Thus, it cannot be debated that there is an unprecedented amount of information that is now subject to exclusive rights. What can be questioned, however, is whether this means that there is a decrease in the amount of publicly accessible knowledge.

Increased patenting could be explained in two ways. One is that the innovation environment is becoming more robust and producing more inventions entitled to patent protection. The other is that patents are replacing trade secrets as the major strategy for internalizing the gains associated with technological advances. In either case, the domain of accessible knowledge benefits from the upswing in issuances. Since the other side of the patent coin is disclosure, more patents mean more information is revealed in the specifications, with the result that more information is available for immediate use.[33] Furthermore, all the information in a patent becomes accessible once the term expires. Significantly, that term is considerably shorter (two generations shorter) than the copyright term and in some cases, it is shorter than the period in which a trade secret is likely to stay secret. And while it is true that the number of patent attorneys is growing at a faster pace than spending on research and development[34]—which may suggest that some information that was previously allowed to fall immediately into the public domain is now being privatized—it is also conceivable that the productivity of scientific research is increasing (or that the complexity of inventive output is increasing), requiring a change in the ratio between spending on R&D and spending on patent advice.[35]

There are other reasons to think that the domain of accessible knowledge is growing. In countries that previously measured the patent term from the date of issuance, the TRIPS Agreement (which measures the term from application) could, if examination is conducted quickly, decrease the time of exclusivity.[36] More important, at least in the United States, there are several judicial changes that have weakened patent protection.

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[31] The number of U.S. patents has tripled from 66,290 in 1980 to 184,172 in 2001. *See* Mann, *supra* note at 22.

[32] The number of practitioners affiliated with the American Bar Association Intellectual Property Section increased 39% between 1996-2002. *See* NAS Patent Report, supra note , at 26; *see also* Mann, supra note ; John R. Barton, Reforming the Patent System, 287 Science 1933 (2000).

[33] See, e.g., R. Polk Wagner, Information Wants To Be Free: Intellectual Property and the Mythologies of Control, 103 Colum. L. Rev. 995 (2003).

[34] See Mann, supra note ; Barton, supra note .

[35] Cf. Arti K. Rai, The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, And Access In The Post-Genomics Era, 2001 U. Ill. L. Rev. 173, 189-92 (describing efficiencies in biotechnology research). Of course, it is also possible that patent prosecution has enjoyed even higher productivity gains: computerization makes it easier to draft applications and amendments; the Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 9 I.L.M. 978, and the European Patent Convention, Convention on the Grant of European Patents, Oct. 5, 1973, 13 I.L.M. 268 decrease the work involved in filing a multiplicity of national applications.

[36] TRIPS art. 33. In the United States for example, a 17 year term from issuance is longer than a 20 year term from application if examination takes more than 3 years, as it does in several fields, including biotechnology. However, it is probably more likely that the term is growing: for patents pending at the time the TRIPS Agreement went into force, the term is the longer of the two. *See generally* Mark A.

First, the establishment of the United States Court of Appeals for the Federal Circuits channels all patent appeals to a single court.[37] Thus, patentees can no longer forum shop for sympathetic judges. Second, the probability that particular activity will be regarded as infringing has decreased because the Federal Circuit is using its authority to significantly narrow the scope of patent claims.[38] Specifically, it has strengthened the requirements of disclosure. Emphasizing the comprehensibility of the patent to a person of ordinary skill in the art, the court has invalidated a series of patents on the ground that they claimed more than they enabled that person to do, or failed to describe the invention in sufficient detail.[39] The court has also made it clear that even valid patents are dependent on what the ordinary artisan can understand and cannot be interpreted in ways that extend protection beyond what is disclosed.[40] In addition, the court has substantially weakened the doctrine of equivalents. This doctrine, which expands patent claims beyond their literal meaning to include substitutions within the capability of an ordinary artisan, would, absent the Supreme Court's repeated intervention, have been overruled.[41] Even after the Supreme Court reaffirmed the doctrine's continued vitality, the Federal Circuit has continued to chip away at it.[42] Finally, claims drafted in means-plus-function format, which were once read broadly, are now limited by their specifications.[43]

Lemley, *An Empirical Study of the Twenty-Year Patent Term*, 22 Am. Intell. Prop. L. Ass'n Q.J. 369 (1995). Further, TRIPS does not set a maximum limit on the term and the U.S. Patent Act is busily accumulating a series of patent term extensions to deal with problems in particular industries. See 35 U.S.C. §§ 154-156.

[37] 28 U.S.C. § 1295. See generally, Arti K. Rai, Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform, 103 Colum. L. Rev. 1035 (2003); Rochelle Cooper Dreyfuss, A Case Study in Specialized Courts, 64 N.Y.U. L. Rev. 1 (1989).

[38] Willliam M. Landes and Richard A. Posner, The Economic Structure of Intellectual Property Law 338 (2003), citing Donald R. Dunner, J. Michael Jakes, and Jeffrey D. Jarceski, A Statistical Look at the Federal Circuit's Patent Decisions: 1982-1994, 3 Fed. Cir. Bar J. 151, 152 (1995).

[39] See, e.g., University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916 (Fed. Cir. 2004) and cases discussed therein.

[40] See, e.g., ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1090-1091 (Fed. Cir. 2003); Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997). See also Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed.Cir.1998).

[41] See, e.g., London v. Carson Pirie Scott & Co., 946 F.2d 1534 (Fed. Cir. 1991)(Judge Lourie); Charles Greiner & Co. v. Mari-Med Mfg. Co., 962 F.2d 1031 (Fed. Cir. 1992)(Judge Rader); American Home Products Corp. v. Johnson & Johnson, 25 U.S.P.Q.2d 1954 (Fed. Cir. 1992)(Judge Plager). The Supreme Court brought a halt to the Federal Circuit's most zealous attempts to curtail the doctrine of equivalents in Warner-Jenkinson Co. v Hilton Davis Chemical Co., 520 US 17, 40, 39 n 8 (1995) and then again in Festo Corp. v Shoketsu Kinzoku Kogyo Kabashuki Co., 122 S Ct 1831 (2002). According to *Festo*, the doctrine of equivalents retains its vitality but cannot be used to capture ground surrendered during prosecution through a narrowing amendment.

[42] See, e.g., Honeywell Intern. Inc. v. Hamilton Sundstrand Corp. 370 F.3d 1131 (Fed. Cir. 2004)(extending the rule in *Festo* to the act of restating a dependent claim in independent form, even when the claim had never been rejected or amended or narrowed); Glaxo Wellcome, Inc. v. Impax Laboratories, Inc, 356 F.3d 1348 (Fed. Cir. 2004)(utilizing a doctrine of "infectious estoppel," under which subject matter surrendered by amendment of one claim is also surrendered for other claims containing the same limitation found in the first claim).

[43] See, e.g., Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384 (Fed.Cir.1992).

Still, it is likely that those who fear commodification have the stronger arguments. On the international front, the TRIPS Agreement broadens the base of inventors who are eligible for patents in each country; the Patent Cooperation Treaty and the European Patent Convention makes it cheaper for inventors to take advantage of the TRIPS opportunity.[44] Thus, there may have been inventions that would not have formerly been protected in multiple WTO members that now will be. And since the compliance mechanism of the TRIPS Agreement forces nations that may have taken a relaxed attitude toward certain infringements to enforce intellectual property rights more fully,[45] the effect is a reduced ability to engage in what Pam Samuelson calls intellectual property arbitrage—avoidance of the patent laws of one country by utilization of inventions in places where they are not protected.[46]

As to developments in the United States, the Federal Circuit is likely a net benefit to patentees, despite the changes it has made to the law on infringement and patent scope. Judges versed in technology, who have only one tool (patent law) with which to advance the nation's agenda of promoting innovation, and who know that the health of their docket depends on active patenting, are at least as likely to be sympathetic to patentees as to public access interests.[47] Furthermore, there are several substantive legal changes that can be regarded as posing concrete threats to scientific progress.

The first change is in the coverage of patent law: the Supreme Court's decisions in Diamond v. Chakrabarty (on the patentability of bioorganisms)[48] and Diamond v. Diehr (on computer software),[49] along with the Federal Circuit's decision in State Street Bank v. Signature Financial Group (on business methods),[50] have combined to extend

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[44] On the PCT and EPC, see supra, note .

[45] TRIPS Agreement, arts. 42, 64. This effect is heightened by unilateral actions taken by the United States to promote intellectual property protection internationally, see 19 U.S.C. §§ 2411-2420 (1994).

[46] *See* Pamela Samuelson, Intellectual Property Arbitrage: How Foreign Rules Can Affect Domestic Protection, *in* International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime (Keith E. Maskus & J. H. Reichman eds., Cambridge U. Press, forthcoming 2004); Pamela Samuelson, Intellectual Property Arbitrage: How Foreign Rules Can Affect Domestic Protection, 71 U. Chi. L. Rev. 223 (2004).

[47] Although we restrict our analysis to developments in the United States, it is worth noting that to the extent that these developments can be attributed to the establishment of a technocratic court so specialized that it sees patent law as the only tool for promoting innovation, these developments may become pervasive, for there are other nations that are also considering a move to specialized patent adjudication, see, e.g., Simon Zekaria, EU Bids for European Patent Court, Eupolitix.com, http://www.eupolitix.com/EN/News/200402/f8a15ca7-6eab-4db1-a642-3f0f4225f287.htm; cf. Toshiko Takenaka, Comparison of U.S. and Japanese Court Systems for Patent Litigation: A Special Court or Special Divisions in a General Court, http://www.law.washington.edu/Casrip/Symposium/Number5/pub5atcl6.pdf

[48] 447 U.S. 303 (1980).

[49] 450 U.S. 175 (1981).

[50] 149 F.3d 1368 (Fed. Cir. 1998). This case was the culmination of a long fight over the terms under which software would be protected. The Supreme Court entertained three cases on computer software (the other two were Gottschalk v. Benson, 409 U.S. 63 (1972), and Parker v. Flook, 437 U.S. 584 (1978)); the Federal Circuit and its predecessor court also entertained a series of cases on this issue, see, In re Alappat, 33 F.3d 1526 (Fed.Cir.1994) (in banc); Arrhythmia Research Technology Inc. v. Corazonix Corp., 958 F.2d 1053 (Fed.Cir. 1992), In re Abele, 684 F.2d 902 (CCPA 1982); In re Walter, 618 F.2d 758, 205 USPQ 397 (CCPA

patent protection to new subject matter. That is, in earlier eras, end-products were considered the sole subjects of patent protection. These were products directed at consumers—the products of technology, and not the targets of science. Discoveries mainly of interest to science stayed in the public domain. For example, in Funk Bros. Seed Co. v. Kalo Inoculant Co., the Supreme Court held that packets containing mixtures of bacteria were "no more than the discovery of some of the handiwork of nature and hence unpatentable;"[51] and in Brenner v. Manson,[52] the Court defined the utility required for patent protection as end-use (rather than research-use) utility. But both the new biology and computer science break down these dichotomies: advances in these fields are inherently dual in character.[53] Biotechnology inventions, for example, can have immediate commercial application as diagnostics or treatments and thus qualify for patent protection, even though they have enormous import to biomedical research. Similarly, mathematical algorithms may be the basis of commercial software, but they simultaneously function as building blocks of knowledge.[54]

A determination could have been made to follow an approach analogous to the idea-expression and merger doctrines of copyright law, and to deny protection to inventions that merge scientific principles with technological application.[55] The decision to do otherwise means that the number of patents will increase. Even more worrying, however, is the power that these "upstream" patents exert. Consider, for example, patents on applications of NF-κB, a cell-signaling pathway;[56] a patent claiming all antibodies recognizing CD34, an antigen found on stem cells,[57] and a test for the gene BRCA1, which is linked to one form of breast cancer. These patents can be (and in some cases, have been) asserted not only in *product markets*—against those who use the patented products to treat or test patients, but also in *innovation markets*—against those who utilize the inventions for research purposes: scientists who study pharmaceutical products that function via the NF-κB pathway; researchers who need CD34 to conduct stem cell research; and those who want to exclude BRCA1-caused breast cancer in order

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1980); In re Freeman, 573 F.2d 1237 (CCPA 1978), and for business methods, In re Meyer, 688 F.2d 789 (CCPA 1982): In re Maucorps, 609 F.2d 481(CCPA 1979).

[51] 333 U.S. 127, 131 (1948). *See also* O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853)(holding that abstract principles are not statutory subject matter).

[52] 383 U.S. 519 (1966).

[53] *See, e.g.,* Francis Narin and Dominic Olivastro, *Status Report: Linkage Between Technology and Science*, 21 Research Policy 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).

[54] *See, e.g.,* Donald S. Chisum, *The Patentability of Algorithms*, 47 U. Pitt. L. Rev. 959, 1017 (1986). S*ee also* Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business*, 16 SANTA CLARA COMP. & HIGH TECH. L.J. 263 (2000)(noting that business method patents have similar problems in that they control broad ranges of business activity); Charles Vorndran and Robert L. Florence, *Bioinformatics*: *Patenting the Bridge Between Information Technology and the Life Sciences*, 42 IDEA 93 (2002)(showing that bioinformatics inventions can be categorized as upstream science, algorithms, and business methods).

[55] See, e.g., Baker v. Selden, 101 U.S. 99 (1879); Computer Assocs. Int'l, Inc. v. Altai, Inc., 982 F.2d 693, 707 (2d Cir.1992).

[56] See NAS Patent Report at 62; U.S. Patent No. 6,410,516; Arti Rai and Rebecca Eisenberg, Bayh-Dole Reform and the Progress of Biomedicine, 66 Law and Contemp. Probs. 289 (2003).

[57] See Avital Bar-Shalom and Robert Cook-Deegan, *Patents and Innovation in Cancer Therapeutics: Lessons from CellPro*, 80 The Milbank Quarterly, 637 (2002).

to find other genetic susceptibilities to this set of diseases. Unlike the case with most end products, there are no substitutes—no invent-arounds—for those who are working in the relevant areas. And as noted earlier, researchers do not have the option—as they would in copyright—of independently re-creating the technology in clean rooms.

Secondly, observers worry that the standard of nonobviousness is declining.[58] Statutorily, the nonobviousness requirement prevents patenting when a person of ordinary skill in the art could have arrived at the claimed "invention" by building on existing art, or combining it, in an incremental way. This test is arguably being diluted by recent decisions. One problem is said to be the Federal Circuit's "obvious to try" doctrine.[59] While it might seem that no special incentives are needed for advances that are obvious to try, the Federal Circuit's view is that a patent should nonetheless be available in situations where the inventor faces a large number of alternatives, not all of which will necessarily pan out.[60] Admittedly, it is easy to understand why the court might favor this approach. As sciences mature, it can become fairly clear where (and what) work needs to be done; without the possibility of a patent reward, no one may be willing to methodically pursue those prospects. What can be disputed is the Federal Circuit's implementation of this approach. Observers are concerned that the court has an unrealistic idea of which undertakings are risky. Further, when it examines the number of choices, the court fails to consider that modern science makes heavy use of automated equipment that can test alternatives quickly, cheaply, and easily.[61]

The way the court looks at combinations of prior art is similarly problematic. Here, the Federal Circuit is working hard to make examiners realize that putting known information together can be an inventive process. It is trying to prevent examiners from using the patent disclosure against the applicant, as a guide for understanding how to assemble prior knowledge. To that end, the court has been requiring examiners to demonstrate what it was in the prior art that would have led the ordinary artisan to combine references.[62] However, as salutary as the court's goals may be, the result of its approach is that examiners may be disabled from considering general tacit knowledge, some of which is such common wisdom (or common sense) that it is not likely to be published (or, indeed, publishable).[63]

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[58] See, e.g., Dan L. Burk and Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003); Dan L. Burk and Mark A. Lemley, *Is Patent-Law Technology-Specific?*, 17 BERK. TECH. L.J. 1155 (2002)(criticizing decisions on biotechnology).

[59] See NAS Patent Report, supra note , at 72-78; FTC Report, supra note 29, Ch. 4, at 8-19.

[60] See NAS Patent Report, supra note , at 75 (citing In re O'Farrell, 853 F.2d 894 (Fed.Cir.1988)).

[61] One could go further and by analogy to the decision in Feist Publications, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340 (1991), for copyright, argue that the obvious-to-try doctrine, which essentially protects works on the basis of the "sweat labor" invested in them, is inconsistent with constitutional limitations on Congress's intellectual property powers.

[62] See, e.g., In re Lee, 277 F.3d 1338 (Fed. Cir. 2002); In re Dembiczak, 175 F.3d 994 (1999).

[63] There is also substantial concern with the Federal Circuit's use of commercial success as a factor demonstrating inventiveness, see, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986)(also suggesting other so-called secondary considerations, including failure of others, long-felt need, and unexpected results). Although one can certainly argue that if an advance were marketable, it would have been invented if it was easy to do, it is sometimes the case that success is due to other factors, such as collateral developments or good marketing. Mistakes on patentability are especially costly when

The availability of patents on trivial variations and marginal improvements essentially withdraws from the public domain information that, effectively, was already there: either it was described in the literature, or was so easily grasped, the patent system was not needed to encourage the advance. Additionally, making incremental improvements subject to patent rights undermines the patent term because patentees can engage in so-called "evergreening"—extending the effective term by patenting an improvement just as the term on the underlying invention is about to expire.[64]

The low level of skill that the court attributes to people of ordinary skill in the art also creates other problems for the system's effect on progress. Since the tests for disclosure, enablement, the doctrine of equivalents, and inventiveness all turn on the abilities of a person of ordinary skill in the art, and the court attributes the same level of knowledge in every place where the test applies, a low level of skill does more than make patents easier to acquire. Because an unimaginative artisan is also unable to learn much from disclosures or to make substitutions in ingredients, patents are becoming narrower. While narrow patents may appear to improve access, patentees can get around that problem by simply obtaining more patents.[65] These create problems of their own: thickets of rights that newcomers to a field must wade through to determine their freedom of action,[66] and more work for the patent office (leading to more opportunities to make mistakes). By measuring the scope of a patent by what a person of ordinary skill can do and patentability by what a person with that *same* level of skill can't do, the court has created a seamless web of patenting, thereby depriving the public of room to "tinker"—to play around with a technology and learn from it. [67]

The fourth reason that observers worry about access relates to defenses to infringement. Here, the most significant problem is the narrowing of the experimental use defense. Traditionally, noncommercial users and in particular, university researchers, have benefited from a common law defense that permitted unauthorized use for the "gratification of scientific tastes, or for curiosity, or for amusement."[68] In addition, there is a statutory defense permitting use of patented drugs to generate premarket clearance data,[69] which had been applied to preclinical as well as clinical usages (which is to say, experiments that generate clearance data and also create spillover benefits for other

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an invention is commercially successful. Further, litigators claim that instructions on commercial success lead juries to disregard the evidence that tends to show obviousness.

[64] FTC Report, supra note , at Ch. 5, 6.

[65] Landes and Posner, supra __ at 339-340; Hall, supra note .

[66] See, e.g., Carl S. Shapiro, Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting, in 1 Innovation Policy and the Economy 1-2 (Adam Jaffe et al. eds., 2001), available at http://faculty.haas.berkeley.edu/shapiro/thicket.pdf.

[67] This term was coined by Edward Felten, a Princeton University computer science professor, see Tinkerers' Champion, Science Technology Quarterly, http://www.economist.com/science/tq/displayStory.cfm?story_id=1176171 (June 20, 2002).

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

[69] 35 U.S.C. § 271(e).

research).[70] Recently, however, both defenses have been narrowed. The common law defense is now unavailable for work done "in keeping with the alleged infringer's legitimate business regardless of commercial implications."[71] Since research is a research university's business, its scientists can (presumably) no longer avail themselves of the defense. And while it is true that academics have not traditionally been sued for infringement, that norm may erode now that the Federal Circuit has spoken.[72] As to the statutory defense, it is now available only for clinical research, work whose *sole* purpose is to produce data for premarket clearance purposes.[73]

In similar fashion, the court has been unsympathetic with arguments that innovation is fueled not only though patenting, but also through vibrant competition. Hence, it has been unreceptive to promoting access through antitrust law, by utilizing doctrines of patent misuse, or by redefining the availability of remedies. Instead, it has enthusiastically enforced derogations from the first sale doctrine[74] and it has permitted a patentee to refuse to deal with potential licensees.[75] Further, the court is willing to award infringement damages to patentees who have not themselves exploited their inventions—despite a strong dissenting voice, which argued that withholding relief would ensure public enjoyment of the benefits of inventiveness.[76]

d. Are there constraints on reform?

Another difference between the commodification debate in copyright and patent law relates to views on the constraints under which would-be reformers operate. One arguable difference lies in the relationship between intellectual property rights and industrial organization; the other, in the obligations of international law.

i. Industrial organization. On the cultural side, the debate over commodification is, to a large extent, a debate over whether current forms of industrial organization make sense in light of technological developments. Thus, it has been argued that new methods of distribution, particularly the Internet, make the role of publishers superfluous,[77] and

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[70] Prior to this decision, research that had other uses in addition to generation of premarket clearance data could take advantage of the defense, see, e.g., Amgen, Inc. v. Hoechst Marion Roussel, Inc., 3 F.Supp.2d 104, 107-08 (D.C. Mass. 1998); Abtox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997); Telectronics Pacing Systems v. Ventritex, Inc., 982 F.2d 1520 (Fed. Cir. 1992). *See generally*, Nicholas Groombridge and Sheryl Calabro, Integra Lifesciences v. Merck—*Good for Research or Just Good for Research Tool Patent Owners*?, 22 BIOTECH. L. REP. 462 (2003).

[71] Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

[72] See Walsh, et al., supra note , at 324-28. The Federal Circuit has been unsympathetic to university researchers in other ways as well, see, e.g., Griffith v. Kanamaru, 816 F.2d 624, 628 (1987)(refusing to give academics leeway to delay work in order to provide students with interesting projects).

[73] Integra Life Sciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed.Cir.2003), *cert. granted*, 73 U.S.L.W. 3069 (U.S. Jan. 7, 2005).

[74] See Monsanto Co. v. McFarling, 302 F.3d 1291 (Fed. Cir. 2002), *later proceeding*, 363 F.3d 1336 (Fed. Cir. 2004); Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700 (Fed. Cir. 1992).

[75] In re Independent Service Organizations Antitrust Litigation, 203 F.3d 1322 (Fed. Cir. 2000).

[76] Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1547-48 (Fed. Cir. 1995); 1562-63 (J. Nies, dissenting).

[77] June Besek and Jane C. Ginsburg, THE FUTURE OF ELECTRONIC PUBLISHING: A PANEL DISCUSSION, 25 Colum. J.L. & Arts 91 (2002); Neil Weinstock Netanel, Book Review, Cyberspace 2.0, 79 Tex. L. Rev. 447 (2000).

that new methods of production, exemplified by Linux, make the concept of authorship anachronistic.[78] Since copyrights are largely viewed as protecting authors and publishers, the argument is that *no* commodification is now needed or (less dramatically) that moves toward *more* commodification are misguided attempts to preserve outmoded industrial forms. In short, reformers of the copyright system see substantial room for simply reversing the commodification trend (or, international obligations to one side, eliminating some or all copyrights).

Perhaps because the costs of scientific training and research remain so high, there are few in the technology community who believe that disintermediation or reliance on peer-to-peer production will lead to an optimal level of innovation.[79] To the contrary, observers regard patents as of enduring—or even increasing—importance. In this regard, two interrelated developments are of particular significance.

The first is that there is an increase in specialization. In the life sciences, for example, there are now firms that focus only on manufacturing research tools; others that mainly screen drugs against target proteins. Woody Powell has documented the effect of specialization on the way research is organized. He notes that traditional pharmaceutical companies get larger and larger because they bring the talent they need inside the firm through hiring. Further, they vertically integrate by joining research, development, distribution, and marketing under one roof. In contrast, modern biotech companies tend to rely on networking: they stay small and acquire the expertise they need on each project through serial collaborative ventures.[80] Ronald Mann has observed a somewhat analogous situation in the software industry, where new technologies are first developed in small start-ups, which later grow, license, or get acquired.[81] This is in sharp contrast to the cultural industries, which have undergone substantial consolidation, facilitated by regulatory liberalization and repeal of cross-ownership rules.[82]

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[78] Jack M. Balkin, Digital Speech And Democratic Culture: A Theory Of Freedom Of Expression For The Information Society, 79 N.Y.U. L. Rev. 1 (2004); Yochai Benkler, Through the Looking Glass: Alice and the Constitutional Foundations of the Public Domain, 66 Law and Contemp. Probs. 173, 181 (2003); Yochai Benkler, Coase's Penguin, or, Linux and The Nature of the Firm, 112 Yale L.J. 369, 375-90 (2002); Yochai Benkler, From Consumers to Users: Shifting the Deeper Structures of Regulation Toward Sustainable Commons and User Access, 52 Fed. Comm. L.J. 561, 562 (2000).

[79] Yochai Benkler may be an exception, see id. However, a close reading of his work makes it clear that he is analogizing from the copyright experience without considering the differences in such issues as training costs, production methods, infrastructure needs, the size of initial investments, need for premarket clearance, or the cost of consumer education. For a less doctrinaire view, see Arti Rai: Open and Collaborative Biomedical Research, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=574863 (2004).

[80] Walter M. Powell, *Networks of Learning in Biotechnology: Opportunities and Constraints Associated with Relational Contracting in Knowledge-Intensive Fields*, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 251 (Rochelle Dreyfuss, Diane L. Zimmerman and Harry First, eds. 2001); Walter W. Powell, Inter-organizational Collaboration in the Biotechnology Industry, 151 (No. 1) J. Instit'l and Theoretical Ec. 197, 205 (1996).

[81] Mann, supra note . See also Bronwyn Hall and Rosemary Ziedonis, The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 32 RAND J. Econ. 101 (2001).

[82] For a discussion, see Dinwoodie and Dreyfuss, supra note __ [CWRU]; Yochai Benkler, *A Political Economy of the Public Domain: Markets in Innovation Goods Versus the Marketplace of Ideas, in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 267, 291-292 (Rochelle Cooper Dreyfuss et al. eds., 2001).

This shift in technological production has put significant pressure on the patent system. Firms specialized in focused upstream work need upstream patents to attract funding and protection against free riders. In an environment in which networking is key to survival, patents are also needed to as signals of business and technical competence. They let investors know that a firm has exclusive technical knowledge that can be exploited and that its principals understand the business steps that need to be taken to exploit that knowledge effectively. Patents also alert others in the potential network to the scientific capabilities that the patenting firm possesses.[83] In addition, of course, patents create a way for firms to transfer information—patents along with associated know-how—and to enter into collaborative arrangements without losing control over what they uniquely know.[84]

The second development, also somewhat unique to technological products, is the changing behavior of universities. At one time, much academic work quickly became freely (or close to freely) accessible to the public, either because there was a norm against patenting or because the work was funded by the government and the government's practice was to license their patents on a nonexclusive basis. With the passage of the Bayh Dole Act in 1980,[85] this changed. Although the Act merely *permits* universities to retain patent rights in federally funded inventions, universities have adopted patenting with considerable enthusiasm. The ability to protect profits in their work makes universities attractive partners in the networks described above. The technology transfer offices created to deal with Bayh Dole have also tended to take on lives of their own, encouraging licensing and assigning of patent rights; guiding faculty activity in ways that promote the patentability of their work and, arguably, changing faculty expectations in ways that favor commercialization.[86]

The bottom line is that reformers of the patent system must walk a fine line. These new patents potentially chill progress for the reasons set out earlier, and also because they increase transaction costs, require heterogeneous licensors to agree to terms (which has proved very difficult),[87] allow patentees to disguise coordinated actions that

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[83] *See, e.g.,* Clarisa Long, *Patent Signals*, 69 U. Chi. L. Rev. 625 (2002); Bronwyn H. Hall, Exploring the Patent Explosion, http://emlab.berkeley.edu/users/bhhall/papers/BHH%20Mannheim03.pdf (2003).

[84] See, e.g., Robert P. Merges, Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations, 84 Calif. L. Rev. 1293 (1996).

[85] 35 U.S.C. §§ 200-212.

[86] See, e.g., David Mowery et al., The Effects of the Bayh-Dole Act on U.S. University Research and Technology Transfer, in INDUSTRIALIZING KNOWLEDGE: UNIVERSITY-INDUSTRY LINKAGES IN JAPAN AND THE UNITED STATES 269, 275 (Lewis M. Branscomb et al. eds., 1999) ("The Bayh-Dole Act is contemporaneous with a sharp increase in U.S. university patenting and licensing activity."); Robert Kneller, Technology Transfer: A Review for Biomedical Researchers, 7 CLINICAL CANCER RESEARCH 761 (2001); Jerome H. Reichman, Overlapping Proprietary Rights in University-Generated Research Products: The Case of Computer Programs, 17 COLUM.-VLA J. L. & ARTS 51, 51-125 (1992) (providing an overview of development of U.S. proprietary rights with an emphasis on commercial university research).

[87] Rebecca S. Eisenberg, *Bargaining Over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging*, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY, supra note . An

restrain competition,[88] and pose formidable barriers to entry.[89] At the same time, however, there are myriad business models, deals, cross licenses, and, in the litigation area, settlements and standoffs, that are predicated on patents and on their continued availability. For example, it would be difficult to repeal Bayh Dole because universities now rely on the income their patents generate and their collaborators rely on the exclusivity the patents provide. Even a less dramatic action, such as cutting back on upstream patenting, could prove problematic. In the commercial sector, there are firms that now rely on patent rights. University technology transfer offices are costly to maintain; to justify them, universities need a large portfolio of inventions upon which to base patent applications and licenses. To the extent that academics work on fundamental discoveries and not incremental applications, patents on such advances are arguably key to the efficiency of university patenting operations.[90]

ii. International obligations. Because both copyright and patent law are subject to the TRIPS Agreement, one might expect that the debate on whether international law constrains reform would be the same in both arenas. Certainly, reformers of copyright law would be as unable as reformers of patent law to simply eliminate intellectual property rights entirely. Nonetheless, there is an important variation in the tenor of the debate, largely stemming from the fact that international copyright law has not changed to the extent that international patent law has. Thus, while it is true that the category of copyrightable subject matter has grown (through for example, the inclusion of computer programs[91] and live musical performances,[92]) and that the scope of copyright protection has expanded (for example, it now includes rental rights,[93]) the TRIPS Agreement mainly relies on the previously-existing norms of the Berne Convention, which TRIPS subsumed by reference.[94] Although the TRIPS Agreement gave these obligations a bite previously lacking, to a significant extent, copyright obligations under the Agreement are relatively well understood by member states, copyright holders, scholars, and critics.[95]

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example is the licensing practices of Myriad Pharmaceuticals in connection with its patent on breast cancer genes, see Walsh, supra note , at 312.

[88] Robert P. Merges and Richard R. Nelson, On the Complex Economics of Patent Scope, 90 Colum. L. Rev. 839 (1990).

[89] See, e.g., Carl Shapiro, supra note ; Bronwyn H. Hall and Rosemary H. Ziedonis, The Determinants of Patenting in the U.S. Semiconductor Industry, 1980-1994, 32 RAND J. Econ. 101 (2001); Michael A. Heller and Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 Science 698 (May 1, 1998).

[90] See, e.g., University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916 (Fed. Cir. 2004).

[91] TRIPS art. 10.

[92] Art. 14

[93] Art. 11.

[94] See TRIPS art. 9(1), referencing the Berne Convention for the Protection of Literary and Artistic Works, July 24, 1971, 1161 U.N.T.S. 31 [hereinafter Berne Convention]. The first version of the Berne Convention was concluded in 1886. TRIPS also restated the basic exceptions rule slightly, compare TRIPS art. 13 with Berne art. 10 and codified the understanding that computer programs were to be protected under copyright.

[95] Although many copyright issues have been raised in the TRIPS Council, there has been only one WTO complaint that has gone through dispute resolution on copyright, s*ee* United States–Section 110(5) of the US Copyright Act, WTR/DS/160/R (Report of WTO Dispute Settlement Panel, 2000).

The situation is somewhat different for patents. The prior international instrument, the Paris Convention,[96] concentrated on national treatment, priority rules, and local working regulations; TRIPS created the first set of substantive requirements, cast as minimum levels of protection. Examples include the nondiscrimination provision, which states that "patents shall be available and patent rights enjoyable without discrimination … as to the field of technology;[97] restrictions on compulsory licensing;[98] and limitations on defenses to infringement.[99] These provisions are not well understood and, indeed, have spawned several disputes that have gone through to adjudication by the dispute settlement body (the DSU). [100] The compulsory licensing provision has already become the target of discussion in a succeeding diplomatic round.[101] As a result of the substantial uncertainty attached to the meaning of the new patent obligations, those who would like to reform patent law find that they must contend not only with arguments about the wisdom of their suggestions, and with constraints clearly imposed by TRIPS, but also with the claim that their proposals are inconsistent with (untested) international obligations.

II. Protecting the domain of accessible knowledge

Part I demonstrated that one could certainly take the position that commodifiation is proceeding in ways that threaten open science, but that there are at least two constraints on reform. First, reducing the incidence of patents is a delicate matter because innovation is heavily organized around their availability. Second, new international requirements make it difficult to say how much leeway member states have to revise their laws. To explore these issues, we have been examining responses to the move to upstream patenting—to patents that protect fundamental principles of knowledge. We are particularly interested in this issue because we see it as at the intersection of many of the developments traced above: it represents a problem in its own right; it is responsible for some of the increase in the numbers of patents in the system; it is at the heart of university involvement in the patent system and a prime exemplar of the Federal Circuit's patent-dominated views on innovation.

In a previous article, we looked at three approaches that a country might take to deal with the impact of these developments on the creative environment. We considered a direct attack on the expansion of patentable subject matter and concluded that unless

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[96] Paris Convention for the Protection of Industrial Property, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].
[97] TRIPS, art. 27.1
[98] Art. 31.
[99] Art. 30.
[100] *See e.g.,* India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/D550/AB/R (Report of the Appellate Body, 1997)[hereinafter India-Patent Protection]; Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R (Report of WTO Dispute Settlement Panel, 2000) (hereinafter Canada-Pharmaceutical Products).
[101] The Doha Declaration undertook to revise art. 31(f) as it applies to importation of pharmaceuticals to countries that lack the capacity to manufacture them for the local market, *see* Declaration on the TRIPS Agreement and Public Health, Adopted on 14 November 2001, WT/MIN(01)DEC/2 [hereinafter Doha Declaration], at http:// docsonline.wto.org/DDFDocuments/t/WT/min01/DEC2.doc (Nov. 20, 2001).

Article 27's requirement of technological neutrality is read narrowly, excluding particular subject matter (such as bioinformatics) from the scope of protection may be impermissible. We then looked at enacting a fair-use type defense to infringement as a way of reversing restrictive interpretations of the research exemption, and concluded that the viability of such an approach is heavily dependent on how it is interpreted by domestic courts—specifically, on whether courts track the international standards laid down by the TRIPS Agreement's "three part tests." Additionally, we noted that this approach might also trigger a technological-neutrality argument. Finally, we considered an approach that would protect fundamental researchers from patent infringement suits, if they agreed to make the work accomplished with patented technology publicly available. We suggested that such a remedies-based approach may interfere with the obligations set out in Articles 41-45. However, because the remedies provisions of the Agreement contemplate more deference to national exigencies than do other provisions of TRIPS, it was our view that this may be the strategy most likely to pass muster.

In this piece, we continue our consideration of approaches to the problem of upstream patenting. Here, we look at invigorating the nonobviousness requirement for patentability, at altering the scope of rights, and—because the remedies approach appears so promising—at a strategy recently proposed by the National Academies of Sciences Committee on Intellectual Property Rights in the Knowledge-Based Economy to give certain infringers immunity from suit by, essentially, condemning patent rights for use in government-funded research.[102]

a. *Nonobviousness.* As noted, many observers of the patent system are particularly concerned with what they consider erosion of the obviousness standard. In their view, it is this phenomenon that is mainly responsible for the ease with which minor innovations can now be protected and for the ability of patentees to extend the effective duration of protection by patenting successive minor improvements. If, they say, the standard were re-invigorated, there would be fewer patents, and information that was patented would be released more quickly into the public domain.

In fact, several modifications are being implemented or are under active consideration. The Federal Circuit is already retrenching on some of the substantive positions that have been criticized. For example, the court recently declined to reverse a decision rejecting a patent on the ground that the examiner had considered tacit knowledge.[103] There is also some movement on procedure. The Patent Office now takes a "second look" before issuing business method patents, where the problem of tacit

[102] See NAS Patent Report, supra note (suggesting that government funded work be deemed as within the government contractor provisions of 28 U.S.C. § 1498).

[103] See, e.g., In re Berg, 320 F.3d 1310 (Fed Cir. 2003). The court has also emphasized the need for a nexus between commercial success and specific activity of the patentee, see, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1130 (Fed. Cir. 2000). Such a requirement, if taken seriously, would be helpful because it would focus decisionmakers on the question whether the patentee's efforts and contribution were unique—which is to say, inventive.

knowledge has been particularly acute.[104] Serious consideration is being given to other ideas as well, including the adoption of a post-grant inter-partes opposition procedure,[105] revisions in the incentive structure within the PTO,[106] and the use of experts to provide advice on such matters as the general state of knowledge in the field and the inventiveness of those with ordinary skill in the art.[107]

More drastic changes may also be considered. As noted earlier, the statute refers to the "person having ordinary skill in the art"[108]—that is, the invention must be something that the person of ordinary skill could not have done with the prior art available at the time of the invention. This language reads as if the requirement depends on historical facts—what persons of ordinary skill knew at the time the invention was invented. If that were the case, then perfecting a measurement of what inventors knew would solve the problem. Arguably, however, the "person with ordinary skill in the art," as used for nonobviousness, is a term of art (what was once called a "legal fiction"); it is not meant as an empirical question, but rather the term provides cover for judges and the patent office to pursue particular social goals. As Mark Lemley and Dan Burk have argued, the level of skill should be set sector by sector, depending on the needs of each industry.[109]

Implementing this approach might result in the standard of inventiveness being raised for some technologies and lowered for others. However, it is rather likely that the Lemley-Burk suggestion will lead to a general rise in the standard of inventiveness. To see why, it is necessary to remember that the person-with-ordinary-skill formulation is used not only for obviousness, but also as a benchmark for determining compliance with the various disclosure requirements,[110] and to decide the scope of the patent right.[111] These issues could be decoupled. If each is analyzed separately (as Lemley and Burk suggest),[112] then the decision on what a person of ordinary skill knows will no longer represent a compromise among policies and will instead optimize the law on each issue individually. For disclosure, where the goal is to induce inventors to reveal maximal amounts of information, retaining a low level of skill might be desirable. For claiming purposes, the level could be set empirically so that scientists could intuit the scope of the claims based on their actual knowledge. If the goal for nonobviousness is to prevent

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[104] See, e.g., Linda E. Alcorn, Pursuing Business Method Patents In the US Patent and Trademark Office, 20 Computer and Internet Law. 27, 30 (2003)(noting large reduction in business method patents issues after institution of a second look procedure within the PTO).

[105] See, e.g., FTC Report, supra note at 7; NAS Patent Report, supra note , at 5.

[106] See, e.g., Robert P. Merges, As Many As Six Impossible Patents Before Breakfast: Property Rights For Business Concepts And Patent System Reform, 14 Berkeley Tech. L. J. 577 (1999).

[107] See Rebecca S. Eisenberg, Obvious To Whom? Evaluating Inventions From the Perspective of Phosita, 19 Berkeley Tech. L.J. 885, 899-900 (2004).

[108] 35 U.S.C. § 103. See also Graham v. John Deere Co., 383 U.S. 1 (1966).

[109] See Burk and Lemley, Policy Levers, supra note , at 1674.

[110] See § 112: by common law, decisions on enablement, written description, and best mode all look at whether the person of ordinary skill in the art could learn enough from the disclosure.

[111] See, e.g., Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605 (1950).

[112] Burk and Lemley, Policy Levers, supra note , at 1680.

known material from being privatized, the level of skill attributed to persons in the art could then be raised.

For example, in the spirit of another suggestion made by Rebecca Eisenberg, if the level of skill in each area were separately determined, it could be measured for nonobviousness by whether the invention exceeds what a person "with an ordinary level of inventiveness in the art" could accomplish. Furthermore, courts could consider the way research is actually conducted—with robots and other automated equipment that makes it easier to try many alternatives, and in collaborative teams, that in combination know more than any one ordinary artisan. Once it is recognized that those who choose to work in a field do so because they have a flair for it and are capable of modest imaginative stretches, and that they often work in groups that facilitate combining pieces of diverse information, the kinds of incremental developments that produce such problems as patent thickets and evergreening would become unprotectable.

Such an approach might not do too much violence to the ways in which industry is organized as it would preserve patents for significant discoveries—the ones around which most deals are likely organized. It would also preserve patenting in the arena in which university researchers are active. But would raising the inventive step through any of these approaches violate the TRIPS Agreement?

We believe that it should not. Article 27(1) requires only that member states offer protection to inventions that are they are "new, involve an inventive step and are capable of industrial application." It does not provide a precise definition of the height of that step, perhaps reflecting the fact that such assessments vary over time, among member states, and arguably even between different technologies.[113] The panel in *Canada-Pharmaceutical Patents* was reluctant to impose a controlling international norm absent a clear dictate in the Agreement and in the face of diverse national approaches.[114] Indeed, this is a place where deference to such choices is especially warranted because national scientific communities are organized and financed differently. Cultural and economic structures may either impede or facilitate collaboration; wealth affects the availability of robotics.

States should be given even greater latitude with respect to those changes that are viewed as merely fixing mistakes caused by failure to revise the standard of skill as more becomes known in the art. In our prior paper, we argued that in assessing normalcy (for the purposes of analyzing the TRIPS compatibility of exceptions to patent rights), that it was difficult to see how the position of expanded protection in 2004 has any greater claim to determine international norms than the position that existed in 1994 when the TRIPS Agreement was negotiated.[115] The proposition holds more generally. Thus,

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[113] *See* Graeme B. Dinwoodie, *Incorporating International Norms in the Development of Contemporary Copyright Law.* 62 Ohio State Law Journal 733-782 (2001)(noting that WTO panels are willing to adopt a dynamic interpretation of certain parts of the TRIPS Agreement).
[114] *See* Canada-Patent Protection of Pharmaceutical Products, *supra* note .
[115] *See* Dinwoodie and Dreyfuss, *supra* note , at __.

restoring the threshold of protection to a prior internationally-acceptable level should, we believe, have a presumptive validity in TRIPS disputes.

Of course, the gambit of "restoring prior levels of protection" might be open to abuse by member states seeking to cut patent protection to below TRIPS-mandated levels. Perhaps the concept of nonviolation complaints, which would be much harder to sustain, might provide a vehicle for the critical assessment of reforms enacted under this rubric. Admittedly, many scholars and policymakers fear that nonviolation complaints might be a Trojan horse for the further upwards expansion of international intellectual property norms. But the effect of nonviolation complaints greatly depends upon the conditions that the TRIPS Council imposes for the prosecution them.[116] Prior GATT-jurisprudence, implicitly endorsed by the Appellate Body in *India-Pharmaceutical Patents*, suggests that nonviolation complaints would be sustained only upon proof of reliance (and hence denial of legitimate expectations) and injury.[117] In formulating the terms under which a nonviolation complaint would be upheld, the TRIPS Council could also propose different burdens of proof, or require other elements to make out a complaint (such as proof of intent).[118]

b. *Scope*. As noted earlier, one action the Federal Circuit has taken is to narrow patent scope by interpreting the enablement and written description requirements in light of the knowledge of an artisan with a lamentably low level of skill in the field. Another approach, which may make better sense, especially if there is no decoupling of skill levels for scope and inventiveness, is an approach being pioneered by Germany and contemplated by Switzerland. It limits the scope of human gene sequence patents to the utility recited in the disclosure.[119]

The advantages of narrowing scope are evident. The human genome contains surprisingly few genes; each has multiple activities, many of which are poorly understood.[120] Furthermore, when the purpose is to learn more about how the human organism works, the human genome cannot be "invented around." By limiting each patentee to the utility that patentee has identified, the law creates opportunity (and patent incentives) for others to find and elucidate other biological activities associated with the patented gene. There are also reasons to prefer this approach to the Federal Circuit's. In some cases, narrowing scope by understating the level of skill in the art allows second-

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[116] In Paragraph 11(1) of the Ministerial Declaration on Implementation-Related issues and concerns, agreed at Doha on November 14, 2001, Member States directed that "The TRIPS Council . . . continue its examination of the scope and modalities for [non-violation complaints. . . . and make recommendations to the Fifth Session of the Ministerial Conference [in Cancun 2003]. It is agreed that, in the meantime, members will not initiate such complaints under the TRIPS Agreement." No resolution of the issue was reached at the Cancun Ministerial Conference

[117] *See* India-Patent Protection , *supra* note. *See also* Dreyfuss and Lowenfeld, supra note __, at 285-88.

[118] *See* Dinwoodie and Dreyfuss, *supra* note __, at __[CWRU].

[119] Ned Stafford, German Bio patent law passed, The Scientist, Dec. 10, 2004, http://www.biomedcentral.com/news/20041209/01. A similar approach is being considered in Switzerland, see Jane Burgermeister, Swiss patent proposal prompts criticism, 22 Nature Biotechnology 1323 (2004). The problem under art. 27 is greater than we think it should be under an ideal interpretation of "discrimination," see Dinwoodie and Dreyfuss, supra note __, at __ [JIEL].

[120] Nicholas Wade, Count of Human Genes Drops Again, N.Y. Times, Sec. A, p. 22, col. 3 (Oct. 21, 2004).

comers to make minor changes that allow them to compete in the patentee's primary market without having made similar investments.[121] Further, misstating the level of skill in the art diminishes the notice value of the patent claims because people in the art cannot use their actual skill to determine the metes and bounds of the invention.

Of course, narrowing the scope of patents in the manner enacted in Germany has costs. The patents envisioned by the statute could provide inadequate incentives. Proliferating patents exacerbates the problem of patent thickets, producing more work for patent offices and other researchers. Multiple patents on a single gene could also complicate cross development agreements, licensing negotiations, and other transactions.

As to TRIPS compliance, both the German and American approaches would initially be analyzed under Article 28, which delineates the rights that must be accorded a patent owner. Where the subject matter of the patent is a product, the patent confers the exclusive rights, among other things, to make or use the patented product; if the subject matter is a process, the patentee also obtains the exclusive right to use products obtained directly by that process. The TRIPS Agreement is silent on the definition of these terms, a silence that leaves the finely-grained question of scope to member states.

It is unsurprising that the TRIPS Agreement would leave scope questions to member states.[122] Scope is the ultimate locus for balancing access and incentives interests; the task is intrinsically imprecise because it requires contextually-dependent information that cannot be easily acquired. As a result, international lawmakers are not well situated to craft definitive rules on scope. Nor are national lawmakers in much of a better position. Accordingly, they must be given latitude to fashion their own approach to questions of scope.[123] Furthermore, there is little consensus among member states on issues that affect scope, including, for example, the doctrine of equivalents. It is, as the *Canada-Pharmaceutical Panel* acknowledged, not the role of dispute settlement to forge such consensus.[124]

The German approach is, however, likely to encounter a serious challenge under Article 27(1), which requires that patents be enjoyable "without discrimination … as to the field of technology." The German law limits scope (or limits patentees to process patents) only when the invention is in the field of genomics. In a previous article, we suggested that differential treatment of patentable subject matter does not always arise to a violation of Article 27. In particular, we said that a claim based on disparate treatment required proof of discriminatory intent and could be rebutted by demonstrating a

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[121] An example may be the technology at issue in Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361 (Fed. Cir. 1997), where the defendant used information that arguably was known in the art to invent around the patentee's method of recombinantly producing human growth hormone.

[122] *See* Rochelle Cooper Dreyfuss and Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*¸37 Va. J. Int'l L. 275, 305 (1997).

[123] See, e.g., Nash v. CBS, Inc., 899 F.2d 1537, 1541 (7th Cir. 1990). See also Eldred v. Ashcroft, 537 U.S. 186, 207 n.15 (2002), noting how hard it is to determine what is fair compensation or income necessary to finance particular creative enterprises; Sony Corp. v. Universal City Studios, Inc., 464 U.S. 417, 431 (1984).

[124] *See Canada-Pharmaceutical Products*, *supra* note , at ¶ __.

legitimate purpose.[125] In this case, however, the discrimination is *de jure*; there is doubt as to whether in such cases, a member state can still defend its differential treatment successfully.

Of course, it might be argued that Article 27's antidiscrimination provision applies only to the question of patentable subject matter, and not to other aspects of patent law, such as scope. There is contrary authority in the *Canada-Pharmaceutical Products* case, were a panel viewed Article 27 as structural, applying it formalistically to an exception otherwise compliant with Article 30. We took a dim view of that result, suggesting that Article 30 alone defined the conditions under which exceptions were permissible.[126] But the argument for applying Article 27 to other provisions of TRIPS is more persuasive when addressing questions of rights. These provisions could be regarded as elaborating on the basic availability of patents; in contrast Article 30 is about conditions under which member states can derogate from those rights. Furthermore, Article 30 specifies that exceptions must be limited, which is somewhat inconsistent with a requirement of technological neutrality. No such textual inconsistency is evident when Article 27 is superimposed on Article 28.

c. *Condemnation.* In its recent study of the patent system, the National Academies' Committee on Intellectual Property Rights in the Knowledge-Based Economy suggested that if the real problem is the risk that patentees will block valuable research opportunities, one solution is to use the government's authority to condemn property for public use. In the United States, this could (almost) be accomplished administratively because there is already statutory authority for the government to provide authorization and consent to a government contractor to utilize patented technology.[127] Thus, agencies funding research could simply declare the recipients of the funding to be government contractors, authorized to utilize patented inventions without permission of the patentee.[128]

Because the Constitution prohibits takings without just compensation,[129] patentees would have a right to be paid. However, under the statute, there is no right to injunctive relief. Further, the right to be paid is vindicated against the *United States*, not the party utilizing the invention; such actions are brought in the United States Court of Federal Claims. As the Committee points out, these payments are limited to "reasonable costs and fees" (which, they hint, is below market rates). Relief does not include punitive awards (such as the treble damages that are ordinarily recoverable for willful infringement).

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[125] JIEL at 436.
[126] JIEL at 443.
[127] 28 U.S.C. § 1498.
[128] A similar approach is being suggested in the United Kingdom, see Public Health Genetics Unit (UK), W.R. Cornish, M. Llewelyn, and M. Adcock, Intellectual Property Rights (IPRs) and Genetics 9, 24 (2003), http://www.phgu.org.uk/about_phgu/s-ipr1.doc (suggesting an enhanced role for Crown Use of patented materials).
[129] U.S. Constitution, Amend. V.

There are clear disadvantages to relying on this approach. It would protect only researchers whose work is funded by the federal government; it could not be used by other researchers, even if they are engaged in work of high social value. Moreover, if the Committee is right that compensation is at a below-market rate, the availability of this immunity could reduce patent value. Condemnation also has distributive consequences. Those with a taste for cutting edge technology can indulge their preferences cheaply because taxpayers—including taxpayers uninterested in innovation—pay the costs of the researcher's inputs.[130]

On the other hand, there are also some clear advantages. While it is true that only federal government researchers would benefit, the government funds a great deal of work, much of it of high social value, such as military defense research and medical research. The government also tends to award its money based on objective indicia of merit, such as competitive bidding or peer review. Much of the work accomplished on such projects have spillover benefits for other research, sometimes even for work that is rather far afield. Thus, more taxpayers may be benefiting than one might suppose. Or to put it another way, if there is reason for the government to underwrite the primary research costs, that same justification would favor funding the use of the patented inventions needed to accomplish that research. And although patentees may not be awarded a market return from the Court of Federal Claims, they would still collect more than they would under certain of the fair use regimes that are also under consideration.[131]

It is also worth noting that because of the way that the Supreme Court interprets the Eleventh Amendment, researchers at state universities already enjoy limited immunity from monetary damages.[132] Although they can presumably be sued for injunctive relief,[133] some work requires only a single use of a patented technology. Thus, there is already some capacity within the system for research to be accomplished without authorization. The Academies' recommendation essentially expands on the Supreme Court's approach, but does so in a context in which the patentee's right to compensation is clear. And it creates a more level playing field among academics.

Although the TRIPS compatibility of immunity for states has been debated,[134] whether this approach is a violation has not been considered by WTO panels. Articles 30 and 31 establish basic rules for when national law may create an exception to the exclusive rights of the patentee. Article 30 provides that exceptions from liability for patent infringement are permissible if they (a) are limited, (b) do not unreasonably

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[130] This approach could also have consequences unrelated to innovation issues, such as for the government's tort liability.

[131] See, e.g., Maureen A. O'Rourke, Toward a Doctrine of Fair Use in Patent Law, 100 COL. L. REV. 1177, 1205 (2000); see generally, Rochelle 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, 50 ADVANCES IN GENETICS 195 (F. Scott Kieff ed. 2003).

[132] Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank 527 U.S. 627 (1999); College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board, 527 U.S. 666 (1999).

[133] Ex parte Young, 209 U.S. 123 (1908).

[134] See, e.g., http://www.uspto.gov/web/offices/com/speeches/00-20.htm (announcing consideration of the *Florida Prepaid* case by the U.S. Patent and Trademark Office in a conference in 2000).

conflict with a normal exploitation of a patent, and (c) do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. Although an argument could be made that this provision would support condemnation,[135] the Academies' proposal contemplates a level of use that likely exceeds the limitations allowed.

Article 31, which is explicitly applicable to "use by the government or third parties authorized by the government," is thus the more likely focus of analysis. That provision addresses in great detail the circumstances in which a member state may subject patentees to compulsory licenses and the conditions that must be included in such licenses. It has not, however, been the subject of authoritative interpretation by a WTO panel or the Appellate Body. A significant discussion of the limits and constraints of Article 31 have played out in the debate over access to essential medicines, which found political (though uncertain legal) expression in the Doha Declaration.[136] While the need for this Declaration highlights the uncertainly surrounding the application of Article 31, none of the principles articulated in it are helpful in applying the Article in this context.

Looking at the bare text of the Articles, Eleventh Amendment immunity would appear to put the United States in a position of some vulnerability with respect to TRIPS compliance.[137] The Academies' proposal, because it offers some compensation to patentees, has more potential to pass muster. It could easily be amended to conform to other requirements, such as the obligation (absent national emergency) to first seek privately negotiated licenses.[138] But in the final analysis, it might not be possible to craft a solution that fits with all the conditions of Article 31. For example, subsection (a) requires case-by-case determinations. But part of the Academies' goal is to reduce transaction costs; determining each situation on its own merits would undermine that objective.

However vulnerable condemnation looks as against the text of Article 31, it is another question whether it is inconsistent with the policy purposes of TRIPS. In this connection, it is important to note that the TRIPS Agreement was not adopted in a trade or broader international law vacuum. International law arguments drawn from the Universal Declaration of Human Rights,[139] the Convention on Biological Diversity,[140] and international intellectual property agreements outside the scope of WTO dispute settlement,[141] should inform the analysis of Articles 30-31, and it is upon those

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[135] JIEL
[136] *See* Doha Declaration, *supra* note .
[137] *See generally* Mitchell N. Berman, R. Anthony Reese, and Ernest A. Young, *State Accountability for Violations of Intellectual Property Rights: How to "Fix" Florida Prepaid (and How Not To)*, 79 Tex. L. Rev. 1037 (2001).
[138] *See* TRIPS Agreement, *supra* note __, art. 31(b).
[139] *See* The Universal Declaration of Human Rights**,** G.A. res. 217A (III), U.N. Doc A/810 at 71 (1948)
[140] *See* Convention on Biological Diversity, June 5, 1992, U.N. Doc. UNEP/Bio.Div./N7-INC5/4, 31 I.L.M. 818 (1992); *see also* The Convention on Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs): Relationships and Synergies, Conference of the Parties to the Convention on Biological Diversity, Third Meeting, Buenos Aires, Argentina, Nov. 4-15, 1996.
[141] *See* WIPO Copyright Treaty, WIPO Copyright Treaty, Dec.20, 1996, 36 ILM 65 (1997).

arguments that the United States might have to rely to sustain statutory reform along the lines suggested by the Academies' Report.[142]

The condemnation proposal has the capacity to ameliorate some of the conditions that have threatened the domain of accessible knowledge. And, more broadly, the long-term credibility of the international intellectual property system depends in part upon its flexibility in allowing member states to fashion a balance of private and public rights in ways that accommodate its own social and economic structure. That structure has an institutional component, reflecting varied national choices as to the respective roles of private industry, the academy, and the government. When the government is funding inventions, the devices by which those inventions reach and enrich the public domain might understandably differ from the devices that are appropriate for private industry. Interpretations that constrained member states to adopt a single mix of these institutional variables, by imposing a uniform set of constraints without regard to institutional context, would effect international political reform of a much more intrusive nature than contemplated by TRIPS negotiators. Of course, the TRIPS Agreement does not draw this distinction—indeed, Article 31's explicit application to government use essentially assimilates government and private enterprises.[143] But we believe that the text of the Agreement must be infused by the general philosophy, also stated in the Agreement, that member states must have the flexibility to implement the agreement consistent with domestic political and economic structures.[144]

III. Mapping the International Domain of Accessible Knowledge

Part II discussed a variety of adaptations of patent law that might be made in order better to protect and develop the domain of accessible knowledge. In that Part, we attended both to the merits of different proposals and to their compatibility with international obligations. In effect, we have followed Pam Samuelson's lead, but we are drawing two maps of the domain of accessible knowledge—one under national law; the other under international law. Overlaying our two mappings identifies the points at which international law constrains member states from *extending* the borders of public space. Thus, we saw a depressing disconnect between the reforms best suited to achieving the intrinsic goals of patent law and the likelihood of those reforms being TRIPS-compliant. If members of the WTO are to create an effective public domain, they will need to loosen the restraints at the international frontier, and thus to allow national buttressing of the public domain. Our aggressive interpretations of the TRIPS Agreement are efforts in that direction. But states may also want to redraw the international map more radically, to use it to constrain member states from *invading* the borders of public space.

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[142] WTO panels have on occasion been willing to look to ancillary international law to assist in the interpretation of the WTO Agreements, including in TRIPS Disputes. *See* United States–Section 110(5), *supra* note .

[143] *See* Daniel Gervais, The TRIPS Agreement: Drafting History and Analysis 242, 250 n.9 (1998).

[144] *See* TRIPS Agreement, *supra* note __, art. 1(1); Gervais, *supra* note 97, at 92; India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/D550/AB/R, ¶ 59 (Report of the Appellate Body, 1997). See also *Canada-Pharmaceutical Products*, *supra* note , at ¶ __.

Each of the approaches to protecting the public domain analyzed in Part II revealed an obstacle that international law imposes; an obstacle that must be overcome if states are to have the latitude they need to protect public interests. First, the availability of a procedure for lodging disputes, while an important innovation of the TRIPS Agreement, is making the threat of challenge *too* credible, chilling national attempts to keep their laws responsive to changing technology. Second, the Agreement is interpreted formalistically, creating obligations that may not have been intended by the member states. Third, the Agreement—and decisions interpreting it—lack normative content, making it difficult for member states to ground arguments for protecting public access.

The first problem was demonstrated in our discussion of nonobviousness. Raising the inventive step ought to be easy, especially if it restores pre-TRIPS thresholds of protection. However, a country seeking to make such a move is likely to encounter resistance from pro-patent interests, claiming that the change would violate the TRIPS Agreement. Such a move could be made presumptively valid, but offering such a presumption might lend itself to abuse by countries seeking to deny patent protection altogether. Thus, we suggested that the TRIPS Council adopt conditions for bringing nonviolation complaints that would raise the threshold for challenging certain adjustments to the level of protection. By requiring the complainant to establish elements (such as intent) which are absent in the context of violation complaints, member states would gain breathing room to experiment.[145]

Our examination of patent scope showed the disjuncture produced by formalism. We saw that the American approach to narrowing patent claims is probably unobjectionable under TRIPS, while the German provision—which is likely to work better as a matter of patent policy—is extremely vulnerable to challenge. The discordance is produced by the way in which the requirement of technological neutrality is assessed, which is wholly out of step with the way states actually apply their laws. That is, although domestic patent laws read trans-substantively (in that the same terminology typically applies to all fields), many of the provisions are malleable. Treated empirically, "the person with ordinary skill in the art" clearly results in field-to-field or state-to-state differences; arguably, it is sometimes also regarded as a term of art, in which case it is explicitly interpreted to pursue technology-specific goals. To allow states to maintain these traditions, the formalism of Article 27 must be relinquished in favor of an interpretation that permits states to justify actions that distinguish among fields. For example, Germany should be allowed to counter a challenge to its special treatment of gene sequences by demonstrating why narrowing scope is uniquely necessary in biotechnology. Alternatively, the antidiscrimination principle should be read as confined to the core focus of art. 27 (patentable subject matter), leaving Germany's provision to be assessed solely under Article 28 (scope).

The normative vacuum can be discerned in the analysis of condemnation. Admittedly, Article 31 of TRIPS is intended to regulate national condemnation of patent rights. However, the scope of discretion left to member states is ambiguous and insufficient. Our exploration of the National Academies' proposal demonstrated as

[145] See *supra* text accompanying notes at .

much; the rigidity of Article 31 is equally evident in the post-TRIPS debate over access to essential medicines.[146] In part, the problem is, once again, procedural inflexibility (case by case determinations are not, for example, always feasible). But the suffocating detail of Article 31 is also evidence of the framers' lack of foresight. The provision leaves states unable to address new problems because the text of the Article provides little guidance on when it is reasonable for governments to intervene. And while Article 30 also permits a state to enact exceptions to rights, and even uses terms like "normal" and "unreasonable," our previous work showed that decisionmakers are not evaluating challenges from a normative perspective, even when invited to do so.[147] The Doha Declaration provides a template for reconfiguring these provisions because it recognizes the need for flexibility and explicitly refers to "public international law." Thus, it provides a basis for using a rich set of principles to justify actions that preserve the public domain in the face of technological change.

But even if the constraints of international law are lifted or loosened, it can be argued that international intellectual property law should be framed to do more, that it should be viewed not only as an obstacle to be overcome, but also as an affirmative protection of the public domain against encroachments by member states. In fact, there is a basis for such efforts in the TRIPS Agreement: Article 7 takes account of *both* the producers and users of technological knowledge and seeks a *balance* of rights and obligations, while Article 8 specifically invokes the public interest, including health and nutrition, as objectives to be pursued in formulating national laws. However, these provisions have not received much attention. Indeed, the *Canada-Pharmaceutical Products* Panel warned against resort to these articles, on the theory that their use would alter the deal struck in the Uruguay Round.[148] The Panel apparently missed the point that the core function of intellectual property law is to pursue a balance of interests.

Thus, while it may be true that scientists have long appreciated that the public domain is more than a place where old intellectual property goes to die, they need to impress their views on international patent scholars and lawmakers. Indeed, advocates would do well to draw on the developing discourse in copyright, which has placed the value of a strong public domain at the center of the debate. Rooting protection in the affirmative case would accomplish several goals. TRIPS adjudicators might more readily resort to broader principles of international law and intellectual property theory, including the "Objectives" and "Principles" of the Agreement laid out in Articles 7 and 8. More important, borrowing the terms of the commodification debate in copyright and articulating a positive case for access interests would reframe the next round of TRIPS negotiations. It would provide a theoretical basis for constructing an *internationally* accessible domain of knowledge.

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[146] Doha, see *supra* note . In the case of essential medicines, the core problem was subsection (f), which only allowed member states to authorize manufacture for domestic use, which failed to address the needs of countries that lacked manufacturing capacity.
[147] JIEL at 438-43.
[148] Canada-Pharmaceutical Products, ¶ 7.26.

In essence, this move would entail development of what we have separately called "substantive maxima" or "users' rights."[149] The seeds for such a shift can be found in a variety of existing international sources. Article 2(8) of the Berne Convention provides that "the protection of this Convention shall not apply news of the day or to miscellaneous facts having the character of mere items of press information;" Article 5(1) of the Information Society Directive mandates an exception for ephemeral copies; and Article 5 of the Software Directive requires states of the EU to permit decompilation of a program to obtain interoperability information. Extrapolating these examples into a general philosophy of user rights would bring international intellectual property law full circle and secure to the public protection that mirrors the rights that innovators enjoy under the Berne and Paris Conventions.

CONCLUSION

The public domain of science is likely shrinking, but more through the effects of technological change than through legal efforts to privatize culture. International law heavily circumscribes the capacity to redraw the public/private boundaries in ways that ensure an optimal public domain. Scholars might thus view international law as an obstacle around which national patent policymakers must navigate. But the function of international intellectual property law should be conceptualized more broadly. Informed by the value of a strong domain of accessible knowledge, international law could help member states resist scientific and technological commodification.

[149] Graeme B. Dinwoodie, Federalized Functionalism: The Future of Design Protection in the European Union, 24 Am. Intell. Prop'y L. Ass'n Q. J. 611, 715 n.274 (1996); Rochelle Cooper Dreyfuss, TRIPS-Round II: Should Users Strike Back?, 71 U. Chi. L. Rev. 21 (2004).