

Tailoring the Patent System for Specific Industries

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Summary

Congressional interest in the patent system has been demonstrated by the enactment of the Leahy-Smith America Invents Act (AIA) in the 112th Congress. Most of the provisions of the AIA apply to any type of patented invention, whether it consists of a chemical compound, mechanical device, electrical circuit, or other technology. However, other AIA provisions are specific to particular types of inventions, including business methods, tax strategies, and human organisms. The AIA reflects the principle that, for the most part, patentable inventions are generally subject to the same statutory provisions. However, a number of exceptions exist to this concept of technological neutrality.

This blended architecture has for many years prompted inquiry into whether the patent system operates best as a uniform system that applies neutrally to all inventions, or whether it could or should be tailored to meet the specific needs of different industries. Technologies and industrial sectors arguably differ in ways salient to the patent system. Among these distinctions are the costs and risks of research and development, the availability of trade secret protection as an effective alternative to patenting, the number of patents that cover a particular product, and the patterns of patent acquisition and enforcement of firms within that sector. The patent system involves a number of parameters that could potentially be adjusted to meet the needs of individual sectors, including the speed with which applications are reviewed, the scope of exclusive rights afforded by a patent, and the term of the patent.

While some observers suggest the desirability of sector-specific patent principles, others believe them to be infeasible and unwise. They observe that legislative efforts to define particular industries may prove difficult, that attorneys may sometimes be able to draft patents artfully so as to fall within a favored category, and that U.S. industry is dynamic and resistive to a static statutory definition. In addition, U.S. membership within the World Trade Organization (WTO) may limit the ability to tailor the patent system to account for different industries and inventions, to the extent that compliance with WTO standards is desired. The WTO-administered Agreement on Trade-Related Aspects of Intellectual Property, or TRIPS Agreement, in part requires WTO member states to make patent rights available without discrimination as to the field of technology. The TRIPS Agreement admits some exceptions exist to this principle of technological neutrality, however.

Should Congress believe current circumstances to be appropriate, then no action need be taken. To the degree WTO compliance is desired, Congress could also legislate along the lines permitted by the TRIPS Agreement. Notably, although the TRIPS Agreement generally disallows discrimination with respect to technological fields, it permits distinctions on other grounds. Congress could also make use of regulatory exclusivities and other complementary intellectual property rights that the TRIPS Agreement regulates less heavily.

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Introduction

The recent enactment of the Leahy-Smith America Invents Act (AIA)[1] demonstrates congressional interest in the patent system. Most of the provisions of the AIA apply to any type of patented invention. For example, the first-inventor-to-file priority system,[2] prior user rights,[3] and post-grant and *inter partes* review proceedings[4] apply equally to chemical compounds, electrical appliances, mechanical devices, and any other invention that may be protected by a patent. However, other AIA provisions are specific to particular types of inventions. That statute limited the availability of patents on tax strategies,[5] prohibits the issuance of patents claiming human organisms,[6] and creates "transitional proceedings" that apply exclusively to patents pertaining to business methods.[7] The AIA also allows "prioritization of examination of applications for products, processes, or technologies that are important to the national economy or national competitiveness.... "[8]

The AIA reflects the principle that, for the most part, the U.S. patent system operates in a uniform manner. All patentable inventions are generally subject to the same statutory provisions.[9] A number of exceptions exist to this concept of technological neutrality, however. For example, statutory provisions limit the enforceability of patents claiming methods of medical treatment;[10] call for patent term extension for certain products regulated by the Food and Drug Administration (FDA);[11] and establish specialized patents for designs and plants.[12]

This blended architecture has for many years prompted inquiry into whether the patent system operates best as a uniform system that applies neutrally to all inventions, or whether it could or should be tailored to meet the specific needs of different industries.[13] Commentators have proposed, for example, that software patents should receive shorter terms than patents on other inventions,[14] and that patents on genes should be subject to compulsory licenses that allow individuals to use the patented technology upon paying a license fee.[15] Unenacted legislation in

[1] P.L. 112-29, 125 Stat. 284 (2011). See CRS Report R42014, *The Leahy-Smith America Invents Act: Innovation Issues*, by Wendy H. Schacht and John R. Thomas.

[2] Ibid. at § 3.

[3] Ibid. at § 5.

[4] Ibid. at § 6.

[5] Ibid. at § 14.

[6] Ibid. at § 33.

[7] Ibid. at § 18.

[8] Ibid. at § 25.

[9] Clarisa Long, "Our Uniform Patent System," 55 *The Federal Lawyer* (2008), 44.

[10] 35 U.S.C. § 287(c).

[11] 35 U.S.C. § 156.

[12] 35 U.S.C. §§ 161, 171.

[13] Michael W. Carroll, "One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights," 70 *Ohio State Law Journal* (2009), 1361.

[14] Mark H. Webbink, "A New Paradigm for Intellectual Property Rights in Software," *Duke Law & Technology Review* (2005), 12.

[15] Daniel M. Lorentzen, "Do These Genes Fit? Genes as Patentable Subject Matter," 60 *Drake Law Review* (2012), 933.

the 112th Congress, H.R. 6245, proposed patent litigation reforms that would apply to patents claiming computer software and hardware, but not to other sorts of inventions.

Notably, U.S. membership in the World Trade Organization (WTO) may influence congressional willingness to promulgate industry-specific patent statutes. One component of the WTO agreements, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),[16] requires patents to be available and enforceable "without discrimination as to ... the field of technology...."[17] Although the TRIPS Agreement allows for some limited exceptions to this rule of technological neutrality,[18] one consequence of U.S. membership in the WTO may be a restricted ability to tailor the patent statute to particular inventions and industries.[19]

This report considers the possibility of modifying the U.S. patent system to meet the needs of specific industries. After providing a brief review of the patent system, the report identifies different industrial traits, such as the pace of innovation, product cycle, and the cost of research and development, which potentially suggest the desirability of tailored patent rights. It then considers possible points of adjustment within the patent system, including patent term, scope of exclusive rights, and the availability of remedies for infringement. The report then discusses potential difficulties associated with distinguishing among industries within the patent system, including the provisions of the TRIPS Agreement. The report closes with concluding observations.

Patent Fundamentals

The patent system covers a broad variety of inventions.[20] U.S. patents cover traditional subject matter such as machines, pharmaceuticals, and manufacturing processes, along with high-tech inventions in the fields of biotechnology, computer software, and nanotechnology. No matter what the sort of technology, however, the patent system in large measure operates under the same general principles.

In particular, all inventors who wish to obtain patent rights must file an application at the U.S. Patent and Trademark Office (USPTO). USPTO examiners then review the application to ensure that certain statutory requirements are met. These statutory requirements—including that the invention be adequately described in the patent application,[21] and that the invention must not have been obvious to a skilled artisan[22]—apply to every invention for which a patent is sought. Similarly, once a patent has issued, the statutory term is set uniformly to 20 years from the date of filing no matter what the type of invention.[23] All patents received the identical exclusive rights—

[16] Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (1994).

[17] Ibid. at Art. 27.

[18] Ibid.

[19] Dan L. Burk & Mark A. Lemley, "Is Patent Law Technology-Specific?," 17 *Berkeley Technology Law Journal* (2002) 1155.

[20] 35 U.S.C. § 101 (patents available on machines, manufactures, compositions of matter, and processes).

[21] 35 U.S.C. § 112(a).

[22] 35 U.S.C. § 103.

[23] 35 U.S.C. § 154(a)(2).

namely, the right to prevent others from making, using, selling, offering to sell, or importing the patented invention in the United States.[24]

Some exceptions exist to this general notion of standardization. The United States has long provided for the protection of industrial designs through so-called "design patents."[25] The Patent Law Treaties Implementation Act of 2012, P.L. 112-211, recently caused U.S. law to conform to the Hague Agreement Concerning the International Registration of Industrial Designs, the leading international agreement on these specialized rights. The United States also established two sorts of intellectual property rights for plants: plant patents, which are administered by the USPTO;[26] and plant variety protection certificates, which are administered by the Department of Agriculture.[27] In addition, the Hatch-Waxman Act extends the terms of patents covering pharmaceuticals, medical devices, and other products which are subject to premarketing approval by the FDA.[28] As well, over the years private legislation has increased the terms of a number of particular patents.[29]

Further, some commentators observe that the statutory provisions for patents are stated fairly generally. In their view, these broad parameters provide courts and the USPTO with some ability to recognize the diverse characteristics of distinct technologies and tailor their rulings accordingly.[30] For example, one core patentability requirement is that the invention must not have been obvious to a person of ordinary skill in the art.[31] The courts have arguably developed nuanced obviousness principles that take into account whether the invention falls within a predictable art, including many mechanical and electrical inventions, as compared to a less predictable art, such as some branches of chemistry and biotechnology. Inventions within these latter, less predictable arts may possibly be more readily able to satisfy the obviousness requirement and therefore are more likely to be patented.[32]

Despite these exceptions, the Patent Act of 1952, as amended by such legislation as the American Inventors Protection Act[33] and AIA, is generally worded in a neutral fashion.[34] The uniform treatment provided by the patent system may be contrasted with the diversity of the technologies and industries to which patents pertain, however, a topic this report takes up next.

[24] 35 U.S.C. § 271(a).

[25] 35 U.S.C. § 171-173.

[26] 35 U.S.C. §§ 161-164.

[27] 7 U.S.C. §§ 2321-2582.

[28] 35 U.S.C. § 156. See CRS Report R41114, *The Hatch-Waxman Act: Over a Quarter Century Later*, by Wendy H. Schacht and John R. Thomas.

[29] See CRS Report RS21129, *Pharmaceutical Patent Term Extensions: A Brief Explanation*, by Wendy H. Schacht and John R. Thomas.

[30] Dan L. Burk and Mark A. Lemley, "Policy Levers in Patent Law," 89 *Virginia Law Review* (2003), 1575.

[31] 35 U.S.C. § 103(a).

[32] See Briana Barron, "Structural Uncertainty: Understanding the Federal Circuit's Lead Compound Analysis," 16 *Marquette Intellectual Property Law Review* (Summer 2012), 401.

[33] P.L. 106-113.

[34] Michael W. Carroll, "One for All: The Problem of Uniformity Cost in Intellectual Property Law," 55 *American University Law Review* (2006), 845.

The Role of Patents Within Different Industries

Commentators have for many years recognized that technologies and industries vary in ways that are salient to the patent system. In particular, the costs and risks of conducting R&D differ widely among industries. Arguably the patent incentive should be greater for innovative efforts that are expensive and more likely to fail.[35] Similarly, some sectors are marked by stand-alone, discrete advances, while others feature steady, cumulative innovation. Firms that operate within the latter sorts of industries may have greater need to access technologies invented and patented by others.[36]

As well, product cycles also vary markedly across the U.S. economy. For example, patients may use a particular pharmaceutical for decades, even as consumers quickly discard their old mobile telephones and other electronics in favor of new devices. Industries with compact product cycles may be better served by short application pendency periods at the USPTO and also may be less concerned with lengthy terms of patent protection.[37]

Still another factor may be the practical availability of trade secret protection.[38] Competitors may readily reverse engineer many electrical and mechanical products, for example. Firms within these industries must therefore seek patent rights or enjoy no effective intellectual property rights whatsoever. On the other hand, certain chemical and biotechnology inventions may be more plausibly maintained as trade secrets. Arguably greater encouragement is needed for public disclosure of chemical and biological inventions through the patent system.[39]

The number of patents that cover a particular product also varies widely among industry. Within the pharmaceutical industry, often only a handful, and sometimes only one or two patents cover an individual drug. In contrast, numerous patents may cover a particular electronics product. As RPX Corporation, a self-described "comprehensive patent risk management firm," explains:

> Modern products and services incorporate numerous technology components. The evolution of mobile devices provides an example. Based on our research, we believe there are more than 250,000 active patents relevant to today's smartphones, a significant increase compared to our estimate of approximately 70,000 patents that were active and relevant to mobile phones in 2000. This growth can be attributed to the expanded set of features and functionality incorporated in today's smartphones, including touchscreens, internet access, streaming video, media playback, application store readiness and other web-based services, and WiFi connectivity options.[40]

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[35] For discussion of how the features of a patent system might pertain to R&D costs, see Robert M. Hunt, "Economics and the Design of Patent Systems," 13 *Michigan Telecommunications & Technology Law Review* (Spring 2007), 457.

[36] See Mark A. Lemley, "The Myth of the Sole Inventor," 110 *Michigan Law Review* (2012), 709 (discussing how cumulative innovation witnessed in many industries may impact patent law principles).

[37] See Sarah A. Geers, "Common Sense and the Fact Finder Without Skill in the Art: The Role of Objective Evidence in Achieving Proper Technology Specificity," 40 *Seton Hall Law Review* (2010), 425 (discussing patent system design in relation to distinct industry product cycles).

[38] See CRS Report R41391, *The Role of Trade Secrets in Innovation Policy*, by John R. Thomas.

[39] For a general discussion of the relationship between patents and trade secrets, see J. Jonas Anderson, "Secret Inventions," 26 *Berkeley Technology Law Journal* (2011), 917.

[40] See Daniel O'Connor, "One in Six Active U.S. Patents Pertain to the Smartphone," Disruptive Competition Project (Oct. 17, 2012) (available at http://www.project-disco.org/intellectual-property/one-in-six-active-u-s-patents-pertain-to-the-smartphone/).

These "vast disparities in patent-to-product" ratios may influence the perceptions of different business enterprises over the value of individual patents as compared to larger portfolios of intellectual property rights.[41]

Another arguable distinction among industries is the detectability of patents that are pertinent to particular products.[42] Fields such as small-molecule chemistry employ an internationally recognized, standardized nomenclature to identify the composition of a particular compound. As a result, firms within the agricultural, industrial, and pharmaceutical chemical industries may enjoy some confidence that they will be able to identify patents that are relevant to products they wish to sell.[43] In contrast, fields such as software arguably have yet to develop a standardized terminology for identifying programs, procedures, algorithms, and other sorts of machine instructions. The lack of conventions for identifying software inventions potentially impacts the patent system, arguably making the identification of pertinent patents difficult for firms in the computer industry.[44]

Implications for the Patent System

In view of these and possibly other distinctions between technologies and markets, policymakers may not be particularly confident that a one-size-fits-all patent system ideally encourages innovation throughout a diverse array of industries.[45] Observers have for many years suggested that the statute distinguish among the varying inventions and industries for which patents are available. In theory, many aspects of the patent system could be tailored to reflect the needs of distinct technology sectors. Some possible points of adjustment include:

- The speed with which the USPTO reviews patent applications could be adjusted to meet the needs of industries with varying product cycles.
- Patents could be more difficult to obtain within some fields than others depending upon the perceived need of the patent incentive to encourage innovation.
- Patents on inventions capable of being protected by trade secrets in whole or in part—for example, biotechnologies or chemical processes—might be required to have more complete technical disclosures in order to allow others to practice the invention expeditiously.
- The term of protection could vary among technologies depending upon the pace of innovation within particular fields.

[41] Graeme B. Dinwoodie and Rochelle C. Dreyfuss, "Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement," 13 *Michigan Telecommunications & Technology Law Review* (2007), 445.

[42] See James Bessen and Michael J. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovation at Risk* (Princeton University Press 2008), 46-72.

[43] See Christa J. Laser, "A Definite Claim on Claim Indefiniteness: An Empirical Study of Definiteness Cases of the Past Decade with a Focus on the Federal Circuit and the Insolubly Ambiguous Standard," 10 *Chicago-Kent Journal of Intellectual Property* (2010), 25.

[44] Ibid.

[45] Dan L. Burk and Mark A. Lemley, "Is Patent Law Technology-Specific?," 17 *Berkeley Technology Law Journal* (2002) 1155.

- The scope of exclusive rights could be adjusted in order to immunize select individuals or enterprises—such as physicians or universities—from liability for patent infringement.
- Compulsory licenses could be made available for categories of patented inventions perceived to fulfill an important public need—for example, healthcare or environmental technologies—thereby allowing third parties to use the invention without the permission of the patent proprietor.

Congress has implemented some of these technology-specific measures. Among other examples, the Hatch-Waxman Act extends the terms of patents covering pharmaceuticals, medical devices, and other products which are subject to premarketing approval.[46] Congress also imposed restrictions upon the enforceability of patents claiming medical procedures.[47] Specialized patent rights exist both for industrial designs and plants.[48]

More recently, the deliberations that led to the enactment of the Leahy-Smith America Invents Act (AIA)[49] again placed focus upon the role of the patent system within different industries. One topic that focused attention upon these distinctions concerned the award of remedies when firms or individuals are found to infringe patents. Broadly speaking, the patent law allows courts to award two sorts of remedies against infringers: (1) injunctions, or court orders requiring an entity to cease future infringements;[50] and (2) damages, consisting of an award of money to compensate patent proprietors for financial losses suffered due to infringements.[51] The legislative history of the AIA reveals that certain representatives of the pharmaceutical and information technology sectors often held different views about the state of the law of patent remedies.[52]

With respect to injunctions, prior to 2006 courts would virtually always enjoin an adjudicated infringer from future practice of the patented invention. Some observers—particularly those from the information technology sector—believed that this "automatic injunction" rule was particularly unfair when the patented invention supported a single function in a multifunctional product, such as an automobile, smart phone, or computer software.[53] They also believed that this rule encouraged the assertion of patents of dubious quality and offered patent proprietors too much leverage during licensing and settlement negotiations.[54] However, other observers—primarily from the pharmaceutical sector—asserted that absent the award of an injunction, competitors would not respect the exclusive rights afforded by a patent.[55]

[46] 35 U.S.C. § 156.

[47] 35 U.S.C. § 287(c).

[48] 35 U.S.C. §§ 171-173 (designs); 35 U.S.C. §§ 161-164 (plants).

[49] P.L. 112-29, 125 Stat. 284 (2011).

[50] 35 U.S.C. § 283.

[51] 35 U.S.C. § 284.

[52] See CRS Report RL33367, *Patent Reform: Issues in the Biomedical and Software Industries*, by Wendy H. Schacht.

[53] See Lea Shaver, "Illuminating Innovation: From Patent Racing to Patent War," 69 *Washington & Lee Law Review* (2012), 1891.

[54] Nicholas P. Chan, "Balancing Judicial Misvaluation and Patent Hold-Up: Some Principles for Considering Injunctive Relief After *Ebay*," 59 *UCLA Law Review* (2012), 746.

[55] Paul M. Schoenhard, "Who Took My IP? Defending the Availability of Injunctive Relief for Patent Owners," 16 *Texas Intellectual Property Law Journal* (2008), 187.

A predecessor, unenacted version of the AIA, the Patent Reform Act of 2005,[56] proposed changes to the principles governing injunctions in patent law. Section 7 of that bill provided that in deciding whether to issue an injunction or not, "the court shall consider the fairness of the remedy in light of all the facts and the relevant interests of the parties associated with the invention." Perhaps because of the discordant view of different patent stakeholders as to the availability of injunctions in the patent community, this provision was identified as one of the most controversial within the bill.[57]

While debate about congressional action with respect to injunctions in patent law continued, the Supreme Court issued its decision in *eBay Inc. v. MercExchange, L.L.C.* in 2006.[58] There the Court unanimously held that an injunction should not automatically issue based on a finding of patent infringement. Under the *eBay* ruling, courts must weigh equitable factors traditionally used to determine if an injunction should issue, including whether the patent proprietor suffered an irreparable injury; the award of damages would be inadequate to compensate for that injury; that considering the balance of hardships between the patent owner and infringer, an injunction is warranted; and that the public interest would not be disserved by a permanent injunction.[59]

Following the *eBay* decision, Congress did not include legislative provisions concerning injunctive relief in the AIA. Some commentators believe that the Supreme Court struck an appropriate balance by addressing concerns of information technology firms that were concerned that patent holders would assert their rights after the launch of a commercially successful product in an effort to extort an unreasonably large royalty using the threat of an injunction; but also recognized that most often a prevailing patent holder would be awarded an injunction.[60] Further, the early prediction that "the biotech and pharmaceutical industries have little to fear in the post-*eBay* world"[61] appears to have been correct, for the great majority of judicial decisions declining the award of a permanent injunction have concerned information technology patents.[62]

A second, arguably divisive issue between the information technology and pharmaceutical industries pertains to damages. Marketplace realities often render the determination of an appropriate damages award a difficult affair in patent litigation. In some cases, the product or process that is found to infringe may incorporate numerous additional elements beyond the patented invention. For example, the asserted patent may relate to a single component of a touch screen display, while the accused product consists of an entire smartphone. In such circumstances, a court may apply "the entire market value rule,"[63] which "permits recovery of damages based upon the entire apparatus containing several features, where the patent-related feature is the basis

[56] H.R. 2795, 109th Congress.

[57] George H. Pike, "The Next Step in Patent Reform," 28 *Information Today* no. 10 (Nov. 1, 2011), 1.

[58] 547 U.S. 388 (2006).

[59] See Mark P. Gergen *et al.*, "The Supreme Court's Accidental Revolution: The Test for Permanent Injunctions," 112 *Columbia Law Review* (2012), 203.

[60] William C. Rooklidge and Alyson G. Barker, "Reform of a Fast-Moving Target: The Development of Patent Law Since the 2004 National Academies Report," 91 *Journal of the Patent and Trademark Office Society* (2009), 153.

[61] Michael Beylkin, "Much Ado About Nothing: The Biotech and Pharmaceutical Industries Have Little to Fear in the Post-*eBay* World," 6 *Journal of Telecommunications & High Technology Law* (2007), 179.

[62] See University of Houston Law Center, *PatStats: U.S Patent Litigation Statistics* (available at http://www.patstats.org).

[63] LaserDynamics, Inc. v. Quanta Computer, Inc., 694 F.3d 51 (Fed. Cir. 2012).

for consumer demand."[64] On the other hand, if the court determines that the infringing sales were due to many factors beyond the use of the patented invention, the court may apply principles of "apportionment" to reach a just measure of damages for infringement.[65]

Some believe that current damages standards have resulted in the systemic overcompensation of patent owners.[66] Such overcompensation may place unreasonable royalty burdens upon producers of high technology products, ultimately impeding the process of technological innovation and dissemination that the patent system is meant to foster. Others believe that current case law appropriately accounts for apportionment concerns. These observers are concerned that this reform might overly restrict damages in patent cases, thereby discouraging voluntary licensing and promoting infringement of patent rights. Limited damage awards for patent infringement might prevent innovators from realizing the value of their inventive contributions, a principal goal of the patent system.[67]

As discussion of damages reform has proceeded before Congress, the courts have also been active. One of the more notable cases on patent damages principles arose from the efforts of Lucent Technologies, Inc., to enforce its so-called "Day patent," which related to a method of entering information into fields on a computer screen without using a keyboard.[68] In 2002, Lucent brought an infringement suit against computer manufacturer Gateway, Inc., asserting that certain pre-installed Microsoft software infringed the Day patent. At trial, the jury found the Day patent not invalid and infringed. Lucent sought damages of $561.9 million based on 8% of Microsoft's infringing sales, while Microsoft asserted "that a lump-sum payment of $6.5 million would have been the correct amount for licensing the protected technology." The jury then awarded Lucent a single lump-sum amount of $357.7 million.[69]

The litigation in *Lucent v. Gateway* captured the attention of many observers. In a March 3, 2009, letter addressed to Senator Patrick Leahy, Senator Arlen Specter requested a delay in Senate action on the pending patent reform bill until the Federal Circuit heard oral argument in the case.[70] Observing a "symbiotic relationship between the judicial and legislative branches with regard to changes to the patent system," Senator Specter believed that "oral argument has the potential to facilitate a compromise or clarify the applicability of damages theories in various contexts."[71]

In its subsequent decision, the Federal Circuit upheld the lower court's determination that the Day patent was not invalid and infringed. In the most anticipated portion of the opinion, the appellate court also struck down the jury's damages award as not supported by substantial evidence.[72]

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[64] State Industries, Inc. v. Mor-Flo Industries, Inc., 883 F.2d 1573 (Fed. Cir. 1989).

[65] See LaserDynamics v. Quanta, *supra*.

[66] See Amy L. Landers, "Let the Games Begin: Incentives to Innovation in the New Economy of Intellectual Property Law," 46 *Santa Clara Law Review* (2006), 307.

[67] See William C. Rooklidge, "Reform of the Patent Laws: Forging Legislation Addressing Disparate Interests," 88 *Journal of the Patent and Trademark Office Society* (2006), 9.

[68] Lucent Technologies, Inc. v. Gateway, Inc., 580 F.3d 1301 (Fed. Cir. 2009).

[69] Ibid. at 1308.

[70] The letter is available at http://www.fr.com/files/uploads/attachments//patentdamages//03-03-09-Specter-to-PJL-Patents.pdf.

[71] Ibid.

[72] 580 F.3d at 1335.

Some commentators have viewed the lengthy opinion as doing much to dampen speculative damages awards, particularly with respect to patents from the information technology sector.[73] Following that opinion, Lucent and Microsoft have reportedly settled the litigation.[74] Of broader interest, Congress also chose not to address damages for patent infringement within the AIA.

The timely issuance of *eBay* and *Lucent v. Gateway* may have contributed to congressional belief that courts were appropriately addressing injunctions and damages, respectively. As a result, Congress did not endeavor to reconcile the perceived needs of industries with different innovation and marketplace environments. Another legislative possibility, at least in theory, was to enact distinct remedial rules for different categories of inventions. This report next explores whether industry-specific rules are a practical possibility for patent legislation.

The Feasibility of Sector-Specific Patent Rules

In view of the concerns noted above, commentators have gone so far to say that "it has become increasingly difficult to believe that a one-size-fits-all approach to patent law can survive."[75] To the extent the current patent system creates a blanket set of rules that apply comparably to distinct industries, it likely over-encourages innovation in some contexts and under-incentivizes it in others.[76] Further, some observers have asserted that the need of firms to identify and access the patented inventions of others may differ among industries.[77] As a result, the case can be made that distinct industrial, technological, and market characteristics that exist across the breadth of the U.S. economy compel industry-specific patent statutes.

However, others have questioned the wisdom and practicality of such line-drawing.[78] The following concerns, among others, have been identified:

- Over its long history, the U.S. patent system has flexibly adapted to new technologies such as biotechnology and computer software. Legislative adoption of technology-specific categories may leave unanticipated, cutting-edge technologies outside the patent system.[79]
- Defining a specific industry or category of technologies may prove to be a contested proposition.[80]
- Over time, new industries may emerge and old industries may consolidate. The dynamic nature of the U.S. economy suggests greater need for legislative oversight within a differentiated patent regime.[81]

[73] See Bo Zeng, "*Lucent v. Gateway:* Putting the "Reasonable" Back into Reasonable Royalties," 26 *Berkeley Technology Law Journal* (2011), 329.

[74] "Microsoft and Alcatel-Lucent Settle Patent Dispute," *Computer News Middle East* (Jan. 19, 2012).

[75] Dreyfuss and Dinwoodie, *supra*.

[76] See Alan Devlin, "Patent Law's Parsimony Principle," 25 *Berkeley Technology Law Journal* (2010), 1693.

[77] See Alan Devlin, "Systematic Bias in Patent Law," 61 *DePaul Law Review* (2011), 57.

[78] See Luigi Orsenigo and Valerio Sterzi, *Comparative Study of the Use of Patents in Different Industries*, Knowledge, Internationalization and Technologies Studies Working Paper 33/2010 (2010).

[79] Ibid.

[80] See Lewis Kaplow, "Why (Ever) Define Markets?," 124 *Harvard Law Review* (2010), 437.

[81] Burk and Lemley, *supra*.

- Even if an industry or technology remains relatively stable, the innovation environment within it might change. For example, technological or scientific advances might open new possibilities for research and development within hidebound industries—but also increase expense and risk for those firms.[82]
- Distinct patent rights among industries or technologies may lead to strategic behavior on behalf of patent applicants. For example, a computer program that controls a fuel injector within an automobile could possibly be identified as either an automobile-related or a computer-related invention.[83]
- The legislative effort to enact sector-specific patent laws may provide an opportunity for politically savvy firms to exert more lobbying and political power, at the possible expense of less sophisticated firms.[84]

In addition to these practical concerns, U.S. membership in the World Trade Organization (WTO) may restrict congressional ability to tailor the patent system to account for different industries and inventions, to the extent that compliance with WTO standards is desired. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) is a WTO-administered treaty that stipulates minimum standards for many forms of intellectual property protection.[85] Article 27, paragraph one of the TRIPS Agreement expressly provides that, with some exceptions, "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

At the time it was drafted, the TRIPS Agreement standard of technological neutrality was arguably intended to provide for patent protection for a variety of inventions for which patents were previously unavailable in many countries.[86] For example, certain jurisdictions did not allow patents to issue on pharmaceuticals and agricultural chemicals prior to joining the WTO. The wording of Article 27.1 appears to have broader implications than merely requiring WTO member states to grant patents on pharmaceuticals and other previously unpatentable inventions, however. Its principle of nondiscrimination seems broadly to require that all inventions in all fields of technology be treated identically—a reading that would block, for example, discriminating in favor of particular inventions as well as against them.[87]

Article 27 expressly permits some limited exceptions to this concept of homogeneity. In particular, WTO members may exclude from patentability inventions whose commercial exploitation would violate the public order or morality. However, inventions may not be exempted from patentability merely because their use is illegal.[88] In addition, diagnostic,

[82] Orsenigo and Sterzi, *supra*.

[83] See Kristen Osenga, "The Shape of Things to Come: What We Can Learn About Patent Claim Length," 28 *Santa Clara Computer & High Technology Law Journal* (2012), 617.

[84] Burk and Lemley, *supra*.

[85] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

[86] See Robert Weissman, "A Long, Strange Trips: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries," 17 *University of Pennsylvania Journal of International Economic Law* (1996), 1069.

[87] See Rebecca S. Eisenberg, "The Role of the FDA in Innovation Policy," 13 *Michigan Telecommunications & Technology Law Review* (2007), 345.

[88] TRIPS Art. 27.2.

therapeutic, and surgical methods may also be excluded from patentability.[89] In addition, WTO member states may deny patents on "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes." However, if a WTO member state opts to do so, it must protect plant varieties through an alternative specialized system, typically known as "plant breeder's rights."[90] In addition, the TRIPS Agreement allows for "security exceptions" that permit WTO members to take any action considered necessary for the protection of "essential security interests."[91]

In addition, Article 30 of the TRIPS Agreement allows for "exceptions to rights conferred." The TRIPS Agreement stipulates that each WTO member state must provide patent proprietors with the right to exclude others from making, using, selling, offering to sell, and importing the patented invention.[92] Article 30 then reads:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 30 appears to contemplate limited exceptions to the patent rights for such reasons as scientific experiments or use of a patented product for purposes of obtaining regulatory approval.[93]

At first glance, Article 30 of the TRIPS Agreement might seem to provide WTO member states with the ability to provide technology-specific exceptions despite the wording of Article 27.1. However, one dispute settlement panel of the WTO has "concluded ... that the anti-discrimination rule of Article 27.1 does apply to exceptions of the kind authorized by Article 30."[94] Stated differently, the WTO has reasoned that even exceptions to a patent owner's exclusive rights must be technology neutral.

The WTO's conclusion that even exceptions to a patent holder's exclusive rights must operate in a uniform manner has attracted some critical commentary. On one hand, if an exception to a patent holder's exclusive rights must apply to all technologies and industries, it is less likely to be "limited" and therefore compatible with Article 27.1.[95] On the other hand, the WTO reasoned that "the TRIPS Agreement [required] governments to apply exceptions in a nondiscriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers."[96]

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[89] Ibid. at Art. 27.3(a).

[90] Ibid. at Art. 27.3(b).

[91] Ibid. at Art. 73.

[92] Ibid. at Art. 28.

[93] See Scott Taylor, "Where Are the Green Machines? Using the Patent System to Encourage Green Invention and Technology Transfer," 23 *Georgetown International Environmental Law Review* (2011), 577.

[94] Panel Report, Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R (Mar. 17, 2000) [hereinafter "Canada Pharmaceutical"].

[95] See Dinwoodie and Dreyfuss, *supra*.

[96] Canada Pharmaceutical, paragraph 7.92.

The WTO dispute resolution panel in the *Canada Pharmaceutical* case further observed:

> [I]t is not true that Article 27 requires all Article 30 exceptions to be applied to all products. Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas.[97]

The distinction drawn by the WTO panel between the terms "field of technology" and "certain product areas" arguably does not shimmer with clarity. The panel's opinion obtains no further guidance as to the meaning of "certain product areas." However, some commentators have suggested that patent statutes may permissibly draw distinctions based on narrow categories of goods or services, in contrast to broader fields of technological endeavor. For example, Wesley A. Cann, Jr., an emeritus member of the University of Connecticut business school faculty, has asserted that "[e]ven if Article 30 would not allow a limited exception to be directed at the entire pharmaceutical industry (a position that is still open to substantial doubt), it can be argued that an exception could be made for those particular pharmaceuticals aimed at the prevention and treatment of HIV/AIDS."[98]

As a result, the membership of the United States within the WTO provides a possible constraint against tailoring the patent system to meet the perceived needs of specific industries. To the extent that WTO compliance is desired, the U.S. patent system must ordinarily act in a homogenous manner with respect to particular fields of technology. The TRIPS Agreement does permit some specific exceptions, however, for such subject matter as diagnostic, therapeutic, and surgical methods; matters of national security; and, as explained by the *Canada Pharmaceutical* WTO panel, "certain product areas."

Concluding Observations

The patent system involves numerous parameters, including the requirements to obtain a patent, the scope of proprietary rights, and the term of protection. In theory these attributes could be tailored to meet the needs of different sectors. Defining industry-specific or technology-specific patent doctrines presents some practical difficulties, however, and may also give rise to incompatibilities with the WTO TRIPS Agreement.

Should Congress consider current circumstances with respect to the patent system to be appropriate, then no action need be taken. However, should Congress believe that different sectors possess distinctive needs with respect to the patent system, a number of options exist. As noted, the TRIPS Agreement provides for a number of limited exceptions to the general rule of technological neutrality. U.S. legislation could simply track the exceptions identified by the provisions of the TRIPS Agreement, with particular reference to their interpretation by WTO dispute resolution panels.

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[97] Ibid.

[98] Wesley A. Cann, Jr., "On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply Under a Theory of Progressive Global Constitutionalism," 25 *University of Pennsylvania Journal of International Economic Law* (2004), 755.

Congress could also potentially draw distinctions among grounds not identified by Article 27.1 of the TRIPS Agreement—namely, the place of invention, the field of technology, and whether products are imported or produced locally. For example, the Leahy-Smith America Invents Act (AIA) established an infringement defense based upon the prior commercial use of the patented invention by the accused infringer.[99] The AIA stipulated that this defense was unavailable if the patented invention was made by an institution of higher education, however.[100] This "university exception" appears to comply with the TRIPS Agreement because it draws a distinction based upon the identity of the inventor, rather than on a ground identified in Article 27.1.

Another option is the establishment of additional intellectual property rights that complement patents. For example, Congress has established so-called "regulatory exclusivities," a term that refers to a period of time during which a regulated product is afforded protection from competing applications for marketing approval.[101] Most notably, the food and drug laws establish a number of regulatory exclusivities that apply to pharmaceuticals and are administered by the Food and Drug Administration. In contrast to patents, regulatory exclusivities are not subject to extensive regulation by the TRIPS Agreement.[102] As a result, at least with respect to regulated industries, regulatory exclusivities may provide a more flexible instrument for legislative tailoring of intellectual property rights.[103]

Whether legal doctrines should be expressed as discrete rules or more generally phrased standards is a long-standing debate within the field of jurisprudence.[104] Placed within the context of congressional consideration of our intellectual property laws, the debate suggests that distinct rules for different sectors form one possibility for patent reform. Yet Congress may also craft broader principles that may be appropriately applied across the diverse industries and technologies to which the patent system pertains. Determining whether a rule or a standard provides the most appropriate vehicle for a particular reform to our patent laws remains a matter of legislative judgment.

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[99] P.L. 112-29, 125 Stat. 284 (2011), at § 5.

[100] Ibid. (establishing 35 U.S.C. § 273(e)(5)).

[101] See Yaniv Heled, "Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?," 18 *Michigan Telecommunications & Technology Law Review* (2012), 419.

[102] See Christina Bucci, "Responsible Patent Protections: Preserving Public Health Objectives in the Trans-Pacific Partnership Agreement," 26 *Pacific McGeorge Global Business & Development Law Journal* (2013), 213.

[103] See Eisenberg, *supra*.

[104] See David Olson & Stefania Fusco, "Rules Versus Standards: Competing Notions of Inconsistency Robustness in Patent Law," 64 *Alabama Law Review* (2013), 647.