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Patents and Regulatory Exclusivities: Issues in Pharmaceutical Innovation and Competition

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Summary

Patents and regulatory exclusivities have each been the subject of congressional interest in recent years. Patents, which are administered by the U.S. Patent and Trademark Office (USPTO), allow for a uniform 20-year term of protection for a variety of inventions. In contrast, regulatory exclusivities apply to drugs and biologic medicines regulated by the Food and Drug Administration (FDA). Federal legislation establishes a complex range of regulatory exclusivities applicable to, among other subjects, new chemical entities, orphan drugs, and generic drugs. In general, these intellectual property rights require the FDA to protect an approved drug from competing applications for a set period of time.

Patents and regulatory exclusivities each create intellectual property rights for their proprietors, but operate through distinct mechanisms. Patents must be enforced through litigation in federal court and may be invalidated during judicial proceedings. In contrast, the FDA ordinarily maintains regulatory exclusivities through agency procedures, without the intervention of the rights holder. Unlike patents, regulatory exclusivities may restrict the sale of public domain medicines. And although patents traditionally provided a longer term of protection, more recently enacted regulatory exclusivities tend to have more comparable durations.

The patent system has traditionally served as the primary innovation incentive for new medicines. But recent legislative trends may elevate the regulatory exclusivity from a supplemental protection scheme to the primary driver of innovation within the pharmaceutical industry. For example, the Generating Antibiotics Incentives Now (GAIN) Act and the Biologics Price Competition and Innovation Act created regulatory exclusivities of 10 to 12 years, respectively, for certain products.

Legislation introduced most recently before the 113th Congress, the MODDERN Cures Act, H.R. 3116, would have continued to expand the role of regulatory exclusivities. That unenacted legislation would have effectively allowed brand-name pharmaceutical firms, in certain circumstances, to exchange their patents for a 15-year period of regulatory exclusivity. While proponents of the legislation believe it would provide a more certain and effective innovation incentive for the pharmaceutical industry, others assert that it significantly expands intellectual property rights and represents a windfall for the brand-name drug industry. These proposals have been placed before the 114th Congress in the form of a discussion draft of the 21st Century Cures Act.

Congress has several options as it considers the relationship between patents and regulatory exclusivities. If the current situation is deemed satisfactory, then no action need be taken. Other options include rationalizing the various terms of protection and scope of rights that regulatory exclusivities provide. Congress may also consider providing distinct names for the regulatory exclusivities and ensuring that these rights do not remove safe and effective medicines from the public domain.

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Introduction

Both patents and regulatory exclusivities have been the subject of congressional interest in recent years. The 112th Congress made significant changes to the patent system through the Leahy-Smith America Invents Act (AIA).[1] The 113th Congress considered additional patent system reforms, including the Innovation Act.[2] The Innovation Act passed the House of Representatives in the 113th Congress and has been introduced in the 114th Congress in virtually identical form. As well, the 111th and 112th Congresses created new forms of regulatory exclusivity for biologic medicines and qualified infectious disease products, respectively.[3]

The patent system has traditionally served as the primary innovation incentive for new medicines. Patents, which are administered by the U.S. Patent and Trademark Office (USPTO), allow for a uniform 20-year term of protection for a variety of inventions.[4] A patent may be awarded on any process, machine, manufacture, or composition of matter that is useful, novel, and nonobvious.[5] Patents issued by the USPTO provide their owners with the right to exclude others from practicing the invention or importing it into the United States.[6]

Starting with the Orphan Drug Act,[7] Congress has also developed a new form of intellectual property right in order to promote the marketing of new drugs. Regulatory exclusivities apply to drugs and biologic medicines regulated by the Food and Drug Administration (FDA). Federal legislation establishes a complex range of regulatory exclusivities applicable to, among other subjects, new chemical entities, orphan drugs, and generic drugs.[8] In general, these intellectual property rights require the FDA to protect an approved drug from competing applications for a set period of time. For the past three decades, regulatory exclusivities have served alongside patents as a parallel, shorter-term exclusion mechanism for the vast majority of innovative pharmaceuticals.

Contemporary legislative trends may elevate the regulatory exclusivity from a supplemental protection scheme to the primary driver of innovation within the pharmaceutical industry.[9] Recent laws have increased the term of regulatory exclusivities to periods that begin to rival those of patents. The Biologics Price Competition and Innovation Act of 2009 created a 12-year regulatory exclusivity,[10] and under the Generating Antibiotics Incentives Now (GAIN) Act a "qualified infectious disease product" that consists of a new chemical entity enjoys an exclusivity period of

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

[2] H.R. 3309, 113th Cong. (2013).

[3] See Food and Drug Administration Safety and Innovation Act (FDASIA), P.L. 112-144, 126 Stat. 993 (2012) (incorporating the Generating Antibiotics Incentives Now, or GAIN Act, which extended periods of regulatory exclusivity for "qualified infectious disease products"); Patient Protection and Affordable Care Act, P.L. 11-148, 124 Stat. 119 (2010) (incorporating the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which established periods of regulatory exclusivity for biologics).

[4] 35 U.S.C. §154(a)(2).

[5] 35 U.S.C. §§101, 102, 103.

[6] 35 U.S.C. §271.

[7] P.L. 97-414, 96 Stat. 2049 (1982).

[8] See generally John R. Thomas, *Pharmaceutical Patent Law* (2d ed. 2010), pp. 9-26.

[9] *See* Amanda Fachler, "The Need for Reform in Pharmaceutical Protection: The Inapplicability of the Patent System to the Pharmaceutical Industry and the Recommendation of a Shift Towards Regulatory Exclusivities," *Fordham Intellectual Property, Media and Entertainment Law Journal*, no. 24 (2014), p.1059.

[10] 42 U.S.C. §262(k)(7)(A).

10 years.[11] Legislation considered by previous sessions of Congress, the MODDERN Cures Act, would have extended this paradigm.[12] That unenacted legislation would have effectively allowed brand-name pharmaceutical firms, in certain circumstances, to exchange their patents for a 15-year period of regulatory exclusivity.[13] These proposals have been placed before the 114th Congress in the form of a discussion draft of the 21st Century Cures Act.

This report reviews the evolving nature of patents and regulatory exclusivities within the pharmaceutical industry. It begins by introducing the patent system, with emphasis upon its application to the pharmaceutical industry. This report next discusses the growing number of FDA-administered regulatory exclusivities and compares them to the patent right. It then reviews the MODDERN Cures Act and the Innovation Act, legislation that appears to continue a trend towards distinct treatment of pharmaceuticals as subjects of intellectual property. This report concludes with a discussion of legislative issues and options with respect to the two intellectual property rights.

Introduction to Pharmaceutical Patents

U.S. law currently calls for what may be seen as a two-track utility patent system.[14] One patent system pertains to pharmaceuticals, biologics, medical devices, and other FDA-regulated products. The other applies to all other fields of high-technology endeavor. The mainstream patent system requires inventors who wish to obtain rights to file a patent application at the USPTO.[15] USPTO examiners then review the application to ensure that certain statutory requirements are met.[16] Among these statutory requirements is that the invention must be adequately described in the patent application and not have been obvious to a skilled artisan.[17] Once a patent has issued, the statutory term is twenty years from the date the application was filed.[18] Patent proprietors obtain the right to exclude others from practicing the patented invention in the United States.[19]

Pharmaceutical patents work much in the same manner, but with some important modifications introduced by the Hatch-Waxman Act and related legislation.[20] First, in order to compensate for regulatory approval delays at the FDA, the term of pharmaceutical patents may be extended by up to five years.[21] However, the total period during which the patent proprietor holds both marketing approval and a term-extended patent may not exceed fourteen years.[22] Second, pharmaceutical patents may be enforced against generic competitors before they actually market their products.

[11] 21 U.S.C. §505E(g).

[12] H.R. 3116, 113th Congress.

[13] Ibid. at §201(c).

[14] Utility patents, the usual sort of patent provided for in 35 U.S.C. §101, may be distinguished from distinct sorts of patents for plants, 35 U.S.C. §161, and for industrial designs, 35 U.S.C. §171.

[15] 35 U.S.C. §111.

[16] Ibid. §131.

[17] Ibid. §103, 112.

[18] Ibid. §154(a)(2).

[19] Ibid. §271.

[20] The Hatch-Waxman Act is more formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, P.L. 84-417, 98 Stat. 1585 (1984).

[21] 35 U.S.C. §156.

[22] Ibid. §156(c)(3).

In particular, brand-name firms may pursue patent litigation as soon as a generic firm seeks marketing approval from the FDA.[23]

In addition, if a pharmaceutical patent holder prevails in litigation, it automatically blocks the generic drug company from marketing its product throughout the life of the patent.[24] In other sorts of patent cases, the patent proprietor must demonstrate that it has suffered an irreparable injury that cannot otherwise be remedied, that a balance of hardships between the plaintiff and defendant favors the issuance of an injunction, and that the public interest would not be disserved by a permanent injunction.[25] Pharmaceutical patent holders may also automatically block generic competitors from marketing their products for a period of 30 months from when patent litigation begins.[26] This remedy is similar to a "preliminary injunction," a measure that is usually regarded as "exceptional" and awarded only after strong showings from the proponent of the injunction.[27]

Although these rules favor brand-name pharmaceutical firms, the Hatch-Waxman Act balanced them against other provisions that favor generic companies. Due to the "*Bolar* exemption,"[28]generic firms may commence work on a competing version of an approved drug at any time during the life of a brand-name firm's patent without facing infringement liability, so long as that work furthers compliance with FDA requirements.[29] Further, a generic firm may obtain marketing approval from the FDA by filing an Abbreviated New Drug Application, or ANDA, that relies upon the safety and efficacy data developed by a brand-name firm.[30] The ANDA process allows a generic manufacturer to avoid the considerable costs and delays associated with filing a full-fledged New Drug Application.[31]

This blended architecture sets pharmaceutical patents apart, but it also ensures that broader developments within the patent system impact them. For example, if the U.S. Supreme Court issues a decision setting forth the standards of nonobviousness in a patent dispute involving automobile parts,[32] or discusses claim definiteness in a case concerning an exercise machine,[33] the new rules also apply to pharmaceutical patents. Legislative reforms also ordinarily apply to all patented inventions. The recent shift of the United States from a first-to-invent to a first-inventor-to-file priority system, for example, applies to pharmaceutical patents as well as patents from other industrial sectors.[34]

[23] Ibid. §271(e)(1).

[24] Ibid. §271(e)(4)(A).

[25] eBay Inc. v. Mercexchange, L.L.C., 547 U.S. 388 (2006).

[26] 21 U.S.C. §355(j)(5)(B)(iii).

[27] Precision Links Inc. v. USA Products Group, Inc., 527 Fed. Appx. 852, 857 (Fed. Cir. 2013).

[28] The term "*Bolar* exemption" refers to Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984).

[29] 21 U.S.C. §271(e)(1).

[30] 21 U.S.C. §355(j)(1).

[31] See Vikrama Chandrashekar, "Getting Even Less Than What They Paid For: The Plight of Generic Drug Consumers Under the *Levine-Mensing* Dichotomy," *University of Colorado Law Review*, vol. 86 (2015), p. 259.

[32] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

[33] Nautilus, Inc. v. Biosig Instruments, Inc., 134 S.Ct. 2120 (2014).

[34] Leahy-Smith America Invents Act, P.L. 112-29, 125 Stat. 284 (2011).

Introduction to Regulatory Exclusivities

The term "regulatory exclusivity" generally refers to a period of time during which the FDA affords an approved drug protection from competing applications for marketing approval. Congress has established fifteen regulatory exclusivities. In particular, the Federal Food, Drug, and Cosmetic Act (FFDCA) identifies twelve different sorts of regulatory exclusivities:

- Ten-Year Transitional Exclusivity;[35]
- Seven-Year Orphan Drug Exclusivity;[36]
- Five-Year New Chemical Entity Exclusivity;[37]
- Five-Year Enantiomer Exclusivity;[38]
- Five-Year Qualifying Infectious (QI) Disease Product Exclusivity;[39]
- Five-Year QI Act Antibiotic Exclusivity;[40]
- Three-Year QI Act Antibiotic Exclusivity;[41]
- Three-Year New Clinical Study Exclusivity for an Original NDA;[42]
- Three-Year New Clinical Study Exclusivity for a Supplemental NDA;[43]
- Two-Year Transitional Exclusivity;[44]
- Six-Month Pediatric Exclusivity;[45] and
- 180-Day Generic Exclusivity.[46]

In addition, the Public Health Service Act calls for three additional regulatory exclusivities which apply to biologics. Brand-name firms are entitled to a four-year period during which no application to market a follow-on biologic may be filed[47] and a 12-year period in which no follow-on biologic may be approved.[48] A first interchangeable biologic also obtains a period of regulatory exclusivity, typically a period of one year following its first commercial marketing.[49]

The five-year new chemical entity (NCE) exclusivity provides an example of how these intellectual property rights work in practice. A drug is judged to be an NCE if the FDA has not previously approved its active ingredient. During the five-year period that commences from the

[35] 21 U.S.C. §355(j)(5)(F)(i).

[36] 21 U.S.C. §360cc.

[37] 21 U.S.C. §355(j)(5)(F). "New chemical entity" exclusivity is sometimes termed "new molecular entity" exclusivity.

[38] 21 U.S.C. §355(a)(1). The Court of Appeals for the Federal Circuit discussed the role of enantiomers in drug discovery in *Saofi-Syntholabo v. Apotex, Inc.*, 550 F.3d 1075, 1080 (Fed. Cir. 2009).

[39] 21 U.S.C. §355f.

[40] 21 U.S.C. §355(v)(2)(A)(i)(II).

[41] 21 U.S.C. §§355(v)(1)(A); 355(v)(2)(A)(i)(I).

[42] 21 U.S.C. §355(j)(5)(F)(iii).

[43] 21 U.S.C. §355(j)(5)(F)(iv).

[44] 21 U.S.C. §355(j)(5)(F)(v).

[45] 21 U.S.C. §355a.

[46] 21 U.S.C. §355(j)(B)(iv).

[47] 42 U.S.C. §262(k)(7)(B).

[48] 42 U.S.C. §262(k)(7)(A).

[49] 42 U.S.C. §262(k)(6).

date the FDA approved the drug for sale,[50] the agency may not accept an application submitted by a generic company seeking marketing approval.[51] As a result, the practical effect of NCE exclusivity is to restrict a potential generic manufacturer from bringing a product to market for five years plus the length of FDA review of the generic application.

Comparing Patents and Regulatory Exclusivities

The growing prominence of this intellectual property right invites comparison between regulatory exclusivities and patents.[52] In particular, although regulatory exclusivities have sometimes been described as "pseudo-patents,"[53] this characterization is apt only at a level of rough approximation. This report reviews the salient distinctions between these innovation incentives next.

Acquisition and Enforcement

Like most rights, patent rights are not self-enforcing. They must be asserted by their proprietors through litigation in the federal courts.[54] Even the patent owner prevails on the merits of validity, infringement, and potentially other issues, it must demonstrate entitlement to an injunction in order to block a competitor's use of the patented invention.[55] In addition, as Mark Lemley and Carl Shapiro have aptly phrased the concept, patent rights are notoriously probabilistic.[56] Put differently, patents provide not so much the right to exclude but the right to try to exclude.[57] Courts hold on the order of one-half of the patents that are litigated to have been improvidently granted and therefore invalid.[58]

In contrast, the FDA enforces regulatory exclusivities automatically, without the intervention of the proprietary rights holder, and sometimes without even his knowledge. The FDA renders the usually routine judgment about whether an applicant should enjoy a regulatory exclusivity or not, and then withholds marketing approval for the congressionally determined period of time.[59] As a result, regulatory exclusivities provide a far more certain and readily administered proprietary interest than do patents.

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[50] The five-year period may be decreased to four years in the event of a patent dispute between the brand-name and generic firms. See 21 U.S.C. §355(j)(5)(F)(ii).

[51] Although the NCE exclusivity blocks applications from generic firms, it does not bar a sponsor that has conducted preclinical and clinical trials itself from filing a full New Drug Application (NDA) at the FDA. See Thomas, supra, at 433.

[52] See Maxwell R. Morgan, "Regulation of Innovation Under Follow-On Biologics Legislation: FDA Exclusivity as an Efficient Innovation Mechanism," *Columbia Science and Technology Law Review*, vol. 11 (2010), p. 93.

[53] See, e.g., Robert Alan Hess, "Excavating Treasure from the Amber of the Prior Art: Why the Public Benefit Doctrine is Ill-Suited to the Pharmaceutical Sciences," *Food and Drug Law Journal*, vol. 66 (2011), p. 105.

[54] 35 U.S.C. §281.

[55] See Sanofi-Sythelabo v. Apotex, Inc., 470 F.3d 1368 (Fed. Cir. 2006) (patent proprietor awarded preliminary injunction following expiration of thirty-month stay of marketing approval).

[56] Mark A. Lemley and Carl Shapiro, "Probabilistic Patents," *Journal of Economic Perspectives*, vol. 19 (2005), p. 75.

[57] 35 U.S.C. §282 (listing "defenses in any action involving the validity or infringement of a patent").

[58] See Lemley and Shapiro, supra, at 75.

[59] Valerie Junod, "Drug Marketing Exclusivity Under United States and European Union Law," Food and Drug Law Journal, vol. 59, pp. 479, 492 (2004) ("Marketing exclusivity confers a very strong protection to the pioneer company because competitors cannot really challenge it.").

The Public Domain

Patent, copyright, trademark, and other intellectual property rights, with some controversial exceptions,[60] ordinarily strive to maintain the public domain.[61] Once a work enters the public domain, it becomes "free as the air to common use" and cannot be privately appropriated.[62] In pursuit of this goal, the USPTO examines applications to ensure that the inventions they claim are novel and nonobvious.[63] The courts may also invalidate improvidently granted patents that claim public domain technologies.[64]

In contrast, regulatory exclusivities may be granted even with respect to pharmaceuticals that had previously fallen within the public domain. Colchicine, an ancient cure for gout that has been marketed in the United States since the nineteenth century, provides an example of this possibility. For many years a number of firms sold colchicine as a generic drug; due to its grandfathered status under the 1938 Food, Drug, and Cosmetic Act, no conclusive safety and efficacy studies had been conducted. In 2006, as part of its Unapproved Drugs Initiative, the FDA required enterprises that wished to continue to sell colchicine to conduct clinical trials and other safety and efficacy studies. One firm, Mutual Pharmaceutical Co., complied.[65]

The FDA subsequently awarded a three-year exclusivity for gout and a seven-year exclusivity for another indication, familial Mediterranean fever, in keeping with the Hatch-Waxman[66] and Orphan Drug Acts.[67] Mutual immediately increased the price of its colchicine product, Colcrys, from $0.09 to $4.85 per tablet.[68] Generic colchicine products immediately became unavailable in the United States as of September 2010, with an estimated cost to the Medicaid program of $50 million per year.[69] Although the colchicine matter appears to have run its course as of early 2015,[70] this incident reveals that even pharmaceuticals previously considered to fall within the public domain may be the subject of regulatory exclusivities.

Scope of Rights

Regulatory exclusivities and patents also differ in their extent of protection. The scope of a regulatory exclusivity generally provides a tighter fit with the products brand-name firms sell than do patents. FDA-administered regulatory exclusivities are of commensurate scope with the drugs they approve. In contrast, patent claims may be drafted before the FDA has approved a

[60] See Golan v. Holder, 132 S.Ct. 873 (2011) (recognizing that U.S. compliance with the Berne Convention for the Protection of Literary and Artistic Works required restoration of copyright protection for certain works that had fallen into the public domain).

[61] See Joseph P. Liu, "The New Public Domain," *University of Illinois Law Review*, vol. 2013, p. 1395.

[62] International News Service v. Associated Press, 248 U.S. 215, 250 (1918) (Brandeis, J., dissenting).

[63] 35 U.S.C. §§102, 103.

[64] Ibid. §282(b).

[65] Aaron S. Kesselheim and Daniel H. Solomon, "Incentives for New Drug Development—The Curious Case of Colchicine," *New England Journal of Medicine*, vol. 362, p. 2045 (2010).

[66] 21 U.S.C. §355(c)(3)(E)(iii).

[67] 21 U.S.C. §360cc.

[68] Elisabeth Rosenthal, "The Soaring Cost of a Simple Breath," *New York Times*, Oct. 12, 2013 (reporting costs of five dollars per pill per colchicine, a "drug you could find in Egyptian mummies.").

[69] Keselheim and Solomon, supra.

[70] See FDA, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=204820&TABLE1=OB_Rx.

product and focus upon distinguishing an invention from the disclosures of earlier patents and publications.[71] As a result, a brand-name firm's patents may not fully correspond to the products it actually sells. In some cases, generic firms are able to market competing products without infringing the brand-name firm's patents.[72]

Term

Issued patents last twenty years from the date its corresponding application was filed,[73] subject to the term extension rules of the Hatch-Waxman Act and other legal provisions.[74] In contrast, regulatory exclusivities traditionally were effective for relatively shorter periods of time. Among the earlier cohort of exclusivities, those awarded to generic firms[75] and in exchange for pediatric studies[76] endure only for about six months each, while the longest such right, the orphan drug exclusivity,[77] extends seven years. Since the advent of the Hatch-Waxman Act, each of these rights usually provided a short-term period of enhanced protection that expired well before corresponding patents did.

More recent legislation has extended the terms of regulatory exclusivities. The Biologics Price Competition and Innovation Act (BPCIA) of 2009 awarded brand-name firms a twelve-year period of exclusivity during which no application for licensure of a follow-on biologic product may be approved.[78] In 2012, Congress addressed "qualified infectious disease products"—products that addressed antibiotic-resistant "super-bugs" such as drug-resistant tuberculosis and *Staphylococcus aureus*. The Generating Antibiotics Incentives Now (GAIN) Act added five years to the term of other regulatory exclusivities that the product enjoys.[79] As a result, a new chemical entity that qualified under the GAIN Act and was the subject of pediatric studies would enjoy a total exclusivity period of 10 years and 6 months.[80] These newer periods of regulatory exclusivity are more comparable to the maximum 14-year period of patent protection guaranteed by the Hatch-Waxman Act.

[71] Rebecca S. Eisenberg, "The Role of the FDA in Innovation Policy," *Michigan Telecommunications and Technology Law Review*, vol. 13 (2007), pp. 345, 355 ("Patents cover inventions, and inventions do not necessarily correspond to product markets.").

[72] See Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July 2002, p. 20 (observing that out of Hatch-Waxman litigation involving 40 drug products, generic firms prevailed 14 times due to a successful argument of noninfringement).

[73] 35 U.S.C. §154(a)(2).

[74] Ibid. §156.

[75] 21 U.S.C. §355(j)(B)(iv). The generic exclusivity more precisely lasts for 180 days.

[76] 21 U.S.C. §355a.

[77] 21 U.S.C. §360cc.

[78] 42 U.S.C. §262(k)(7)(B). The BPCIA formed part of the Patient Protection and Affordable Care Act, P.L. 111-148, 124 Stat. 119 (2010).

[79] 21 U.S.C. §505E(g). The GAIN Act was enacted as Title VIII of the Food and Drug Administration Safety and Innovation Act (FDASIA), P.L. 112-144, 126 Stat. 993 (2012).

[80] The product would obtain a five-year exclusivity as a new chemical entity, 21 U.S.C. §355(j)(5)(F)(ii), an additional five-year exclusivity in keeping with the GAIN Act, 21 U.S.C. §505E(g), and yet another six-month exclusivity for the completion of pediatric studies under 21 U.S.C. §355a.

Recent Legislative Proposals

Statutory distinctions between the pharmaceutical industry and other industrial sectors with respect to intellectual property may be increasing, however. As discussed below, this trend may be observed in proposed legislation with respect to both patents and regulatory exclusivities.

The Innovation Act

Legislation introduced in the 114th Congress, the Innovation Act, is intended to address such concerns as trolling,[81] infringement lawsuits against end users,[82] and transparency of patent ownership.[83] In particular, the bill would have required patent pleadings to include a detailed description of the accused infringement.[84] Plaintiffs in infringement cases would also be required to disclose to the USPTO the identity of individuals or enterprises with ownership of the asserted patents.[85] In addition, the Innovation Act would establish a stay of litigation against end users who employ a manufacturer's equipment.[86]

None of these proposed reforms would apply to pharmaceutical patents, at least to the extent they are enforced against generic competitors in keeping with the Hatch-Waxman Act. At each instance the Innovation Act expressly exempted litigation brought under the auspices of the Hatch-Waxman Act.[87] These exceptions suggest that the concerns which animated the Innovation Act are more prominent within the electronics, software, and other high-tech industries,[88] in comparison with the pharmaceutical sector.[89] A predecessor version of the Innovation Act passed the House of Representatives in the 113th Congress but was ultimately not enacted. If enacted by the 114th Congress, the Innovation Act would continue to distinguish pharmaceutical patents from those pertaining to other sorts of inventions.

The MODDERN Cures Act

Legislation introduced in the last several sessions of Congress, but not enacted, would have continued to emphasize regulatory exclusivities as a driver of pharmaceutical innovation. The Modernizing Our Drug and Diagnostics Evaluation and Regulatory Network Cures Act,[90] or MODDERN Cures Act, would have required a drug sponsor to identify a therapy that addresses

[81] CRS Report R42668, *An Overview of the "Patent Trolls" Debate*, by Brian T. Yeh; Gerald N. Magliocca, "Blackberries and Barnyards: Patent Trolls and the Perils of Innovation," *Notre Dame Law Review*, vol. 82 (2007), p. 1809.

[82] Skyler R. Peacock, "Why Manufacturing Matters: 3D Printing, Computer-Aided Designs, and the Rise of End-User Patent Infringement," *William and Mary Law Review*, vol. 55 (2014), p. 1933.

[83] Tom Ewing, "Indirect Exploitation of Intellectual Property Rights by Corporations and Investors," *Hastings Science and Technology Law Journal*, vol. 4 (2012), p. 1.

[84] H.R. 9 at §3.

[85] Ibid. at §4.

[86] Ibid. at §5.

[87] Ibid. at §3(a); §4(a); §5(a).

[88] See Stefania Fusco, "Markets and Patent Enforcement: A Comparative Investigation of Non-Practicing Entities in the United States and Europe," *Michigan Telecommunications and Technology Law Review*, vol. 20 (2014), p. 439 (2014).

[89] See Jeremiah S. Helm, "Why Pharmaceutical Firms Support Patent Trolls: The Disparate Impact of eBay v. Mercexchange on Innovation," Michigan Telecommunications and Technology Law Review, vol. 13 (2006), p. 331.

[90] H.R. 3116, 113th Congress.

"one or more unmet medical needs."[91] If the FDA granted marketing approval to such a "dormant therapy," then the sponsor would have obtained fifteen years of regulatory exclusivity.[92] The MODDERN Cures Act would have also required that the sponsor disclaim the portion of any patent term that would extend beyond the fifteen-year period of regulatory exclusivity.[93]

Although not enacted, the concepts behind the MODDERN Cures Act have been extended further in a discussion draft recently circulated before the 114th Congress. A portion of the nearly 400-page 21st Century Cures Act duplicates the provisions of the MODDERN Cures Act.[94] The discussion draft proposes to increase the length of a brand-name firm's exclusivities by six months in the event that it obtains FDA approval of a new indication of a previously approved drug, provided that the new approval relates to a rare disease or condition.[95] The draft of the 21st Century Cures Act also proposes to increase the period of three-year new clinical study exclusivity if the brand-name firm demonstrates to the FDA that the new studies support a new indication or use, or improve a previously known treatment by promoting greater patient compliance with the treatment regimen, reduce side effects, or otherwise provide notable benefits to patients.[96]

The draft 21st Century Cures Act would also amend the GAIN Act by allowing the owner of an approved application on a qualified infectious disease product to transfer up to 12 months of the five-year extension of exclusivity to another product.[97] Stated differently, a brand-name firm selling a tuberculosis drug could transfer up to 12 months of its exclusivity to a more profitable product directed towards hypertension or heart disease, for example. This "wildcard" exclusivity could even be sold to another firm. However, upon receipt of the conveyed exclusivity period, the recipient must make a "donation" to the National Institutes of Health of an amount not to exceed 5% of the sales of the recipient drug in the United States.

Some commentators strongly support enactment of the MODDERN Cures Act and related legislation.[98] Attorney and former pharmaceutical executive Robert A. Armitage asserts that brand-name firms may choose not to develop a new drug if they believe that the extent of patent protection is uncertain for that product. In his view, it is "unacceptable" that "a highly promising experimental medicine cannot proceed into development because its projected patent life is too short, the patent protection seems too tenuous, or patent protection was simply unavailable."[99] He therefore concludes that a "certain and fixed" period of exclusive rights provided by the MODDERN Cures Act presents a superior alternative.[100]

Other observers are more guarded in their assessment of the proposed legislation. C. Scott Hemphill, a member of the faculty of Columbia Law School, has expressed concern that these

[91] Ibid. at §201(a)(2)(A).

[92] Ibid. at §201(i)(4)(B).

[93] Ibid. at §201(c). The MODDERN Cures Act was introduced as H.R. 3497 in the 112th Congress and H.R. 3116 in the 113th Congress. Senator Hatch introduced a parallel bill, the Dormant Therapies Act of 2014, in the 113th Congress.

[94] Discussion Draft, Subtitle L, at 101-18.

[95] Ibid., Subtitle N, pp. 123-131. This proposal is similar to that put forward in the 113th Congress as H.R. 5750, the Orphan Product Extensions Now Accelerating Cures and Treatments Act ("Open Act") of 2014.

[96] Ibid.

[97] Ibid., §1063, pp. 59-68.

[98] See Robert A. Armitage, "The Hatch-Waxman Act: A Path Forward for Making It More Modern," William Mitchell Law Review, vol. 40 (2014), p. 1200.

[99] Ibid., p. 1258.

[100] Ibid.

proposals offer "a large increase in protection for all novel drugs."[101] In particular, he observes that the previously proposed legislation provides the term "unmet medical need" with an expansive definition.[102] As a result, Mr. Hemphill believes that virtually any drug with a new active ingredient would qualify for a 15-year protection period under the legislation.[103] He believes that this legislation would "grant a windfall for a large number of drugs that would have been developed anyway."[104]

Concluding Observations

The MODDERN Cures Act and related legislation suggest that the pharmaceutical industry may place increasing reliance upon regulatory exclusivities to support innovation. This trend appears to align with intuitions over the political economy of the patent system. Recent discussion of the America Invents Act[105] and Innovation Act[106] demonstrates that the patent system involves a diverse range of stakeholders. As a result, Congress may be more readily able to introduce reforms to drug regulation, including regulatory exclusivities, than to the patent system.[107]

The membership of the United States in the World Trade Organization (WTO) also restricts congressional ability to tailor the patent system to specific industries. The WTO Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS Agreement") requires signatories to provide patent protection "without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."[108] The brand-name pharmaceutical industry is said to have promoted this language because it would require WTO member states to amend national laws that disallowed the issuance of patents on pharmaceutical products.[109] But the TRIPS Agreement seems to bar discrimination in favor of pharmaceutical patents as well as against them.[110]

On the other hand, the TRIPS Agreement places few restrictions upon the award of regulatory exclusivities by WTO member.[111] Indeed, unlike patents, they are arguably not even required.[112] Virtually any desired behavior by participants within a regulated industry could be promoted through a specifically tailored regulatory exclusivity. The development of ethnic medicines,[113]

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[101] C. Scott Hemphill, *Testimony Before the House Committee on Energy and Commerce Hearing on 21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients*, June 11, 2014, p. 4.

[102] Section 201(i)(1)(B) of the MODDERN Cures Act explains that the a drug may address "unmet medical needs" even if a therapy for that condition currently exists, provided that the drug produces different side effects, is more useful as a combination therapy, or if it provides greater "compliance or convenience."

[103] Hemphill, supra, p. 4.

[104] Ibid., p. 5.

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

[106] H.R. 3309, Innovation Act, 113th Cong. (2013). This legislation was not enacted.

[107] Eisenberg, supra.

[108] TRIPS Agreement, Art. 27(1).

[109] Peggy B. Sherman and Ellwood F. Oakley, III, "Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs," *American Business Law Journal*, vol. 41 (2004), pp. 353, 364.

[110] Eisenberg, supra, p. 365.

[111] TRIPS Agreement, Article 39.

[112] Carlos Maria Correa, "Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals," *Chicago Journal of International Law*, vol. 3 (2002), pp. 69, 72.

[113] See Shubha Ghosh, Race-Specific Patents, "Commercialization, and Intellectual Property Policy," *Buffalo Law*

personalized medicines,[114] and treatments for any particular medical condition that excites legislative interest would be worthy candidates for new regulatory exclusivities. The award of regulatory exclusivities need not even be tied to a particular disease or to the novelty of the active ingredient approved. Regulatory exclusivities could just as easily be awarded for such activities as domestic manufacturing, employing environmentally sound packaging, or donating medications to the poor.

In view of the increasing prominence of regulatory exclusivities, Congress may choose to consider several steps that would improve the rationality of this intellectual property system. The fifteen current regulatory exclusivities arguably offer a diverse assortment of proprietary interests. Some exclusivities block the ability of competitors to submit applications at the FDA altogether,[115] while others allow the agency to receive an application but bar its approval.[116] Some protect the data package the brand-name firm has submitted to the FDA,[117] but others bar marketing permission whether the data has been referenced or not.[118] The term of most of the regulatory exclusivities commences on the date the FDA awards marketing approval,[119] but one begins on the date of first sale.[120] Most of the regulatory exclusivities run their full term subject to wavier by the rights holder, yet at least one can be forfeited[121] and the term of another truncated.[122] One so-called "exclusivity" may actually be shared by competitors.[123] Some exclusivities are merely additive, meaning that in the absence of an existing proprietary right, no exclusivity is awarded at all.[124] And of course the term of regulatory exclusivities varies markedly, from 180 days to 12 years.[125]

As an alternative to these *ad hoc* distinctions, Congress may consider developing categories of scopes of protection that can be easily referenced. For example, the regulatory exclusivities could be divided into categories based upon the extent of protection, including (1) denial of approval of any competing product for the same indication, as provided under the Orphan Drug Act,[126] (2) denial of access to the sponsor's data package, as is the case for the new chemical entity

Review, vol. 56 (2008), p. 409.

[114] See Dov Greenbaum, "Incentivizing Pharmacogenomic Drug Development: How the FDA Can Overcome Early Missteps in Regulating Personalized Medicine," *Rutgers Law Journal*, vol. 40 (2008), p. 97.

[115] See, e.g., 42 U.S.C. §262(k)(7)(B) (providing for a four-year period during which no application for a follow-on biologic may be filed at the FDA).

[116] See, e.g., 21 U.S.C. §355(j)(5)(F)(iii) (blocking the approval of ANDAs for a three-year period in exchange for new clinical studies).

[117] See, e.g., 21 U.S.C. §355(j)(F)(ii) (prohibiting an ANDA applicant's reference to the NDA holder's data package for five years).

[118] See 21 U.S.C. §360cc (seven-year period of orphan drug exclusivity).

[119] See, e.g., 21 U.S.C. §355(j)(5)(F) (new chemical entity exclusivity).

[120] See 21 U.S.C. §355(j)(B)(iv) (180-day generic exclusivity).

[121] See 21 U.S.C. §355(j)(D)(i) (forfeiture of 180-day generic exclusivity).

[122] See 21 U.S.C. §355(j)(F)(ii) (new chemical entity reduced by up to one year in the event of patent litigation).

[123] See John R. Thomas, Pharmaceutical Patent Law 451 (2d ed. 2010) (multiple first ANDA applicants may share the 180-day generic exclusivity).

[124] See, e.g., 21 U.S.C. §355a (pediatric exclusivity).

[125] Compare 21 U.S.C. §355(j)(B)(iv) (180-day generic exclusivity) with 42 U.S.C. §262(k)(7)(A) (biologics).

[126] 21 U.S.C. §360cc.

exclusivity,[127] and (3) protection limited to a specific use, formulation, or route of administration of an approved drug, the scope of rights provided by the new clinical study exclusivity.[128]

Congress might also choose to assign specific names to the various regulatory exclusivities. The relevant food and drug laws do not actually name each right, instead setting industry, the bar, and commentators to that task. Consistency of terminology has not been a hallmark of this collective project. In particular, some sources employ the terms "marketing exclusivity" and "data protection" synonymously with "regulatory exclusivity" in order to reference the entire constellation of FDA-administered proprietary rights.[129] However, others distinguish between these terms. Under this usage, "data protection" merely prohibits generic firms from referencing the data package submitted by sponsors, while a "marketing exclusivity" provides a more patent-like protection against all competition.[130] The confusion has reached the point where Members of Congress have written to the FDA in order to advise the agency of the distinction between these two sorts of exclusionary interests.[131] Legislation could assign a specific name to each of the exclusivities.

In addition, incidents such as the ongoing colchicine matter remind us that the award of regulatory exclusivities does not explicitly account for the interests of patients and other enterprises who had believed the drug to be available within the public domain. Congress may wish to ensure that regulatory exclusivities incorporate exceptions that provide for the continued sale of safe and effective medicines that are currently available to the public. Should the FDA desire clinical testing on old drugs to confirm their safety and efficacy, publicly funded trials may provide an alternative financing mechanism.

One comparative advantage of regulatory exclusivities is that their term is more certain than that of patents. Courts may invalidate patents during litigation.[132] Patents are also subject to post-grant proceedings at the USPTO that may result in their rejection. [133] In contrast, the grant of a regulatory exclusivity is a more straightforward and virtually uncontestable determination. This certainty is undermined to a degree by certain regulatory exclusivities that act to prohibit generic firms from filing paperwork at the FDA necessary to obtain marketing approval. For these regulatory exclusivities—notably the five-year New Chemical Entity exclusivity[134]—the effective term of the exclusivity consists of the sum of (1) the specified statutory period during which generic firms may not file applications for marketing approval; and (2) the period of time the FDA requires to determine whether the application complies with regulatory requirement. As agency workloads vary so too will the effective period of the exclusivity. Congress may wish to consider whether regulatory exclusivities should uniformly bar FDA approval of a competing application, rather than submission of the application in the first place.

[127] 21 U.S.C. §355(j)(F)(ii).

[128] 21 U.S.C. §355(j)(F)(iv).

[129] See, e.g., Daniel I. Gorlin, "Staving Off Death: A Case Study of the Pharmaceutical Industry's Strategies to Protect Blockbuster Franchises," *Food and Drug Law Journal*, vol. 63 (2008), pp. 823, 831.

[130] See, e.g., G. Lee Skillington and Eric M. Solovy, 'The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement," *Northwestern Journal of International Law and Business*, vol. 24 (2003), pp. 1, 40.

[131] Letter to FDA from Representatives Anna G. Esho, Jay Islee and Joe Barton, Docket No. FDA-2010-N-0477 (Dec. 21, 2010) (explaining to the FDA the views of these Members of Congress regarding the operation of the regulatory exclusivities created by the BPCIA).

[132] 35 U.S.C. §282.

[133] 35 U.S.C. §311 (*interpartes* review).

[134] 21 U.S.C. §355(j)(5)(F).

Increasing congressional reliance upon regulatory exclusivities to promote innovation within the pharmaceutical innovation marks an important shift in the intellectual property landscape of the United States. These specialized rights may be tailored to the particular industry they serve without impact upon the patent regime as a whole, an advantage that in turn may make consensus over reforms to the patent system more achievable. Some commentators have expressed concern, however, that regulatory exclusivities may expand the intellectual property rights given to brand-name firms to the detriment of public health. Obtaining a balance between providing incentives for pharmaceutical innovation, on one hand, and ensuring public access to medications, on the other, remains an important legislative determination.

Author Information

John R. Thomas
Visiting Scholar

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