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# Proprietary Rights in Pharmaceutical Innovation: Issues at the Intersection of Patents and Marketing Exclusivities

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## Summary

In combination, patents and marketing exclusivities provide the fundamental framework of intellectual property incentives for pharmaceutical innovation in the United States. Patents, which are administered by the United States Patent and Trademark Office (USPTO), provide their owner with the ability to exclude others from practicing the claimed invention for a limited time. In contrast, marketing exclusivities are administered by the Food and Drug Administration (FDA). Alternatively known as "data exclusivity" or "data protection," a marketing exclusivity prevents generic competitors from referencing the preclinical and clinical test data that manufacturers of brand-name pharmaceuticals generated in order to demonstrate the safety and effectiveness of their products. The FDA currently awards qualifying innovators with marketing exclusivities for the development of new chemical entities or orphan drugs, as well as for the performance of new clinical studies and pediatric studies.

Although patents and marketing exclusivities are separate entitlements that are administered by different federal administrative agencies and that depend upon distinct criteria, they both create proprietary rights in pharmaceutical innovation. These rights in turn allow innovators to receive a return on the expenditure of resources leading to the discovery. Once these rights expire, the marketplace for that drug is open to generic competition.

Several innovation policy issues have arisen concerning the relationship of patents and marketing exclusivities. Some observers believe that marketing exclusivities are unnecessary because patents are generally available for pharmaceutical innovation. On the other hand, some observers believe that the terms of the marketing exclusivities established by U.S. law are too short. In particular, they note that comparable European standards are often considerably longer than their U.S. counterparts.

International agreements require each World Trade Organization (WTO) member state to treat all patented inventions in the same manner. As a result, marketing exclusivities provide Congress with a more flexible option for stimulating specific sorts of desirable private activity than do patents. Indeed, the 109th Congress is currently considering expanding upon existing marketing exclusivities in order to encourage the development of bioterrorism countermeasures. WTO Agreements, as well as recent Free Trade Agreements to which the United States is a signatory, also oblige nations to provide some manner of protection to pharmaceutical test data.

Although general patent reform legislation has been the subject of significant discussion during the 109th Congress, current legislative proposals do not appear particularly to impact the relationship between patents and marketing exclusivities. Some maintain that continued attention to the impact of broadly oriented patent reforms upon the pharmaceutical industry is appropriate.

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# Proprietary Rights in Pharmaceutical Innovation: Issues at the Intersection of Patents and Marketing Exclusivities

Congressional interest in stimulating innovation within the pharmaceutical industry has been reflected in considerable congressional activity. Some federal laws have provided pharmaceutical firms with the possibility of obtaining proprietary rights as an incentive for the development of new drugs. The Drug Price Competition and Patent Term Restoration Act of 1984,[1] commonly known as the Hatch-Waxman Act,[2] included provisions establishing one form of proprietary rights, the so-called marketing exclusivity. Marketing exclusivities consist of a period of time during which the Food and Drug Administration (FDA) affords an approved drug protection from competing applications for marketing approval.[3] This latter concept is sometimes termed "data exclusivity" or "data protection."[4]

The Hatch-Waxman Act also modified the basic rules relating to patent protection for pharmaceuticals. Patents, which are issued by the U.S. Patent and Trademark Office (USPTO), provide their owner with the ability to exclude others from practicing the claimed invention for a limited time.[5] A statutory exemption from claims of patent infringement based upon acts reasonably related to seeking marketing approval from the FDA; specialized litigation procedures for challenging patent validity and infringement; and restoration of patent term to compensate for FDA marketing approval delays were among the reforms accomplished by the Hatch-Waxman Act.[6]

In order to update the Hatch-Waxman Act to achieve what Congress determined was an appropriate balance between incentives for innovation and competition within the pharmaceutical industry, the Medicare Prescription Drug and Modernization Act of 2003 introduced significant reforms to the former statute.[7] Other statutes, ranging

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[1] P.L. 84-417, 98 Stat. 1585 (1984).

[2] *See, e.g.*, Laura J. Robinson, "Analysis of Recent Proposals to Reconfigure Hatch-Waxman," 11 *Journal of Intellectual Property Law* (2003), 47.

[3] *See* (name redacted), *Pharmaceutical Patent Law* (Bureau of National Affairs, 2005), 18.

[4] *See* Valerie Junod, "Drug Marketing Exclusivity Under United States and European Union Law," 59 *Food & Drug Law Journal* (2004), 479.

[5] 35 U.S.C. § 271(a) (2004).

[6] Thomas, *supra* note 3, at 12-19.

[7] P.L. 108-173, 117 Stat. 2066.

from the Orphan Drug Act[8] to the Best Pharmaceuticals for Children Act,[9] have also employed the marketing exclusivity mechanism in order to establish incentives to engage in socially desirable activity. The 109th Congress is currently considering further modifications to the existing marketing exclusivity framework in order to encourage the research and development of counterterrorism measures.[10]

Both marketing exclusivities and patents are intended to encourage drug developers to invent new pharmaceutical products, or to generate new information concerning existing products, by shielding their innovations from competition for a limited period of time. Although both mechanisms serve the same basic innovation policy goals, they are in fact separate entitlements that are administered by different federal administrative agencies and that depend upon different criteria.[11] Together, these two incentives provide a relatively complex system of proprietary rights that regulate the timing of patent litigation, the introduction of generic competition, and ultimately the rate of return that pharmaceutical firms may obtain upon their innovative products.

Although both patents and marketing exclusivities have been available within the pharmaceutical industry for over two decades, commentators have raised a number of innovation policy issues in this context. Some observers question the need for the FDA to grant marketing exclusivities given the availability of pharmaceutical patents.[12] On the other hand, others believe that the terms of the marketing exclusivities established by U.S. law are too short in view of European standards.[13] Issues have also arisen with respect to the use of marketing exclusivities to encourage specific sorts of innovation and with the obligations of other nations to grant marketing exclusivities in the manner of U.S. law.

This report introduces and analyzes innovation policy issues concerning proprietary rights in pharmaceutical innovation. It begins with a review of the policy and procedures relating to both patents and marketing exclusivities. The report then discusses current domestic and international issues that exist at the intersection of these two techniques. The report closes with a summary of congressional issues and alternatives.

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[8] Orphan Drug Act, P.L. 97-414, 96 Stat. 2049 (1982).

[9] P.L. 107-109, 115 Stat. 1408 (2002).

[10] S. 1873, Biodefense and Pandemic Vaccine and Drug Development Act of 2005.

[11] CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984*, by (name redacted) and (name redacted).

[12] Rebecca S. Eisenberg, "Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development," 72 *Fordham Law Review* (2003), 477.

[13] Junod, *supra* note 4, at 501.

# Introduction to the Patent System

## Policy Goals

The patent system serves to promote the creation and disclosure of technological information. Some commentators believe that absent a patent system, individuals and institutions would be less likely to engage in research and development. Without the availability of patent protection, new inventions could be easily copied by "free riders" who incurred no cost to develop and perfect the technology involved. The resulting inability of inventors to capitalize on their inventions would likely lead to an environment where too few inventions are made. By providing individuals with exclusive rights in their inventions for a limited time, the patent system allows inventors to realize financial benefits from their inventions.[14]

Other observers believe that if the patent system were unavailable, innovators would maintain their inventions as trade secrets so that competitors could not exploit them. Trade secrets do not enrich the collective knowledge of society, however, nor do they discourage others from engaging in duplicative research. The patent system avoids these inefficiencies by requiring inventors to consent to the disclosure of their inventions in issued patent instruments.[15]

Legal scholars have offered additional explanations for the patent laws. The patent system may stimulate technological advancement by inducing individuals to "invent around" patented technology. Issued patent instruments may point the way for others to develop improvements, exploit new markets or discover new applications for the patented technology.[16] Moreover, the patent system may encourage patentees to exploit their proprietary technologies during the term of the patent. The protection provided by a patent's proprietary rights increases the likelihood a firm will continue to refine, produce and market the patented technology.[17] Finally, the patent law has been identified as a facilitator of markets. Absent patent rights, an inventor may have scant tangible assets to sell or license, and even less ability to police the conduct of a contracting party. By reducing a licensee's opportunistic possibilities, the patent system lowers transaction costs and makes technology-based transactions more feasible.[18]

The patent system has inspired numerous critics, however. Some detractors have asserted that the patent system is unnecessary due to market forces that already

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[14] Roger E. Schechter and (name redacted), *Principles of Patent Law* § 1.3.1 (Thomson West 2004).

[15] *See, e.g.*, Grant v. Raymond, 31 U.S. 218, 247 (1832).

[16] R. Polk Wagner, "Information Wants to Be Free: Intellectual Property and the Mythology of Control," 103 *Columbia Law Review* (2003), 995.

[17] F. Scott Kieff, "Property Rights and Property Rules for Commercializing Inventions," 85 *Minnesota Law Review* (2000), 697.

[18] *See* Robert P. Merges, "Intellectual Property and the Costs of Commercial Exchange: A Review Essay," 93 *Michigan Law Review* (1995), 1570.

suffice to create an optimal level of invention. The desire to gain a lead time advantage over competitors, as well as the recognition that technologically backwards firms lose out to their rivals, may well provide sufficient inducement to invent without the need for further incentives.[19] Others believe that the inventions that fueled the most dynamic sectors of modern industry, such as biotechnologies and computer software, arose at a time when patent rights were unavailable or uncertain.[20]

While these justifications and criticisms have varying degrees of intuitive appeal, none of them has been empirically validated. No authoritative study conclusively demonstrates that society obtains more rapid technological development with patents than it would without them. As a result, the rationales for, and criticisms of, the patent system remain open to challenge.[21]

## Patent Acquisition and Enforcement

The Patent Act of 1952[22] (also known as the Patent Act) obliges innovators to prepare and submit applications to the USPTO if they wish to obtain patent protection.[23] USPTO officials known as examiners then assess whether the application merits the award of a patent.[24] In deciding whether to approve a patent application, a USPTO examiner considers whether the submitted application fully discloses and distinctly claims the invention.[25] The examiner will also determine whether the invention itself fulfills certain substantive standards set by the patent statute. To be patentable, an invention must be useful, novel and nonobvious. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides a tangible benefit.[26] To be judged novel, the invention must not be fully anticipated by a prior patent, publication or other knowledge within the public domain.[27] A nonobvious invention must not have been readily within the ordinary skills of a competent artisan at the time the invention was made.[28]

If the USPTO allows the patent to issue, the patent proprietor obtains the right to exclude others from making, using, selling, offering to sell or importing into the

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[19] *See* Frederic M. Scherer and David Ross, *Industrial Market Structure and Economic Performance* (Rand McNally & Co., 3d ed. 1990).

[20] *See, e.g.*, Pamela Samuelson, "*Benson* Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program — Related Inventions," 39 *Emory Law Journal* (1990), 1025.

[21] CRS Report RL31951, *Innovation, Intellectual Property, and Industry Standards*, by (name redacted), May 29, 2003.

[22] P.L. 82-593, 66 Stat. 792 (codified at Title 35 United States Code).

[23] 35 U.S.C. § 111 (2004).

[24] 35 U.S.C. § 131 (2004).

[25] 35 U.S.C. § 112 (2004).

[26] 35 U.S.C. § 101 (2004).

[27] 35 U.S.C. § 102 (2004).

[28] 35 U.S.C. § 103 (2004).

United States the patented invention.[29] The term of the patent is ordinarily set at twenty years from the date the patent application was filed.[30] Patent title therefore provides inventors with limited periods of exclusivity in which they may practice their inventions, or license others to do so. The grant of a patent permits the inventor to receive a return on the expenditure of resources leading to the discovery, often by charging a higher price than would prevail in a competitive market.

Once the patent is issued, its proprietor bears responsibility for monitoring its competitors to determine whether they are using the patented invention or not. Patent owners who wish to compel others to observe their intellectual property rights must usually commence litigation in the federal district courts. The U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") possesses exclusive national jurisdiction over all patent appeals from the district courts,[31] while the U.S. Supreme Court possesses discretionary authority to review cases decided by the Federal Circuit.[32]

## Fundamentals of Marketing Exclusivity

The U.S. government regulates the marketing of pharmaceuticals and agricultural chemicals in the interest of public health.[33] Under this regime, the developer of a new drug — known as its "sponsor" — must demonstrate that the product is safe and effective before it can be distributed to the public. This showing requires a sponsor to conduct both preclinical and clinical investigations of drugs that have not been previously tested.[34] In deciding whether to issue marketing approval or not, the FDA evaluates the test data that the sponsor submits in a so-called New Drug Application (NDA).

The FDA maintains the test data incorporated into a NDA in confidence.[35] In addition, because the required test data is ordinarily quite costly to generate, sponsors of new pharmaceuticals ordinarily do not disclose them to the public. Otherwise the

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[29] 35 U.S.C. § 271(a) (2004).

[30] 35 U.S.C. § 154(a)(2) (2004).

[31] 28 U.S.C. § 1295(a)(1) (2004).

[32] 28 U.S.C. §1254(1) (2004).

[33] CRS Report RL30989, *The U.S. Drug Approval Process: A Primer*, by Blanchard Randall IV.

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

[35] *See* James T. O'Reilly, "Implications of International Drug Approval Systems on Confidentiality of Business Secrets in the U.S. Pharmaceutical Industry," 53 *Food & Drug Law Journal* (1998), 123.

sponsor's competitors could file their own NDAs using that test data, and thereby avoid the expenses of developing the information themselves.[36]

Prior to the introduction of the Hatch-Waxman Act, federal law contained no separate provisions addressing generic versions of brand-name drugs that the FDA had previously approved for marketing.[37] The result was that a would-be generic drug manufacturer had to file its own NDA in order to market its drug.[38] Some generic manufacturers could rely on published scientific literature demonstrating the safety and efficacy of the drug. Because these sorts of studies were not available for all drugs, however, not all generic firms could file these so-called paper NDAs.[39] Further, at times the FDA would request additional studies to address safety and efficacy questions that arose from experience with the drug following its initial approval.[40] The result was that some generic manufacturers were forced to prove independently that their pharmaceuticals were safe and effective, even though their products were chemically identical to those of previously approved drugs.

Some commentators believed that the approval of a generic drug was a needlessly costly, redundant, and time-consuming process prior to the Hatch-Waxman Act.[41] These observers noted that although patents on important drugs had expired, manufacturers were not moving to introduce generic equivalents for these products due to the level of resource expenditure required to obtain FDA marketing approval.[42] As the introduction of generic equivalents often causes prices to decrease, the interest of consumers was arguably not being served through these observed costs and delays.[43]

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[36] Rebecca S. Eisenberg, "Pharmaceutical Innovation and Cost: An American Dilemma," 5 *Yale Journal of Health Policy, Law & Ethics* (2005), 717.

[37] *See* Alfred B. Engelberg, "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?," 39 *Idea: Journal of Law and Technology* (1999), 389.

[38] *See* James J. Wheaton, "Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984," 34 *Catholic University Law Review* (1986), 439.

[39] *See* Kristin E. Behrendt, "The Hatch-Waxman Act: Balancing Competing Interest or Survival of the Fittest?," 57 *Food & Drug Law Journal* (2002), 247.

[40] *Id.*

[41] *See, e.g.,* Justina A. Molzon, "The Generic Drug Approval Process," 5 *Journal of Pharmacy and Law* (1996) , 275 ("The Act streamlined the approval process by eliminating the need for [generic drug] sponsors to repeat duplicative, unnecessary, expensive and ethically questionable clinical and animal research to demonstrate the safety and efficacy of the drug product.").

[42] *See* Jonathon M. Lave, "Responding to Patent Litigation Settlements: Does the FTC Have It Right Yet?," 64 *University of Pittsburgh Law Review* (2002), 201 ("Hatch-Waxman has also increased the generic drug share of prescription drug volume by almost 130% since its enactment in 1984. Indeed, nearly 100% of the top selling drugs with expired patents have generic versions available today versus only 35% in 1983.").

[43] *See, e.g.,* Henry Grabowski, *Health Reform and Pharmaceutical Innovation*, 24 *Seton Hall Law Review* (1994), 1221 (noting that one "analysis of generic competition in the late 1980s

(continued...)

In response to these concerns, the Hatch-Waxman Act created a new type of application for market approval of a drug. This application, termed an "Abbreviated New Drug Application" (ANDA), may be filed at the FDA.[44] An ANDA may be filed if the active ingredient of the generic drug is the bioequivalent of the approved drug. An ANDA allows a generic drug manufacturer to rely upon the safety and efficacy data of the original manufacturer. The availability of the ANDA mechanism often allows a generic manufacturer to avoid the costs and delays associated with filing a full-fledged NDA. ANDAs also allow a generic manufacturer, in many cases, to place its FDA-approved bioequivalent drug on the market as soon as any relevant patents expire.[45]

The Hatch-Waxman Act placed certain limits upon the ability of generic competitors to reference the data generated by the manufacturers of brand-name drugs. These limitations — termed marketing exclusivities — consist of a period of time during which a competitor's ability to obtain FDA permission to sell a generic version of a previously approved brand-name drug is restricted. The federal food and drug laws establish several different sorts of marketing exclusivities, relating to new chemical entities, new clinical studies, orphan drugs, and pediatric studies.[46] This report describes each of these marketing exclusivities below.

## New Chemical Entity Exclusivity

The Hatch-Waxman Act established a five-year exclusivity that is available to drugs that qualify as a new chemical entity (NCE). The purpose of this "NCE exclusivity" is to encourage the development of innovative drug products that include an entirely new active ingredient (commonly termed the "active moiety"), in contrast to "me-too" drugs that incorporate chemical variants of previously known compounds. NCE exclusivity prevents a subsequent generic applicant from relying upon the data submitted by the innovative drug company during a five-year period. As a result, generic firms are precluded from relying upon this data for five years from the date of the approval of the NDA for that active moiety.[47]

A drug is judged to be an NCE if the FDA has not previously approved that drug's active ingredient.[48] The Hatch-Waxman Act expressly stipulates that a drug does not qualify as an NCE if it consists of the salt or ester of a previously approved

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[43] (...continued)
found that generic prices decline on average to about one-third of the brand name's price within two years of initial market entry.").

[44] 21 U.S.C. § 355(j)(1) (2004).

[45] *See, e.g.*, Sarah E. Eurek, "Hatch-Waxman Reform and Accelerated Entry of Generic Drugs: Is Faster Necessarily Better?," 2003 *Duke Law and Technology Review* (Aug. 13, 2003), 18

[46] *See generally* Elizabeth H. Dickinson, "FDA's Role in Making Exclusivity Determinations," 54 *Food & Drug Law Journal*. 195 (1999).

[47] 21 U.S.C. §355(j)(5)(F)(ii) (2004).

[48] *See* 21 C.F.R. §314.108(a) (2004).

active ingredient.[49] During that five-year period of NCE exclusivity, the FDA may not accept a generic drug company's application to market a drug product containing the same active moiety protected under the NCE exclusivity. This prohibition holds even if these applications are directed toward a different use, dosage form, or ester or salt of the active ingredient.[50] NCE exclusivity does not preclude the FDA from accepting an application submitted by an entity that has performed all the required preclinical and clinical studies itself.[51]

The Hatch-Waxman Act allows the five-year term of NCE exclusivity to be decreased to four years under one circumstance. If the NDA holder owns patents that the generic applicant believes are invalid or not infringed, then the generic applicant is allowed to file its application one year early — upon the expiration of four, rather than five years from the date the NDA was approved.[52] The apparent purpose of this provision is to allow additional time for brand-name and generic pharmaceutical firms to put their patent affairs in order prior to generic marketing.

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 the FDA review of the generic application.[53] If, for example, the FDA requires two years to approve a particular generic application, the real-world impact of the NCE exclusivity has been seven years of protection. In this respect NCE exclusivity operates differently from other forms of FDA-administered exclusivities. These exclusivities generally prevent the FDA from approving applications, rather than accepting them in the first instance.[54]

## New Clinical Study Exclusivity

In order to encourage improvements upon drugs that are already in use, the Hatch-Waxman Act also provided for a three-year new clinical study exclusivity period. New clinical study exclusivity may be awarded with respect to either an NDA[55] or supplemental NDA[56] that contains reports of new clinical studies conducted by the sponsor that are essential to FDA approval of that application. The FDA has granted new clinical study exclusivity for such changes as new dosage

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[49] 21 U.S.C. §355(j)(5)(F) (2004).

[50] 21 U.S.C. §355(j)(5)(F) (2004).

[51] Dickinson, *supra* note 46, at 200.

[52] 21 U.S.C. §355(j)(5)(F)(ii) (2004). Stated in more technical terms, a generic firm may file a paragraph IV application with respect to an NCE four years after the approval date of the NDA.

[53] *See* Marvin M. Goldenberg, "Medicare and the New Generic Drug Legislation," 29 *Pharmacy and Therapeutics* no. 2 at 89, 90 (Feb. 2004).

[54] Dickinson, *supra* note 46, at 200.

[55] 21 U.S.C. §355(j)(5)(F)(iii) (2004).

[56] 21 U.S.C. §355(j)(5)(F)(iv) (2004).

forms, new indications, or for a switch from prescription to over-the-counter status for the drug.[57]

The Hatch-Waxman Act imposes four requirements that an investigation must fulfill in order to qualify for new clinical study exclusivity.[58] First, the study must be new, in that it could not have been previously used for another FDA drug approval proceeding. Second, the study must be a clinical study on humans, as compared to a preclinical study, and not a bioavailability or bioequivalence study.[59] Third, the study must have been "conducted or sponsored" by the applicant. FDA regulations stipulate that an applicant that has provided "substantial support" for the investigation fulfills this requirement.[60] The statement of a certified public accountant that the applicant provided 50 percent or more of the cost of conducting the study qualifies as substantial support, and the FDA will also entertain explanations of why the applicant should be considered to have "conducted or sponsored" the study if the applicant provided less than half of the funding for that study.[61]

Finally, the study must be "essential to the approval" of the application or supplement. The FDA has defined the term "essential to approval" as meaning "that there are no other data available that could support approval of the application."[62] A study that provides useful background information, but is not essential to approving the change in the drug, does not provide sufficient basis for an FDA award of new clinical study exclusivity.[63]

In contrast to NCE exclusivity, new clinical study exclusivity does not prevent the FDA from accepting a generic application with respect to the drug. If the new clinical study exclusivity continues to bar the issuance of marketing approval at the close of FDA review, the FDA will issue a tentative approval for the generic product that will become effective once the new clinical study exclusivity has run its course.[64]

In addition, new clinical study exclusivity only applies to the use of the product that was supported by the new clinical study.[65] If, for example, the new studies support a new indication or dosage form of the previously approved ingredient, then the three-year exclusivity applies only to that particular use or dosage form. The

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[57] Dickinson, *supra* note 46, at 201.

[58] 21 U.S.C. §355(j)(5)(F)(iii)-(iv) (2004).

[59] *See* 21 C.F.R. §314.108(a) (2004).

[60] *Id.*

[61] *Id.*

[62] *Id.*

[63] *See* Upjohn Co. v. Kessler, 938 F. Supp. 439 (W.D. Mich. 1996).

[64] *See* Dickinson, *supra* note 46, at 201.

[65] *See* Junod, *supra* note 4, at 500.

FDA is not barred from approving a generic drugs for other indications or dosage forms.[66]

A drug product may be subject both to NCE exclusivity and new clinical study exclusivity during the life of that product. Commonly, a new drug will initially enjoy a five-year NCE exclusivity. Later in the life of that product, the sponsor of the drug may perform additional clinical trials to qualify the drug for additional three-year exclusivities.[67]

As with NCE exclusivity, new clinical study exclusivity does not preclude the FDA from approving a full NDA. If the sponsor of that subsequent NDA has performed all the required preclinical and clinical studies itself, the FDA may approve the NDA without regard to the new clinical trial exclusivity.[68]

## Pediatric Exclusivity

Brand-name firms may qualify for a six-month pediatric exclusivity upon the completion of studies on the effects of a drug upon children.[69] This six-month period begins on the date that the existing patent or data exclusivity protection on the innovator drug would otherwise expire.[70] Pediatric exclusivity extends to any drug product with the same active ingredient (also known as the drug's "active moiety").[71] The purpose of the pediatric marketing exclusivity is to improve the availability of appropriate pediatric labeling on drug products.[72]

Congress first established pediatric marketing exclusivities with the Food and Drug Administration Modernization Act of 1997 (FDAMA).[73] Although the FDAMA included a sunset provision effective January 1, 2002,[74] Congress subsequently reauthorized these provisions in the Best Pharmaceuticals for Children Act (BPCA) in 2002.[75] In turn, the BPCA sunsets on October 1, 2007, although it is of course subject to future legislative extensions.[76]

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[66] *See* Thomas J. Parker *et al.*, "FDA Marketing Exclusivity for Single Enantiomers of Previously Approved Racemates," 15 *Journal of Proprietary Rights* (Jan. 2003), no. 1 at 8.

[67] *See* Junod, *supra* note 4, at 489.

[68] Dickinson, *supra* note 46, at 200.

[69] 21 U.S.C. §355a (2004).

[70] 21 U.S.C. §355a (2004).

[71] 21 U.S.C. §355a(b) (2004); Dickinson, *supra* note 46, at 203.

[72] *See* Karena J. Cooper, "Pediatric Marketing Exclusivity — As Altered by the Best Pharmacueticals for Children Act of 2002," 58 *Food & Drug Law Journal* (2002), 519.

[73] P.L. 105-115, 111 Stat. 2296, at §11 (1997) (introducing 21 U.S.C. §355a).

[74] *Id.* (introducing 21 U.S.C. §355a(j)).

[75] P.L. 107-109, 115 Stat. 1408 (2002).

[76] *Id.* at §8 (codified at 21 U.S.C. §355a(n)).

In enacting the FDAMA and BPCA, Congress responded to concerns that many FDA-approved drugs had not yet been clinically tested upon children. Investigations upon a pediatric population tends to raise a number of complexities, including issues of informed consent, the changes that occur in children as they grow, and the inability of children to describe accurately the effect of a medication. As a result, most drugs are tested solely upon adults. By establishing a pediatric marketing exclusivity, Congress hoped to encourage additional pediatric testing, which in turn could allow medications to be labeled for use by children.[77]

Pursuant to the FDAMA and BPCA, the FDA issues written requests to NDA applicants and holders to perform pediatric studies with respect to the drug. An FDA written request contains such information as the indications and the number of patients to be studied, the labeling that may result from such studies, the format of the report to be submitted to the FDA, and the timeframe for completing the studies. Response to this written request is wholly voluntary. If the innovative drug company submits a report to the satisfaction of the FDA, however, then it will be awarded the six-month pediatric marketing exclusivity.[78]

Notably, the food and drug laws do not condition pediatric exclusivity upon the success of the study. The six-month marketing exclusivity period may be obtained whether or not the study successfully demonstrates safety and effectiveness in children. Thus, the FDAMA and BPCA were merely intended to create incentives for drug sponsors to conduct research and submit their results to the FDA.

The effect of a pediatric exclusivity is to extend the approved manufacturer's existing patent or marketing exclusivity protection for an additional six months.[79] Note that pediatric exclusivity does not actually extend the term of a patent; rather, it is a marketing exclusion administered by the FDA.

## Orphan Drug Exclusivity

In 1982, Congress enacted the Orphan Drug Act[80] in order to encourage firms to develop pharmaceuticals to treat rare diseases and conditions.[81] Such drugs are

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[77] *See* Lauren Hammer Breslow, "The Best Pharmaceuticals for Children Act of 2002: The Rise of the Voluntary Incentive Structure and Congressional Refusal to Require Pediatric Testing," 40 *Harvard Journal on Legisilation* (2003), 133; Michael S. Labson, "Pediatric Priorities: Legislative and Regulatory Initiatives to Expand Research on Use of Medicines in Pediatric Patients," 6 *Journal of Health Care Law & Policy* (2002), 34; Karl R. Karst, "Pediatric Testing of Prescription Drugs: The Food and Drug Administration's Carrot and Stick for the Pharmaceutical Industry," 49 *American University Law Review* (2000), 739.

[78] 21 U.S.C. §355a(b) (2004).

[79] *Id.*

[80] Orphan Drug Act, P.L. 97-414, 96 Stat. 2049 (1982) (codified as amended at 21 U.S.C. §§ 360aa-360ee (2000), 26 U.S.C. § 45C (2000), 42 U.S.C. § 236 (2000)).

[81] *See*, e.g., Gary A. Pulsinelli, "The Orphan Drug Act: What's Right With It," 15 *Santa Clara Computer & High Technology Law Journal* (1999), 299; Li-Hsien Rin-laures, (continued...)

called "orphan drugs" because firms may lack the financial incentives to sponsor products to treat small patient populations.[82] Congressional encouragement takes a number of forms under the Orphan Drug Act, including FDA protocol assistance,[83] tax breaks,[84] and a grants program through which researchers may compete for grants to conduct clinical trials to support the approval of orphan drugs.[85]

The most commercially significant of all of these benefits is a seven-year term of orphan drug marketing exclusivity.[86] This period commences from the date the FDA issues marketing approval on the drug.[87] The original version of the Orphan Drug Act extended marketing approval only to drugs that were not patented. However, Congress amended the statute in 1985 to provide for marketing exclusivity both for patented and unpatented products.[88]

Orphan drug marketing exclusivity applies only to the indication for which the drug is approved. As a result, the FDA could approve a second application of the same drug for a different use. The FDA cannot approve the same drug made by another manufacturer for the same use, however, unless the original sponsor approves or the original sponsor is unable to provide sufficient quantities of the drug to the market.[89]

As originally enacted, the Orphan Drug Act defined an orphan drug as one for which there was no "reasonable expectation that the cost of developing . . . will be recovered from sales in the United States of such drug."[90] In 1984, Congress changed the definition to its present form.[91] Currently, in order to qualify for orphan drug status, the drug must treat a rare disease or condition (1) affecting less than 200,000 people in the United States, or (2) affecting more than 200,000 people in the United States, but for which there is no reasonable expectation that the sales of the drug

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[81] (...continued)
"Recent Developments Concerning the Orphan Drug Act," 4 *Harvard Journal of Law and Technology* (1991), 269. The Orphan Drug Act also applies to varying degrees to biologics and medical devices, which, along with drugs, are commonly termed "orphan products."

[82] *See, e.g.*, David B. Clissold, "Prescription for the Orphan Drug Act: The Impact of the FDA's 1992 Regulations and the Latest Congressional Proposals for Reform," 50 *Food & Drug Law Journal* (1995), 125.

[83] 21 U.S.C. §360aa (2004).

[84] 26 U.S.C. § 45C (2004).

[85] 21 U.S.C. §360ee (2004).

[86] 21 U.S.C. §360cc (2000).

[87] *Id.*

[88] Orphan Drug Amendments of 1985, P.L. 99-91, 99 Stat. 387 (1985).

[89] 21 U.S.C. § 360cc(b) (2004).

[90] Orphan Drug Act, P.L. 97-414, § 526(a)(2), 96 Stat. 2049 (1982) (codified as amended at 21 U.S.C. § 360bb(a)(2) (2000)).

[91] Health Promotion and Disease Prevention Amendments of 1984, P.L. 98-551, 98 Stat. 2815 (1984).

would recover the costs.[92] As can be appreciated, the effect of this change was to allow drug sponsors to avoid making a showing of unprofitability if the target population consisted of less than 200,000 persons.

The original version of the Orphan Drug Act allowed a sponsor to request orphan drug status at any time prior to FDA marketing approval. Congress amended the statute in 1988, however, to require that the sponsor make this designation request prior to the submission of an application for marketing approval.[93]

Pediatric exclusivity may also extend the period of marketing exclusivity enjoyed by an orphan drug. If a product is subject to both orphan drug marketing exclusivity and pediatric exclusivity, the total period of exclusivity is therefore seven years, six months.[94]

# Innovation Policy Issues

Two decades of experience with the Hatch-Waxman Act have resulted in diverse opinions concerning the system of incentives for innovation within the pharmaceutical industry. As pharmaceutical firms may obtain patents from the USPTO, some observers question the need for the FDA to grant marketing exclusivities as well.[95] Other observers essentially take the opposite view, asserting that the marketing exclusivities available under U.S. law should be lengthened to match European standards.[96] Issues have also arisen with respect to the use of marketing exclusivities to encourage the private sector to develop bioterrorism countermeasures, as well as whether other nations are obligated by World Trade Organization (WTO) agreements to grant marketing exclusivities similar to U.S. law. This report reviews these issues in turn.

## Policy Justifications for Marketing Exclusivities

Several scholarly commentators have called into question the viability of FDA marketing exclusivities. They have explained that the developer of a NCE will ordinarily be able to obtain a patent covering the product itself. In addition, the sponsor of new clinical studies may be able to procure patents covering any new methods of medical treatment that these studies reveal.[97] Further, marketing exclusivities most often run concurrently with, but expire prior to, patents covering the approved pharmaceutical. As a result, the practical effect of these marketing exclusivities is to award exclusive rights for discoveries that could not fulfill the

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[92] 21 U.S.C. §360bb(a)(2) (2004).

[93] Orphan Drug Amendments of 1988, P.L. 100-290, 102 Stat. 90 (1988) (codified as amended at 21 U.S.C. § 360bb(a)(1) (2000)).

[94] 21 U.S.C. §355a(b)(1)(B) (2004).

[95] Eisenberg, *supra* note 12.

[96] Junod, *supra* note 4.

[97] Junod, *supra* note 4.

requirements of the Patent Act.[98] The justification for the award of patent-like protections for such "sub-patentable" inventions is, in the view of some observers, not particularly clear.[99]

On the other hand, some commentators believe that NCE and new clinical study exclusivities have an important policy role to play in pharmaceutical innovation. For example, new clinical study exclusivity may provide important incentives for pharmaceutical firms that the patent system does not. Rebecca Eisenberg, a member of the law faculty of the University of Michigan, observes that patent protection "does a better job of motivating the development of the initial R&D that is necessary to bring new products to market then it does of motivating the development of new information about old drugs."[100] This situation is due to the generally limited scope of patents resulting from new clinical studies. Usually such patents are limited to new methods of medical treatment that are discovered for a known product, and thus are commonly of diminished impact upon competitors in comparison with that cover drug products themselves. Under this view, new clinical study exclusivities provide needed incentives for pharmaceutical firms to continue to develop new information regarding approved drugs. It should be appreciated, however, that new clinical study exclusivity applies only to the use of the product that was supported by the new clinical study — and, in particular, not to uses of the drug that were already known — and as a result it may also be of less value in the marketplace than NCE exclusivity.[101]

In addition, the availability of NCE exclusivity may encourage more dramatic innovation than does the patent system. Compounds that are similar to known pharmaceuticals may nonetheless be patented in appropriate circumstances. Because all patented compounds are subject to the same term and scope of protection, patented "me too" drugs are subject to the same entitlements under the Patent Act as more dramatic advances. The availability of NCE exclusivity may therefore provide pharmaceutical firms with additional incentives to engage in more ambitious research and development efforts. NCE exclusivity may also be justified by the additional expenses an innovative pharmaceutical firm must bear not just to identify a promising new pharmaceutical, but also to shepherd it through the costly and time-consuming FDA marketing approval process.

With respect to pediatric and orphan drug exclusivity, certain critics believe that they have led to higher drug prices without a corresponding benefit to the public.[102] They believe that the pediatric exclusivity creates a windfall for brand-name pharmaceutical companies, which in some cases may obtain far greater revenues

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[98] Eisenberg, *supra* note 12.

[99] *See* Mark D. Janis, "Second Tier Patent Protection," 40 *Harvard International Law Journal* (1999), 151.

[100] Eisenberg, *supra* note 12.

[101] Thomas, *supra* note 3, at 353.

[102] The views of these critics are presented in Robert Steinbrook, "Testing Medications in Children," 347 *New England Journal of Medicine* iss. 18 at 1462 (Oct. 31, 2002), and "House Panel Acts on Pediatric Testing," 55 *Medicine & Health* iss. 36 at 5 (Oct. 8, 2001).

through six months of marketing exclusivity than they expended on their pediatric studies. Other observers take a more positive view, going so far to describe the pediatric exclusivity as "one of the most extraordinarily successful federal initiatives that has ever been accomplished for children."[103]

Detractors of orphan drug exclusivity contend that because the statute relies upon a market-oriented strategy to promote drug development, it had resulted in high drug prices.[104] Perhaps motivated by these concerns, the 101st Congress passed legislation that allowed for shared orphan drug marketing exclusivity, and terminated orphan drug marketing exclusivity altogether if the prevalence of the disease increased to more than 200,000 people in the United States.[105] President George H.W. Bush pocket vetoed this legislation in 1990, however, believing that this legislation would "discourage development of desperately needed orphan drugs."[106] On the other hand, some observers note that the Orphan Drug Act has coincided with a large increase in the number of pharmaceuticals available to treat rare diseases and conditions.[107]

## The Term of Marketing Exclusivities

Although some commentators believe that marketing exclusivities are inappropriate or unnecessary, others assert that current U.S. terms of marketing exclusivity fall short of international standards and should be lengthened. In this regard, U.S. law is often contrasted with the substantially longer terms of marketing exclusivity available within the European Union. A European Union law enacted in 2004, which applies to new drugs seeking marketing authorization after October 30, 2005,[108] provides a so-called 8+2+1 standard for innovative pharmaceuticals. Under this standard, a generic firm cannot submit the European version of an ANDA until eight years have passed following the award of marketing approval for the so-called

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[103] Richard Gorman, Testimony Before the House of Representatives Committee on Energy and Commerce, Subcommittee on Health (May 3, 2001) (available at [http://www.aap.org/advocacy/washing/Testimony_303_gorman.htm]). Dr. Gorman was affiliated with the American Academy of Pediatrics at the time of his testimony.

[104] *See, e.g.*, Anticompetitive Abuse of the Orphan Drug Act: Invitation to High Prices: Hearings Before the Subcomm. on Antitrust, Monopolies & Business Rights of the Senate Comm. on the Judiciary, 102d Cong., 2d Sess. 198 (1992).

[105] Orphan Drug Amendments Act of 1990, H.R. 4638.

[106] Memorandum of Disapproval, H.R. 4638, 137 CONG. REC. H74 (Jan. 3, 1991).

[107] *See* U.S. Food and Drug Administration, Office of Orphan Drugs Development (available at [http://www.fda.gov/orphan/index.htm]). *See, e.g.*, David Duffied Rohde, "The Orphan Drug Act: An Engine of Innovation? At What Cost?," 55 *Food & Drug Law Journal* (2000), 125; Robert A. Bohrer & John T. Prince, "A Tale of Two Proteins: The FDA's Uncertain Interpretation of the Orphan Drug Act," 12 *Harvard Journal of Law & Technology* (1999); 365; John J. Flynn, "The Orphan Drug Act: An Unconstitutional Exercise of the Patent Power," 1992 *Utah Law Review* 389.

[108] Council Directive 2004/27/EC, Art. 10, 2004 O.J. (L 136) 34.

reference medicinal product.[109] However, marketing approval cannot be awarded until ten years have elapsed from the date of first marketing authorization.[110]

This ten-year period can be extended by one additional year if the drug's sponsor obtains marketing approval for a new therapeutic indication. The new indication must "bring significant clinical benefit in comparison with existing therapies."[111] The "+1" provision is analogous to the three-year new clinical trial exclusivity available in the United States, although important distinctions exist. Only new therapeutic indications are entitled to an additional year of protection. Unlike the United States, new strengths, dosage forms, routes of administration are not entitled to protection. In Europe, the drug's sponsor obtains only a single one-year extension, even if it obtains marketing approval for multiple new uses.[112] In further contrast to the United States, the one-year period is effective against all uses of the drug, both old and new.[113]

Some commentators believe that levels of marketing exclusivity available under the Hatch-Waxman Act should be extended to levels of protection prevailing in Europe. As explained by attorney Valerie Junod, supporters of this view "contend that the U.S. pharmaceutical industry suffers from a competitive disadvantage because drugs sold in the United States benefit from a much shorter five-year exclusivity period" in comparison with the "ten-year period of European data protection."[114] One of the original sponsors of the Hatch-Waxman Act, Senator Orrin Hatch, has also stated:

> [T]he Hatch-Waxman Act provides for five years of marketing exclusivity for all new chemical entity drugs, independent of patent protection. In contrast, it is my understanding that most European nations . . . have adopted a 10-year data exclusivity rule. Why not consider harmonizing and move to the European standard for this important information which, but for Hatch-Waxman, would be considered proprietary information?[115]

Further consideration of this proposal would focus upon factors such as the need for non-patent incentives for the development of chemical entities, the value of harmonization of the laws of the United States and its leading trading partners, and the effect this proposal would have upon the availability of generic competition.

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[109] Council Directive 2004/27/EC at Art. 10, ¶1.

[110] *Id.*

[111] *Id.*

[112] *See* Junod, *supra* note 7, at 513.

[113] *Id.*

[114] *Id.* at 501.

[115] Pharmaceutical Research and Development, 148 *Cong. Rec.* S7875-02 (Aug. 1, 2002).

## Expansion of Marketing Exclusivities

The 109th Congress is currently considering the use of marketing exclusivity mechanisms in order to encourage the private sector to develop bioterrorism countermeasures. One of these bills, the Biodefense and Pandemic Vaccine and Drug Development Act of 2005, S. 1873, would allow specified biological, chemical, radiological, and nuclear agents, as well as certain toxins, to qualify as a "rare disease or condition" under the existing provisions of the Orphan Drug Act. As such, certain countermeasure products designed to diagnose, mitigate, prevent, or treat harm from one of these agents or toxins would be entitled to orphan drug exclusivity. S. 1873 further stipulates that the period of orphan drug exclusivity will be ten years, rather than seven years, with respect to these countermeasures.

Existing federal legislation has employed marketing exclusivities to encourage specific forms of technological innovation, such as the development of new chemical entities and orphan drugs. This option remains more attractive than an alternative possibility — extending the terms of patents on particular kinds of inventions — due to international agreements that restrict the enactment of technology-specific measures within the patent system. One component of the international agreement forming the World Trade Organization (WTO) is the so-called TRIPS Agreement, or Agreement on Trade-Related Aspects of Intellectual Property Rights.[116] Under Article 27 of the TRIPS Agreement, "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."[117] Although the TRIPS Agreement allows for some exceptions to this general principle of technological neutrality,[118] they are of very narrow application. As a result, efforts to extend patent terms for favored technologies, such as bioterrorism countermeasures, may not comport with the international obligations of the United States. The creation, or extension, of marketing exclusivities therefore remains a treaty-compliant option for stimulating select forms of technological development.

## International Issues

In addition to establishing a principle of "technological neutrality" for the patent system, the TRIPS Agreement also requires each WTO member state to establish protections for pharmaceutical test data under certain conditions. Article 39.3 of the TRIPS Agreement specifically provides:

> Members, when requiring as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except

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[116] See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, 33 I.L.M. 1197 (1994) [hereinafter "TRIPS Agreement"].

[117] TRIPS Agreement, Art. 27 ¶1.

[118] *Id.* at Art. 30.

> where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Some commentators have observed that Article 39.3 establishes broad parameters using vague language.[119] In particular, terms such as "new chemical entities," "considerable effort," and "unfair commercial use" receive no further definition within the TRIPS Agreement. As a result, the precise nature of the obligations Article 39.3 imposes upon WTO member states is not entirely clear.[120]

Given the uncertainties with respect to Article 39.3 of the TRIPS Agreement, the United States has entered into certain Free Trade Agreements (FTAs) that require their signatories to provide five years of marketing exclusivity for pharmaceuticals that utilize new chemical entities. For example, Article 15.10:1(a) of the Dominican Republic-Central America-United States FTA provides:

> If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.[121]

The term "new product" is generally defined as "one that does not contain a chemical entity that has been previously approved in the territory of the Party."[122]

Certain of the FTAs additionally require their signatories to allow a three-year term of marketing exclusivity in various circumstances for pharmaceuticals that do not qualify as new products.[123] For example, the Australia-United States FTA provides in part:

> With respect to pharmaceutical products, if a Party requires the submission of: (a) new clinical information (other than information related to bioequivalency) or (b) evidence of prior approval of the product in another territory that requires such new information, which is essential to the approval of a pharmaceutical product, the Party shall not permit third persons not having the consent of the person providing the information to market the same or a similar pharmaceutical product on the basis of the

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[119] *See* Lorna Brazell, *A World United? The US Approach to the Protection of Regulatory Data* (Jan. 12, 2005) (available at [http://www.bilaterals.org]).

[120] *Compare* G. Lee Skillington and Eric M. Solovy, "The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement," 24 *Northwestern Journal of International Law & Business* (2003), 1, *with* Carlos Maria Correa, "Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals," 3 *Chicago Journal of International Law* (2002), 69.

[121] U.S.-Chile FTA, Art. 17.10(1).

[122] *See, e.g.*, DR-CAFTA Art. 15.10:1(c).

[123] *See, e.g.*, U.S.-Bahrain FTA Art. 14.9(2)(a); U.S.-Jordan FTA Art. 22 n.10.

> marketing approval granted to a person submitting the information for a period of at least three years from the date of the marketing approval by the Party or the other territory, whichever is later.[124]

The use of FTAs to stipulate marketing exclusivity periods is controversial. Because the FTA marketing exclusivity requirements arguably exceed those of the TRIPS Agreement, some commentators believe that the FTAs have provided the United States with a vehicle for advancing the interests of innovative pharmaceutical firms at the expense of the public health needs of developing countries. As Carlos Correa, a member of the University of Buenos Ares faculty, explains: "The CAFTA [Central American Free Trade Agreement] denies the right of developing countries to use to the fullest extent possible the flexibilities allowed by the TRIPS Agreement to protect public health."[125]

On the other hand, the TRIPS Agreement already obliges WTO members to protect pharmaceutical test data against "unfair commercial use."[126] In this light, the FTA marketing exclusivity provisions may be seen as affirming and further specifying an existing obligation. It should also be noted that the minimum marketing exclusivity provisions compelled by the FTAs are substantially less than European standards. Finally, any international agreement involves an exchange of promises between the signatory states. The partners to a particular FTA would appear to be best situated to determine the advantages and disadvantages of entering into that agreement for themselves.

## Concluding Observations

In combination, patents and marketing exclusivities provide the fundamental framework of intellectual property incentives for pharmaceutical innovation in the United States. Due to the TRIPS Agreement's obligation of technological neutrality with respect to the patent system,[127] marketing exclusivities provide Congress with a more flexible option for stimulating specific sorts of desirable private activity than do patents. As such, marketing exclusivities have been, and likely will continue to be, the most viable option for encouraging the development of discrete classes of products regulated by the FDA.

The potential for expanded use of marketing exclusivities in turn raises a number of innovation policy issues. In the United States, marketing exclusivities are viewed primarily as supplementing patent protection, in that they provide more limited protections for inventions that do not meet Patent Act requirements, or

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[124] U.S.-Australia FTA, Art. 17.10(2).

[125] Carlos M. Correa, "Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines," 36 *Case Western Reserve Journal of International Law* (2004), 79.

[126] TRIPS Agreement, Art. 39(3).

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

effectively delay the onset of patent litigation for inventions that do.[128] Expanding the availability of marketing exclusivities, in addition to lengthening their term to European levels, increases the possibility that marketing exclusivities will trump patents as the primary form of intellectual property protection for certain FDA-regulated products. The decision to supplant the primacy of the current regime of USPTO-procured and judicially enforced patent rights with a system of automatic, FDA-administered marketing exclusivities presents a number of trade-offs that policy makers may wish to consider. Among them are the impact of the contemplated exclusivity periods upon both the incentives for pharmaceutical innovation and the availability of medications to consumers; the desirability of individualized determinations about the technical merits of the pharmaceutical invention; and whether the USPTO or FDA is the better institution for awarding proprietary rights to pharmaceutical innovators.

International harmonization provides another significant issue with respect to marketing exclusivities. Even as some commentators have expressed concerns over the use of FTAs to encourage trading partners to establish marketing exclusivities at domestic levels, others observe that European levels of protection are substantially longer than their Hatch-Waxman analogues. Future dialogue may concern setting global marketing exclusivity standards in view of national goals and priorities.

Finally, policy makers may appreciate that general patent reform legislation has been the subject of significant discussion during the 109th Congress.[129] Current legislative proposals do not appear to impact the fundamental landscape of patents and marketing exclusivities within the pharmaceutical industry. Because legislative reform efforts are still underway, however, congressional attention to the impact of broadly oriented patent reforms upon the pharmaceutical industry may be appropriate.

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[128] Eisenberg, *supra* note 12.

[129] See CRS Report RL32996, *Patent Reform: Innovation Issues*, by (name redacted) and (name redacted).