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Bioterrorism Countermeasure Development: Issues in Patents and Homeland Security

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Wendy H. Schacht
Specialist in Science and Technology
Resources, Science, and Industry Division

John R. Thomas
Visiting Scholar
Resources, Science, and Industry Division

Bioterrorism Countermeasure Development: Issues in Patents and Homeland Security

Summary

Congressional interest in the development of bioterrorism countermeasures remains strong, even after passage of legislation establishing Project BioShield. During the 109th Congress, several bills were introduced (although not enacted), including S. 3, the Protecting America in the War on Terror Act, S. 975, the Project Bioshield II Act, and S. 1873, the Biodefense and Pandemic Vaccine and Drug Development Act, that would have generated additional incentives for the creation of new technologies to counteract potential biological threats. These bills proposed reforms to current policies and practices associated with intellectual property, particularly patents, and the marketing of pharmaceuticals and related products.

Patent ownership appears to be important in the promotion of innovation, particularly in the pharmaceutical sector. Patent title provides a limited-time monopoly over the use of a discovery in exchange for the public dissemination of information contained in the patent application. This permits the inventor to receive a return on the expenditure of resources but does not guarantee that the patent will generate commercial benefits. The requirement for patent publication is expected to stimulate additional innovation to meet similar demands in the marketplace.

Currently, the Bayh-Dole Act and the Hatch-Waxman Act include provisions that utilize patent ownership to facilitate the development and commercialization of new pharmaceuticals. The Hatch-Waxman Act also contains FDA marketing approval policies that are designed to promote the creation of new drugs. Similar market-exclusivity provisions are contained in the Orphan Drug Act.

S. 3 and S. 975 allowed for the restoration of that portion of the patent term used during the FDA approval process, and/or the extension of a patent term to reward technological innovation in the area of bioterrorism countermeasures. The proposed legislation also provided for additional FDA-administered marketing exclusivities for eligible and designated countermeasures. S. 1873 permitted a countermeasure product to qualify as an orphan drug and increases market exclusivity from seven years to ten years.

Encouraging the development of new counterterrorism technologies and ensuring affordable access to new drugs and medical devices are both significant goals. These aspirations may potentially conflict, however. Introducing augmented patent- and exclusivity-based incentives may stimulate innovative firms to engage in the R&D for new countermeasures, as well as to shepherd these products through time-consuming and costly marketing approval procedures. Commentators have expressed concern, however, over whether such heightened protections for innovators will be in proportion with the risks and costs of developing new countermeasures. Striking a balance between encouraging the development of new countermeasures and maintaining the traditional goals of our public health system is a central concern of the current discussion with respect to homeland security.

This report will be updated if events warrant.

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Bioterrorism Countermeasure Development: Issues in Patents and Homeland Security

Introduction

Congressional interest in the development of bioterrorism countermeasures remains strong, even after passage of legislation establishing Project BioShield.[1] Several bills considered, but not enacted during the 109th Congress, including S. 3, the Protecting America in the War on Terror Act of 2005, S. 975, the Project Bioshield II Act, and S. 1873, the Biodefense and Pandemic Vaccine and Drug Development Act, would have generated additional incentives for the creation of new products and processes by the private sector to counteract potential biological threats. These bills proposed reforms to current policies and practices associated with intellectual property, particularly patents, and the marketing of pharmaceuticals and related products.

Patents appear to be important in the promotion of innovation, particularly in the pharmaceutical sector. This report explores the role of patents in encouraging the development and commercialization of new inventions and discusses the relationships between patent ownership and the generation of biomedical products. However, the grant of a patent on a pharmaceutical does not permit marketing of the product without the approval of the Food and Drug Administration (FDA). Thus, this report also examines policies concerning the use of FDA marketing exclusivity as an additional incentive to industry research and development (R&D) in this arena. Current law and suggested legislative changes are discussed to provide a context for any further exploration of related issues during the 110th Congress.

Patents and Innovation

Patent law is based upon the Patent Act of 1952, codified in Title 35 of the United States Code. According to the statute, one who "invents or discovers any new and useful process, machine, manufacture, or any composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."[2] Patents are issued by the United States Patent and Trademark Office (USPTO), generally for a term of 20 years from the date of filing. The patent grants its owner the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention. To be afforded patent rights, an invention must be judged to consist of patentable

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[1] P.L. 108-276, see also CRS Report RS21507, *Project BioShield*, by Frank Gottron.

[2] 35 U.S.C.§101

subject matter, possess utility, and be novel and nonobvious. The application must fully disclose and distinctly claim the invention for which protection is sought.[3]

The grant of a patent does not necessarily provide the owner with an affirmative right to market the patented invention. Pharmaceutical products are also subject to marketing approval by the Food and Drug Administration. Federal laws typically require that pharmaceutical manufacturers demonstrate that their products are safe and effective in order to bring these drugs to the marketplace. USPTO issuance of a patent and FDA marketing consent are distinct events that depend upon different criteria.

The patent system is grounded in Article I, Section 8, Clause 8 of the U.S. Constitution and is intended to stimulate new discoveries and their reduction to practice, commonly known as innovation. The Constitution states that "The Congress Shall Have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . . ." The award of a patent permits the creator of an idea to exclude others, temporarily, from use of that concept without compensation. It also places the information associated with an invention within the public arena.

Patent ownership is perceived to be an incentive to innovation, the basis for the technological advancement that contributes to economic growth. It is through the commercialization and use of new products and processes that productivity gains are made and the scope and quality of goods and services are expanded. Award of a patent is intended to stimulate the investment necessary to develop an idea and bring it to the marketplace embodied in a product or process. Patent title provides the recipient with a limited-time monopoly over the use of his discovery in exchange for the public dissemination of information contained in the patent application. This is intended to permit the inventor to receive a return on the expenditure of resources leading to the discovery but does not guarantee that the patent will generate commercial benefits. The requirement for publication of the patent is expected to stimulate additional innovation and other creative means to meet similar and expanded demands in the marketplace.

Innovation produces new knowledge. One characteristic of this knowledge is that it is a "public good," a good that is not consumed when it is used. This "public good" concept underlies the U.S. patent system. As John Shoven of Stanford University points out, "the use of an idea or discovery by one person does not, in most cases, reduce the availability of that information to others."[4] Therefore the marginal social cost of the widespread application of that information is near zero

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[3] For more information see 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 ("The Hatch-Waxman Act")*, by Wendy H. Schacht and John R. Thomas.

[4] John B. Shoven, "Intellectual Property Rights and Economic Growth," in *Intellectual Property Rights and Capital Formation in the Next Decade*, eds. Charls E. Walker and Mark A. Bloomfield (New York: University Press of America, 1988), 46.

because the stock of knowledge is not depleted. "Ordinarily, society maximizes its welfare through not charging for the use of a free good."[5] However, innovation typically is costly and resource intensive. Patents permit novel concepts or discoveries to become "property" when reduced to practice and therefore allow for control over their use. They "create incentives that maximize the difference between the value of the intellectual property that is created and used and the social cost of its creation."[6]

Studies demonstrate that the rate of return to society as a whole generated by investments in research and development (R&D) leading to innovation is significantly larger than the benefits that can be captured by the person or organization financing the work. Some estimate that the social rate of return on R&D spending is over twice that of the rate of return to the inventor.[7] Ideas often are easily imitated as the knowledge associated with an innovation is dispersed and adapted to other products and processes that, in turn, stimulate growth in the economy. That can happen in the absence of appropriability defined as "factors, excluding firm and market structure, that govern an innovator's ability to capture the profits generated by an innovation."[8] The appropriability of an invention depends on the level of competition in the industry and the type of information related to the innovation; the more competition and the more basic the knowledge, the less appropriable it is.[9] The difficulty in securing sufficient returns to spending on research and development has been associated with underinvestment in those activities.

The patent process is designed to resolve the problem of appropriability. If discoveries were universally available without a means for the inventor to realize a return on investments, there would result a "much lower and indeed suboptimal level of innovation."[10] While research is often important to innovation, some commentators have noted that it can constitute less than a quarter of the cost of commercializing a new technology or technique, thus requiring the expenditure of a substantial amount of additional resources to bring most products or processes to the marketplace. The grant of a patent provides the inventor with a mechanism to capture the returns to his invention through exclusive rights on its practice for 20

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[5] Robert P. Benko, "Intellectual Property Rights and New Technologies," in *Intellectual Property Rights and Capital Formation in the Next Decade*, 27.

[6] Stanley M. Besen and Leo J. Raskind, "An Introduction to the Law and Economics of Intellectual Property," *Journal of Economic Perspectives*, Winter 1991, 5.

[7] For a list of relevant research in this area see Council of Economic Advisors. *Supporting Research and Development to Promote Economic Growth: The Federal Government's Role*, October 1995, 6-7.

[8] David J. Teece, "Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing, and Public Policy," in *The Competitive Challenge,* ed. David J. Teece, (Cambridge: Ballinger Publishing Co., 1987), 188.

[9] Edwin Mansfield. "Intellectual Property Rights, Technological Change, and Economic Growth," in, *Intellectual Property Rights and Capital Formation in the Next Decade*, 10-11.

[10] Kenneth W. Dam, "The Economic Underpinnings of Patent Law," *Journal of Legal Studies*, January 1994, 247.

years from date of filing. That is intended to allow the inventor to recoup his research spending and to encourage those investments necessary to further develop an idea and generate a marketable technology.

Issuance of a patent furnishes the inventor with a limited-time monopoly, the benefits of which are mitigated by other factors, particularly the requirements for information disclosure, the length of the patent, and the scope of rights conferred. The process of obtaining a patent places the concept on which it is based in the public domain. In return for a monopoly right to the application of the knowledge generated, the inventor must publish the ideas covered in the patent. As a disclosure system, the patent can, and often does, stimulate other firms or individuals to invent "around" existing patents to provide for parallel technical developments or meet similar market needs.

Patents may also provide a more socially desirable outcome than its chief legal alternative, trade secret protection. Trade secrecy guards against the improper appropriation of valuable, commercially useful information that is the subject of reasonable measures to preserve its secrecy.[11] Taking the steps necessary to maintain secrecy, such as implementing physical security, imposes costs that may ultimately be unproductive for society.[12] Also, while the patent law obliges inventors to disclose their inventions to the public,[13] trade secret protection requires firms to conceal them. The disclosure obligations of the patent system may better serve the objective of encouraging the diffusion of advanced technological knowledge.

The patent system thus has dual policy goals — providing incentives for inventors to invent and encouraging inventors to disclose technical information.[14] Disclosure requirements are factors in achieving a balance between current and future innovation through the patent process, as are limitations on scope, novelty mandates, and nonobviousness considerations.[15] Patents give rise to an environment of competitiveness with multiple sources of innovation, which is viewed by some experts as the basis for technological progress. This is important because, as Robert Merges (now at the University of California, Berkeley) and Richard Nelson (Columbia University) found in their studies, in a situation where only "a few

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[11] American Law Institute, Restatement of Unfair Competition Third §39, 1995.

[12] David D. Friedman, et al., "Some Economics of Trade Secret Law," 5 *Journal of Economic Perspectives*, 1991, 61.

[13] 35 U.S.C. §112 (2000).

[14] Robert P. Merges, "Commercial Success and Patent Standards: Economic Perspectives on Innovation," *California Law Review*, July 1988, 876.

[15] *The Economic Underpinnings of Patent Law*, 266-267. Scope is determined by the breath of the claims made in a patent. Claims are the technical descriptions associated with the invention. In order for an idea to receive a patent, the law requires that it be "new, useful [novel], and nonobvious to a person of ordinary skill in the art to which the invention pertains."

organizations controlled the development of a technology, technical advance appeared sluggish."[16]

Not everyone agrees that the patent system is a particularly effective means to stimulate innovation. Some observers believe that the patent system encourages industry concentration and presents a barrier to entry in some markets.[17] Others believe that the patent system too frequently attracts speculators who prefer to acquire and enforce patents rather than engage in socially productive activity.[18] Still other commentators suggest that the patent system often converts pioneering inventors into technological suppressors, who use their patents to block subsequent improvements and thereby impede technological progress.[19]

Some experts argue that patents do not work as well in reality as in theory because they do not confer perfect appropriability. In other words, they allow the inventor to obtain a larger portion of the returns on his investment but do not permit him to capture all the benefits. Patents can be circumvented and infringement cannot always be proven. Thus, patents are not the only way, nor necessarily the most efficient means, for the inventor to protect the benefits generated by his efforts. A study by Yale University's Richard Levin and his colleagues concluded that lead time, learning curve advantages (e.g. familiarity with the science and technology under consideration), and sales/service activities were typically more important in exploiting appropriability than were patents. That was true for both products and processes. However, patents were found to be better at protecting products than processes. The novel ideas associated with a product often can be determined through reverse engineering — taking the item apart to assess how it was made. That information then could be used by competitors if not covered by a patent. Because it is more difficult to identify the procedures related to a process, other means of appropriation are seen as preferable to patents, with the attendant disclosure requirements.[20]

Role of Patents in Pharmaceutical/Biomedical R&D

The utility of patents to companies varies among industrial sectors. Patents are perceived as critical in the drug industry. That may reflect the nature of R&D performed in this sector, where the resulting patents are more detailed in their claims

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[16] Robert P. Merges and Richard R. Nelson, "On the Complex Economics of Patent Scope," *Columbia Law Review*, May 1990, 908.

[17] See John R. Thomas, "Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties," *University of Illinois Law Review*, 2001, 305.

[18] Ibid.

[19] *On the Complex Economics of Patent Scope*, 839.

[20] Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson, and Sidney G. Winter. "Appropriating the Returns for Industrial Research and Development," *Brookings Papers on Economic Activity*, 1987, in *The Economics of Technical Change*, eds. Edwin Mansfield and Elizabeth Mansfield (Vermont, Edward Elgar Publishing Co., 1993), 254.

and therefore easier to defend.[21] In contrast, one study found that in the aircraft and semiconductor industries patents are not the most successful mechanism for capturing the benefits of investments. Instead, lead time and the strength of the learning curve were determined to be more important.[22] Research undertaken by Wesley Cohen (Duke University) and his colleagues demonstrated that patents were considered the most effective method to protect inventions in the drug industry when biotechnology is included.[23]

The high cost of drug development and the concomitant uncertainty associated with clinical trials necessary for marketing approval lends significance to patents in the pharmaceutical arena. Studies by Joseph DiMasi of Tufts University and others indicate that the capitalized cost of bringing a new drug (defined as a "new molecular entity" rather than a new formulation of an existing pharmaceutical product) to the point of marketing approval is $802 million (2000 dollars).[24] Additional research done by Federal Trade Commission analysts found the costs to be even higher; between $839 million and $868 million (2000 dollars).[25] At the same time, the total capitalized costs appear to be growing at an annual rate of 7.4% above general price inflation.[26]

A large portion of new drug costs (in terms of money and time) are associated with the size and breath of clinical trials necessary to obtain FDA marketing approval. According to a study supported by the Federal Reserve of Boston, only 10% of potential drug candidates reach the human trial phase and only a small portion of these actually reach the market.[27] In research presented at a conference sponsored by the Federal Reserve Bank of Dallas, Duke University's Henry Grabowski found that only 1% of drug compounds reach the human trial stage and 22% of those entering clinical trials receive FDA approval.[28] Iain Cockburn (Boston

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[21] Ibid., 255 and 257. See also: *Intellectual Property Rights, Technological Change, and Economic Growth,* 12 and 13.

[22] *Appropriating the Returns for Industrial Research and Development*, 253.

[23] Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, NBER Working Paper 7552, Cambridge, National Bureau of Economic Research, February 2000, available at [http://www.nber.org/papers/w7552].

[24] Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski. "The Price of Innovation: New Estimates of Drug Development Costs," 22 *Journal of Health Economics,* 2003. Capitalized cost includes the "time cost" associated with an investment and the cost of testing drug products that fail.

[25] Christopher P. Adams and Van V. Brantner, *Estimating the Costs of New Drug Development: Is it Really $802m?*, Federal Trade Commission, December 2004, available at [http://media.romanvenable.net/images/drugCost.pdf].

[26] *The Price of Innovation: New Estimates of Drug Development Costs*, 180

[27] Carrie Conway, "The Pros and Cons of Pharmaceutical Patents," *Regional Review*, Federal Reserve Bank of Boston, March, 2003, available at [http://www.findarticles.com].

[28] Henry G. Grabowski, "Patents, Innovation, and Access to New Pharmaceuticals," *Journal*
(continued...)

University) notes that "as drug discovery became more science-intensive, . . .it became not just more expensive but also more difficult to manage."[29] Furthermore, returns to new drug introductions vary widely and the median new drug does not bring in sufficient profits to cover the costs of bringing the product to the marketplace.[30] According to research by Grabowski, John Vernon (Duke University), and DiMasi, only 34% of new drugs (new chemical entities) introduced generated profits that equaled the industry average R&D cost.[31]

Patents are particularly important in the pharmaceutical sector because of the relative ease of replicating the finished product. Imitation costs vary among industries. For example, while it is expensive, complicated, and time consuming to duplicate an airplane, it is relatively simple to chemically analyze a pill and reproduce it.[32] The degree to which industry perceives patents as effective has been characterized as "positively correlated with the increase in duplication costs and time associated with patents."[33] In certain industries, patents significantly raise the costs incurred by nonpatent holders wishing to use the idea or invent around the patent — an estimated 40% in the pharmaceutical sector, 30% for major new chemical products, and 25% for typical chemical goods — and are thus viewed as significant. However, in other industries, patents have much smaller impact on the costs associated with imitation (e.g. in the 7%-15% range for electronics), and may be considered less successful in protecting resource investments.[34]

The significant costs of pharmaceutical R&D, coupled with the uncertainty of the clinical trial process, lend consequence to patents in this area because "the disparity between the investments of innovators and those of imitators is particularly large in pharmaceuticals — almost as large as when software pirates simply copy the diskettes of an innovator."[35] While the capitalized cost of developing a new drug to the point of market approval is over $800 million, it takes only between $1 million

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[28] (...continued)
of International Economic Law, 2002, 851.

[29] Iain Cockburn, "The Changing Structure of the Pharmaceutical Industry," *Health Affairs*, Janurary/February 2004, 15.

[30] Henry G. Grabowski, "Patents and New Product Development in the Pharmaceutical and Biotechnology Industries," *Science and Cents: Exploring the Economics of Biotechnology*, Proceedings of a 2002 Conference, Federal Reserve Bank of Dallas, 95-96 available at [http://www.dallasfed.org/research/pubs/science/grabowski.pdf] and Henry Grabowski, John Vernon, and Joseph A. DiMasi, "Returns on Research and Development for 1990s New Drug Introductions," 20 *Pharmacoeconomics*, 2002.

[31] *Returns on Research and Development for 1990s New Drug Introductions*, 23.

[32] Federic M. Scherer, "The Economics of Human Gene Patents", 77 *Academic Medicine,* December 2002, 1350.

[33] *Appropriating the Returns for Industrial Research and Development*., 269.

[34] Edwin Mansfield, Mark Schwartz, and Samuel Wagner. "Imitation Costs and Patents: An Empirical Study," *The Economic Journal*, December 1981, in *The Economics of Technical Change*, 270.

[35] *The Economics of Human Gene Patents*, 1352.

and $2 million to obtain approval for a generic version of the pharmaceutical.[36] This difference is a result of the costs associated with clinical trials needed to demonstrate the safety and efficacy of a new drug, data that could be utilized by generic companies if not protected by a patent.[37]

Legislative Developments

In order to explore options for incentives to encourage the development and marketing of new bioterrorism countermeasures, it might be instructive to look at the state of current legislation that may be relevant to the surrounding issues. The Bayh-Dole Act and the Hatch-Waxman Act include provisions that utilize patent ownership to facilitate the development and commercialization of new pharmaceuticals (or, as is the case with the Bayh-Dole Act, all technologies). The Hatch-Waxman Act also contains FDA marketing approval policies that are designed to promote the creation of new drugs. Similar, market-exclusivity provisions are contained in the Orphan Drug Act. These laws are discussed below to provide the existing legal context within which new approaches may be considered.

The Bayh-Dole Act

P.L. 96-517, Amendments to the Patent and Trademark Act, commonly referred to as the "Bayh-Dole Act" after its two main sponsors, former Senators Birch Bayh and Robert Dole, evolved out of congressional interest in developing a uniform federal patent policy to promote the utilization of inventions made with the support of the federal research establishment.[38] Such action was deemed necessary because, at the time the legislation was under consideration, only 5% of federally-owned patents were being used. While there were possibly several reasons for such a low level of utilization (including no market applications), this was thought by many to be one consequence of the practice by most agencies of taking title to all inventions made with government funding and only permitting the nonexclusive licensing of contractor inventions.[39] Without title to inventions, or at least exclusive licenses, companies were deemed to be less likely to engage in and fund the additional R&D necessary to bring an idea to the marketplace. The Bayh-Dole Act, by providing universities, nonprofit institutions, and small businesses with ownership of patents arising from federally-funded R&D, offers an incentive for cooperative work and commercial application. Royalties derived from intellectual property rights provide the academic community an alternative way to support further research and the

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[36] *Patents, Innovation, and Access to New Pharmaceuticals*, 852.

[37] *The Economics of Human Gene Patents*, 1352

[38] House Committee on Science and Technology, *Government Patent Policy*, 95th Cong., 2nd sess., May 1978, H.Rept. Prt. 4.

[39] *Ibid.*, 5.

business sector a means to obtain a return on their financial contribution to the endeavor.[40]

Each nonprofit organization (including universities) or small business is permitted to elect (within a reasonable time frame) to retain title to any "subject invention" made as a result of R&D funded by the federal government; except under "exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this [legislltion]."[41] The owner of the intellectual property must commit to commercialization of the patent within a predetermined time frame agreed to by the supporting agency and the performing organization. As stated in the House report on one of the relevant bills, "the legislation establishes a presumption that ownership of all patent rights in government funded research will vest in any contractor who is a nonprofit research institution or a small business."[42]

Certain rights are reserved for the government to protect the public interest. The government retains "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world. . . ." The government also retains "march-in rights" that enable the federal agency to require the contractor (whether he owns title or has an exclusive license) to "grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants. . ." with due compensation, or to grant a license itself under certain circumstances. The special situation necessary to trigger march-in rights involves a determination that the contractor has not made efforts to commercialize within an agreed upon time frame or that the "action is necessary to alleviate health or safety needs. . ." that are not being met by the contractor.[43] To date, the government has never exercised these march-in rights.

Other provisions of the Bayh-Dole Act "authorize" the government to withhold public disclosure of information for a "reasonable time" until a patent application can be made. Licensing by any contractor retaining title under this act is restricted to companies which will manufacture substantially within the United States. Initially, universities were limited in the time they could grant exclusive licenses for patents derived from government sponsored R&D to large companies (5 of the *then* 17 years of the patent). This restriction, however, was voided by P.L. 98-620, the Trademark Clarification Act of 1984. According to Senate Report 98-662, extending the time frame for licensing to large firms "is particularly important with technologies such

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[40] For discussion of this law, additional provisions, and implementation see CRS Report RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, by Wendy H. Schacht and CRS Report RL32324, *Federal R&D, Drug Discovery, and Pricing: Insights from the NIH-University-Industry Relationship*, by Wendy H. Schacht.

[41] *Government Patent Policy*, 5.

[42] House Committee on the Judiciary, *Report to Accompany H.R. 6933*, 96th Congress., 2d. Sess., H.Rept. 96-1307, Part 1, 3.

[43] 15 U.S.C. §203.

as pharmaceuticals, where long development times and major investments are usually required prior to commercialization."[44]

The Hatch-Waxman Act

P.L. 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act),[45] as amended by Title XI of P.L. 108-173, the Medicare Prescription Drug and Modernization Act of 2003, made several significant changes to the patent laws as they applied to pharmaceutical products in an attempt to balance the need for innovative new drugs and the availability of less expensive generic products. The Hatch-Waxman Act established several practices intended to make it easier for generic drugs to reach the market while permitting brand name companies to recover a portion of their intellectual property rights lost during the pharmaceutical approval process.[46]

The changes legislated in the Hatch-Waxman Act include methods for extending the term of a patent to reflect regulatory delays encountered in obtaining marketing consent from the Food and Drug Administration (FDA); a statutory exemption from patent infringement for activities associated with regulatory marketing approval; mechanisms to challenge the validity of a pharmaceutical patent; and a reward for disputing the validity, enforceability, or infringement of a patent claiming an approved drug. The Hatch-Waxman Act also requires the FDA provide periods of marketing exclusivity for a pharmaceutical independent of the rights conferred by patents.

The infringement provisions in the Hatch-Waxman Act apply to pharmaceutical patents and differ from traditional procedures associated with other patented products and processes. A statutory exemption is created for certain claims of patent infringement based on acts reasonably related to seeking FDA approval to market a drug that has been patented by another firm. The company making a generic product is permitted to use data paid for and compiled by the original manufacturer to establish the drug's safety and efficacy. The generic firm must only prove that their product is bioequivalent to the innovator drug. This may allow a bioequivalent drug to reach the market as soon as the patent on the original pharmaceutical expires. Nowhere else in patent law does such a robust "experimental use" exemption exist.[47]

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[44] Senate Committee on the Judiciary, *Report to Accompany S. 2171*, 98th Cong., 2d Sess. S.Rept. 98-662, 1984, 3.

[45] 21 U.S.C. § 355 and following.

[46] For a detailed discussion of the Hatch-Waxman Act see 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 (The Hatch-Waxman Act)*, by Wendy H. Schacht and John R. Thomas, and CRS Report RL32377, *The Hatch-Waxman Act: Legislative Changes Affecting Pharmaceutical Patents*, by Wendy H. Schacht and John R. Thomas.

[47] See CRS Report RL32651, *Scientific Research and the Experimental Use Privilege in Patent Law*, by John R. Thomas.

Additional, special provisions for addressing pharmaceutical patents are contained in the 1984 Act, including specific procedures for challenging the enforceability, validity, or infringement of approved drug patents. To encourage such patent challenges, generic applicants that file a challenge in court receive 180 days of market exclusivity provided by the FDA after that patent is found invalid, not infringed, or unenforceable or when the patent expires.

To balance such arrangements that appear to favor generic manufacturers, the Hatch-Waxman Act provides that the patent term for pharmaceuticals may be extended for a *portion* of the time lost during the FDA approval process. As noted above, ordinarily patent term is set at 20 years from the date the patent application is filed. The 1984 Act provides that for pharmaceutical patents, the patent term may be extended to reflect part of the time lost during clinical testing. More specifically, this term extension is equal to one-half the time between the effective date of the investigational new drug application and the submission of the new drug application (NDA), plus the entire time lost during FDA approval of the NDA.[48]

The Hatch-Waxman Act sets some limits on the length of the term restoration. The entire patent term restored may not exceed five years. Further, the remaining term of the restored patent following FDA approval of the NDA may not exceed 14 years.[49] The act also provides that the patentee must exercise due diligence to seek patent term restoration from the USPTO or the period of lack of diligence will be offset from the augmented patent term.[50] Patent term extension does not occur automatically. The patent owner or its agent must file an application the USPTO requesting term extension within 60 days of obtaining FDA marketing approval.

The Hatch-Waxman Act also established so-called "marketing exclusivities" administered by the FDA. The term "marketing exclusivity" refers to a period of time during which the FDA affords an approved drug protection from competing applications for marketing approval. During this time, the FDA will not accept applications for market approval of generic versions of the brand name pharmaceutical. Two sorts of marketing exclusivities are available to innovative drug companies under the Hatch-Waxman Act: five-year new chemical entity exclusivity,[51] and three-year new clinical study exclusivity.

A drug qualifies as a new chemical entity, or NCE, if the FDA has not previously approved that drug's active ingredient.[52] The purpose of 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-

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[48] 25 U.S.C. § 156.

[49] 35 U.S.C. § 156(c).

[50] 35 U.S.C. § 156(d)(2)(B)

[51] Some authorities refer to this sort of exclusivity as new molecular entity, or NME exclusivity. See Gerald J. Mossinghoff, "Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process," 54 *Food and Drug Law Journal,* 1999, 187.

[52] See 21 C.F.R. §314.108(a).

too" drugs that consist of chemical variants of previously known compounds.[53] The statute expressly stipulates that a drug does not qualify as an NCE if it consists of the salt or ester of a previously approved active ingredient as these are considered only minor chemical changes to the active ingredient.[54] 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, firms are precluded from filing generic applications for five years from the date of the approval of the NDA for that active moiety.[55]

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.[56] 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, which generally prevent the FDA from approving applications, rather than accepting them in the first instance.[57]

Alternatively, a pioneer drug company may obtain a three-year new clinical study exclusivity in exchange for submitting an NDA[58] or supplemental NDA[59] that contains reports of new clinical studies of a known drug 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 forms, new indications, or for a switch from prescription to over-the-counter status for the drug. The purpose of the three-year new clinical study exclusivity is to encourage improvements upon drugs that are already known.

The Hatch-Waxman Act imposes four requirements that an investigation must fulfill in order to qualify for new clinical study exclusivity.[60] 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

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[53] See *Abbott Labs. v. Young*, 920 F.2d 984, 986 (D.C. Cir. 1990)

[54] 21 U.S.C. §3 55(c)(3)(E) (2004) (with respect to §505(b)(2) applications); 21 U.S.C. § 355(j)(5)(F) (2004) (with respect to ANDAs).

[55] 21 U.S.C. § 355(c)(3)(E)(ii) (with respect to §505(b)(2) applications); 21 U.S.C. § 355(j)(5)(F)(ii) (with respect to ANDAs).

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

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

[58] 21 U.S.C. §355(c)(3)(E)(iii) (with respect to §505(b)(2) applications); 21 U.S.C. § 355(j)(5)(F)(iii) (with respect to ANDAs).

[59] 21 U.S.C. § 355(c)(3)(E)(iv) (with respect to §505(b)(2) applications); 21 U.S.C. § 355(j)(5)(F)(iv) (with respect to ANDAs).

[60] 21 U.S.C. § 355(c)(3)(E)(iii)-(iv) (with respect to §505(b)(2) applications); 21 U.S.C. § 355(j)(5)(F)(iii)-(iv) (with respect to ANDAs).

a preclinical study, and not a bioavailability or bioequivalence study. Third, the study must have been "conducted or sponsored" by the applicant. Finally, the study must be "essential to the approval" of the application or supplement. The FDA has defined the term "essential to the approval" as meaning "that there are no other data available that could support approval of the application."[61] A study that is interesting and provides useful background information, but not essential to approving the change in the drug, does not provide sufficient basis for an FDA award of new clinical study exclusivity.[62]

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. In addition, new clinical study exclusivity only applies to the use of the product that was supported by the new clinical study.[63] 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 FDA is not barred from approving a generic drugs for other indications or dosage forms.[64]

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.

Orphan Drug Act

Congress enacted the Orphan Drug Act[65] in order to encourage firms to develop pharmaceuticals to treat rare diseases and conditions.[66] Such drugs are called "orphan drugs" because firms may lack the financial incentives to sponsor products

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[61] See 21 C.F.R. § 314.108(a)

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

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

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

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

[66] 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. The Orphan Drug Act also applies to varying degrees to biologics and medical devices, which, along with drugs, are commonly termed "orphan products."

to treat small patient populations.[67] Among the incentives offered via this legislation was a seven-year term of orphan drug marketing exclusivity.[68] This period commences from the date the FDA issues marketing approval on the drug.[69]

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 for the same drug for a different use. The FDA cannot approve the same drug made by another firm 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.[70]

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."[71] Congress changed the definition to its present form in 1984.[72] 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 would recover the costs.[73] This change allows drug sponsors to avoid showing unprofitability if the target population consisted of less than 200,000 persons.

Proposals for Change

Legislation introduced during the 109th Congress would have expanded upon existing mechanisms in the patent and food and drug laws to encourage the development of bioterrorism countermeasures. These bills would have allowed for the restoration of that portion of the patent term used during the FDA approval process, and/or the extension of a patent term to reward technological innovation in the area of bioterrorism countermeasures. These bills also provided for additional FDA-administered marketing exclusivities for eligible and designated countermeasures. While no legislation was enacted, a discussion of the relevant provisions may provide a framework for further discussion of the issues during the 110th Congress.

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[67] *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.

[68] 21 U.S.C. §360cc.

[69] *Id.*

[70] 21 U.S.C. § 360cc(b).

[71] 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)).

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

[73] 21 U.S.C. § 360bb(a)(2).

Patent Term Fundamentals

As noted previously, several mechanisms exist for lengthening the basic 20-year patent term. Among them are Hatch-Waxman Act provisions compensating patent proprietors for delays in FDA regulatory approval proceedings.[74] This term extension is potentially available for a single patent relating to a drug product, or to a medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.[75]

Under current law, the period of extension is ordinarily set to one-half of the clinical testing phase, less any period during which the applicant did not act with due diligence, plus the entirety of the FDA approval phase.[76] The nature of the regulated product sets the precise dates that commence the testing and approval phases that together comprise the regulatory review period. For a human drug, antibiotic, or human biological product, the clinical testing phase begins on the date the Investigational New Drug (IND) application is filed, while the FDA approval phase period starts on the date of filing of either the New Drug Application (NDA) or Product License Application (PLA).[77] For a patent claiming a medical device, the clinical testing date commences on the effective date of the Investigational Device Exemption (IDE) or, if no IDE was submitted, on the date on which the applicant began the first clinical investigation involving the device. The FDA approval phase commences on the date on which the application for product approval or notice of completion of a product development protocol under Section 515 of the Federal Food, Drug, and Cosmetic Act was initially submitted.[78] Other sorts of regulated products, such as veterinary biological products and food or color additives, are addressed in an analogous manner.

The Hatch-Waxman Act capped the maximum extension period to five years, or a total effective patent term after the extension of not more than fourteen years.[79] In addition, the Hatch-Waxman Act does not go so far as to provide a patent term extension in the usual sense — that is to say, a temporal extension of the original right to exclude others from practicing the patented invention. During the period of term extension, the rights provided by the patent are instead limited, generally speaking, to the specific use that the FDA has approved. For example, in the case of an extended product patent, the patent's rights during the extension period are generally "limited to any use approved for the product" that subjected it to regulatory approval delays at the FDA.[80]

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[74] 35 U.S.C. § 156 (2004).

[75] 35 U.S.C. § 156(f) (2004).

[76] 35 U.S.C. § 156(c) (2004).

[77] 37 C.F.R. § 1.740(a)(10)(I) (2004).

[78] 37 C.F.R. § 1.740(a)(10)(v) (2004).

[79] 35 U.S.C. § 156(b) (2004).

[80] 35 U.S.C. § 156(b)(1) (2004).

Proposed Patent Term Restoration Reforms

Proposed legislation in the 109th Congress included provisions that act similarly with respect to patent term restoration on bioterrorism countermeasures, although they potentially allowed for longer periods of expansion of patent term than is currently available under the Hatch-Waxman Act. It should be noted that the Hatch-Waxman Act refers to the lengthening of patent life in compensation for delays in FDA marketing approval as an "extension of patent term."[81] However, the legislation used the word "restoration" to refer to this concept, while employing the word "extension" in the context of a distinct reward for technological innovation in the area of bioterrorism countermeasures.

Both S. 3, The Protecting America in the War on Terror Act of 2005, and S. 975, The Project Bioshield II Act, would have introduced a new 35 U.S.C. § 156a into the Patent Act of 1952. As with current law, these statutes would have lengthened an eligible patent on a bioterrorism countermeasure on a day-per-day basis for the time lost during the FDA approval phase. These bills would also extend patent term on a day-per-day basis during the entire period of the clinical testing phase, however, rather than merely for one-half of that period as provided in the Hatch-Waxman Act.[82] In contrast to the Hatch-Waxman Act, the proposed legislation placed no cap upon the maximum period of increase in patent term.

Notably, the Hatch-Waxman Act sets the first day of the regulatory review period as the date that the drug sponsor's commences clinical studies at the FDA. However, both S. 3 and S. 975 considered the regulatory review period to commence on the later of either the date the clinical testing phase begins at the FDA, or the date upon which the USPTO issues the patent sought to be extended.[83] In circumstances where the USPTO issues the patent after the sponsor has commenced clinical studies at the FDA, the relevant regulatory review period under current law may actually be longer than under the proposed legislation.

Both S. 3 and S. 975 stipulated that this patent term restoration is mutually exclusive with respect to "extension of patent term" available under current law.[84] As a result, only a single patent that claims a countermeasure product may be lengthened by either the period established by the "extension of patent term" provision of the existing Hatch-Waxman Act or the new "restoration of patent terms relating to countermeasure products" under proposed 35 U.S.C. § 156a, but not both.

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[81] 35 U.S.C. § 156 (2004).

[82] S. 3 at § 113(c) (introducing 35 U.S.C. § 156a(b)); S. 975 at § 331(b) (introducing 35 U.S.C. § 156a(b))).

[83] S. 3 at § 113(c) (introducing 35 U.S.C. § 156a(a)(2)); S. 975 at § 331(b) (introducing 35 U.S.C. § 156a(a)(2)).

[84] S. 3 at § 113(c) (introducing 35 U.S.C. § 156a(b)(4)); S. 975 at § 331(b) (introducing 35 U.S.C. § 156a(b)(4)).

Proposed Patent Term Extension Reforms

Legislation offered during the 109th Congress also would have created the possibility of "patent term extension," codified at 35 U.S.C. § 158, that has no direct analogy under current law. Under S. 3 and S. 975, this term extension would be available to entities that have developed FDA-approved countermeasure products. The period of term extension under both bills ranged from a minimum of six months to a maximum of two years.[85] The Secretary of Health and Human Services would be granted discretion to set the period of term extension based upon such factors as the nature of the threat to be countered, the difficulty and expense in developing the countermeasure, and the impact of patent extension upon consumers and healthcare providers.[86]

Considerable discussion occurred with respect to whether the term extension provided by proposed 35 U.S.C. § 158 must be applied to a patent claiming the countermeasure itself, or instead to any one patent that the countermeasure innovator selects within its intellectual property portfolio. The concept that a countermeasure innovator could enjoy expanded patent life with respect to an unrelated product has been termed a "wild card" term extension.[87] Under this regime, a countermeasure innovator could potentially obtain a term extension of a patent relating to a best-selling mainstream pharmaceutical, thereby shielding it from generic competition for an additional period of six months to two years. Supporters of a wild card patent term extension urge that patent-based incentives on profitable products, such as "blockbuster" drugs, are needed to encourage firms to develop potentially less profitable countermeasures.[88] Detractors have expressed concerns over the equities of requiring patients to finance the development of countermeasures through the purchase of medications to treat their particular illnesses or medical conditions.[89]

S. 975 appeared to employ this "wild card" patent term extension concept. That bill stipulated that patents eligible for the extension period of six months of two years must relate to "designated products," with that term in turn generally defined as any drug, antibiotic drug, device, or biological product.[90] This definition contrasts with

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[85] S. 3 at § 113(c) (introducing 35 U.S.C. § 158(a)(d)(1)); S. 975 at § 301(b)(4)(a)(iv).

[86] S. 3 at § 113(d) (introducing 35 U.S.C. § 158(a)(d)(2)); S. 975 at § 301(b)(4)(a)(ii).

[87] See Chris Mondics, "Drug firms on Senate agenda," *Philadelphia Inquirer,* April 10, 2005, A5.

[88] McKenna, Long & Aldridge, Press Release, *'Bioshield' Drug-Patent Plan Draws Fire,* April 1, 2005 available at [http://www.mckennalong.com/news-inthe-1273.html].

[89] Generic Pharmaceutical Association, Press Release, *Legislation Promoted as a Countermeasure Against Bioterrorism Would Counter Bipartisan Measures to Constrain Prescription Costs,* February 8, 2005 available at [http://www.gphaonline.org//AM/Template.cfm?Section=Home].

[90] S. 975 at § 331(c) (introducing 35 U.S.C. § 158(a)(3)).

that provided with respect to term restoration as compensation for FDA regulatory review, which expressly stated that the patent must claim a countermeasure product.[91]

The situation with respect to S. 3 was less clear. In a statement on the floor of the Senate, Senator Judd Gregg appeared to disavow the notion that S. 3 created "wild card" exclusivity. According to that statement, S. 3 created "additional incentives involving marketing exclusivity that could be granted for up to two years for the product that was used as a countermeasure. This is an important distinction from the so-called 'wild card' exclusivity idea, which would allow a company to extend the patent protection of a different product . . . ."[92] It should be noted, however, that S. 3 expressly restricted the availability of term restoration to patents that claim countermeasure products, but incorporated no similar restriction with regard to term extension.[93] As a result, some observers expressed concerns about whether the bill provided "wild card" exclusivity or not.[94]

Proposed Marketing Exclusivity Reforms

As noted previously, the food and drug laws provide for certain FDA-administered marketing exclusivities. Among these exclusivities is the five-year new chemical entity exclusivity,[95] a three-year new clinical trials exclusivity,[96] and a seven-year orphan drug exclusivity.[97] Subject to certain exceptions, these exclusivities generally prevent the FDA from granting marketing approval with respect to another sponsor's competing drug during the statutory period.[98]

S. 975 would have expanded upon these existing mechanisms with respect to new drugs that were developed by certified researchers and that qualify as countermeasure products. In particular, the five-year new chemical entity exclusivity would be doubled to ten years; the three-year new clinical studies exclusivity would

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[91] *Id.* at § 331(b) (introducing 35 U.S.C. § 156a(a)(3)(A)).

[92] Senator Judd Gregg, *Congressional Record,* April 6, 2005, S3264.

[93] Compare S. 3, § 113(c) (introducing 35 U.S.C. § 156a(a)(3)) with S. 3, § 113(d) (introducing 35 U.S.C. § 158(a)(2)).

[94] See "GphA to Gregg: Clarify That 'Wildcard Exclusivity' Not in S. 3," *INSIDE CMS*, March 10, 2005.

[95] See 21 U.S.C. § 355j(c)(3)(E)(ii) (2004) (with respect to § 505(b)(2) applications); 21 U.S.C. § 355(j)(5)(F)(ii) (2004) (with respect to Abbreviated New Drug Applications).

[96] See 21 U.S.C. § 355j(c)(3)(E)(iii), (iv) (2004) (with respect to § 505(b)(2) applications); 21 U.S.C. § 355(j)(5)(F)(iii), (iv) (2004) (with respect to Abbreviated New Drug Applications).

[97] See 21 U.S.C. § 360cc(a) (2004).

[98] In addition, under the five-year new chemical entity exclusivity, the FDA will not consider applications for a generic version of a new chemical entity for five years after approval of the original. As a result, the practical period of exclusivity is five years plus the time that the FDA takes to review the competitor's application. See Valerie Junod, *Drug Marketing Exclusivity Under United States and European Union Law*, 59 FOOD & DRUG L.J., 2004, 479.

be doubled to six years; and the seven-year orphan drug exclusivity would be extended to ten years.[99] No comparable provision appeared in S. 3.

S. 1873 allowed specified biological, chemical, radiological, and nuclear agents, as well as certain toxins, to qualify as a "rare disease or condition" under 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 stipulated that the period of orphan drug exclusivity will be ten years, rather than seven years, with respect to these countermeasures.

March-In Rights

As discussed above, the Bayh-Dole Act provides the government with the right to "march-in" and license to another manufacturer a patent that was originally developed by a contractor during federally-funded R&D under certain, very specific conditions. This right has never been exercised. However, some in industry view this provision as a potential barrier to on-going innovation. S. 975 would have permitted the owner of a patent related to a countermeasure made under the conditions triggered by the Bayh-Dole Act to request that the government agency that funded the original research waive its march-in rights.[100] No comparable provision appeared in S. 3.

It should be noted that in addition to the march-in rights afforded to the government under the Bayh-Dole Act, the government also has the authority to take private property for public use under "eminent domain."[101] While most frequently applied to real estate, the general principle generally applies to intellectual property as well.[102] As a result, the U.S. government effectively enjoys the ability to declare a "compulsory license" that allows it to use a patented invention without obtaining the permission of the patentee. In turn, the federal government has consented to a suit by private patent owners in order to obtain compensation for government uses.[103] Section 1498(a) of Title 28 of the U.S. Code provides in part:

> Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Claims Court for the recovery

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[99] S. 975 at § 331(e) (introducing 21 U.S.C. § 505C).

[100] S. 975 at 331(d)

[101] For a discussion of this and related topis see CRS Report RL32051, *Innovation and Intellectual Property Issues in Homeland Security*, by John R. Thomas.

[102] Thomas F. Cotter, "Do Federal Uses of Intellectual Property Implicate the Fifth Amendment?," 50 *Florida Law Review,* 1998, 529.

[103] See Lionel Marks Lavenue, "Patent Infringement Against the United States and Government Contractors Under 28 U.S.C. § 1498(a) in the United States Court of Federal Claims," 2 *Journal of Intellectual Property Law,* 1995, 389.

> of his reasonable and entire compensation for such use and manufacture.

The remaining paragraphs of § 1498 provide analogous provisions pertaining to other intellectual property rights, including copyright, plant variety protection certificates, and semiconductor mark works.[104]

Under § 1498(a), all patent suits against the U.S. government are litigated in the U.S. Court of Federal Claims. These Court proceedings are conducted using the same general standards as does litigation between private parties. The patent owner represents itself, while the Attorney General and Department of Justice are responsible for representing the U.S. government in § 1498 cases.[105] Unlike private patent suits, however, there are no jury trials in § 1498 cases.[106] Appeals from the United States Court of Claims proceed to the U.S. Court of Appeals for the Federal Circuit.[107]

As compared to remedies available in patent infringement suits against private parties, the remedies available in § 1498(a) suits are more limited. In private patent litigation, the adjudicated infringer is ordinarily enjoined from using the patented invention throughout the remaining term of the patent.[108] The adjudicated infringer may also have to compensate the patent owner for profits lost due to the infringement.[109] Additionally, if a court deems the defendant to have been a "willful infringer," the court may order the defendant to pay the patent owner up to three times the actual damages suffered.[110]

In contrast, § 1498(a) limits available remedies to "reasonable and entire compensation" to the patent owner. As a result, the government may not be enjoined from practicing a patented invention. The courts have also generally limited the damages that the government must pay to the patentee to the level of a "reasonable royalty."[111] A "reasonable royalty" for purposes of patent infringement damages is "the amount that a person desiring to manufacture or use a patented article, as a business proposition, would be willing to pay as a royalty and yet be able to make or

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[104] 28 U.S.C. § 1498 (2000).

[105] 28 U.S.C. § 516 (2000).

[106] 28 U.S.C. § 2402 (2000).

[107] 28 U.S.C. § 1295(a)(3) (2000).

[108] 28 U.S.C. § 283 (2000).

[109] See *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc*., 575 F.2d 1152 (6th Cir. 1978).

[110] 35 U.S.C. § 284 (2000).

[111] See Tektronix, Inc. v. United States, 552 F.2d 343 (Ct. Cl. 1977). Some more recent precedent has suggested that in some cases, the U.S. government may be obliged to pay the full lost profits of the patentee rather than a reasonable royalty. See Gargoyles, Inc. v. United States, 113 F.3d 1572 (Fed. Cir. 1997). However, reportedly the last instance that an award of lost profits was made for government use of a patented invention was in 1930. David M. Schlitz & Richard J. McGrath, "Patent Infringement Claims Against the United States Government," 9 *Federal Circuit Bar Journal,* 2000, 351.

use the patented article, in the market at a reasonable profit."[112] Finally, tripled damages for willful infringement are not available against the government.[113]

Concluding Observations

The use of patent ownership and marketing exclusivity to encourage innovation in the pharmaceutical industry is reflected in existing law and government policy. Studies have shown that these efforts appear to have been successful in facilitating the development and commercialization of new technologies.[114] As such, there appears to be congressional interest in utilizing and expanding this approach for the specific purpose of generating innovative bioterrorism countermeasures. While no legislation was enacted during the 109th Congress, three of the bills introduced, S. 3, S. 975, and S. 1873 established regimes under which patent terms would be restored and/or extended and market exclusivity periods increased to reward innovation in this arena. Although different in the specific provisions, these bills built upon incentives that have been used in the past.

Encouraging the development of new counterterrorism technologies, on one hand, and ensuring affordable access to new drugs and medical devices, on the other, are both significant goals. These aspirations may potentially conflict, however. Introducing augmented patent- and exclusivity-based incentives may stimulate innovative firms to engage in the research and development of new countermeasures, as well as to shepherd these products through time-consuming and costly marketing approval procedures. Commentators have expressed concern, however, over whether such heightened protections for innovators will be in proportion with the risks and costs of developing new countermeasures. Detractors have also questioned the propriety of financing the development of antiterrorism technologies through increased prices upon distinct medical products via the wild card patent term extension. Striking a balance between encouraging the development of new countermeasures and maintaining the traditional goals of our public health system is a central concern of the current discussion with respect to homeland security.

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[112] Wright v. United States, 53 Fed. Cl. 466 (2002).

[113] DeGraffenried v. United States, 228 Ct. Cl. 780 (1981).

[114] See *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology* and *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 (The Hatch-Waxman Act).*