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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")

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Summary

Congressional interest in the availability of drugs has focused attention on the role of patents in the pharmaceutical industry. The industry has been described as patent-intensive. Enterprises within this sector frequently obtain patent protection and enforce patent rights, and reportedly place a higher comparative value on patents than do competitors in many other markets.

The patent law is based upon the Patent Act of 1952, codified in Title 35 of the United States Code. This statute allows inventors to obtain patents on processes, machines, manufactures, and compositions of matter that are useful, new, and nonobvious. Granted patents confer the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.

The Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 Act) – commonly known as the "Hatch-Waxman Act" – made several significant changes to the patent laws designed to encourage innovation in the pharmaceutical industry while facilitating the speedy introduction of lower-cost generic drugs. These changes include provisions for extending the term of a patent to reflect regulatory delays encountered in obtaining marketing approval by the Food and Drug Administration (FDA); a statutory exemption from patent infringement for activities associated with regulatory marketing approval; establishment of mechanisms to challenge the validity of a pharmaceutical patent; and a reward for disputing the validity, enforceability, or infringement of a patented and approved drug. The 1984 Act also provides the FDA with certain authorities to offer periods of marketing exclusivity for a pharmaceutical independent of the rights conferred by patents.

Many experts agree the 1984 Act has had a significant effect on the availability of generic substitutes for brand name drugs. Generics generally are rapidly available after patent expiration and at lower prices. Given increasing investment in research and development (R&D) and the gains in research intensity of the pharmaceutical industry, it appears that the Act has not deterred the search for and the development of new drugs. However, some question whether or not the law remains necessary to achieve the stated goals. Critics maintain that the need for patent-related incentives for innovation is mitigated by other federal activities. Supporters of the existing approach argue that these incentives are precisely what are required and have given rise to a robust pharmaceutical industry. Of fundamental interest may be a determination of the continued validity of the intent behind the law after 18 years. At issue is whether or not the environment in which the original legislation was enacted still exists and if adjustments should be made to reflect any changes.

This background report covers issues through the year 2002. For the latest information on further initiatives, see CRS Issue Brief IB10105, *The Hatch-Waxman Act: Proposed Legislative Changes Affecting Pharmaceutical Patents.*

Contents

Introduction 1

Role of Patents in Pharmaceutical Innovation 2

Principles of Patentability 5
- Patentable Subject Matter 5
- Utility 6
- Novelty and Nonobviousness 8

Patent Acquisition Procedures 9
- Preparing a Patent Application 9
- USPTO Examination 10
- Publication of Pending Patent Applications 10
- Interferences 11
- Post-Grant USPTO Proceedings 11

Patent Term 12

Patent Enforcement 13
- The Exclusive Rights 13
- The Process Patents Amendment Act of 1988 15
- Infringement Litigation 16
- Remedies 17

Patent Assignments and Licenses 17

The Drug Price Competition and Patent Term Restoration Act of 1984 18
- Background of the 1984 Act 18
  - The Role of the FDA and the USPTO in the Pharmaceutical Industry 18
  - The Generic Drug Approval Process 19
  - Generic Drug Development and Patent Infringement 20
- Principal Provisions of the 1984 Act 23
  - Accelerated Generic Drug Approval Process 23
  - Patent Term Restoration 23
  - Market Exclusivity 24
  - Patent Infringement 25
- Subsequent Legislative Developments 28

Implementation of the 1984 Act 29
- Brief Overview of the Pharmaceutical Industry 30
- Effects on Generic Drugs 31
- Effects on Brand Name Drugs 32
- Possible Issues and Potential Concerns 36

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")

Introduction

Congressional interest in methods to provide drugs at lower cost, particularly for the elderly, has rekindled a discussion over the role the federal government plays in facilitating the creation of new pharmaceuticals for the marketplace. Among the various federal laws that affect technology development are those dealing with intellectual property rights, particularly patents. Legislation concerning the ownership of inventions is intended to encourage additional private sector investments often necessary to further develop marketable products. The current approach attempts to balance the public sector's interest in new and improved technologies with concerns over providing companies valuable benefits without adequate accountability or compensation. Questions have been raised as to whether or not this balance is appropriate, particularly with respect to drug discovery. Critics maintain that the need for technology development incentives in the pharmaceutical and/or biotechnology sectors is mitigated by industry access to government-supported work at no cost, monopoly power through patent protection, and additional regulatory and tax advantages such as those conveyed through the Drug Price Competition and Patent Term Restoration Act and the Orphan Drug Act. Supporters of the existing approach argue that these incentives are precisely what are required and have given rise to robust pharmaceutical and biotechnology industries.

This report examines the role of patents in pharmaceutical innovation and provides an overview of the general principles of patent law as applied to inventions of the pharmaceutical industry. The study explores the provisions of several relevant statutes including the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 Act), commonly known as the "Hatch-Waxman Act."[1] Issues and opportunities associated with the implementation of this law are addressed, since the

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[1]For additional discussion of the Hatch-Waxman Act, including legislative activity see: Congressional Research Service, *The "Hatch-Waxman" Act: Selected Patent-Related Issues*, by Wendy H. Schacht and John R. Thomas, RL31379, April 1, 2002 and Congressional Research Service, *The Hatch-Waxman Act: Proposed Legislative Changes*, by Wendy H. Schacht and John R. Thomas, IB10105, updated regularly.

pharmaceutical industry has been described as a patent-intensive one.[2] Enterprises within this sector frequently obtain patent protection and enforce patent rights, and reportedly place a higher comparative value on patents than do competitors in many other markets.[3]

Role of Patents in Pharmaceutical Innovation

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 (currently 20 years from the date of filing). It also places the information associated with an invention within the public domain.

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 application 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 typically is knowledge-driven – based on the application of knowledge, whether it is scientific, technical, experiential, or intuitive. Innovation also produces new knowledge. One characteristic of knowledge that underlies the patent system is that it is a "public good," a good that is not exhausted when it is used. As John Shoven of Stanford University points out, "[t]he 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

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[2]Bale Jr., Harvey E., "Patent Protection and Pharmaceutical Innovation," 29 *New York University Journal of International Law and Politics* (1996-97), 95.

[3]Bale, Jr., Harvey E., "The conflicts between parallel trade and product access and innovation: the case for pharmaceuticals," 1 *Journal of International Economic Law* (1998), 637, 641.

[4]John B. Shoven, "Intellectual Property Rights and Economic Growth," in eds. Charls Walker and Mark A. Bloomfield, *Intellectual Property Rights and Capital Formation in the*

(continued...)

application of that information is near zero 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. It is estimated 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, the knowledge associated with an innovation 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 the 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, studies have shown that it constitutes only 25% of the cost of commercializing a new technology or technique. Thus, it is the expenditure of a substantial amount of additional resources that brings most products or processes to the marketplace. The grant of a

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[4](...continued)
Next Decade, (New York, University Press of America, 1988), 46.

[5]Robert P. Benko, "Intellectual Property Rights and New Technologies," in Walker, et. al., *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]Mansfield, *Intellectual Property Rights, Technological Change, and Economic Growth*, 10-11.

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

patent provides the inventor with a means to capture the returns to his invention through exclusive rights on its practice for 20 years from date of filing. That is intended to encourage those investments necessary to further develop an idea and generate a marketable technology.

Issuance of a patent provides the inventor with a limited-time monopoly that is influenced by other mitigating 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.

The patent system thus has dual policy goals – providing incentives for inventors to invent and encouraging inventors to disclose technical information.[11] 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.[12] They 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 (Boston University) and Richard Nelson (Columbia University) found in their studies, when only ". . . a few organizations controlled the development of a technology, technical advance appeared sluggish."[13]

Not everyone agrees that the patent system is a particularly effective means to stimulate innovation. It is argued that patents do not work in reality as well 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 the former than the latter. The novel ideas associated with a product often can be determined through

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

[12]Dam , *The Economic Underpinnings of Patent Law*, 266-267.
Scope is determined by the number of 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." See footnote 12, p. 7.

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

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.[14]

The utility of patents to companies varies among industrial sectors. Patents are perceived as critical in the drug and chemical industries. That may reflect the nature of R&D performed in these sectors, where the resulting patents are more detailed in their claims and therefore easier to defend.[15] 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.[16] 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."[17] 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 important. 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.[18]

Principles of Patentability

Patentable Subject Matter

Patent law is based upon the Patent Act of 1952, codified in Title 35 of the United States Code. Section 101 defines the subject matter that may be patented. 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

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[14]Richard C. Levin and Alvin K. Klevorick, Richard R. Nelson, 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.

[15]Ibid., 255 and 257. See also: Edwin Mansfield. "Intellectual Property Rights, Technological Change, and Economic Growth," in Walker, et. al., *Intellectual Property Rights and Capital Formation in the Next Decade*, 12 and 13.

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

[17]Ibid., 269.

[18]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.

requirements of this title."[19] An invention that falls within one of the four statutory categories – processes, machines, manufactures, and compositions of matter – may be subject to a so-called "utility patent."

Actors within the pharmaceutical industry principally claim inventions that are compositions of matter or processes. In addition to such things as mixtures and alloys, compositions of matter include chemical compounds.[20] When a composition of matter is presented in the fashion of a patent claim, it is defined in terms of its constituent elements.

A patent claim that is expressed as a series of steps is known as a process or method claim. Process claims are commonly divided into two sorts: "method of using" and "method of making" claims.[21] Suppose that an inventor manufactures a new pharmaceutical compound and also discovers that the compound may be used to treat a particular ailment. The manner in which the pharmaceutical may be employed to achieve a result may be drafted in the form of a claim towards a method of using. As well, the inventor may obtain claims for a method of making the compound, stating the techniques he employed to synthesize the compound.

Section 100(b) of the Patent Act notes that a process "includes a new use of known process, machine, manufacture, composition of matter, or method."[22] The statute thus allows inventors to obtain a proprietary interest in a newly discovered property of a known product. Suppose, for example, that an inventor discovers that a well-known chemical compound, understood to act as an explosive, also serves as a heart medication. The inventor could not obtain patent protection on a compound that already lies within the public domain. But he could seek a patent claiming a process of using the compound as a heart medication.[23]

Utility

Section 101 of the Patent Act also mandates that patents issue only to "useful" inventions.[24] Utility ordinarily presents a minimal requirement that the invention be capable of achieving a pragmatic result.[25] Patent applicants need only supply a single, operable use of the invention that is credible to persons of ordinary skill in the art. Although the utility requirement is readily met in most fields, it may present a significant obstacle to patentability for pharmaceutical inventions. Here, inventors sometimes synthesize compounds without a precise knowledge of how they may be used to achieve a practical working result. When patent applications are filed

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[19]35 U.S.C. § 101.

[20]*See Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

[21]*See In re Pleuddemann*, 910 F.2d 823 (Fed. Cir. 1990).

[22]35 U.S.C. § 100(b).

[23]*See Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985).

[24]35 U.S.C. § 101.

[25]*See Mitchell v. Tilghman*, 86 U.S. (19 Wall.) 287, 396 (1873).

claiming such compounds, they may be rejected as lacking utility within the meaning of the patent law.

The utility requirement should be viewed in light of the considerable incentives chemists, biologists and physicians possess to obtain patent protection on compounds of interest as soon as possible. For example, in the case of pharmaceutical compounds, food and drug authorities require considerable product testing before the pharmaceutical can be broadly marketed. Before investing further time and effort on laboratory testing and clinical trials, actors in the pharmaceutical field desire to obtain patent rights on promising compounds even where their particular properties are, as yet, not well understood. But when patent applications are filed too close to the laboratory bench, inventors have discovered that the utility requirement may block the issuance of a patent.

The Supreme Court opinion in *Brenner v. Manson* addressed such a situation.[26] The inventor Manson filed a patent application claiming a method of making a known steroid compound. Although the particular compound Manson was concerned with was already known to the art, chemists had yet to identify any setting in which it could be gainfully employed. However, as skilled artisans knew that another steroid with a very similar structure had tumor-inhibiting effects in mice, Manson's new method of making the compound was a research tool of interest to the scientific community.

The U.S. Patent and Trademark Office (USPTO) Board of Patent Appeals affirmed the examiner's rejection of the application. The Board reasoned that because Manson could not identify a single use for the steroid he produced, the utility requirement was not satisfied. The Board was unimpressed that a similar compound did have beneficial effects, noting that in the unpredictable art of steroid chemistry, even minor changes in chemical structure often lead to significant and unforeseeable changes in the performance of the compound. Manson then appealed to the Court of Customs and Patent Appeals (CCPA), which reversed. Key to the CCPA's reasoning was that the sequence of process steps claimed by Manson would produce the steroid of interest. According to the CCPA, because the claimed process worked to produce a compound, the utility requirement was satisfied.

The Supreme Court granted certiorari and once more reversed, thereby upholding the Patent Office rejection. At least within the context of scientific research tools, the Court imposed a requirement that an invention may not be patentable until it has been developed to a point where "specific benefit exists in currently available form."[27] Chief among the Court's concerns was the breadth of the proprietary interest that could result from claims such as those in Manson's application. "Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. . . . . Such a patent may confer power to block whole areas of scientific

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[26]385 U.S. 419 (1966).

[27]Ibid., p. 534-35.

development, without compensating benefit to the public."[28] The Court closed by noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. 'A patent system must be related to the world of commerce rather than to the realm of philosophy.'"[29]

Although *Brenner v. Manson* appears to take a strict view of the utility requirement, a more recent lower court opinion on utility, *In re Brana*,[30] suggests a more limited role. Like Manson, Brana claimed chemical compounds and stated they were useful as antitumor substances. The scientific community knew that structurally similar compounds had shown antitumor activity during both *in vitro* testing, done in the laboratory using tissue samples, and *in vivo* testing using mice as test subjects. The latter tests had been conducted using cell lines known to cause lymphocytic tumors in mice.

The USPTO Board rejected the application for lack of utility, and on appeal the United States Court of Appeals for the Federal Circuit (Federal Circuit) reversed. Among the objections of the USPTO was that the tests cited by Brana were conducted upon lymphomas induced in laboratory animals, rather than real diseases. The Federal Circuit responded that an inventor need not wait until an animal or human develops a disease naturally before finding a cure.[31] The USPTO further argued that Brana cited no clinical testing, and therefore had no proof of actual treatment of the disease in live animals. The Federal Circuit reasoned that proof of utility did not demand tests for the full safety and effectiveness of the compound, but only acceptable evidence of medical effects in a standard experimental animal.[32]

The holding of *Brana*, along with its failure to discuss or even cite *Brenner v. Manson*, suggests that the Federal Circuit will adopt a more liberal approach to the utility requirement than did the Supreme Court.[33] The Federal Circuit did indicate that, in cases where the invention lacks a well-established use in the art, the applicant must disclose a specific, credible use within the patent's specification.[34]

Novelty and Nonobviousness

To be patentable, a pharmaceutical invention must be judged both new and nonobvious. To be considered novel, the invention must not be wholly anticipated by the so-called "prior art," or public domain materials such as publications and other

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[28]Ibid., p. 535.

[29]Ibid., p. 536 (quoting *Application of Ruschig*, 343 F.2d 965, 970 (CCPA 1965)).

[30]51 F.3d 1560 (Fed. Cir. 1995).

[31]Ibid., p. 1565.

[32]Ibid ., p. 1568.

[33]Machin, Nathan. Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act, 87 *California Law Review* (1999), p. 421, 432.

[34]51 F.3d at 1564-68.

patents.[35] The nonobviousness requirement is met if the invention is beyond the ordinary abilities of a person of ordinary skill in the art in the appropriate field.[36]

Patent Acquisition Procedures

Preparing a Patent Application

An inventor who wishes to obtain patent protection must first prepare an application. Although inventors may represent themselves before the USPTO, the vast majority engage the services of a patent attorney or agent for this purpose. An application must include several components. First, the application must be accompanied by a filing fee. As of October 1, 2002, the filing fee was set to $740.[37]

The application must also contain a specification, or description of the invention. Section 112 subjects the specification to three requirements.[38] First, the specification must enable persons of ordinary skill in the art to which the patent pertains to make and use the invention.[39] Second, the specification must contain a "written description" of the invention, sufficient to show that the inventor was in possession of the invention at the time he filed the application.[40] Finally, the specification must detail the "best mode" contemplated by the inventor of practicing the invention.[41]

Section 112 also requires that the specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."[42] The claims are considered the most important part of the patent instrument, setting forth the boundaries of the invention that the inventor claims as his own. Claims are subject to a requirement of definiteness, which mandates that they be sufficiently precise so that others may have notice of the patentee' proprietary interest.[43]

Inventors possess no duty to perform a prior art search prior to filing a patent application. However, if an applicant does know of a prior art reference that is

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[35] 35 U.S.C. § 102.

[36] 35 U.S.C. § 103(a).

[37] 37 C.F.R. § 1.16.

[38] 35 U.S.C. § 112 ¶ 1.

[39] *See Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984).

[40] *See Vas-Cath Inc. v. Marhurkar*, 935 F.2d 1555 (Fed. Cir. 1991).

[41] *See Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043 (Fed. Cir. 1995).

[42] 35 U.S.C. § 112 ¶ 2.

[43] *See Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565 (Fed. Cir. 1986).

material to the patentability of the claimed invention, then he must disclose it to the USPTO.[44]

USPTO Examination

Once an inventor has completed an application, he must forward it to the USPTO for further consideration. Prosecution of a patent at the USPTO is an *ex parte* procedure. Members of the public, and in particular the patent applicant's competitors, do not participate in patent prosecution procedures. As well, USPTO examiners do not possess a competing interest relative to the applicant. Instead, they assist the applicant in fulfilling the statutory requirements for obtaining a patent grant.[45]

Once the USPTO receives a patent application, USPTO staff will forward it to the examining group bearing responsibility for that sort of invention. A supervisory patent examiner then assigns the application to an individual examiner. The examiner will review the application and conduct a search of the prior art. The examiner then judges whether the application properly discloses and claims a patentable invention.

The examiner must notify the applicant of her response to the application. Termed an Office Action, this response may allow the application to issue or reject it in whole or in part.[46] If the claim is rejected, the examiner ordinarily must establish a prima facie case of unpatentability by a preponderance of the evidence.[47]

If a rejection has resulted, the attorney will usually respond by either amending the claims or asserting that the rejection was improper. An examiner who remains unconvinced by the applicant's response will issue a second Office Action termed a "Final Rejection." The applicant ordinarily has three options: abandon the application, persist in prosecution by filing a so-called "continuing application," or seek review of the examiner's action by filing a petition to the Commissioner or appeal to the Board of Patent Appeals and Interferences.[48]

Publication of Pending Patent Applications

The Domestic Publication of Foreign Filed Patent Applications Act of 1999 requires the USPTO to publish pending patent applications 18 months from the earliest filing date (to which they are entitled under the law).[49] Significantly, if an applicant certifies that the invention disclosed in the application will not be the

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[44]37 C.F.R. § 1.56.

[45]Levine, Russell E., et al., "Ex Parte Patent Practice and the Rights of Third Parties," 45 *American University Law Review* (1996), 1987.

[46]35 U.S.C. § 132.

[47]*See In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992).

[48]35 U.S.C. §§ 120, 133, 134.

[49]American Inventors Protection Act of 1999, Pub. L. No. 106-113.

subject of a patent application in another country that requires publication of applications 18 months after filing, then the application shall not be published in the United States. This Act also creates provisional rights, equivalent to a reasonable royalty, owed from persons who employ the invention as claimed in the published patent application.[50]

Interferences

Sometimes multiple individuals seek patent rights on the same invention. For example, two companies may have contemporaneously developed a particular pharmaceutical and filed patent applications. In such cases, the USPTO will declare a so-called "interference" proceeding.[51] A patent interference is a complex administrative proceeding that ordinarily results in the award of a patent to one of its participants. The prevailing party in the interference is usually the individual who was the first to invent the claimed technology. [52]

Post-Grant USPTO Proceedings

USPTO involvement in the patent system does not necessarily end when it formally grants a patent. Two significant post-grant proceedings are worthy of note here. First, a patentee may employ the reissue proceeding to correct a patent that he believes to be inoperative or invalid.[53] For example, suppose that subsequent to the issuance of a patent, the patentee discovers prior art that would invalidate the patent due to anticipation or obviousnesss. By incorporating additional limitations into the patent claims through the reissue proceeding, the patentee may yet be able to define a patentable advance over the prior art.

The second significant post-grant proceeding is known as reexamination. A feature of U.S. law since 1981, the reexamination statute allows that any individual, including the patentee, a licensee, and even the USPTO Director himself, may cite a patent or printed publication to the USPTO and request that a reexamination occur.[54] If the USPTO determines that this reference raises "a substantial new question of patentability,"[55] then it will essentially reinitiate examination of the patent.[56] A certificate of cancellation results if the USPTO judges the claims to be unpatentable over the cited reference. Otherwise the USPTO issues a certificate of confirmation upholding the claims in their original or amended form.[57]

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[50]35 U.S.C. § 122.

[51]35 U.S.C. § 135.

[52]35 U.S.C. § 102(g).

[53]35 U.S.C. § 251.

[54]35 U.S.C. § 302.

[55]35 U.S.C. § 303.

[56]35 U.S.C. § 304.

[57]35 U.S.C. § 307.

The Optional Inter Partes Reexamination Procedure Act of 1999 provides third parties with an additional option.[58] They may employ the traditional reexamination system, which has been renamed an *ex parte* reexamination. Or, they may opt for a minimal degree of participation in a newly minted *inter partes* reexamination. During *inter partes* reexamination, third party requesters may opt to submit written comments to accompany patentee responses to the USPTO. The requester may also appeal USPTO determinations that a reexamined patent is not invalid to the USPTO Board and the Court of Appeals for the Federal Circuit. To discourage abuse of *inter partes* reexamination proceedings, the statute provides that third party participants are stopped from raising issues that they raised or could have raised during reexamination.

Amendments to a patent introduced during reissue or reexamination may trigger so-called "intervening rights" that benefit competitors of the patentee. Congress recognized that third parties may have made commercial decisions based upon the precise wording of the claims of an issued patent. If these claims are later amended during reissue or reexamination, this reliance interest could be frustrated. The patent statute therefore allows the competitors of a reissued or reexamined patent to sell, continue to use, or otherwise employ the claimed invention in appropriate circumstances.[59]

Patent Term

Once the USPTO issues a patent, that patent enjoys an effective term established by the statute. The publication of this report finds the patent law in a transition period concerning patent term. For patents resulting from publications filed after June 8, 1995, the patent term is ordinarily twenty years from the date the patent application was filed.[60] For patents issued prior to June 8, 1995, as well as for patent resulting from applications pending at the USPTO as of that date, the patent endures for the greater of twenty years from filing or seventeen years from grant.[61]

Although the life of the patent is measured from the filing date, individuals gain no enforceable rights merely by filing a patent application. These rights accrue only at such time that the patent issues, and potentially include the power to enjoin infringers and obtain an award of damages. If the application was published in accordance with the Domestic Publication of Patent Applications Filed Abroad Act of 1999, then the patentee also obtains provisional rights equivalent to a reasonable royalty. Although provisional rights extend from the time the patent application was published, the patentee may not assert them until the patent issues.

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[58]American Inventors Protection Act of 1999, Pub. L. No. 106-113. *See* Janis, Mark D., "Inter Partes Reexamination," 10 Fordham Intellectual Property, Media & Entertainment Law Journal (2000), 481.

[59]35 U.S.C. §§ 252, 307(a).

[60]35 U.S.C. § 154(a).

[61]*See* Lemley, Mark A. An Empirical Study of the Twenty-Year Patent Term, 22 *American Intellectual Property Law Association Quarterly Journal* (1994), p. 369.

Four significant qualifications may alter the basic patent term. Most significant for the pharmaceutical industry is that the term of a patent may be extended under 35 U.S.C. § 156. This provision was introduced by the Drug Price Competition and Patent Term Restoration Act of 1984.[62] This complex statute authorizes increased patent terms on inventions that have been subject to a premarket approval process under the Federal Food, Drug and Cosmetic Act.

Under 35 U.S.C. § 154(b), patentees may also obtain term extensions of up to five years due to certain prosecution delays, including the declaration of an interference of the successful pursuit of appeal to the Board of Patent Appeals and Interferences or federal court. As well, the Patent Term Guarantee Act of 1999 provides certain deadlines that, if not met by the USPTO, result in an automatic extension (day for day) of the term of individual patents. Among these deadlines are fourteen months for a First Office Action and four months for a subsequent Office Action. The prosecution also must be completed within three years of the filing date, with exceptions granted for continuing applications and appeals.

Finally, enjoyment of the full patent term is subject to the payment of maintenance fees. A patent expires after four, eight, or twelve years if maintenance fees are not timely paid on each occasion. As of October 1, 2002, the amounts due are $880 by the fourth year, $2,020 by the eighth year, and $3,100 by the twelfth year.[63]

Patent Enforcement

The Exclusive Rights

A patent provides its proprietor with exclusive rights in the patented invention. An individual who "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."[64] Modern courts consider the phrase "patented invention" to mean the invention as recited in the claims. If an accused product or process meets every element and limitation of the claims, then the patent is said to be literally infringed.[65]

As noted, the Patent Act states that all unauthorized "uses" of the patented invention constitute an infringement. In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,[66] the Federal Circuit held that this language on its face prohibits all unauthorized uses of the patented invention, including those that might be deemed "experimental" in character. The *Roche v. Bolar* court did leave open a narrow

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[62]Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[63]37 C.F.R. § 1.16.

[64]35 U.S.C. § 271(a).

[65]*Johnston v. IVAC Corp.*, 885 F.2d 1574, 1580 (Fed.Cir.1989).

[66]733 F.2d 858 (Fed. Cir. 1984).

possibility that the use of a patented invention wholly for experiment, amusement or curiosity might be judged noninfringing. However, where experimental uses of the invention are in fact motivated by commercial purposes, this "experimental use" doctrine will not serve as an infringement defense. As described above, Congress subsequently modified these "experimental use" principles with an eye towards the pharmaceutical industry.

The patent statute also includes provisions concerning contributory infringement and the active inducement of another's infringement.[67] Under these statutes, individuals who encourage the unauthorized practice of another's patent infringement may themselves be liable for patent infringement in certain circumstances. Suppose, for example, that a supplier sells a medication that has both infringing and noninfringing uses. If the supplier provides instructions, distributes advertising or offers training that promotes the infringing use, then it may be guilty of active inducement and liable for patent infringement.[68]

Although the exclusive rights provided by a patent are founded upon the claims, they are not necessarily limited to them. Although the courts have long recognized the value of clear and certain claims, they have sometimes expanded the scope of protection associated with a patent under the so-called "doctrine of equivalents." The doctrine of equivalents arose from judicial efforts to stop competitors who would introduce insignificant modifications from the claimed invention in order to avoid literal infringement.[69] As provided in the 1997 Supreme Court opinion in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, an accused product or process that presents insubstantial differences from the claimed invention will judged an equivalent and therefore an infringement.[70]

A defendant's intent is irrelevant to the outcome of an infringement inquiry. Even an individual who has never previously known of the asserted patent may be found to be an infringer.[71] As well, the exclusive patent rights do not provide an affirmative right for the patentee to employ the invention himself.[72] For example, the fact that an inventor obtains a patent on a pharmaceutical compound does not allow him to market this medication to others. Approval of the appropriate food and drug authorities must also be obtained.

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[67]35 U.S.C. § 271(b), (c).

[68]*See Chimuinatta Concrete Concepts, Inc. v. Cardinal Industries, Inc.*, 145 F.3d 1303 (Fed. Cir. 1998).

[69]*Graver Tank v. Linde Air Products Co.*, 339 U.S. 605 (1950).

[70]520 U.S. 17 (1997).

[71]*See Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1572 n.2 (Fed. Cir. 1996).

[72]*Leatherman Tool Group Inc. v. Cooper Industries Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1996).

The patents of others might also interfere with the patentee's ability to practice his own patented invention.[73] Suppose, for example, that a hypothetical entity, Alpha Co., obtains a patent on a chemical compound using for treating hypertension. Later, another hypothetical entity, Beta Co., discovers that the chemical compound is also useful for treating male pattern baldness. Even if Beta obtains a patent on a method of using the chemical to treat baldness, Beta cannot practice that method without infringing Alpha's patent. Nor can Alpha use the compound to treat baldness without infringing Beta's patent. In this case, the Alpha patent is said to be a blocking, or dominant patent over Beta's improvement or subservient patent. In such instances the holders of the dominant and subservient patent often possess incentives to cross-license one another.

The rights provided by U.S. patents are ordinarily effective only in the United States. They generally provide no protection against acts occurring in foreign countries.[74] Individuals must obtain patent protection in each nation where they wish to guard against unauthorized use of their inventions.

Under the "first sale" or "exhaustion" doctrine, an authorized, unrestricted sale of a patented product depletes the patent right with respect to that product. As a result of this doctrine, the purchaser of a patented good ordinarily may use or resell the good without further regard to the patentee. The courts have reasoned that when a patentee sells a product without restriction, it impliedly promises its customer that it will not interfere with the full enjoyment of the product.[75]

The Process Patents Amendment Act of 1988

Special infringement provisions concerning process patents impact the pharmaceutical industry. Traditionally the patent law held that a process claim could be directly infringed only by the performance of those steps. Suppose, for example, that an inventor holds a patent on a particular method of making a pharmaceutical. By itself, the act of selling the pharmaceutical does not infringe this method patent. The seller would also have to make the pharmaceutical by the patented method in order to be liable for infringement.[76]

This general principle was altered to some degree in the Process Patents Amendment Act of 1988.[77] There, Congress provided process patent owners with the right to exclude others from using or selling in the United States, or importing into

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[73] *See Bio-Technology General Corp. v. Genentech Inc.*, 80 F.3d 1553, 1559 (Fed. Cir.), *cert. denied*, 117 S. Ct. 274 (1996).

[74] *See Dowagiac Mfg. Co. v. Minnesota Moline Plow Co.*, 35 U.S. 641, 650 (1915).

[75] *See Intel Corp. v. ULSI Corp.*, 995 F.2d 1566 (Fed. Cir. 1993), *cert. denied*, 510 U.S. 1092 (1994).

[76] *See Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770 (Fed. Cir. 1993).

[77] Pub. L. No. 100-418.

the United States, products made by a patented process.[78] For example, suppose that an enterprise based abroad manufactures a pharmaceutical employing a process patented in the United States. If the foreign company exports the pharmaceutical into the United States, it may face liability even though it performed every step of the patented process abroad.

A number of exceptions limit liability under the Process Patents Amendment Act. If the accused product is materially changed by subsequent processes, or becomes a trivial or nonessential component of another product, then there is no infringement.[79] The Process Patents Amendment Act also included complex provisions that modified the usual scheme of remedies available for patent infringement.[80] Among other features, they include a grace period for individuals unaware of the patent implications of a particular process. Such persons may, upon receiving notice of infringement, dispose of infringing products and avoid liability.

The Process Patents Amendment Act also modified the burden of proof for certain charges of process patent infringement. Ordinarily, the patentee is the moving party during infringement litigation and bears the burden or proving that infringing acts have occurred.[81] However, Congress recognized that patentees may face great difficulties in proving that a particular product resulted from the performance of the patented process. The Patent Act therefore creates a presumption that a product is made by a patented process if two conditions are met.[82] First, there must be a substantial likelihood that the product was made by the patented process. Second, the plaintiff must have made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine. The effect of the presumption is that the accused infringer has the burden of asserting that the accused product was not made by the patented process.

Infringement Litigation

The patentee may file a civil suit in federal district court in order to enjoin infringers and obtain monetary remedies.[83] Although issued patents enjoy a presumption of validity, accused infringers may assert that the patent is invalid or unenforceable.[84] In patent matters, appeals from the district courts go to the United States Court of Appeals for the Federal Circuit. The Federal Circuit also hears

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[78]35 U.S.C. § 271(g).

[79]35 U.S.C. § 271(g)(1), (2). *See Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568 (Fed. Cir. 1996).

[80]35 U.S.C. § 287(b).

[81]*Rohm and Haas Co. v. Brotech Corp.*, 127 F.3d 1089 (Fed. Cir. 1997).

[82]35 U.S.C. § 295.

[83]35 U.S.C. § 281.

[84]35 U.S.C. § 282.

appeals from the USPTO. Federal Circuit decisions are subject to review at the Supreme Court.[85]

Remedies

The Patent Act sets forth the remedies a patentee may obtain upon a finding of infringement. Section 283 allows courts to "grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, or such terms as the court deems reasonable."[86] A patentee may also obtain a preliminary injunction against an accused infringer. Courts assess the traditional four factors when considering whether to grant such an injunction. The factors are typically stated as: (1) the probability of success on the merits; (2) the possibility of irreparable harm to the patentee if the injunction is not granted; (3) the balance of hardships between the parties; and (4) the public interest.[87]

The Patent Act also provides for the award of damages "adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer."[88] In practice, patentees seek lost profits damages when they are able to make the required showing. Otherwise a reasonable royalty serves as the default measure of damages. The Patent Act limits recovery to six years prior to the filing of the complaint or counterclaim for patent infringement.[89] Courts ordinarily award prejudgment interest in order to afford the patentee full compensation for the infringement.[90]

Patent Assignments and Licenses

Patents possess the attributes of personal property and may be assigned or licensed to others.[91] An assignment, which is essentially the sale of the patent, must be in writing to be effective.[92]

A patent owner may also grant a license. A license is generally not a full ownership interest in the patented invention. Instead, a patent license amounts to a promise by the patentee not to sue the licensee for infringement in exchange for some

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[85]The Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982).

[86]35 U.S.C. § 283.

[87]*See Mentor Graphics Corp. v. Quickturn Design Systems, Inc.*, 150 F.3d 1374, 1377, 47 USPQ2d 1683, 1685 (Fed. Cir. 1998).

[88]35 U.S.C. § 284.

[89]35 U.S.C. § 286.

[90]*See General Motors Corp. v. Devex Corp.*, 461 U.S. 648 (1983).

[91]35 U.S.C. § 261.

[92]Ibid.

consideration.[93] Licenses are generally classified as either exclusive or nonexclusive. An exclusive licensee has received a promise that it alone may make, use, sell, offer to sell, or import into the United States the patented invention without facing an infringement suit.[94]

The Drug Price Competition and Patent Term Restoration Act of 1984

The Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 Act)[95] introduced several significant changes to the patent laws. These include patent term extension; a statutory exemption for patent infringement relating to regulatory marketing approval; procedures for challenging the validity of pharmaceutical patents; and a reward for challenging the validity, enforceability, or infringement of a patented and approved drug. Through these provisions, the 1984 Act attempts to balance two competing objectives within the pharmaceutical industry. First, the 1984 Act aimed to encourage the introduction of widely available generic drugs. Second, the 1984 Act hoped to ensure that adequate incentives remain for individuals to invest in the development of new drugs.[96]

The 1984 Act is today commonly known as the "Hatch-Waxman Act."[97] At the time of its enactment, however, the 1984 Act was generally referred to as the "Waxman-Hatch Act."[98] In light of this conflicting nomenclature, this report refers to the Drug Price Competition and Patent Term Restoration Act of 1984 as the 1984 Act.

Background of the 1984 Act

The Role of the FDA and the USPTO in the Pharmaceutical Industry. Both the Patent and Trademark Office and the Food and Drug Administration (FDA) have a role to play in the pharmaceutical industry. The USPTO allows patents to issue on the compounds that comprise a pharmaceutical as well as methods of making and using them. Patents confer the right to exclude others from making,

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[93] *Spindelfabrik Suessen-Schurr v. Schubert & Salzer*, 829 F.2d 1075, 1081 (Fed.Cir. 1987), *cert. denied*, 484 U.S. 1063 (1988).

[94] Adelman, Martin J., et al., *Cases and Materials on Patent Law* (1998), 1231.

[95] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[96] Rea, Teresa Stanek, "Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act–An Introduction of Speakers," 54 *Food Drug Law Journal* (1999), 223, 224.

[97] *See, e.g., Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997).

[98] *See, e.g.*, McGough, Kevin J. , "Preserving the Compromise: The Plain Meaning of Waxman-Hatch Exclusivity," 45 *Food, Drug and Cosmetic Law Journal* (1990), 487.

using, selling, offering to sell, or importing into the United States the patented invention.[99]

The grant of a patent does not provide its proprietor with the affirmative right to market the patented invention, however.[100] For many products of the pharmaceutical industry, the FDA must approve the product for sale to consumers. Federal laws generally require that pharmaceutical manufacturers show their products are safe and effective in order to market these products.[101]

USPTO issuance of a patent and FDA marketing approval are distinct events that depend upon different criteria.[102] The FDA might consider a pharmaceutical safe and effective for consumer use, for example, but the USPTO could rule that the compound does not present a sufficient advance over public domain knowledge to be worthy of a patent. Alternatively, it is readily within the power of the FDA to judge that a pharmaceutical presents too great a risk for use as a medication within the United States, despite the fact that the USPTO has allowed a patent to issue claiming that pharmaceutical.

As a result of the independence of patent ownership and marketing approval, the pharmaceutical industry must account for both. In order to sell a drug without fear of civil or criminal liability, an enterprise must both obtain FDA approval and consider whether that drug has been patented. Often the entity which owns the patent on a pharmaceutical is the first to be awarded marketing approval. Sometimes the enterprise which has been awarded marketing approval and the patent owner are separate entities, however. In this latter case, the patentee may commence infringement litigation against the approved drug manufacturer. A court may issue an injunction and award monetary liability for patent infringement despite the fact of FDA marketing approval.

Although the 1984 Act maintained the independence between the award of a patent and the process of seeking FDA market approval, it did establish a procedural interface between these two events. Before describing these procedures in greater detail, this report first considers core features of the patent and food and drug laws as they stood prior to the 1984 Act.

The Generic Drug Approval Process. Since 1962, federal law has required pharmaceutical manufacturers to demonstrate that their products are safe and effective.[103] Prior to the 1984 Act, however, the federal food and drug law

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[99]35 U.S.C. § 271(a).

[100]Chisum, Donald S., *Principles of Patent Law* (Foundation Press, New York, New York, 1998), 5.

[101]21 U.S.C. § 355(b). Prior to 1962, the drug approval process was solely directed towards safety. *See* Mossinghoff, Gerald J., "Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process," 54 *Food and Drug Law Journal* (1998), 187.

[102]See *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995).

[103]21 U.S.C. § 355(b). Prior to 1962, the drug approval process was solely directed towards
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contained no separate provisions addressing generic versions of drugs that had previously been approved.[104] The result was that would-be generic drug manufacturers had to file their own "New Drug Application" (NDA) in order to market their drug. Some generic manufacturers could rely on published scientific literature demonstrating the safety and efficacy of the drug. These sorts of studies were not available for all drugs, however. Further, at times the Food and Drug Administration requested additional studies to deal with safety and efficacy questions that arose from experience with the drug following its initial approval. The result is that some generic manufacturers were forced to prove independently that the drug was safe and effective, even though their product was identical to that of a previously approved drug.

Some commentators believed that the approval of a generic drug was a needlessly costly, duplicative and time-consuming process prior to the 1984 Act.[105] FDA safety and efficacy requirements sometimes required clinical trials, for example, which could prove very expensive. Some observers noted that although patents on important drugs had expired, manufacturers were not moving to introduce generic equivalents for these products.[106] 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.[107]

Generic Drug Development and Patent Infringement. The patent law grants patent proprietors the right to exclude others from making, using selling, offering to sell, or importing into the United States the patented invention.[108] Accused infringers may offer several defenses to avoid liability for patent infringement, however. One potential defense lies under the so-called "experimental use" doctrine. Perhaps the first discussion of this infringement defense occurred in the 1813 decision in *Whittemore v. Cutter*.[109] There, Justice Joseph Story explained that "it could never have been the intention of the legislature to punish a man, who constructed such a [patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." By 1861, the court in *Poppenhausen v. Falke* was able to state that the law

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[103](...continued)
safety. *See* Mossinghoff, *supra* note 8, at 187.

[104]Engelberg, Alfred B., "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?," 39 *IDEA: Journal of Law and Technology* (1999), 389, 396. Generic drugs are versions of brand-name prescription drugs that are often sold without a trademark and that contain the same active ingredients, but not necessarily the same inactive ingredients, as the original. *United States v. Generix Drug Co.*, 460 U.S. 435, 455 (1983).

[105]Buchanan, J. Matthew, "Medical Device Patent Rights in the Age of FDA Modernization: the Potential Effect of Regulatory Streamlining on the Right to Exclude," 30 *University of Toledo Law Review* (1999) 305, 316.

[106]Engelberg, supra note 103, at 396-97.

[107]Buchanan, *supra* note 104.

[108]35 U.S.C. § 271(a).

[109]29 F.Cas. 1120, 1121 (C.C.Mass. 1813)(No. 17,600).

was "well-settled that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the rights of the patentee."[110]

Commentators have noted that the number of accused infringers who have successfully pled an experimental use defense are few, however.[111] As a practical matter, perhaps infringement charges were only rarely brought against philosophers or amusement seekers.[112] The possibility of an experimental use defense took on a new characteristic with the advent of drug marketing approval procedures, however. When a competitor becomes interested in marketing the generic equivalent of a drug patented by another, it may wish to commence the clinical trials and other procedures during the term of the patent. As a result, the competitor would be able to market the drug immediately upon expiration of the patent. Whether the regulatory compliance activities of a generic drug manufacturer amounted to a patent infringement, or were exempted by the experimental use defense, was for many years an open legal question.

The 1984 decision of the Court of Appeals for the Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*[113] resolved this question conclusively in favor of a finding of patent infringement. In that case, Roche Products, Inc. (Roche) marketed a prescription sleeping pill under the trademark "Dalmane." Roche also was the proprietor of a patent claiming a chemical compound, flurazepam hcl, that was the active ingredient in Dalmane.[114] The Roche patent issued on January 17, 1967, and expired on January 17, 1984.

Bolar Pharmaceutical Co. (Bolar), a manufacturer of generic drugs, grew interested in marketing a generic equivalent of Dalmane. Bolar recognized that FDA approval of a drug was a time-consuming process and wished to begin selling a generic equivalent immediately after the Roche patent expired. As a result, in mid-1983, Bolar obtained a supply of flurazepam hcl from a foreign manufacturer. It began to form the flurazepam hcl into dosage form capsules to obtain stability data, dissolution rates, bioequivalency studies and blood serum studies necessary to file an NDA with the FDA.

Roche brought suit against Bolar on July 28, 1983, seeking to enjoin Bolar from using flurazepam hcl for any purpose during the life of the patent. The district court ultimately denied Roche's request on October 11, 1983. The district court concluded

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[110]19 F.Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

[111]*See* Note, "Experimental Use as Patent Infringement: The Impropriety of a Broad Exception," 100 *Yale Law Journal* (1991), 2169.

[112]Bee, Richard E., "Experimental Use as An Act of Patent Infringement," 39 *Journal of the Patent Office Society* (1957), 357.

[113]733 F.2d 858 (Fed. Cir. 1984).

[114]*See* U.S. Patent No. 3,299,053 ("Novel 1 and/or 4-substituted alkyl 5-aromatic-3H-1,4-benzodiazepines and benzodiazepine-2-ones.").

that Bolar's use of the compound for federally mandated testing did not infringe the Roche patent because Bolar's use was minimal and experimental.[115]

Roche promptly appealed to the United States Court of Appeals for the Federal Circuit, which reversed the district court. Writing for a three-judge panel, Judge Nichols initially observed that the 1952 Patent Act states that whoever "uses . . . any patented invention, within the United States during the term of the patent therefore, infringes the patent."[116] This language on its face prohibits all unauthorized uses of the patented invention, the Federal Circuit reasoned, and many judicial opinions had so held.[117]

The Federal Circuit next considered two contentions offered by Bolar. First, Bolar urged that the experimental use defense exempted its efforts to comply with federal food and drug law. After reviewing the precedents, Judge Nichols disagreed, concluding:

> Bolar's intended "experimental" use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the [Roche] patent. Bolar may intend to perform "experiments," but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use de minimus. It is no trifle in its economic effect on the parties even if the quantity used is small. It is not dilettante affair such as Justice Story envisioned. We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of "scientific inquiry," when that inquiry has definite, cognizable, and not insubstantial commercial purposes.[118]

Bolar finally urged the Federal Circuit to resolve a perceived conflict between the Food, Drug and Cosmetic Act[119] and the 1952 Patent Act.[120] Bolar observed that substantial regulatory delays were associated with the receipt of FDA marketing approval. According to Bolar, if a generic manufacturer could not commence seeking FDA approval until the appropriate patents had expired, then the patentee could preserve its market exclusivity beyond the statutory patent term. Bolar

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[115]572 F. Supp. 255 (E.D.N.Y. 1983).

[116]35 U.S.C. § 271(a).

[117]733 F.2d at 862-64.

[118]733 F.2d at 863.

[119]Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et seq.).

[120]Pub. L. No. 82-593, 66 Stat. 792 (1952) (codified as amended 35 U.S.C. § 1 et seq.).

characterized this situation as a de facto patent term extension inconsistent with the Patent Act.[121]

The Federal Circuit also rejected this argument. According to Judge Nichols, the judiciary was not the proper forum to engage in policy argumentation inconsistent with the patent statute. The court observed that bills addressing these issues had been placed before Congress and suggested that any aggrieved parties seek redress there.[122] The Federal Circuit remanded the decision to the district court with instructions to fashion the appropriate remedy.[123]

Principal Provisions of the 1984 Act

The Federal Circuit's suggestion that a legislative forum may better suit the interests of the parties proved prophetic. On September 24, 1984, President Ronald Reagan signed into law the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act"). The 1984 Act is codified in Titles 15, 21, 28 and 35 of the United States Code.[124] Although the 1984 Act is a complex statute, observers have frequently noted that it presents a fundamental trade-off: In exchange for permitting manufacturers of generic drugs to gain FDA marketing approval by relying on safety and efficacy data from the original manufacturer's NDA, the original manufacturers received a period of data exclusivity and patent term extension.[125] A review of the legislation's more significant provisions follows.

Accelerated Generic Drug Approval Process. The 1984 Act created a new type of application for market approval of a pharmaceutical. This application, termed an Abbreviated New Drug Application (ANDA), may be filed at the FDA.[126] 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 an ANDA often allows a generic manufacturer to avoid the costs and delays associated with filing a full-fledged NDA. Through the ANDA procedure, a generic manufacturer may often place its FDA-approved bioequivalent drug on the market as soon as the patent on the original drug expires.[127]

Patent Term Restoration. The 1984 Act also provides for the extension of patent term. Ordinarily, patent term is set to twenty years from the date the patent

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[121]733 F.2d at 863-64.

[122]733 F.2d at 864-66.

[123]733 F.2d at 865-67.

[124]The specific provisions are 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301, 355, 360cc; 28 U.S.C. § 2201; and 35 U.S.C. §§ 156, 271, 282.

[125]Glover, Gregory J., "Regulatory Concerns & Market Exclusivity," *Health Care M&A 2000*, 1175 Practising Law Institute (2000), 629, 633.

[126]21 U.S.C. § 355(j).

[127]Ibid.

application is filed.[128] The 1984 Act provides that for pharmaceutical patents, the patent term may be extended for a portion of the time lost during clinical testing. More specifically, this term extension is equal to the time between the effective date of the investigational new drug application and the submission of the NDA, plus the entire time lost during FDA approval of the NDA.[129]

The 1984 Act sets some caps 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.[130] The 1984 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.[131]

Patent term extension does not occur automatically. The patent owner or its agent must file an application with the USPTO requesting term extension within 60 days of obtaining FDA marketing approval. According to a senior legal advisor in the Special Program Law Office of the Patent and Trademark Office, between 50 and 60 such applications are filed each year.[132]

Market Exclusivity. The 1984 Act includes provisions that create market exclusivity for certain FDA-approved drugs. The FDA administers these provisions by issuing approval to market a pharmaceutical to only a single entity. A grant of market exclusivity does not depend on the existence of patent protection and the two rights may actually conflict.

The length of market exclusivity is contingent on whether or not the drug is considered a new chemical entity (NCE). The 1984 Act defines an NCE drug as an approved drug which consists of active ingredients, including the ester or salt of an active ingredient, none of which has been approved in any other full NDA.[133] If the approved drug is not an NCE, then the FDA may not approve an ANDA for a generic version of the approved drug until three years after the approval date of the pioneer NDA.[134]

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[128]35 U.S.C. § 156. Prior to United States adherence to the World Trade Organization, patents were granted a term of 17 years from the date of issuance. On June 8, 1995, the effective patent term was changed to 20 years measured from the date the patent application was filed. Patents in existence as of June 8, 1995, or patents that issued from applications pending at the USPTO as of the date, have a term equal to the greater of 17 years from issuance or 20 years from grant.

[129]35 U.S.C. § 156.

[130]35 U.S.C. § 156(c).

[131]35 U.S.C. § 156(d)(2)(B).

[132]Tyson, Karin L., "The Role of the Patent and Trademark Office Under 35 U.S.C. Section 156," 54 *Food and Drug Law Journal* (1999), 205.

[133]21 U.S.C. § 355(j)(4)(D)(I).

[134]21 U.S.C. § 355(j)(4)(D)(iii).

In contrast, if the approved drug is an NCE, then a would-be generic manufacturer cannot submit an ANDA until five years after the date of the approval of the pioneer NDA.[135] The effect of this provision 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 ANDA. One noted expert has recently observed that the review time for an ANDA exceeds 18 months.[136]

Patent Infringement. The 1984 Act includes elaborate provisions governing the mechanisms through which a potential generic manufacturer may obtain market approval on a drug that has been patented by another. Among these provisions are a statutory exemption from claims of patent infringement based on acts reasonably related to seeking FDA approval; special provisions for challenging the enforceability, validity or infringement of approved drug patents; and a reward for challenging patent enforceability, validity or infringement consisting of 180 days of market exclusivity to the first generic applicant to file a patent challenge against any approved drug.

The 1984 Act modified the 1952 Patent Act by creating a statutory exemption from certain claims of patent infringement. As codified in § 271(e)(1), this provision mandates that: "It shall not be an infringement to make, use, offer to sell, or sell within the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use or sale of drugs or veterinary biological products." This provision effectively overturns the opinion of the Court of Appeals for the Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*[137] As a result, generic manufacturers may commence work on a generic version of an approved drug any time during the life of the patent, so long as that work furthers compliance with FDA regulations.

Courts have interpreted § 271(e)(1) liberally, reasoning that the statute exempts from infringement a wide variety of acts. Exemplary is the decision of United States Magistrate Judge Brazil in *Intermedics, Inc. v. Ventritex, Inc.*[138] There, the court reasoned that it would not always be clear to prospective pharmaceutical suppliers exactly which kinds of information, and in what quantities, would be required to obtain FDA approval. The court therefore concluded that parties should be given some latitude in making judgments about the nature and extent of otherwise infringing activities needed to generate information that would satisfy the FDA.

The *Intermedics* court then applied this reasoning to the facts before it, concluding that a number of accused activities fell within the safe harbor of § 271(e)(1). The court held that device sales to foreign distributors were reasonably related to developing information to be submitted to the FDA because all of the

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[135]21 U.S.C. § 355(j)(D)(ii).

[136]Glover, supra note 124, at 634.

[137]See supra notes 112-122 and accompanying text.

[138]775 F. Supp. 1269 (N.D. Cal.), *affirmed*, 991 F.2d 808 (Fed. Cir. 1993).

devices were resold to FDA-approved clinical investigators.[139] Foreign testing activities were also found noninfringing because the data they generated was also sent to the FDA.[140]

The Supreme Court decision in *Eli Lilly & Co. v. Medtronic* is also notable for its expansive interpretation of § 271(e)(1).[141] There, the Court held that the infringement exemption is available not only to drug and veterinary products, but also to medical devices that cannot be marketed without Food and Drug Administration approval.

Although the 1984 Act provides a safe harbor from patent infringement, it also requires would-be manufacturers of generic drugs to engage in a specialized certification procedure. The core feature of this process is that a request for FDA marketing approval is treated as an "artificial" act of patent infringement. This feature was intended to allow judicial resolution of the validity, enforceability and infringement of patent rights before generic competition enters the market.[142]

Under the 1984 Act, each holder of an approved NDA must list pertinent patents it believes would be infringed if a generic drug were marketed before the expiration of these patents. The FDA publishes this list of patents in its list of approved products.[143] This list is commonly known as the "Orange Book."[144]

An ANDA applicant must certify its intent with regard to each patent associated with the generic drug it seeks to market. Four possibilities exist under the 1984 Act:

(1) that patent information on the drug has not been filed;
(2) that the patent has already expired;
(3) the date on which the patent will expire; or
(4) that the patent is invalid or will not be infringed by the manufacture, use or sale of the drug for which the ANDA is submitted.

These certifications are respectively termed paragraph I, II, III, and IV certifications.[145] An ANDA certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific requirements.[146] An ANDA certified under paragraph III must, even after meeting pertinent regulatory and scientific requirements, wait for approval until the drug's listed patent expires.

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[139]Ibid at 1283.

[140]Ibid at 1284.

[141]496 U.S. 661 (1990).

[142]*See* Engelberg, *supra* note 103, at 402.

[143]21 U.S.C. § 355(b)(1), 355(j)(2)(A)(vi).

[144]Food & Drug Administration, Center for Drug Evaluation & Research, Approved Drug Products with Therapeutic Equivalence Evaluations; Dickinson, Elizabeth A., "FDA's Role in Making Exclusivity Determinations," 54 *Food and Drug Law Journal* (1999), 195, 196.

[145]Mossinghoff, supra note 100, at 189.

[146]21 U.S.C. §§ 355(j)(5)(A), (B)(I).

If the ANDA applicant files a paragraph IV certification, it must notify the proprietor of the patent. The patent owner may bring a patent infringement suit within 45 days of receiving such notification.[147] If the patent owner timely brings a patent infringement charge against the ANDA applicant, then the FDA must suspend approval of the ANDA until one of the following events occurs:

> (1) the date of the court's decision that the listed drug's patent is either invalid or not infringed;
> (2) the date the listed drug's patent expires, if the court finds the listed drug's patent infringed;[148] or
> (3) subject to modification by the court, the date that is thirty months from the date the owner of the listed drug's patent received notice of the filing of a Paragraph IV certification.[149]

The 1984 Act provides prospective manufacturers of generic pharmaceuticals with a reward for challenging the patent associated with an approved pharmaceutical. The reward consists of a 180-day generic drug exclusivity period awarded to the first generic applicant to file a paragraph IV certification. This provision is intended to encourage generic applicants to challenge a listed patent for an approved drug product.[150]

The decision of the United States Court of Appeals for the D.C. Circuit in *Mova Pharmaceutical Corp. v. Shalala* considered the 180-day exclusivity provision and its implementation by the FDA.[151] Before *Mova*, the FDA took the position that in order to win the 180-day exclusivity period, the generic applicant had to defend successfully a patent infringement suit brought by the patentee under paragraph IV. In *Mova*, the D.C. Circuit held that the FDA had improperly imposed this requirement of a successful defense. According to Judge Wald, this requirement was "gravely inconsistent with the text and structure of the statute."[152]

The holding in *Mova* may be considered in light of the reality that no provision of the 1984 Act requires the first entity to challenge a patent to pursue that challenge diligently in the courts. The first patent opponent may file a paragraph IV certification, be charged with infringement by the patentee, and then simply decide not to pursue the matter further. Nonetheless, if the patent has not yet expired, the 1984 Act prevents the FDA from approving a subsequently filed ANDA until 180 days after either (a) a court holds the challenged patent invalid, not infringed or

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[147]21 U.S.C. § 355(c)(3)(C).

[148]35 U.S.C. §§ 271(e)(4)(A).

[149]21 U.S.C. §§ 355(j)(5)(B)(iii)(I)(III).

[150]Dickinson, *supra* note 143, at 199.

[151]140 F.3d 1060 (D.C. Cir. 1998).

[152]140 F.3d at 1069.

unenforceable; or (b) the first patent challenger markets the pertinent pharmaceutical.[153]

Suppose, for example, that generic manufacturer "Alpha" is the first to file a paragraph IV certification. The patentee then commences patent infringement litigation against Alpha in the courts. Assume further that Alpha loses, or that Alpha has a change of heart and decides not to further contest the charge of infringement. Another generic manufacturer, "Beta," then files its own paragraph IV certification. Following a patent infringement lawsuit brought by the patentee against Beta, the courts hold that the patent was invalid.

Under these circumstances, the FDA may not approve a subsequently filed ANDA until Beta has obtained a judicial judgment adverse to the patent. Further, the FDA must wait 180 days after the court's judgment before granting market approval to Beta. Because Beta was not the first to challenge the patent, Beta receives no market exclusivity under the 1984 Act.

Subsequent Legislative Developments

Two significant legislative developments occurred subsequent to the enactment of the 1984 Act. First, Congress incorporated animal drugs into the structure of the 1984 Act with the 1988 Generic Animal Drug and Patent Term Restoration Act.[154]

Second, the Uruguay Round Agreement Act (URAA),[155] also amended the 1984 Act. Among the provisions of the URAA were changes to the term for which patents endure. Prior to the URAA, patents expired 17 years after the date they issued. The URAA provided that patent term would be set to 20 years from the date the patent application was filed. The URAA also included a transitional provision: patents in effect on June 8, 1995, or patent applications pending at the USPTO on that date would get the term of 20 years from the filing date or 17 years from the issue date, whichever was longer. Because the USPTO had issued many patents less than three years after an application had been filed, this so-called "Delta Period" amounted to a patent term extension.[156]

The drafters of the URAA recognized that some individuals may have made commercial plans based on the date they believed a competitor's patent would expire. Such plans would be upset if the term of the patent was unexpectedly increased. The URAA therefore included provisions that accounted for the interests of the patentee's competitors. In essence, the URAA denied the patentee the ability to prevent competitors from using the patented invention during the Delta Period. Instead, the patentee may claim an "equitable remuneration" from those who use the patented

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[153]21 U.S.C. § 355(j)(5)(B)(iv)(I), (II).

[154]Pub. L. No. 100-670, 102 Stat. 3971 (1988).

[155]Pub. L. No. 103-465, 108 Stat. 4809 (1994).

[156]*See Bristol-Myers Squibb v. Royce*, 69 F.3d 1130 (Fed. Cir. 1995).

invention during the Delta Period. These provisions in effect call for a compulsory license.[157]

Although they are not formally associated with the 1984 Act, legislation relating to orphan and pediatric drugs is worthy of mention here. Both the Orphan Drug Act[158] and the Food and Drug Administration Modernization Act,[159] as amended by P.L. 107-109, the Best Pharmaceuticals for Children Act, encourage the research, development and marketing of certain drugs. The Orphan Drug Act provides drug researchers and manufacturers with several incentives concerning pharmaceuticals effective against rare diseases or conditions. These include federal funding of grants and contracts for clinical trials of orphan products; a tax credit of fifty percent of clinical testing costs; and the grant of an exclusive right to market the orphan drug for seven years from the date of FDA marketing approval.[160]

The Food and Drug Modernization Act aimed to increase the number of pharmaceuticals available for children.[161] The Act provides a so-called "pediatric exclusivity" to encourage drug manufacturers to conduct research concerning the effectiveness of their drugs in children. Pediatric exclusivity attaches to any children's drug products with the same so-called "active moiety," which is that portion of the drug that causes its physiological or pharmacological reaction.[162] It typically extends the approved manufacturer's existing protection for an additional six months.[163] The product must be one for which studies on a pediatric population are submitted at the request of the Secretary of Health and Human Services. Note that the Food and Drug Administration Modernization Act does not require that a study be successful in demonstrating safety and effectiveness in a pediatric population in order to trigger the added six-month exclusivity period. Thus, the statute is merely intended to create incentives for enterprises to conduct research and submit their results.[164]

Implementation of the 1984 Act

There has been on-going congressional interest in the 1984 Act since it was passed 18 years ago. Current concerns over the price and availability of drugs in the United States has again focused attention on the legislation because of its effort to

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[157]Mossinghoff, *supra* note 100, at 188.

[158]Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified at 21 U.S.C. § 360aa et seq.).

[159]Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified at 28 U.S.C. § 352(a)).

[160]Dickinson, *supra* note 143, at 201-03.

[161]Ibid.

[162]Karst, Kurt R., "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, 750.

[163]Ibid at 203.

[164]Glover, *supra* note 124.

balance innovation in the pharmaceutical industry and costs to the public. In attempting to determine any results of the implementation of the 1984 Act, it is necessary to consider the state of the pharmaceutical industry in order to assess changes in both the generic drug and brand name (or innovator) drug markets. The relationship between these sectors was the basis for prior congressional action; whether and/or how this relationship has changed to meet the objectives of the law underlies any future discussion on the 1984 Act.

Brief Overview of the Pharmaceutical Industry

The U.S. pharmaceutical industry is "highly innovative and technologically advanced . . . [and] has consistently maintained a competitive edge in international markets."[165] According to the U.S. Department of Commerce, the industry is expected to experience continued growth.[166] Much of this is the result of the substantial investment in research and development. Information provided by the National Science Foundation indicates that R&D performance in the United States by the pharmaceutical industry rose from $1.8 billion in 1980 to $6.3 billion in 1990 and $12.2 billion in 1999.[167] According to the Pharmaceutical Research and Manufacturers of American (PhRMA), U.S. R&D expenditures (domestic and foreign firms) have increased substantially during the period under consideration here: from $1.6 billion in 1980 to $6.8 billion in 1990, to $17.2 billion in 1998, to an estimated $30.3 billion in 2001.[168] As a result of this investment, approximately 1,000 new pharmaceuticals are currently in the process of being brought to the marketplace.

Concurrently, federally-funded research is playing a significant role in private sector R&D, including in the pharmaceutical industry. In FY2000, the National Institutes of Health (NIH) supported $15.7 billion in health-related R&D. This figure represents approximately 20% of the total federal R&D budget, second only to the research funding spent for defense. According to the last relevant survey conducted by NIH, in FY1995 the federal government provided 37% of the total national support for health R&D or $13.4 billion, industry supplied 52% or $18.6 billion, and private non-profits (4% or $1.3 billion), as well as state and local government (7% or $2.4 billion), funded the remainder.[169] These figures show a change from ten years earlier when the federal government provided 46% of national health-related R&D, while industry funded 42% of the total amount spent.

During the 1980s and 1990s, the pharmaceutical industry was among the most profitable of industrial sectors based on standard accounting principles for rate of

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[165]U.S. Department of Commerce and McGraw-Hill. U.S. Trade and Industry Outlook 2000 (Washington, D.C., McGraw-Hill, 1999), 11-16.

[166]Ibid., 11-14.

[167]National Science Foundation. *Science and Engineering Indicators 2002*, [available at http://www.nsf.gov].

[168]Pharmaceutical Research and Manufacturers of America. *Pharmaceutical Industry Profile 2002,* [available at http://www.phrma.org].

[169]National Institutes of Health web site, [available at: http://grants.nih.gov/grants/award].

return. However, these rates are somewhat lower if additional (and significant) investments in research and advertising are accounted for.[170] While profitable, this industry also has become increasingly research intensive, reinvesting sizeable portions of profits back into R&D.[171] The ratio of R&D investment to sales in the pharmaceutical industry has increased from 11.9% in 1980 to 20.3% in 2000. This compares to an average 4% R&D-to-sales ratio for all U.S. industries. In 2001, the ratio declined to 17.7%[172]

Effects on Generic Drugs

Many experts agree that the Drug Price Competition and Patent Term Restoration Act has had a significant effect on the availability of generic substitutes for brand name drugs. "As a result of the 1984 Act, generic firms now enter the market much more rapidly after patent expiration and enter in abundant numbers."[173] Prior to the law, 35% of top-selling drugs had generic competitors after patent expiration; now almost all do.[174] In addition, the time to market for these generic products has decreased substantially. According to the Congressional Budget Office (CBO), the average time between the expiration of a brand name patent and the availability of a generic was 3 years before passage of the 1984 Act. Currently, the generic may be introduced immediately after the original patent expiration if it has received the approval of the FDA as companies are permitted to undertake clinical testing during the time period a patent is in force. In cases where the generic manufacturer is the patent holder, a substitute drug may be brought to market before the patent expires.

The number of prescriptions filled by generics has increased. In 1980, 69% of the prescriptions that were filled in the United States were for drugs that had multiple sources; yet, even in those cases where several drugs were available, generics were substituted in only 25% of the applicable situations.[175] Research conducted by Sherer indicated that the rate generics were dispensed in retail pharmacies rose from 17%

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[170]Iain Cockburn, Rebecca Henderson, Luigi Orsenigo, and Gary P. Pisano. "Pharmaceuticals and Biotechnology," in ed. David C. Mowery, *U.S. Industry in 2000* (National Academy Press, Washington, D.C. 1999), 363.

[171]Michael P. Ryan. *Knowledge Diplomacy, Global Competition and the Politics of Intellectual Property* (Washington, D.C., Brookings Institution Press, 1998), 30.

[172]*Pharmaceutical Industry Profile 2002.*

[173]Henry G. Grabowski and John M. Vernon. "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act," *Journal of Law and Economics*, October 1992, 334.

[174]Congressional Budget Office. *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry* (Washington, D.C., July 1998) [available at http://www.cbo.gov]

[175]F.M. Scherer. *Industry Structure, Strategy, and Public Policy* (New York, HarperCollins, 1996), 373.

in 1980 to 30% in 1989.[176] Similarly, CBO found that in 1980 13% of the prescriptions for multi-source drugs were filled by generic prescriptions; by 1998 they comprised 58% of the total. According to PhRMA, the generic share of the prescription drug market (measured in countable units such as tablets) rose from 18.6% in 1984 when the legislation was passed to 47% in 2000.[177] Almost identical figures are provided by the Generic Pharmaceutical Association (GPhA), the difference being a slightly lower 44% market share for generics in 2000.[178]

Reflecting the lower cost of generic drugs, these drugs represent a much smaller percent of total pharmaceutical sales dollars; 8.4% as compared with brand name drugs at 91.6% of the total spent. GphA estimates that U.S. retail sales of generics totaled $11.1 billion in 2001. [179] Prices for generic drugs tend to fall over time.[180] It should be noted, however, that the market share of generic drugs is not just dependent on prices; other factors such as perception of quality, as well as first to market, also make a difference.[181]

Effects on Brand Name Drugs

While the 1984 Act has led to a discernable increase in the availability of generic drugs, the effects on brand name pharmaceuticals appears more complex. The data suggests that R&D funding, as well as R&D intensity, are increasing. While there are no direct measures of innovation, these figures, along with the number of new drugs approved and those in development, do provide indicators of continuing innovation in the industry. However, it is not clear whether the innovation occurring is facilitated by the 1984 Act or is independent of its provisions. Some experts argue that the expiration of patents and the desire to generate new replacement drugs, not the extension of patent ownership, is the stimulus to innovation.[182]

The portions of the legislation that have accelerated the introduction of generic products have affected the brand name firms in various ways that may or may not influence innovation in the industry. The Congressional Budget Office found that originator drugs lose more than 40% of their market, on average, to generic versions after a patent expires. This is combined with research that indicates the rate of market share decline is increasing. Studies by Grabowski and his colleagues indicate that while these brand name drugs lost more than 31% of their market share (per unit) in the year between 1989 and 1990, during the first six months of 1993, 50% of

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[176]Ibid., 376.

[177]Information posted on [http://www.phrma.org]

[178]Information available at [http://www.gphaonline.org]

[179]Ibid.

[180]*Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Act*, 347.

[181]Ibid., 347.

[182]Alfred B. Engelberg. "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?," *IDEA: The Journal of Law and Technology*, 1999.

market share was lost. The larger "blockbuster" drugs lost up to 90% of sale revenue within one year of the expiration of the patent.[183]

Despite competition from generics that have appreciably lower prices, the prices for brand name drugs often increase after patent expiration. Grabowski and Vernon found that innovator drug prices continued to increase at the same rate as before the introduction of generics even as market shares declined. At the same time, generic prices for the comparable drugs fell.[184] Brand name firms have reacted to the opportunities for establishing a generic market provided in the 1984 Act by "maintaining and even raising the price of the brand-name product on the theory that the demand for it was more inelastic than the demand for the price-sensitive segment; they have embarked on a new aggressive strategy designed to serve the brand-loyal segment and capture a substantial share of the generic market."[185]

Such price increases are based on the recognition that when generic substitutes are available, the market bifurcates. Price-insensitive consumers will pay more for a brand name while consumers that respond to price will buy the generic.[186] One expert, F.M. Scherer notes that ". . .price competition worked much more powerfully *among* relatively undifferentiated generic products than *between* differentiated branded products and undifferentiated generics."[187] To protect their market share, brand name companies focus on developing brand loyalty. They also may encourage doctors to move to improved versions of the drug still covered by patents.[188] An indication of what might be considered the success of this approach is contained in the observation that innovator drugs ". . .keep about half their market in units despite the fact that generics are roughly one-third the price of pioneers [innovator drugs] (measured two years after entry)."[189]

The 1984 Act created mechanisms to address concerns that regulatory requirements for FDA approval of a drug prior to marketing often meant that the owner of a patent associated with a drug did not enjoy the full benefit conferred by that patent. Provisions were included to extend the patent as compensation for some

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[183]Henry G. Grabowski. *The Effect of the 1984 Hatch-Waxman Act on Generic Competition and Drug Innovation*. Testimony before the Senate Committee on the Judiciary, March 5, 1996.

[184]*Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 347.

[185]Morton I. Kamien and Israel Zang. "Virtual Patent Extension by Cannibalization," *Southern Economic Journal*, July 1999.

[186]*Industry Structure, Strategy, and Public Policy*, 377.

[187]Ibid., 379 summarizing the work reported in Richard E. Caves, Michael D. Whinston, Mark A. Hurwitz. "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," *Brookings Papers*, 1991.

[188]*Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 341.

[189]Ibid., 340.

of the regulatory activities.[190] As a result, many experts have concluded that the average effective patent life today is slightly longer than before passage of the 1984 Act. According to CBO, prior to the implementation of this legislation, the average effective patent life of a pharmaceutical was approximately 9 years. Today it is approximately 11.5 years. Research performed by Grabowski and Vernon and reported in 1996 indicates that for the period of time between 1991 and 1993, the 1984 Act ". . .has led to modest increases in patent terms."[191] During these years the average patent life for new drug introductions was 11.7 years, including an average extension of 2.3 years. The maximum 5 year extension was provided to 9% of the new drug introductions and 34% obtained an extension of over 3 years. Other industries average 18 years of effective patent life.[192]

A study by the University of Minnesota's Institute of Pharmaceutical Research in Management and Economics (and funded in part by generic drug manufacturers) looked at the range of patent protection of several major drugs.[193] The researchers at the University found the following:

Drug	Company	Current Patent Protection
Claritin	Schering Plough	9.2 years
Relafen	SmithKline Beecham	11 years
Cardiogen-82	Bristol-Meyers Squibb	12.7 years
Eulexin	Schering Plough	12.3 years
Nimotop	Bayer	13.8 years
Dermatop	Hoechst Marion Roussel	6.8 years
Penetre	Rhone-Poulenc Rorer	9.9 years

In addition to, and separate from, the rights conveyed by a patent, the FDA can provide market exclusivity for an approved drug. Two years of exclusivity are extended to drugs in clinical testing when the 1984 Act was passed. The FDA also will not consider applications for a generic version of a new chemical entity for 5 years after approval of the original. This applies even if there is no patent on the drug. According to CBO, however, this may, in actuality, add more than 5 years because abbreviated drug applications often take more than 30 months, on average, for approval. Added together, this may provide over 7 years of market exclusivity. The Food and Drug Administration also is permitted to grant a 3 year exclusivity period if a new drug application (or supplemental application) necessitates additional clinical investigation. These situations include new dosage forms for already approved drugs, a new use for a drug, or for over-the-counter marketing of a drug. This market exclusivity only pertains to the new indication and does not prevent the approval of a new pharmaceutical if all the required clinical studies are performed to

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[190]For a detailed description of these provisions see: *Introduction to the Drug Price Competition and Patent Term Restoration Act of 1984.*

[191]*The Effects of the 1984 Hatch-Waxman Act on Generic Competition and Drug Innovation.*

[192]Marilyn Werber Serafini. "The Price of Miracles," *National Journal*, March 25, 2000.

[193]Shailagh Murray. "Senate Mulls Bill to Extend Drug Patents," *The Wall Street Journal*, August 5, 1999.

support the same changes.[194] The intent is to encourage on-going innovation on existing pharmaceuticals.

Another mechanism established by the 1984 Act extends market exclusivity if the FDA accepts a new claim for an existing pharmaceutical. For example, Bristol-Myers Squibb repositioned Excedrin as Excedrin Migraine with the same active ingredients. Similarly, J&J/McNeil produces Motrin Migraine Pain as well as Motrin.[195] The argument has been made that the brand name drug companies are creating "improved drug entities" based on their original invention. When approved by the FDA, the changes made permit 3 years of exclusivity on the marketing of the pharmaceutical if a new patent is not forthcoming and an additional 20 years if a patent issues. If the original drug is removed from the market, however, a generic for that pharmaceutical cannot be introduced.[196] Allowing this removal to occur, CBO argues, can prevent generics from coming to market.

Assessing the effect of such provisions, the Congressional Budget Office's 1998 study indicated that the 1984 Act provided brand name drugs with an additional 2.8 years of market exclusivity prior to the entry of generics (including drugs that did not obtain an extension under the terms of the 1984 Act). However, Grabowski and Vernon found that the extent of overall market exclusivity for new drugs has actually decreased in contrast to the situation prior to implementation of the 1984 Act.[197] For example, according to PhRMA, while Inderal, introduced in 1965, experienced 10 years of market exclusivity and Tagamet, introduced in 1977, had 6 years of market exclusivity, Diflucan, introduced in 1990, received only 2 years of exclusivity and Invirase, introduced in 1995, had just 3 months on the market before a generic was introduced.[198]

Despite the ability of the FDA to offer market exclusivity, some experts argue that the 1984 Act ". . .has also significantly curtailed the expected revenues to innovative firms from the latter phases of their drug's life cycle."[199] According to CBO, despite this period of exclusivity, most of the average cost of drug development cannot be recouped. CBO found that the increase in generics has led to an average $27 million (or 12%) decrease in the total return to a new drug (not including antibiotics not covered by the 1984 Act). The "average market price" declines even though the cost of the innovator drug increases because generics make

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[194]Elizabeth H. Dickinson. "FDA's Role in Making Exclusivity Determinations," *Food and Drug Law Journal*, 1999, 201.

[195]Christine Bittar. "As Patents Expire, Look for Extensions," *Brandweek*, June 19, 2000, 98.

[196]Feliza Mirasol. "Generic Drug Industry Faces Regulatory and Patent Issues," *Chemical Market Reporter*, April 12, 1999.

[197]*The Effects of the 1984 Hatch-Waxman Act on Generic Competition and Drug Innovation.*

[198]Information available at [http://www.phrma.org]

[199]*Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 347.

up a larger share of the market.[200] This has occurred at the same time that R&D costs and time to market have increased.[201]

In order to compete with other companies, brand name firms may bring out generic versions of their own drugs before the original patent expires. The intent is to be the first to market and to establish market advantage with pharmacies which "...usually buy the first low-cost alternative, then rarely switch to other brands once customers get used to it." This occurs despite some evidence that the brand name firms price their generics at 10 to25% less than the original drug in contrast to other generic products that typically cost half as much.[202] Upjohn, upon introducing a generic version of Xanax one month before the patent expired, soon controlled 90% of the generic market for similar drugs.[203] However, Syntex, which brought out a generic version of its drug Naprosyn two months prior to patent expiration and initially captured three-quarters of the generic market, found it lost almost two-thirds of this market when other generics were introduced.[204]

Research by Kamien and Zang published in 1999 states that brand name company introduction of generic substitutes ". . .appears to benefit both them and the consumers." Profits increase for these firms above and beyond that which could be made solely with the original drug. This action also allows the firm to raise prices on the innovator pharmaceutical. According to Kamien and Zang, consumers are better off because brand name generics provide a lower cost alternative before the original patent expires, even though this benefit only lasts for a month or two. However, once the patent expires, the brand name company obtains a "first-mover" advantage on the marketplace. At this point, the average price of the brand name and generic drug is lower because of competition. Thus, these two authors argue, the producers of generic drugs are worse off in this situation than both the brand name firms and the public.[205]

Possible Issues and Potential Concerns

Given the increasing investment in research and development and the gains in research intensity of the pharmaceutical industry, it appears that the 1984 Act has not deterred the search for and development of new drugs. In assessing the effects of the 1984 Act, the Congressional Budget Office found that "[o]verall, it appears that the incentives for drug companies to innovate have remained intact since. . ." the passage of the legislation. While brand name companies have experienced some loss due to the increased competition following patent expiration, the extension of patent terms that has resulted from the implementation of the 1984 Act has matched the ". . .

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[200]Ibid., 335.

[201]*The Effects of the 1984 Hatch-Waxman Act on Generic Competition and Drug Innovation.*

[202]Catherine Yang. "The Drugmakers vs. the Trustbusters," *Business Week*, September 5, 1994.

[203]*Virtual Patent Extension by Cannibalization.*

[204]*The Drugmakers vs. the Trustbusters.*

[205]*Virtual Patent Extension by Cannibalization.*

average three-year delay between patent expiration and generic entry that existed before the act (in cases where generic entry occurred)." The report concludes:

> Still, those extensions played an important role in protecting the returns from drug companies' research and development. Without them, the rise in generic market share since 1984 would have dramatically lowered the expected returns from marketing a drug and might have caused the pharmaceutical industry to reduce its investment in R&D. In that case, a successful innovator drug would have been likely to lose over 40 percent of its market to generic competitors just after reaching its peak year in sales. If the pre-1984 level of R&D investment was desirable, then the patent extensions benefitted society by preserving most of the returns from marketing a new drug.

On the other hand, some experts argue that the large and growing private and public investment in pharmaceutical research and development makes it ". . . clear that the patent-related provisions of the '84 Act are no longer necessary to achieve the policy of fostering innovation while insuring public access to older drugs at competitive prices."[206] According to this view, such provisions permit and encourage manipulation. Elimination of patent extension and market exclusivity, such critics maintain, would allow the market to operate at "maximum efficiency."[207] The Congressional Budget Office points out that accelerating FDA review process (by one year) would be more helpful to innovator drugs than providing patent extension. Their research indicates that "the patent extensions available under the [1984 Act] were not sufficient to fully preserve the returns from marketing new brand-name drugs." Shortening the process in FDA by one year, however would provide a net benefit of approximately $22 million for one drug.[208]

Congressional interest in the 1984 Act continues.[209] In further exploring the topic, the Congress is likely to consider various issues surrounding implementation of the legislation. Highlighted below are possible areas for discussion. Among the concerns is whether or not the environment in which the original law was enacted still exists and if adjustments should be made to reflect any changes. Has the implementation of the 1984 Act led to any new, unanticipated benefits or consequences? Of fundamental interest is whether or not the goals and incentives contained in the law remain valid after 18 years.

- In assessing the current environment within which the provisions of the 1984 Act are applied, an important question is whether or not the state of the FDA approval process remains the same as when the original legislation was passed. At the time Congress originally debated the law, the average FDA drug approval time was over 30 months. In 1999, this period had dropped by more than half. The Food and Drug Administration maintains that the mean

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[206] *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*

[207] Ibid.

[208] *How Increased Competition from Generic Drugs has affected Prices and Returns in the Pharmaceutical Industry.*

[209] For additional discussion see the aforementioned CRS products RL31379 and IB10105.

approval time in 1999 was 12.6 months.[210] Concurrently, the number of clinical studies required per new drug application has increased. At issue is whether or not the patent term extension provisions and market exclusivity provisions contained in the 1984 Act accurately reflect the delays associated with the FDA approval process as it operates today.

- In the first session, the 106th Congress enacted the American Inventors Protection Act (P.L. 106-113). This legislation requires that certain deadlines be met by the Patent and Trademark Office in the issuance of a patent. Among these deadlines are 14 months for the first office action, 4 months for a subsequent action, and 4 months between payment of an issuance fee and the grant of a patent. The original patent application must be completed within 3 years of actual filing except if the delays resulted from continuing applications and appeals on behalf of the filing party. If these time constraints are not adhered to, the patent holder may receive a day-for-day extension of the patent term. How might this new law affect the implementation and impact of the 1984 Act?

- Since the passage of the 1984 Act, Congress has created additional market exclusivity provisions for certain drugs. The Orphan Drug Act provides a company the exclusive right to market a drug that has been properly designated (to address diseases that affect less than 2,000 people annually) for 7 years from the date of FDA approval. In addition, the 1997 FDA Modernization Act, as amended by the Best Pharmaceuticals for Children Act, extends market exclusivity for 6 months if companies undertake studies on the use of a drug in children. Do these laws affect the balance between encouraging innovation and encouraging the introduction of generics promoted by the 1984 Act?

- The environment within which pharmaceutical research and development are performed has changed. The costs of R&D have increased; according to DiMasi, R&D costs have shown a 10% compounded annual growth rate.[211] This is reflected in an increase in the R&D intensity of the industry. In 1980, R&D expenditures were 11.9% of sales by research-based pharmaceutical companies; for 2001, it is estimated that R&D will increase to 17.7% of sales (although down from 20.3% in 2000).[212] The use of collaborative partnerships has expanded to help reduce costs. Similarly, there have been an increased number of mergers among pharmaceutical companies. These activities have occurred as the importance of "blockbuster" drugs to a company has increased. Today, the blockbuster drugs a firm develops are its principle source of profits; 10% of drugs account for approximately 80% of global

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[210]Under the provisions of the 1992 Prescription Drug User Fee Act pharmaceutical companies are charged to have certain new drug applications approved by the FDA. It is expected that the FDA will complete the approval process within a specified time frame.

[211]Joseph A. DiMasi. Presentation at a meeting on *Innovation in the Pharmaceutical Industry: New Evidence on Structure, Process, and Outcomes* held by the American Enterprise Institute, October 6, 2000.

[212]http://www.phrma.org

sales.[213] It is the expiration of patents on these blockbuster drugs that typically draw the most attention. Given the current R&D environment within which pharmaceutical companies operate, do the provisions of the 1984 Act provide the necessary incentives for further innovation?

- The biotechnology industry was in its infancy during the period that the 1984 Act was debated and passed. Therefore, some experts argue, the provisions of the law are not relevant to biotechnology products that are an increasing component of the drug industry. The ownership of intellectual property is particularly important to biotechnology companies. The U.S. biotechnology industry is one of the most research-intensive sectors in the world as it committed $9.9 billion to R&D in 1998. However, these firms are typically small and do not yet have profits to finance additional R&D. According to the Biotechnology Industry Organization, most of these companies finance research and development from equity capital not profits. Only 3.5% of biotech firms have sales; therefore most depend on venture capital and IPOs to support on-going R&D.[214] Industry sources maintain that patents are a necessity for raising this equity capital.[215] Biotechnology products involve the growth of a biological component, rather than the development of a chemically synthesized component[216] and some observers believe that the abbreviated bioequivalent determination established under the 1984 Act is not appropriate.[217] Biotech drugs may be similar in their chemical or biological make-up but test differently in clinical trials.[218] Based on these factors, some in the industry maintain there is a need to create regulations similar to those in the original Act for biologics in order to develop a generic sector such that exists in pharmaceuticals.[219]

- The 1984 Act provides rewards for certain activities as discussed above. This leads to concerns over whether or not such a system, while encouraging certain positive efforts, also leads to less beneficial company policies and practices. How do patent term extensions and market exclusivity provisions encourage and/or facilitate activities by firms that might not foster innovation? For example, the law provides the opportunity to extend market exclusivity

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[213]Henry G. Grabowski. Presentation at a meeting on *Innovation in the Pharmaceutical Industry: New Evidence on Structure, Process, and Outcomes* held by the American Enterprise Institute, October 6, 2000.

[214]Biotechnology Industry Organization, "Contributions to New Medicine from Government-Funded Basic Biomedical Research," testimony submitted to the Senate Appropriations Subcommittee on Labor, Health, and Human Services, Education, and Related Agencies, April 1999, [http://www.bio.org].

[215]Adriel Bettleheim, "Drugmakers Under Siege," *CQ Outlook*, September 25, 1999, 10.

[216]*The Price of Miracles.*

[217]David Schmickel. "The Biotechnology Industry Organization's View on Hatch-Waxman Reform, *Food and Drug Law Journal*, 1999, 242.

[218]Ibid., 241-242.

[219]*The Price of Miracles.*

by listing patents in the Orange Book.[220] Some experts argue that this has encouraged firms to list patents for products that are not considered marketable.[221] Others maintain that companies increase the number of patents associated with a particular drug to prevent the introduction of generics. The structure of the patent portfolio for a new drug may reflect the provisions of the 1984 Act; how are the traditional process of research, development, and commercialization affected by considerations of future claims under the law?

- Other concerns have been expressed regarding allegations that brand name firms are paying companies not to bring generics to market. Originally, the FDA required that a generic company that filed an abbreviated new drug application (ANDA) had to be sued for patent infringement and win in court before the agency would offer the 180 days of market exclusivity. FDA guidelines developed in 1998, eliminated the necessity for a "successful defense" by a generic manufacturer against claims of patent infringement prior to receiving the 180 day market exclusivity. The intent of this provision had been to provide an incentive for marketing a generic to recover litigation costs and make full use of the exclusivity provided.[222] However, now the only criteria for market exclusivity is receiving the first to file position. This has led, it is argued, to the filing of ". . . substandard or 'sham' ANDAs as generic companies race to establish themselves as being the first to file."[223] As the regulations now stand, the 180 days is triggered by the commercial marketing of the generic. Some experts maintain that this change allows for activities that conflict with the intent of the law. It has been alleged that certain brand name manufacturers have paid the generic firms granted exclusivity not to begin selling their products so as not to open the market to other generics. The Federal Trade Commission brought suit against Hoechst Marion Roussel and Andrx Pharmaceuticals and a federal judge declared that the firms violated antitrust laws when Hoechst paid Andrx to delay marketing of their generic version of the brand name drug. Another similar case involves Abbott Laboratories and Geneva Pharmaceuticals. The FTC takes a case-by-case approach to the antitrust issue. The companies involved in these situations argue that the agreements are a result of patent disputes, not a means to block market access.[224]

- Addressing the above concerns may provide the context within which to assess the means by which the 1984 Act has attempted to achieve congressional intent. Are patent extensions and market exclusivity provisions the most effective and/or efficient means to encourage innovation or do other mechanisms exist? Are the existing incentives for the development and

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[220]For a discussion of the Orange Book see: *Introduction to the Drug Price Competition and Patent Term Restoration Act of 1984.*

[221]*Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*

[222]"New FDA Guidance Raises Anticompetutuve Concerns, Says National Association of Pharmaceutical Manufacturers," *Business Wire*, June 23, 1998.

[223]*Generic Drug Industry Faces Regulatory and Patent Issues.*

[224]"Driving Up Drug Prices," *New York Times*, July 26, 2000.

marketing of generic drugs the most productive way to offer lower-cost pharmaceuticals to the public? Are they necessary in today's environment? Does the argument that patent expiration, not patent extension, stimulates innovation figure into the discussion? How does the finding by CBO regarding the savings to be achieved by reducing FDA approval time affect an assessment of the results of the implementation of the 1984 Act?

- A more fundamental issue that might be explored is whether or not the goals and incentives in the law remain valid within the present environment? Have the legal reforms served to encourage the introduction of lower-cost generic drugs while simultaneously providing incentives to further pharmaceutical innovation? In light of current events, is the effort to balance these objectives still appropriate and/or necessary?