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Pharmaceutical Patent Term Extensions: A Brief Explanation

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Summary

The pharmaceutical industry appears to place a high value on patents and drug companies frequently obtain patent protection and enforce patent rights. Patents permit the owner to exclude others from making, using, importing, or selling the patented invention. Patents are issued by the U.S. Patent and Trademark Office (USPTO), generally for a term of 20 years from the date of filing. However, certain circumstances permit extensions to the term of the patent, including delays in the initial administrative process at the USPTO. More significantly, the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the "Hatch-Waxman" Act, permits limited extensions to compensate for market time lost during the drug approval process undertaken by the Food and Drug Administration (FDA). Independent of the patent term, the FDA may provide market exclusivity to pharmaceuticals meeting specific conditions under the Hatch-Waxman Act, the Orphan Drug Act, and the Best Pharmaceuticals for Children Act.

Patents are issued by the United States Patent and Trademark Office (USPTO), generally for a term of 20 years from the date of filing. The patent grants its owner the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention. To be afforded patent rights, an invention must be judged to consist of patentable subject matter, possess utility, and be novel and nonobvious. The application must fully disclose and distinctly claim the invention for which protection is sought.

U.S. Patent and Trademark Office-Related Extensions

Patent terms have been extended by several legislative means. The American Inventors Protection Act (P.L. 106-113) requires that certain deadlines be met by the

USPTO in the issuance of a patent. Among these deadlines are 14 months for the first Patent and Trademark 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 process 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 met, the patent holder may receive a day-for-day extension of the patent term.[1] Patentees may also obtain day-for-day term extensions due to delays caused by the declaration of an interference, the imposition of a secrecy order, or the successful pursuit of an appeal to the Board of Patent Appeals and Interferences or federal court.[2] These provisions cover patents in general and are not specific to patents on pharmaceutical products.

"Hatch-Waxman" Act Extensions

The grant of a patent does not provide the owner with an affirmative right to market the invention. Pharmaceutical products are also subject to marketing approval by the Food and Drug Administration (FDA). Federal laws generally require that pharmaceutical manufacturers show their products are safe and effective in order to bring these drugs to the marketplace.[3] USPTO issuance of a patent and FDA marketing consent are distinct events that depend upon different criteria.[4]

Significant delays may accompany the marketing approval process. The Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417), commonly known as the "Hatch-Waxman" Act, permits extensions of pharmaceutical patents to reflect regulatory delays encountered in obtaining FDA permission to market the drug. This term extension is equal to the time between the effective date of the investigational new drug application (NDA) and its submission, plus the entire time lost during FDA approval of the NDA. However, some caps are placed on the length of the term restoration. The entire patent term extension may not exceed 5 years. Further, the remaining term of the restored patent following FDA approval of the NDA may not exceed 14 years. 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.[5]

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[1] See: Congressional Research Service, *Patent Law Reform: An Analysis of the American Inventors Protection Act of 1999 and Its Effect on Small, Entrepreneurial Firms*, by John R. Thomas, RL30451, 29 February, 2000.

[2] 35 U.S.C. sec. 154(b).

[3] 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.

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

[5] For additional information see: Congressional Research Service, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984*, by Wendy H. Schacht and John R. Thomas, RL30756, 18 December 2000.

Market Exclusivity Provisions

In addition to, and separate from, the rights conveyed by a patent, several laws permit the Food and Drug Administration to provide market exclusivity for an approved drug. Under the Hatch-Waxman Act, 2 years of exclusivity are extended to pharmaceuticals in clinical testing when the 1984 Act was passed. Applications for a generic version of a new chemical entity will not be considered by the FDA for 5 years after approval of the original. This applies even if the pharmaceutical is not patented.

The FDA 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 generic drug for other uses not covered by a patent or an existing exclusivity.[6]

Another mechanism established by the Hatch-Waxman Act extends market exclusivity if the FDA accepts a new claim for an existing pharmaceutical. 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.[7]

Market exclusivity provisions are also included in the Orphan Drug Act (P.L. 97-414). A company that develops a drug to treat a disease that affects fewer than 2,000 people annually may receive sole market rights for 7 years from the date of product approval by the FDA. The Food and Drug Administration Modernization Act of 1997 (P.L.105-115), as amended by P.L. 107-109, the Best Pharmaceuticals for Children Act, provides pediatric exclusivities 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 "active moiety" which is that portion of the drug that causes its physiological or pharmacological reaction. It typically extends the approved manufacturer's existing marketing protection for an additional 6 months. 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 and does not require that the study successfully demonstrate safety and effectiveness in the pediatric population.

Extensions for Specific Pharmaceuticals

Additional patent term extensions for specific pharmaceuticals have been enacted by the U.S. Congress in both public and private bills. Since 1980, 7 different products had

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

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

their patents extended in this manner.[8] Six of these are for human use, while the seventh was a pharmacological composition with veterinary applications. Claims of unwarranted regulatory delays provided the motivation for extending the terms of patents associated with each of these products. The pharmaceuticals and the extensions are as follows:

- *Aspartame*, an artificial sweetener regulated as a food additive, was developed by G.D. Searle & Co. Searle petitioned Congress for a term extension based upon FDA approval times that Searle believed to be excessive. Congress responded by extending the aspartame patent by just under 6 years.[9]

- *Forane*, an anesthetic drug, was produced by Ohio Medical Anesthetics, Inc. The FDA marketing approval process consumed over 10 years. According to Ohio Medical Anesthetics, a deficient study claiming that Forane had carcinogenic potential significantly contributed to this delay.[10] The term of the extension was 5 years, 3 months.[11]

- *Impro*, a veterinary product used to increase production in dairy cows, was developed by Impro Products. Impro Products claimed that the United States Department of Agriculture prevented Impro Products from performing the tests needed to obtain marketing approval from 1967 through 1984.[12] Impro received a 15-year term extension.[13]

- *Glyburide*, and its variant *glipizide*, are oral hypoglycemic drugs useful as anti-diabetes therapeutics. They were created by Hoechst AG. Citing FDA marketing approval delays, Congress set the expiration date of 5 patents to the uniform date of April 21, 1992. The resulting term extension ranged from nearly three months to nearly 6 years and 3 months.[14]

- *Lopid* is a cardiovascular drug developed by Warner-Lambert. In 1981, Warner-Lambert and FDA agreed that if Warner-Lambert financed a heart attack prevention study, it would obtain exclusive benefits from any resulting data. During the course of the Warner-Lambert study, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984. Warner-Lambert argued that by creating a streamlined generic

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[8] Private bill permitting patent term extensions through 1979 are discussed in *The History of Private Patent Legislation in the House of Representative*, H. Comm. on the Judiciary, Subcomm. on Courts, Civil Liberties, and the Administration of Justice, 96th Cong., 1st Sess. (1979) (Christine P. Benagh, American Law Division, Congressional Research Service, U.S. Library of Congress).

[9] 96 Stat. 2065 (4 Jan. 1983); P.L. 97-414.

[10] Sen. East, remarks in the Senate, 129 *Congressional Record*, daily ed.,(9 May 1983), S6313.

[11] 97 Stat. 831, 832 (13 Oct. 1983); P.L. 98-127.

[12] S.Rept.98-389, 98th Cong., 2d sess., 1984.

[13] 98 Stat. 3430 (19 Oct. 1984); Private Law 98-34.

[14] 98 Stat. 3434 (19 Oct. 1984); Private Law 98-46.

drug approval process, the 1984 Act destroyed its expected interest in the study data.[15] The term extension totaled 3 years and 6 months.[16]

- *Olestra*, originated by Proctor & Gamble Co, was the subject of a FDA approval process that took 12 years. The term extension for Olestra was rather complex. The legislation allowed two one-year extensions on one of the three Proctor & Gamble patents concerning Olestra. If the FDA granted market approval to Olestra within this extension period, Proctor & Gamble was allowed to request another two years of life for that patent.[17] The FDA did grant market approval in a timely fashion, allowing Proctor & Gamble to benefit from the two-year extension.[18]

- *Daypro*, marketed by G.D. Searle & Co, is an anti-inflammatory agent. Searle claimed that the drug was the subject of an unusually lengthy FDA approval process. The term of the patent was extended for two years.[19]

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[15] S. Rep. No. 100-83, 100th Congress, 1st Ses. 73 (1987).

[16] 102 Stat. 1107, 1569 (23 Aug. 1988); P.L. 100-418.

[17] 107 Stat. 2040 (3 Dec. 1993); P.L. 103-179.

[18] Post, Patrick Larkin, "P&G's olestra finally wins FDA approval," *The Cincinnati Post* 1A (25 Jan. 1996).

[19] 110 Stat. 1321 (26 Apr. 1996); P.L. 104-134.