Overview of the Hatch-Waxman Amendments

Legislative Background

A new brand-name drug generally enters the market with many years of patent protection. During that time, the manufacturer enjoys monopoly status—there is no generic available that can be substituted for the brand-name drug.[1] This monopoly status keeps competition at bay and the brand-name drug price high. When a generic version of the drug becomes available, price competition begins, and consumers finally have access to a lower-priced alternative: The average price per prescription for brand-name drugs is approximately three times the prescription price for generic drugs.[2]

Recognizing that generic competition in the drug industry is good for consumers, Congress passed the Drug Price Competition and Patent Term Restoration Act[3] in 1984 to decrease the "time and expense of bringing generic drugs to market."[4] This statute, commonly known as the Hatch-Waxman Amendments, creates incentives for manufacturers to seek early approval for generic drugs from the Food and Drug Administration (FDA). To balance the incentives for generic manufacturers, Hatch-Waxman also includes provisions designed to protect drug patent holders. While the Hatch-Waxman, Amendments opened the market for generics, the drug industry has manipulated the incentives and protections in the statute to delay generic competition and extend the brand-name monopolies that patent protection confers—activities that not only are inconsistent with Hatch-Waxman's objectives but also have cost consumers and other health care payers hundreds of millions of dollars.

Drug industry strategies that take advantage of loopholes in the Hatch-Waxman Amendments are the basis of many of the lawsuits profiled in Families USA's *Collusion and Anticompetitive Practices: A Survey of Class Action Lawsuits against Drug Manufacturers*. To fully understand the way that the drug industry has used loopholes in the law to stymie competition, it is essential to have some background on the FDA's drug approval process for brand-name and generic drugs, as well as on key provisions of the Hatch-Waxman Amendments.

The Drug Approval Process

Brand-Name Drugs: Obtaining Patents and FDA Approval

Patents and Brand-Name Drugs' Monopoly Status. Early in the drug development process, the drug developer applies to the U.S. Patent and Trademark Office to obtain one or more patents on the drug. These patents typically cover things such as the chemical compounds responsible for the drug's therapeutic action. The full financial value of a drug's patents is not realized until after the drug is approved by the FDA and can be sold to the public. Obtaining patents is a completely separate process from obtaining FDA approval.

The patent time left when a drug comes to market—after drug development and FDA approval—is referred to as the "effective patent life." In the past 20 years, the effective patent life for many brand-name drugs has increased by at least 50 percent due to legislative changes and faster FDA approval.[5] For a drug approved by the FDA in the early to mid-1980s, the effective patent life was typically 8.1 years. By the late 1990s, for many brand-name drugs, a manufacturer could expect to have a post-FDA-approval, patent-protected monopoly for 13.9 to 15.4 years.[6]

FDA Approval. Before a new drug is approved for marketing in the U.S., the FDA requires that the manufacturer conduct a series of clinical trials. For final approval, the manufacturer must submit a New Drug Application (NDA) to the FDA showing that the drug is safe and effective. The NDA also lists the patents that the manufacturer wants to claim on the drug.

Once the FDA approves a new drug, it publishes information on the drug and lists the patents the brand manufacturer has submitted to the FDA in *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the *Orange Book*). The *Orange Book* functions as the industry guide to drug patents; in it, the FDA lists all of the patents that a manufacturer submits. A drug's *Orange Book* listing can evolve—the manufacturer can obtain additional patents, which will add additional time to the brand-name drug's patent-protected monopoly, and submit those patents to the FDA for inclusion in the *Orange Book* at any time.

Generic Drugs

Prior to Hatch-Waxman, generic manufacturers needed to complete a full NDA for the FDA to approve the generic version of a brand-name drug. This was a time-consuming and costly process for bringing to market a version of a product that had already been approved.

Hatch-Waxman streamlined the generic approval process to encourage faster marketing of generics. Under the statute, in lieu of a complete NDA, generic manufacturers can file an "Abbreviated New Drug Application" (ANDA) with the FDA. In the ANDA, generic manufacturers can rely on the brand-name manufacturer's clinical data to show safety and efficacy. However, the generic manufacturer must show that its generic is bioequivalent to the brand-name drug, i.e., that it contains a chemically identical active ingredient that is delivered in the body at the same rate and to the same extent.[7] To encourage generic manufacturers to begin testing and have generics ready for market as soon as a brand-name drug's patent expires, brand-name manufacturers cannot sue generic manufacturers for patent infringement for doing the testing necessary to prepare an ANDA.

Hatch Waxman Incentives and Protections: The Loopholes that the Industry Has Exploited

In addition to shortening the generic application process, Hatch-Waxman incorporates other incentives for manufacturers to seek early approval for generics. These incentives are balanced by protections for brand-name manufacturers. It is by manipulating these inter-related incentives and protections that brand-name manufacturers have used the statute to delay timely competition from generics and to protect brand-name drug monopolies.

ANDA Certifications

When a generic manufacturer files an ANDA, it must make one of four possible certifications for each patent listed in the *Orange Book* for the brand-name version of the drug. Those four certification options are as follows:

- *Paragraph I Certification*: There is no patent data on the drug in the *Orange Book*;
- *Paragraph II Certification*: The relevant patent has expired;
- *Paragraph III Certification*: The manufacturer only wants approval to market the generic after the brand-name patent expires; or
- *Paragraph IV Certification*: There is a patent on the brand-name drug, but it is invalid or will not be infringed by the generic.

The anticompetitive practices flowing from loopholes in Hatch-Waxman relate to Paragraph IV Certifications. With a Paragraph IV Certification, the

generic manufacturer is asserting that the FDA approval process should not be delayed by patent concerns because the listed patent is either invalid or not infringed by the ANDA. To allow brand-name manufacturers to defend against those assertions, the statute requires that a generic manufacturer filing a Paragraph IV Certification notify the brand-name manufacturer and explain the legal basis for the claim that existing patents are invalid or will not be infringed.

The generic manufacturer's act of filing a Paragraph IV Certification gives the brand-name manufacturer an immediate right to file a patent infringement lawsuit, even though there is not any real market competition against the brand. If the brand-name manufacturer files a patent infringement lawsuit within 45 days of receipt of notice of the ANDA filing, this sets in motion a process that stalls approval of the generic. If, at the end of 45 days, the brand-name manufacturer has not sued, the FDA moves forward with the generic approval process, which usually takes about 18 months.[8] Because a Paragraph IV Certification places the generic manufacturer at risk for a patent infringement lawsuit, a generic manufacturer will make this type of certification only if it believes that the brand-name drug manufacturer has filed bogus patents or its generic does not infringe on the brand.

Filing a Lawsuit and the 30 Month Stay

If the brand-name manufacturer sues for infringement within 45 days of notice of the ANDA filing, the FDA is blocked from granting final marketing approval of the generic for up to 30 months—two and a half years. The 30-month delay is shortened only if there is an earlier court judgment or the patent(s) on the drug expire. Merely bringing the patent suit, regardless of the merits of that suit, guarantees a delay in generic competition.

At the end of 30 months, the FDA is free to grant final marketing approval of the generic "subject to the outcome of the pending litigation."[9] This means that the generic manufacturer can go to market even if the lawsuit is still in process. But, if the generic manufacturer later loses the lawsuit, it will have to pay damages to the patent holder.[10] A generic manufacturer is free to withhold its product from the market while patent litigation is pending, and it might choose to do so if the risk of losing the suit is high and the potential cost of damages is higher than revenue that could be obtained from generic sales. If the generic manufacturer elects to stay off the market until litigation is concluded, this can mean even more time that the brand-name drug is without competition. The median time between filing and disposition of a patent suit has been calculated at 36 months, with 10 percent of cases taking over 77 months (more than six years).[11]

Paragraph IV Certification and Generic Exclusivity

To offset the potential cost of litigation associated with filing a Paragraph IV Certification, the first generic manufacturer to file a Paragraph IV Certification receives 180 days—six months—of exclusive marketing rights for the drug's generic version (the Exclusivity Period). During those six months, the FDA cannot approve another generic for marketing, and the brand-name drug is the only competition the generic manufacturer will face.

The 180-day "clock" begins the earlier of (1) the day that the generic is commercially marketed or (2) the day of a court decision finding that the brand-name patent is either invalid or not infringed by the generic.[12] Final marketing approval of an ANDA has no effect on the 180 days of exclusivity unless one of those two events takes place. If there is no court decision and the generic manufacturer does not begin marketing the drug, there can be "prolonged and indefinite delays in the beginning of the" 180-day exclusivity period, placing an ANDA applicant eligible for exclusivity in a position to delay all generic competition for an extended period of time. [13]

The structure of the 180-day exclusivity provision creates an incentive for brand-name manufacturers to try to keep the 180-day clock from starting. Creative brand-name manufacturers have entered into deals with generic manufacturers in which the generic manufacturer withholds its product from the market and shares in the profits from the extended brand-name monopoly.

Incentives and Protections: Creating Patterns of Anticompetitive Practice

The monopoly that patent protection gives brand-name drugs is extremely lucrative. Therefore, it is in the interest of the patent holder to extend that monopoly as long as possible. Despite the intent of the Hatch-Waxman Amendments, crafty brand-name manufacturers have used the 30-month stay and the 180-day generic exclusivity period to extend their monopolies through their own conduct or through partnerships with generic manufacturers.

"Evergreening." This is also referred to as "warehousing" patents. When "evergreening," the brand-name manufacturer separately patents multiple attributes of the product—everything from aspects of the manufacturing process to tablet color or even a chemical produced by the body when the drug is ingested. The brand-name manufacturer keeps adding patents to the *Orange Book*, essentially forcing the generic manufacturer to choose between waiting for the patents (even if bogus) to expire and filing a Paragraph IV Certification, which risks litigation and the associated costs and delays.

Frivolous Lawsuits. Because a lawsuit based on a Paragraph IV Certification immediately halts final market approval of the generic, when a Paragraph IV Certification is filed with the FDA, it is in the brand-name manufacturer's interest to sue, whether the lawsuit has merits or not. This provision, which essentially gives a brand-name manufacturer at least an additional two and a half years of product monopoly, has resulted in a spate of frivolous lawsuits. For example, in one case, the brand-name manufacturer claimed a patent on "a method of use of a metabolite produced by the administration" of the drug.[14] The patent was for the combination of the chemical compound in the drug and stomach acid, which was naturally produced when the drug was ingested. This patent was listed on the day the existing patents on the drug were due to expire. As a result, the FDA could not approve the marketing of a generic that the manufacturer had already loaded on trucks for shipment.[15]

"Sweetheart Deals." The generic manufacturer does not have to go to market when it obtains final FDA approval; it has control over when to introduce its product. Therefore, unless the generic manufacturer prevails in a court decision on the patent case, which would trigger the 180-day exclusivity, it can determine when it will exercise its 180 days of exclusivity. Until then, the FDA cannot approve another generic. With a "sweetheart deal," the brand-name manufacturer and the first generic manufacturer agree that the first generic will *not* go to market, suspending the 180-day "clock" and keeping all other potential generic competitors in limbo. The brand and generic manufacturer share in the financial rewards associated with the extended brand-name monopoly. In one case, the brand-name manufacturer paid the generic manufacturer $10 million per quarter not to market its FDA-approved product, precluding the FDA from granting final market approval for ANDAs submitted by other generic manufacturers.[16]

Ways to Counter Industry Anti-Competitive Practices

The practices discussed have proven to be extremely profitable to brand-name drug manufacturers and, in some cases, to manufacturers of generics as well. Yet they have cost consumers and other health care purchasers hundreds of millions of dollars by delaying competition and keeping drug prices artificially high. There are, however, things that can be done to rectify this situation.

Continued litigation by the Federal Trade Commission, states, consumers, and other payers that are hurt by high prices can force the drug industry to "play fair" by punishing manufacturers that restrain trade or engage in other anticompetitive practices.

There are also legislative solutions. The proposed Greater Access to Affordable Pharmaceuticals Act—introduced by Sens. Charles Schumer (D-NY) and John McCain (R-AZ), and its companion bill introduced in the House by Reps. Sherrod Brown (D-OH) and Jo Ann Emerson (R-MO)—would close the loopholes in current law. It is likely that other bills will also be introduced, such as The Consumer Access to Prescription Drugs Improvement Act, which is being developed by John D. Rockefeller (D-WV). That bill is designed not only to close the loopholes in Hatch-Waxman, but also to increase consumer access to drugs by educating lawmakers, physicians, and the public about drug industry practices and the appropriate use of generics.

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[1] The generic version of a drug is bioequivalent to the brand-name drug, meaning that it contains a chemically identical active ingredient delivered in the body at the same rate and to the same extent.

[2] Michie I. Hunt, *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation* (Washington: National Institute for Health Care Management, August 2000).

[3] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585 (1984), 21 U.S.C. 355 (1994). The Act amends the Food, Drug and Cosmetic Act. It is also known as the Hatch-Waxman Amendments, after the primary sponsors, Sen. Orrin Hatch (R-UT) and Rep. Henry Waxman (D-CA).

[4] Abbreviated New Drug Application Regulations, 54 Federal Register 28,872, 28874 (July 10, 1989).

[5] The Hatch-Waxman Amendments include provisions that not only expedite generic drug approval, but also extended patent time and market exclusivity for brand-name prescription drugs. *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation*, op. cit.

[6] *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation*, op. cit.

[7] Regulations related to bioequivalence are at 21 CFR Part 320. A flow chart summarizing the ANDA review process, including a discussion of the process for determining bioequivalence, can be found on the FDA Web site at (http://www.fda.gov/cder/handbook/anda.htm).

[8] In 2000, the FDA's median approval time for ANDAs was 18.2 months. (Center for Drug Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services CDER Report to the Nation: 2000 [http://www.fda.gov/cder/reports/RTN2000/RTN2000.HTM].)

[9] Abbreviated New Drug Application Regulations, 54 Federal Register at 28,894.

[10] Damages for a patent infringement case would be "treble" or triple damages.

[11] This timeframe was noted in the legislative history at the time the Hatch-Waxman Amendments were passed in 1984 and may very well have become longer in the intervening years. (Zeneca Ltd. V. Pharmachemie B.V., 16 F. Supp. 2d 112, 115-16 [D. Mass, 1998].)

[12] Until March 2000, the FDA interpreted the "court decision" that triggers the start of the 180-day clock for generic exclusivity to be the decision of a court from which no appeal "can be or has been taken," usually meaning a court of appeals. As a result of litigation surrounding the meaning of the term "court decision," FDA changed its interpretation. The court decision that can trigger the start of the 180 days of generic exclusivity is now a district court decision. [Department of Health and Human Services, Food and Drug Administration, Guidance for Industry on Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act; Availability, Docket No. 00D-1197, filed March 30, 2000; Statement by Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health and Human Services, for the Hearing on "Recent Developments Which May Impact Consumer Access To, And Demand For, Pharmaceuticals," before the Subcommittee on Health, House Committee on Energy and Commerce, June 13, 2001.]

[13] Statement by Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health and Human Services, for the Hearing on "Recent Developments Which May Impact Consumer Access To, And Demand For, Pharmaceuticals," before the Subcommittee on Health, House Committee on Energy and Commerce, June 13, 2001.

[14] See In re Buspirone Patent Litigation, ____ F. Supp. 2d_____, 2002 WL 243189, *1 (S.D.N.Y. Feb. 14, 2002).

[15] See In re Buspirone Patent Litigation, ____ F. Supp. 2d_____, 2002 WL 243189, *1 (S.D.N.Y. Feb. 14, 2002).

[16] In re Cardizem CD Antitrust Litigation, 105 F. Supp. 2d 618 (E.D. Mich. 2000)

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