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Pharmaceutical Product Switching: Antitrust Pitfalls


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Law360, New York (January 11, 2013, 12:24 PM EST) -- The terms "product switching," "product hopping" and "line extension" are often used to describe the strategy of protecting market share by reformulating or otherwise modifying an existing branded pharmaceutical product in a manner which requires approval from the U.S. Food and Drug Administration. Under this approach a pharmaceutical company introduces a product line extension to a branded drug product before generic entry, and promotes the extension product instead of the old product. In some instances, the company also removes the old product from the market, and/or changes the product's National Drug Data File (NDDF) code to "obsolete."

State drug product selection (DPS) laws often permit a physician to substitute a so-called "AB-rated" generic for a branded drug, resulting in a reduced market share for the branded product. However, a company can reduce or delay the impact of generic entry to a branded product by product switching, since any approved generic will likely be AB-rated only as to the old product, and therefore can not be substituted for the new line extension product.[1] If the market shifts in favor of the new line extension product by the time generics enter the market with a generic of the old branded product, the impact on the company's sales will thus be reduced. However, antitrust issues can arise for certain product switching scenarios, as further discussed below.

Product Switching Antitrust Cases

Abbott Labs. v. Teva Pharm. USA Inc., 432 F. Supp. 2d 408 (D. Del. 2006).

In 1998, Abbott received FDA approval for a capsule form of TriCor (fenofibrate), a cholesterol-lowering drug. In 1999, two generic companies (Teva Pharmaceuticals and Impax Laboratories) filed abbreviated new drug applications with Paragraph IV certifications challenging TriCor, and Abbott filed suit for patent infringement, triggering a 30-month stay of the ANDAs' approval.[2] While the patent lawsuit was pending, Abbott submitted a new NDA for a new tablet formulation of TriCor, and a new indication that the drug increases "good cholesterol" levels. The NDA was approved in 2001, while the 30-month stay in the capsule patent suit was still pending.

After the NDA was approved, Abbott stopped selling the capsule form of TriCor, bought back supplies of the capsules from pharmacies, and changed the code of the TriCor capsule in the NDDF to "obsolete."[3],[4] When generic companies filed a second wave of ANDAs for the tablet formulation, Abbott filed another patent infringement suit triggering another 30-month stay.[5] Abbott also submitted another NDA for a new TriCor tablet dosage formulation and label change (that the drug did not need to be taken with food). Abbott stopped selling the old tablets, and changed the NDDF code for the old tablet to

"obsolete."[6]

Plaintiffs filed antitrust claims alleging a violation of Section 2 of the Sherman Act, and Abbott moved to dismiss.[7] The district court applied a "rule of reason" analysis to the case, whereby once a plaintiff has demonstrated an anti-competitive effect, the burden shifts to the defendant to present a pro-competitive justification. According to the Court, "judicial deference to product innovation ... does not mean that a monopolist's product design decisions are per se lawful."[8]

The court denied Abbott's motion to dismiss, opining that the company prevented a choice between products "by removing the old formulations from the market while introducing new formulations."[9] The court also held that total foreclosure of the market is not required for an antitrust violation, and since the generic manufacturers could not provide generic substitutes, they were allegedly barred from the most cost-efficient means of competing in the market.[10] The case settled shortly before trial.

Walgreen Co. v. AstraZeneca Pharms., 534 F. Supp. 2d 146 (D.D.C. 2008)

AstraZeneca received FDA approval for Prilosec in 1989. Prior to expiration of a patent covering Prilosec, and before generic entry, the FDA approved Nexium, a line extension of Prilosec. AstraZeneca promoted Nexium to doctors, and stopped promoting Prilosec.[11]

Plaintiffs filed suit alleging that in switching the market from Prilosec to Nexium before generic entry, AstraZeneca engaged in exclusionary conduct in violation of Section 2 of the Sherman Act.[12] The court granted AstraZeneca's motion to dismiss holding that its actions did not reduce consumer choice. Rather, by introducing Nexium into the market, AstraZeneca added an additional choice for consumers.[13] "The fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action."[14]

Prilosec remained on the market, and the generic companies were free to compete with it.[15] The court also noted that a company may enjoy the benefits of patent protection, and that short of false representations or fraud, product switching through sales persuasion did not violate antitrust laws.[16]

Product Switching: Patent Settlements

Patent settlement agreements between brand manufacturers and generic companies to delay entry of generic products into the market often involve a payment from the brand manufacturer to the generic in exchange for delayed entry into the market.

FTC v. Warner Chilcott Holdings Company III Ltd., et al. (D.D.C. 2007)

Ovcon, an oral contraceptive, was originally approved by the FDA in 1976, and was not subject to patent protection. Warner planned to introduce a follow-on chewable version of Ovcon before generic entry on the original product into the market. However, the follow-on product had not gained FDA approval as the entry of generic Ovcon into the market was imminent. Warner entered into an agreement with Barr Pharmaceuticals Inc. to delay entry of Barr's generic Ovcon for five years in exchange for $20 million. The FTC claimed that since Warner's switch strategy could not be implemented in time to delay generic entry, it entered into a horizontal agreement and paid Barr to stay out of the market, which constituted an antitrust violation.[17]

The FTC settled the case with both Warner and Barr. According to the terms of the settlement, Warner was prohibited from entering into any reverse settlement agreements for 10 years, and further, had to take affirmative steps to preserve the market for the first-generation form of its product for which generic competition was imminent. Such

steps prohibited Warner from deleting the NDDF codes for Ovcon, and destroying or buying back existing Ovcon supplies from pharmacies.[18] Barr was also enjoined from entering any reverse settlements for 10 years.[19]
FTC v. Watson Pharm. Inc. et al., 677 F.3d 1298 (11th Cir. 2012).

Watson involved a reverse payment settlement between NDA holder Solvay Pharmaceuticals and ANDA filers Watson Pharmaceuticals and Paddock Pharmaceuticals over AndroGel, a prescription testosterone formulation prescribed for treating hypogonadism. Watson and Paddock filed separate ANDAs having Paragraph IV certifications that the AndroGel patent was invalid or unenforceable, and Solvay filed suit pursuant to 35 U.S.C. § 271(e)(2) in the U.S. District Court for the Northern District of Georgia. Before the Court could rule on the defendants' summary judgment motions, the parties settled. The generic manufacturers agreed to abandon their patent challenges, and refrain from entering the market until 2015, in exchange for a share of Solvay's AndroGel profits.[20]

The FTC filed suit against Solvay, Watson and Paddock alleging that the settlement agreement was an antitrust violation. The FTC alleged that Solvay's plan to introduce an AndroGel product line extension (a different dosage of AndroGel that would allow patients to achieve similar therapeutic benefits with less gel) prior to 2015 was anti-competitive. According to the FTC, Watson accepted a generic entry date of 2015, even though Solvay would have made the switch to the follow-on product by that date, and Watson's product would not be interchangeable with the follow-on product. The FTC alleged that Watson would not have accepted a 2015 entry date in view of Solvay's product switching strategy, without a substantial sharing of AndroGel profits.[21]

The FTC's complaint was dismissed by the district court, and the dismissal was affirmed by the Eleventh Circuit.[22] The settlement agreement was upheld as lawful under the so-called "scope of the patent" test: "[A]bsent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."[23] Under the scope of the patent test, a reverse payment is permitted so long as (1) the exclusion does not exceed the patent's scope, (2) the patent holder's claim of infringement was not objectively baseless, and (3) the patent was not procured by fraud on the U.S. Patent and Trademark Office.[24]

The FTC has petitioned for a writ of certiorari asking the question "[w]hether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held), or instead are presumptively anti-competitive and unlawful (as the Third Circuit has held)?"[25]

King Drug Co. of Florence Inc. v. Cephalon Inc., 702 F.Supp.2d 514 (E.D. Pa. 2010)

The FTC challenged patent settlement agreements between Cephalon and four generic manufacturers regarding generic entry of Cephalon's wakefulness promoting drug Provigil. The agreements delayed generic entry until 2012 in exchange for payments from Cephalon. The FTC alleged that the settlement agreements were anti-competitive because Cephalon planned to introduce its follow-on product Nuvigil (an isomer of Provigil) before 2012, and switch the market from Provigil to Nuvigil.[26]

The court denied Cephalon's motion to dismiss, holding that the FTC's complaint was valid because the scope of the patent test could be used to determine whether Cephalon's Provigil patent was procured by fraud, as alleged by plaintiffs, and if more rights were afforded by the agreements than granted by patent.[27] The precedential weight of the court's holding is questionable in view of the Third Circuit's decision in In re K-Dur.

In re K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012)

In re K-Dur arose as a result of two agreements settling Paragraph IV challenges to the validity of Schering-Plough's patent to a controlled-release formulation of a potassium chloride supplement used to treat side effects from blood pressure medication marketed as K-Dur. Under the agreements, Schering-Plough made payments to the generic companies in exchange for a delay in generic entry into the market. K-Dur wholesalers and retailers challenged the settlements, alleging antitrust violations.[28]

The case was dismissed at the district court level under the scope of the patent test. The district court applied a presumption that the K-Dur patent was valid until the end of its term, and only reverse payments that exceeded the scope of the patent or were made to settle objectively baseless suits would be subject to antitrust scrutiny.[29]

The Third Circuit reversed. According to the court, the intent of Congress in implementing and construing the Hatch-Waxman scheme has been to encourage litigated challenges to weak and narrow patents, and finding that such intent is undermined by permissive antitrust scrutiny of payments to delay generic market entry.[30] The court held that any payment from a patent holder to a generic patent challenger in exchange for delayed market entry in settlement of an ANDA suit is prima facie evidence of an unreasonable restraint of trade.[31]

In so ruling, the court rejected the scope of the patent test and applied a "quick look" rule of reason analysis, shifting the burden to the patent holder to justify the payments, while stopping short of determining that such payments are per se anti-competitive. The patentee may rebut the presumption that such a payment is anti-competitive by showing that: (1) the payment was for a purpose other than delayed entry; or (2) offered some pro-competitive benefit, such as forestalling bankruptcy of a generic competitor. The court emphasized, however, that settlements based on a negotiated entry date without payment are permissible.[32]

Schering-Plough (now Merck & Co. Inc.) has petitioned for a writ of certiorari, asking the question "[w]hether the federal antitrust laws permit a brand-name manufacturer that holds the patent for a drug to enter into a settlement of patent litigation with a prospective generic manufacturer, where the settlement includes a payment from the brand manufacturer to the generic manufacturer but does not exclude competition beyond the scope of the patent?"[33],[34]

Conclusion

Product switching can be a strong tool for branded pharmaceutical companies to protect market share in the face of generic competition. However, antitrust issues can arise when the strategy is used in an unjustified, anti-competitive manner that goes beyond the scope of the patent. With petitions for certiorari pending, the time is ripe for the U.S. Supreme Court to clarify this evolving area law.

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[1] A generic drug must be therapeutically equivalent to the brand drug (generic has the same active ingredient, form, dosage, strength, and safety and efficacy profile), and bioequivalent (rate and extent of absorption in the body is roughly equivalent to the brand drug) in order to be interchangeable with the brand drug. Such generic drugs are either A-rated (there are no known or suspected bioequivalence problems) or AB-rated (actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence).

[2] Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 415-416 (D. Del. 2006).

[3] Id., at 416-417.

[4] The NDDF is a private database that provides information about FDA approved drugs. The NDDF guides pharmacists in determining substitution of generic for brand-name drugs.

[5] Abbott Labs., 432 F. Supp. 2d at 417-418.

[6] Id.

[7] Id., at 418-419.

[8] Unites States v. Microsoft, 253 F.3d 34, 65 (D.C. Cir. 2001).

[9] Abbott Labs., 432 F. Supp. 2d at 422.

[10] Id., at 423.

[11] Walgreen Co. v. AstraZeneca Pharms., 534 F. Supp. 2d 146, 148-149 (D.D.C. 2008).

[12] Id., at 147-148.

[13] Id., at 150-152.

[14] Id., at 152.

[15] Id.

[16] Id., at 151-152.

[17] FTC v. Warner Chilcott Holdings Company III, Ltd., 2007 WL 158746 (D.D.C.).

[18] Id. (Final Order and Stipulated Permanent Injunction).

[19] Id.

[20] FTC v. Watson Pharm., Inc. et al., 677 F.3d 1298 (11th Cir. 2012).

[21] Id.

[22] Id.

[23] Id., at 1312.

[24] Id.

[25] Petition for a Writ of Certiorari, FTC v. Watson Pharm., Inc. et al., 81 USLW 3216 (Oct. 4, 2012) (12-416).

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