Dubious Antitrust Claims Can Harm Innovation in Drug Industry

by Amy Miner

The law generally encourages innovation. Certain tax laws are designed to encourage research and development. Patent laws protect inventions from copycats. The Federal Food, Drug, and Cosmetic Act (FDCA) gives extended exclusivity for conducting clinical trials on children. And it is generally said that antitrust laws encourage firms to innovate, condemning only firms that obtain or maintain monopoly power through exclusionary conduct.

But now it appears that courts may be leaving the door open to condemn "predatory innovation" by pharmaceutical companies. When does product innovation cross the line and become an actionable antitrust violation? Courts initially addressed this issue almost three decades ago in cases that involved allegations of predatory product design of complementary products—from cameras and film to computer main frames and peripherals, where firms allegedly modified one product to render incompatible a competitor's components.[1] Changes adopted even principally to preclude competition were upheld so long as they improved performance or reduced cost, and courts have been reluctant to substitute their judgment for those of the market.

Recent application of "predatory innovation" theory, however, in the pharmaceutical industry—an industry that is constantly developing and improving patentable drugs—may prove problematic for pioneer pharmaceutical companies. This is evident from the recent *Abbott Labs. v. Teva Pharms.* decision, which addressed the appropriate test for determining when a pharmaceutical product change becomes an antitrust violation.[2]

In *Abbott Labs.*, plaintiffs[3] filed claims alleging that Abbott Laboratories and Fournier Industrie ET Sante (collectively, "Abbott")[4] "manipulated the statutory framework [of the Hatch-Waxman Act] … in order to prevent generic substitutes for the branded drug Tri-Cor [used to treat adults with high cholesterol] from having a meaningful opportunity to enter the market."[5] Specifically, the plaintiffs claimed that Abbott violated antitrust law by, on two separate occasions, making minor changes to its TriCor formulation in an effort to preclude generic entry by preventing the generic formulations from becoming AB-rated, which would have allowed, and in many states would have required, pharmacists to dispense the generic instead of TriCor.[6]

Abbott's first change came in 2001, three years after it introduced its TriCor capsule, when it converted its capsules to lower dosage tablets.[7] In connection with that change, Abbott sought to expand the label to include an indication that the tablet formulation could raise "good cholesterol."[8]

After Abbott received Food and Drug Administration (FDA) approval for the tablets, Teva, which had already received FDA approval for its generic, submitted a new ANDA[9] for a generic tablet formulation of TriCor.[10] In response, Abbott filed a patent infringement action against Teva.

Abbott's second change occurred in 2004, while the patent litigation was pending. Abbott introduced a new TriCor tablet with a lower dosage of the active ingredient fenofibrate that did not need to be taken with food.[11] As with its TriCor capsules, Abbott ceased selling its older TriCor tablets, withdrew the product, and changed its National Drug Data File (NDDF)[12] code to "obsolete" to prevent pharmacies from substituting the generic for its new drug. These activities prompted the antitrust claims, which essentially alleged that the loss of the ability to have sales automatically redirected to the generic when a physician prescribed TriCor constituted actionable harm under the antitrust laws.[13]

Abbott's Arguments Rejected

Abbott moved to dismiss the plaintiffs' counterclaims, pressing three arguments. First, Abbott asserted that the plaintiffs' complaint conceded that the changes to the TriCor drugs were improvements and said they should, therefore, be *per se lawful*

Ms. Miner is an Associate with the law firm of Drinker Biddle & Reath LLP

under the antitrust laws. Second, Abbott argued that the plaintiffs were not completely blocked from the marketplace. Finally, Abbott argued that its withdrawal of the older TriCor formulations and changes to the NDDF codes did not constitute antitrust violations because Abbott had no affirmative duty to help its competitors.[14]

The district court rejected all three arguments. Most significantly, it rejected Abbott's *per se* legal argument because it "presuppose[d] an open market where the merits of any new product can be tested by unfettered consumer choice."[15] The court reasoned that by removing the older TriCor drugs from the market, it "prevented such a choice."[16] The court declined to find that the plaintiffs had conceded the reformulations were improvements, and therefore reasoned that the benefits of the newer product must be weighed against any anticompetitive harm.[17] The fact that generics were free to market their own products was not persuasive because, the court said, an antitrust claim may exist if the elimination of the "cost-efficient" means of distribution is proven to restrict competition.[18]

The *Abbott Labs.* decision could open the floodgates to similar litigation involving drug reformulations by brand name pharmaceutical companies. Already we have seen litigation against AstraZeneca alleging that the introduction of Nexium and efforts to convert the market for Prilosec to Nexium in order to impede generic competition violate antitrust law, with plaintiffs arguing Nexium is not superior to Prilosec.[19] Whether additional cases follow is yet to be seen.

Certainly, as the law in this area continues to develop, it is important for pioneer companies to be aware of the potential for claims to be asserted when new formulations are introduced, especially when a company intends to withdraw an older formulation from the market. In such situations, companies should document the legitimate reasons for ceasing sales of the older products and, in certain circumstances, for recalling the older versions. It is important to be mindful that documents discussing product changes, particularly those that focus on eliminating competitors, have the potential of becoming key documents in an antitrust case. This is an important practical lesson even though we all recognize that it is the threat of competition that often drives firms to innovate and introduce new and improved products.

Conclusion

Pharmaceutical companies spend millions of dollars on research and development each year in an effort to not only develop new drugs but to improve existing drugs. The introduction of a new product naturally will have a negative impact on competitors, and the makers of pioneer drugs should not be penalized for legitimate competition.[20] The antitrust laws are designed to address harm to competition—not harm to competitors. Competition is good. It drives innovation. Courts should be dubious of antitrust claims by generic companies that are brought simply because they are frustrated that their ability to a free ride is being impeded by innovation. In sum, the appropriate venue for determining whether a product innovation is a sufficient improvement should be the marketplace, not the courtroom.

1 *See, e.g., California Computer Prods. Inc. v. IBM Corp.*, 613 F.2d 727, 731-32 (9th Cir. 1979); *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 286-87 (2d Cir. 1979), *cert. denied* 444 U.S. 1093 (1980).

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

3 Plaintiffs included various generic manufacturers, including Teva Pharmaceuticals USA, Inc. ("Teva"), sellers, and purchasers.

4 In 1997, Fournier entered into a license agreement with Abbott for Fournier's fenofibrate patent. *See* Defendants' Consolidated Opening Brief in Support of Their Consolidated Motion to Dismiss Plaintiffs' Complaints, at 3.

5 *Abbott Labs.*, 432 F. Supp. 2d at 413.

6 Plaintiffs' counterclaims included allegations of antitrust violations, sham patent litigation and *Walker Process* violations. This article will only address the antitrust counterclaims.

7 The conversion from capsule to tablet occurred while the parties were already involved in litigation in federal court in Illinois. In that litigation, Abbott and Fournier sued Teva and Impax Laboratories for allegedly infringing the capsule formulation of Abbott's TriCor drug. The Illinois litigation resulted in the triggering of the 30-month stay under the Hatch-Waxman Act. Ultimately, the court granted summary judgment in favor of defendants. Shortly after the court granted summary judgment for Teva, the FDA granted final approval of Teva's capsule fenofibrate capsule, which Teva still sells under the name Lofibra. *Abbott Labs.*, 432 F. Supp. 2d at 415-16.

8 *Id.* at 416.

9 ANDA is the Abbreviated New Drug Application, which was introduced under the Hatch-Waxman Act as a means to expedite the FDA approval process by allowing a generic manufacturer to prove it is the bioequivalent of a pioneer drug that previously received FDA approval.

10 Following Teva's ANDA submission, Abbott filed a patent infringement action against Teva in federal court in Delaware. *Abbott Labs.*, 432 F. Supp. 2d at 417.

11 *Id.* at 418.

12 The NDDF is the National Drug Data File, which provides pharmacies with information about FDA approved drugs. When a drug is AB-rated by the FDA it is considered the bioequivalent to and the same dosage, strength and form as the brand name drug. The removal of a brand name drug from the NDDF serves to prevent pharmacies from filling a brand name prescription with a generic substitution.

13 *See, e.g.*, Teva Amended Counterclaim, ¶ 79 (Teva "does not employ – and … should not need to employ – an extensive marketing department like those utilized by brand-name companies.").

14 *See generally Abbott Labs.*, 432 F. Supp. 2d at 419-24.

15 *Id.* at 422.

16 *Id.*

17 *Id.*

18 *Id.*

19 In late 2006, an action filed in federal court in the District of Columbia alleged that defendant undertook efforts to unlawfully convert the market for Prilosec to Nexium in order to impede generic competition. *Walgreen Co. v. AstraZeneca Pharm.*, 06-cv-2084 (D.D.C. 2006). In *AstraZeneca*, plaintiffs allege the defendant violated antitrust laws when it introduced its Nexium drug, which plaintiffs' argue is not superior to Prilosec, shortly before defendant's Prilosec patents expired. Although the defendant filed a motion to dismiss, the court has not issued a decision.

20 Indeed, as the *Abbott Labs* court stated: "innovation inflicts a natural and lawful harm on competitors, [and] a court faces a difficult task when trying to distinguish harm that results from anticompetitive conduct from harm that results from innovative competition." *Abbott Labs.*, 432 F. Supp. 2d at 421.