Advanced Search

Can Antitrust Laws Prevent Abuse Of FDA Risk Programs?

Share us on:

Law360, New York (September 04, 2013, 12:36 PM ET) --

David Balto

For decades we have recognized how the regulatory process can be a fertile environment to secure and abuse market power. Outside the regulatory realm, when market power is secured we can expect the normal forces of competition to often dissipate that power, through new entry or expansion, of other competitive forces. But where market power is secured through regulatory abuse there is no competitive force that can dislodge that power. That is why the antitrust agencies have appropriately focused on regulatory abuse in its enforcement agenda.

Of course, the Federal Trade Commission has led the effort by focusing on regulatory abuse in drug markets. Over the past decade they have brought several enforcement actions challenging conduct such as sham regulatory filings. One of the new areas of concern is the U.S. Food and Drug Administration's Risk Evaluation and Mitigation Strategies ("REMS") program, which limits the distribution of certain drugs that raise safety concerns.

The current controversy is whether a brand-name firm can delay generic brand entry by not distributing samples of their patented drug to competitors who need the samples to receive FDA approval. The district court of New Jersey will be deciding if this conduct violates antitrust laws.

Drug companies Apotex Corp. and Roxane Laboratories Inc. are seeking access to samples of Actelion Pharmaceuticals Ltd.'s high blood pressure medication known as Tracleer. Without these samples, Apotex and Roxane will not be able to demonstrate their generic versions of the drug are bioequivalent, a requirement for FDA approval. Actelion has gone to court seeking a declaratory judgment that they have a right to refuse to deal with competitors and that the Tracleer's REMS program, which requires the drug only be sold and dispensed by certain certified pharmacies, prevents them from providing

competitors with samples.

It has been well documented that generic drug entry into a market benefits consumer welfare. Overall generics have saved consumers $1.07 trillion between 2002 and 2011.[1] In 2011 alone, the use of generic drugs in lieu of brand-named pharmaceuticals saved consumers nearly $193 billion.[2] Without these generics in the market, consumers must pay more for the brand-named drug. The use of REMS to delay generic market entry would therefore harm consumer welfare.

When analyzing the parties' positions, it is best to first understand the purpose behind creating REMS programs. Under the 2007 FDA amendments, REMS are supposed to act as a strategy for the brand-named manufacturer to "manage a known or potential serious risk associated with a drug or biological product."[3] These risks include the recreational misuse of dangerous drugs, like opioids, which can lead to severe injury or death. The mitigation efforts can be broad and can comprise a number of strategies including limiting distribution of approved drugs to specific licensed pharmacists.

Brand-named manufacturers like Actelion argue that a REMS drug cannot be distributed to generic manufacturers due to the limitation of only selling to certain licensed pharmacists. However, both Congress and the FDA have made it clear that the REMS program cannot be used to block or delay FDA approval of generic drugs using the abbreviated new drug application program.[4]

Congress' recent legislation impacting the drug industry was created to promote safety and increased access and availability of generic drugs. As a program, REMS only act as a safety mechanism for post-FDA drug approval. REMS were not meant to "block or delay approval" of a generic drug applying through an ANDA.[5] The Hatch-Waxman Act, which created the ANDA process, [6] allows for an accelerated approval of generic drugs as long as the generic is a bioequivalent to the brand-named drug. If the drugs are bioequivalent, the ANDA allows generic manufacturers access to the brand-named drug's safety and efficacy studies which expedites the application process.

Taken as a whole, Congress has used the ANDA and REMS to facilitate safe, generic entry into the market. Clearly, the purpose of these programs was not to allow brand-named drugs the ability to maintain monopoly power. Therefore, it would appear that brand-named manufacturers relying on REMS to prevent entry by generics is outside of the scope of

Congress' intent.

The question then becomes whether this conduct is in violation of antitrust laws. Given the caselaw, a generic manufacturer likely has one of two antitrust claims: a claim under Section 2 of the Sherman Act or a claim under the Federal Trade Commission Act Section 5.

Section 2 of the Sherman Act penalizes firms that attempt to maintain monopoly power. In Section 2 exclusionary conduct cases, courts are concerned with a company's refusal to deal for the purpose of maintaining their monopoly power.[7] While brand-named manufacturers generally have a right of refusal, a firm's right to refuse to deal is not "unqualified."[8]

In fact, attempting to exclude rivals on a basis other than efficiency might be considered to be predatory behavior. In Aspen, the Supreme Court stated that exclusionary conduct is identified by its ability to "impair the opportunities of rivals" in a way that "either does not further competition on the merits or does so in an unnecessarily restrictive way."[9] By not giving drug samples to generic competition, brand-named manufacturers are impeding the ability of their potential rivals to participate in an otherwise monopolized market contrary to the intent of Congress' ANDA legislation.

A Section 2 claim based on the refusal to sell a drug to a competitor has previously survived a motion to dismiss. In 2008, Lannett Company Inc., filed a complaint againstCelgene Corporation for refusing to sell the drug Thalomid.[10] The complaint stated:

By Refusing to provide samples of its Thalomid® to Lannett for use in bioequivalence testing necessary to obtain approval of an [ANDA] for a thalidomide product, despite Lannett's willingness to pay for the samples, and engaging in other conduct, Celgene has controlled and is controlling an "essential resource" and "essential facility" for the development of that resource, thereby precluding or significantly delaying the development of Lannett's generic thalidomide product in violation of Section 2 of the Sherman Act.[11]

The case was ultimately dismissed after the parties notified the court they had settled their claims against each other.

In their case, Actelion has argued that the most recent exclusionary conduct U.S. Supreme

Court decision, Verizon v. Trinko, stands for the proposition that a claimant must prove a prior history of dealing in order for there to be antitrust liability.[12] They argue that since Apotex and Roxane have never had business arrangements with Actelion, antitrust law should not apply.[13] This argument is likely to fail. In response, the Federal Trade Commission's amicus brief in the Actelion case stated that "neither the Supreme Court nor the Third Circuit has ever held that a prior course of dealing is an essential element of a refusal to deal claim."[14] Instead, the FTC asserts that the proper test is whether the foregone sales are profitable and that Actelion is misstating the evidence of profitability — prior dealing — as the test.[15]

A claimant might also seek relief under the FTC Act Section 5. The FTC uses Section 5 to prevent unfair methods of competition or deceptive acts or practices.[16] Section 5 claims are often used for business conduct that falls outside of the scope of the traditional antitrust laws. The FTC deems actions unfair when it "causes or is likely to cause substantial injury to consumers, cannot be reasonably avoided by consumers, and is not outweighed by countervailing benefits to consumers or competition."[17]

The FTC's amicus brief gives important guidance on Section 2, but it should go further by considering a possible Section 5 claim in this and future REMS cases. While the FTC did not specifically address a potential Section 5 claim in their brief, its unfairness authority can play an important role in addressing the regulatory abuse of the REMs program. However, claimants should be wary that Section 5, in recent years, has not been fully utilized by the FTC.[18] As I have written, Section 5 can play a particularly important role in health care markets.[19] Assuming the likely unfairness associated with brand-named manufacturers using REMS to prevent generic entry, the FTC should apply Section 5 to future cases.

While courts have yet to weigh in on possible antitrust violations in REMS cases, claimants likely have solid legislative record as well as legal theory to support their assertions. Only time will tell how both the courts and the FTC will rule on these matters. The next hearing in Actelion v. Apotex is scheduled for Oct. 17, when oral arguments will be heard for plaintiff's motion for judgment on the pleadings.

--By David A. Balto, Law Offices of David A. Balto

David Balto is a former policy director of the Federal Trade Commission, attorney-adviser to Chairman Robert Pitofsky and antitrust lawyer at the U.S. Department of Justice. He thanks

Jim Kovacs for his contributions to this article.

The opinions expressed are those of the author and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

[1] Press Release, Generic Pharmaceutical Association, New Study Finds Use of Generic Prescription Drugs Saved Consumers and the U.S. Health Care System $1 Trillion over Past Decade (Aug. 2, 2012), available at http://www.gphaonline.com/media/press-releases/20 12/new-study-finds-use-generic-prescription-drugs-sav ed-consumers-and-us-heal.

[2] Generic Pharmaceutical Association, Generic Drug Savings in the U.S. (4th ed. 2012) at 2, available at http://www.gphaonline.org/media//cms/IMSStudyAug2012WEB.pdf.

[3] Fed. Drug Admin., Regulatory Information: Questions and Answers on the Federal Register notice on Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies, available at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/ucm095439.htm

[4] Federal Trade Commission's Brief as Amicus Curiae at 7, Actelion Pharmaceuticals Ltd. v. Apotex Inc., No. 1:12-cv-05743 (D.N.J. Mar. 13, 2013).

[5] See 21 U.C.S. § 355-1(f)(8).

[6] 21 U.S.C. § 355(j).

[7] See Otter Tail Power Co. v. United States, 410 U.S. 366, 378 (1973).

[8] Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 601 (1985).

[9] Id at 605 n.32.

[10] Verified Complaint for Mandatory Injunctive Relief, Lannett Co., Inc. v. Celgene Corp., No. 2:08-cv-03920-TJS, available at http://www.hpm.com/pdf/blog/THALOMID%20-%20Lannett%20Compl%20re%20BE%20Sample.pdf.

[11] Id.

[12] 540 U.S. 398 (2004).

[13] Actelion Pharmaceuticals Ltd. v. Apotex Inc., No. 1:12-cv-05743 (D.N.J. Mar. 13, 2013).

[14] Federal Trade Commission's Brief as Amicus Curiae at 11, Actelion Pharmaceuticals Ltd. v. Apotex Inc., No. 1:12-cv-05743 (D.N.J. Mar. 13, 2013).

[15] Id.

[16] 15 U.S.C. §45(a).

[17] Id.

[18] See David Balto, Reviving Competition in Healthcare Markets: The Use of Section 5 of the FTC Act, Center for American Progress (Oct. 17, 2008), available at http://dcantitrustlaw.com/assets/content/documents/CAP/Reviving%20Competition.pdf.

[19] Id. See also Joshua D. Wright, ABA Spring Meetings: What's Your Agenda (Apr. 11, 2013), available at http://www.ftc.gov/speeches/wright/130411abaspringmtg.pdf.