IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

	)
ACTELION PHARMACEUTICALS LTD.	)

TABLE OF CONTENTS

Other Authorities

The allegations in this case highlight a troubling phenomenon: the possibility that procedures intended to ensure the safe distribution of certain prescription drugs may be exploited by brand drug companies to thwart generic competition. Actavis, Apotex, and Roxane seek to offer competing generic versions of Actelion's brand drug products, Tracleer and Zavesca, pursuant to the regulatory process Congress created in the Hatch-Waxman Act. As part of that process, generic firms are required to test thei

versions. To date, the Commission has not filed any law enforcement actions challenging conduct in this area. The FTC, however, continues to investigate allegations of anticompetitive conduct relating to particular drugs subject to distribution restrictions similar to those at issue in this case and monitor legal and regulatory developments. Although this case involves a dispute between private parties, it may have much broader implications for the Commission's competition mission and the interests of consumers.

II. Regulatory Framework for Competition in the Pharmaceutical Industry

Competition in the pharmaceutical industry occurs within a framework of federal and state laws that balance several policy goals: providing incentives for research and development of innovative new drug products, facilitating entry of lower-cost generic drugs, and ensuring that prescription drugs are safe and effective. Because antitrust analysis "must always be attuned to the particular structure and circumstances of the industry at issue,"

exhibits a similar rate and extent of absorption as the brand product.[5] Allowing generic manufacturers to rely on brands' safety and efficacy studies significantly reduces generic drug development costs and expedites the FDA approval process, while ensuring that generic drugs share the same safety and efficacy profile as their brand counterparts. But to conduct the bioequivalence testing needed to file an ANDA, a generic firm must obtain a limited amount of the brand product. The Hatch-Waxman framework, therefore, cannot function as Congress intended if generic firms are unable to access brand products.

The ANDA process set forth in the Hatch-Waxman Act is complemented at the state level by drug substitution laws that allow a pharmacist presented with a prescription for a brand drug to substitute an AB-rated generic drug, unless the physician or patient specifically directs otherwise. These laws address a unique feature of prescription drug markets that can prevent effective price competition: the physician, who selects but does not pay for the drug, has little incentive to consider price when deciding which drug to prescribe. By providing a mechanism for pharmacists and patients to select drug products based on price, automatic substitution laws have helped drive widespread adoption of lower-cost generic drugs in the United States. As with the ANDA process, however, the effective operation of the substitution system depends on a showing of bioequivalence that is only possible if generic firms can access the brand product.

Together, the Hatch-Waxman Act and state drug substitution laws have been remarkably successful in facilitating generic competition and generating large savings for patients, health care plans, and federal and state governments. The first generic competitor's product is typically offered at a 20% to 30% discount to the brand product.[6] Subsequent generic entry creates greater

[5] 21 U.S.C. §§ 355(j)(2)(A)(ii), (iii), (iv).

[6] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii (2011), *available at* http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf.

price competition, with discounts of 85% or more off the price of the brand name drug.[7] A recent study of 5.6 million prescriptions processed in 2009 revealed that patients and their insurance plans respectively paid an average of $17.90 and $26.67 for generic drugs and an average of $49.50 and $158.25 for brand drugs where no generic existed.[8] In 2011 alone, the use of generic drugs generated an estimated $192 billion in total consumer savings.[9]

B. The Hatch-Waxman Act Balances Innovation and Competition

The Hatch-Waxman Act is not, as Actelion suggests, a "regulatory shortcut" for the benefit of generic drug companies.[10] Rather, Congress designed a carefully calibrated regulatory framework to facilitate the introduction of low-cost generic drugs while preserving incentives for innovation.[11] To encourage innovation, the Act provides several benefits to brand drug companies, including patent-term restoration provisions designed to address the lengthy timeline typically required to develop a new drug product and gain FDA approval.[12] Furthermore, the Act provides for an automatic 30-month stay of generic approval if a brand firm timely files a patent infringement suit, obviating the need to seek a preliminary injunction.[13] Through these provisions, "patent owners received statutory assurance that there would be no generic

---

[7] FTC, *Pay-For-Delay: How Drug Company Pay-offs Cost Consumers Billions* 8 (2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

[8] Wr520 TD-.0001 Th8wa63timides.i923.e.

competitor on the market unless and until their patent rights were adjudicated."[14]

Congress coupled these protections for brand drugs with provisions directed at another "unintended distortion" created by the FDA approval process.[15] Because generic firms must conduct bioequivalence testing with brand product before submitting an ANDA, the Act provides that it "shall not be an act of infringement to make, use, offer to sell, or sell . . . a

REMS was codified in the 2007 Food and Drug Administration Amendments Act (FDAAA).[19] The FDA is authorized to require a REMS when necessary to ensure that a drug's benefits outweigh its risks, and the specific program can take a variety of forms. For example, a REMS might require that pharmacies selling the drug be enrolled in the REMS and that the pharmacist verify that the prescriber and patient are also enrolled before dispensing the drug. In implementing a REMS, brand firms sometimes restrict how the drug is distributed to patients.

Recognizing that certain REMS programs could be used to impede generic competition, Congress included language in FDAAA clarifying that REMS provisions may not be used for such purposes. FDAAA subsection f(8) states that no holder of a REMS-covered drug shall use an aspect of the REMS to "block or delay approval" of an ANDA.[20] Consistent with subsection f(8), the FDA has stated publicly that REMS programs should not be used to block or delay generic competition.[21] In appropriate circumstances, the FDA has issued letters clarifying that a particular brand firm may sell REMS drugs subject to restricted distribution programs to particular generic firms for bioequivalence testing without violating the REMS.[22]

---

[19] 21 U.S.C. § 355-1.

[20] 21 U.S.C. § 355-1(f)(8). Congress has considered, but not enacted, proposals that would give the FDA additional authority to address the competitive issues raised by certain REMS programs.

[21] *See* Center for Drug Evaluation and Research, FDA, Risk Evaluation and Mitigation Strategy (REMS) Public Meeting (July 28, 2010), at 270-71 (statement by Jane Axelrad, Associate Director of Policy, Center for Drug Evaluation and Research), *available at* http://www.fda.gov/downloads/Drugs/NewsEvents/UCM224950.pdf (hereinafter Axelrad Statement); FDA, Risk Evaluation and Mitigation Strategies; Notice of Public Meeting; Reopening of Comment Period, 75 Fed. Reg. 34453, at 34456 (June 17, 2010) (noting FDAAA subsection f(8) and requesting input on steps FDA could take "to ensure that REMS are not used to block or delay generic competition").

[22] *See* Verified Complaint, Exh. A, *Lannett Co. v. Celgene Corp.*, No. 08-cv-3920 (E.D. Pa. Aug. 15, 2008) (letter from FDA to brand manufacturer stating "it is not the agency's intention to permit the restrictions of the [applicable REMS program] to prevent manufacturers of generic drugs from obtaining [the brand product] for use in the bioequivalence testing necessary to

Brand firms have also implemented distribution restrictions for drugs that are not subject to a REMS, as Roxane alleges Actelion has done in the case of Zavesca. Whether implemented as part of a REMS or not, distribution restrictions can raise serious competitive concerns. Ordinarily, generic firms obtain needed samples of a brand product from wholesale distributors. Distribution restrictions may prevent generic firms from purchasing the brand product from these sources. In these instances, a generic firm's only remaining option may be to request to purchase product directly from the brand firm, allowing brand firms to prevent generic competition simply by denying access to the product samples needed for bioequivalence testing. If successful, conduct of the type alleged in this case threatens to undermine the careful balance created by the Hatch-Waxman Act and potentially preser

not barred as a matter of law.

A. Refusing to Sell to Generic Rivals May Constitute Exclusionary Conduct

The Supreme Court recognizes that a monopolist's refusal to deal with its rivals may, under certain circumstances, constitute exclusionary conduct supporting a violation of Section 2 of the Sherman Act.[23] The generic firms' allegations in this case support a plausible theory of exclusionary conduct under this established precedent.[24]

1. Supreme Court Precedent Supports the Alleged Theory of Exclusionary Conduct

The allegations in this case fit within the Supreme Court's existing refusal to deal decisions in *Otter Tail* and *Aspen Skiing*, as clarified in *Trinko*. In *Otter Tail*, the Supreme Court

legitimate, pro-competitive justification.[32]

In *Trinko*, the Supreme Court relied on its decisions in *Aspen Skiing* and *Otter Tail* to explain why Verizon's alleged refusals did not fall within that precedent.[33] In explaining why Verizon's alleged failure to provide the interconnection services mandated by the Telecommunications Act of 1996 was not an unlawful refusal to deal, the Court explained that it has been cautious in recognizing new exceptions to the general principle that a monopolist is ordinarily free to refuse to deal with its rivals.[34] But the Court identified three distinguishing circumstances supporting liability in *Aspen Skiing* and *Otter Tail* that were lacking in *Trinko*.[35] The generic firms' allegations in this case fit all three of these features.

First, the *Trinko* Court explained that, in *Aspen Skiing*, the "unilateral termination of a voluntary *(and thus presumably profitable)* course of dealing suggested a willingness to forsake short-term profits to achieve an anticompetitive end."[36] Actelion argues that this language should be read to mean that without allegations of a "prior history of dealing with the antitrust plaintiff, there can be no antitrust liability."[37] Although some courts in other circuits have interpreted *Trinko* in this way, 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.[38]

---

[32] In this case, Actelion may ultimately demonstrate that its refusal to sell to the generic firms is supported by a legitimate business justification. For purposes of this motion, however, the generic firms contrary allegations are accepted as true. *See* Actavis Counterclaims ¶ 58; Apotex Counterclaims ¶ 65; Roxane Counterclaims ¶¶ 111, 132.

[33] *Trinko*, 540 U.S. at 408-10.

[34] *Id.* at 408.

[35] *Id.* at 408-410.

[36] *Id.* at 409 (emphasis in original).

[37] Actelion Br. at 13.

[38] The Third Circuit has not had occasion to rule on this issue, but dicta in *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 316 (3d Cir. 2007), supports the view that antitrust analysis

Otter Tail makes no mention of a prior course of dealing, and *Trinko*'s discussion of both *Aspen Skiing* and *Otter Tail* undermines the logic of Actelion's position. In *Aspen Skiing*, the existence of a prior course of dealing was significant not as a predicate for liability, but because the voluntary nature of the prior dealing supported the inference that Ski Co.'s foregone sales were profitable, providing evidence that its decision to terminate the arrangement was anticompetitive.[39] In *Trinko*, by contrast, there was no basis to presume that the prior dealing between Verizon and its rivals was profitable for Verizon, as it was compelled by statute, not voluntary. Absent a similar presumption of profitability, the prior dealing between the parties was less probative of whether Verizon's refusal to deal was anticompetitive. In this case, the generic firms have asserted plausible allegations that Actelion sells its products at a substantial profit, and that its refusal to sell to generic rivals may provide evidence of its willingness to sacrifice profitable sales in the short run in order to protect its long-term monopoly profits.

gestures" of a prior course of dealing the "fulcrum of an antitrust violation."[41] Instead, the "essential feature" of viable refusal to deal cases is "a monopoly supplier's discriminating against a customer because the customer has decided to compete with it."[42] Echoing these concerns, the Tenth Circuit has explained that the "initial decisi

its would-be rivals.[51] First, allowing potential generic competitors to purchase product samples from the brand would not undermine the incentive to invest; it would simply maintain the incentive structure Congress created in the Hatch-Waxman Act, under which Actelion retains the ability to exert its patent rights. Second, as Actelion already sells the products to retail and wholesale customers and provides access to research organizations, a one-time sale of a limited quantity to the generic firms would not entail the potential expense and effort the Court feared might be required of Verizon in *Trinko*.[52] Finally, the risk of collusion here is remote because the remedy would not require an ongoing commercial relationship, just a one-time sale. The allegations in this case therefore fall within the established contours of the Supreme Court's refusal to deal precedent.

2. Conduct that Prevents Generic Competition May Undermine the Goals of the Hatch-Waxman Act

Actelion argues that the legislative history of FDAAA supports its position that it has a virtually unqualified right to refuse to sell to generic firms, noting that Congress has considered legislative proposals that would have created a more explicit statutory requirement to address concerns that brand firms may use REMS to prevent generic firms from obtaining the brand product needed for bioequivalence testing.[53] But the broader statutory context undermines any suggestion that Congress intended for REMS to be used to impede the normal operation of the Hatch-Waxman process. As discussed previously, FDAAA subsection f(8) already provides that the sponsor of a REMS drug shall not use the REMS to "block or delay" generic competition.[54]

---

[51] 540 U.S. at 407-08.

[52] *Id.* at 410; *see* Joint Br. at 32 (stating that the generic firms "simply want to make a one-time purchase of samples").

[53] Actelion Br. at 18-20.

[54] 21 U.S.C. § 355-1(f)(8).

Without addressing this existing statutory language, Actelion argues that Congress "considered and rejected an explicit requirement forcing branded companies to supply generic competitors."[55] The Supreme Court in *Otter Tail* held, however, that Congress's decision not to impose an explicit statutory requirement to deal does not bar antitrust liability for a monopolist's refusal to deal.[56] Congress had considered legislation that would have created an explicit statutory obligation for Otter Tail to supply transmission services, but it did not include that requirement in the final legislation.[57] Under these circumstances, the ordinary principles of antitrust law apply, and a regulated monopolist's refusal to deal may violate the Sherman Act.[58]

Furthermore, unlike in *Trinko*, the allegations in this case do not show that the regulatory regime is serving as an "effective steward of the antitrust function."[59] In that case, the Court observed that federal and state regulators were able to take prompt and effective action to address complaints about Verizon's conduct and remedy the competitive concerns.[60] In this case, however, the generic firms allege that they have been unsuccessfully seeking to obtain samples of Actelion's products for several years.[61] Actelion has not argued that the FDA has used its general enforcement authority under the food and drug laws to address allegations that brand firms have used REMS or other restricted distribution programs to block generic competition, instead taking the position that Congress has rejected proposals that would have provided for more explicit statutory obligations.

---

[55] Actelion Br. at 19.

[56] *Otter Tail*, 410 U.S. at 377.

[57] *Id.* at 374.

[58] *Id.* at 374, 377.

[59] 540 U.S. at 413.

[60] *Id.* at 411-13.

[61] *See, e.g.*, Apotex Counterclaims ¶¶ 39-59.

The Supreme Court in *Trinko* also noted that antitrust analysis should "reflect the distinctive economic and legal setting of the regulated industry to which it applies."[62] As the Third Circuit has explained, this guidance is "particularly relevant" to the pharmaceutical industry, in which Congress has drawn a "careful line between patent protection and the need to provide incentives for competition."[63] In this context, antitrust analysis is consistent with the goals of the Hatch-Waxman Act, including Congress's interest in "increas[ing] the availability of low cost generic drugs."[64] If brand firms are able to block generic competition by denying access to the product samples needed to obtain FDA approval, this conduct may prevent the Hatch-Waxman framework from functioning as Congress intended.

3. Bioequivalence Testing for FDA Approval is Exempt from Patent Infringement

Actelion argues that patents covering Tracleer and Zavesca allow it to deny access to generic firms. If the generic firms are able to file ANDAs, and those ANDAs include certifications that Actelion's patents are invalid or not infringed, Actelion may properly seek to enforce its patent rights by filing an infringement action. But at this stage, the generic firms merely seek to perform the testing with the brand product needed to gain FDA approval, an activity that is explicitly exempted from patent infringement liability.[65] Indeed, the purpose of the *Bolar* Amendment was to prevent an "unintended distortion" of the patent laws that would effectively extend the patent holder's "de facto monopoly."[66] The Hatch-Waxman Act paired certain benefits for brand firms with offsetting provisions designed to facilitate generic

---

[62] *Trinko*, 540 U.S. at 411 (citation and quotation marks omitted).

[63] *K-Dur*, 686 F.3d at 216-17.

[64] *Id.* at 217.

[65] 35 U.S.C. § 271(e)(1).

[66] *Eli Lilly*, 496 U.S. at 670.

competition. If a brand firm can effectively block generic firms from accessing brand product, it may be able to prevent generic competition even after its patents on these products expire. If successful, this conduct could upset the balance of the Hatch-Waxman Act and, more broadly, undermine the core principle of the patent system that patents have a limited duration.

B. Distribution Agreements Are Not Immune from Antitrust Scrutiny

Roxane's countercomplaint includes allegations that Actelion's agreements with its distributors violate Section 1 of the Sherman Act, which prohibits unreasonable agreements in restraint of trade. Compared to horizontal agreements among competitors, vertical agreements—such as those between a manufacturer and its distributor—are generally pro-competitive and less likely to pose competitive concern. In some instances, however, vertical agreements may have the effect of reducing competition among horizontal competitors and may therefore violate Section 1. Vertical agreements are properly analyzed under the rule of reason.[67]

Actelion argues that Roxane's Section 1 claims are legally barred for two reasons: (1) distribution restrictions required by the FDA cannot be unlawful agreements; and (2) Actelion's agreements with its distributors are shielded by the single-entity doctrine recognized in *Copperweld Corp. v. Independence Tube Corp*.[68] Actelion's first argument is inconsistent with its position that its right to refuse to sell to potential rivals "exists independently" of any FDA restrictions and would still apply even "if they did not exist."[69] Notably, Roxane has alleged that Actelion has implemented restricted distribution agreements for Zavesca, a product that is not covered by an FDA-mandated REMS. Actelion's basic legal position in this case raises the

---

[67] *See Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877 (2007); *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 726-27 (1988).

[68] 467 U.S. 752, 770-71 (1984).

[69] Actelion Br. at 21.

decades of Supreme Court precedent applying Section 1 to vertical agreements.[73] Instead, as the Supreme Court recently articulated in *American Needle*, the single-entity doctrine examines whether an agreement "joins together separate decisionmakers,"[74] that is, whether those entities are distinct economic actors. Thus, in holding that the various NFL teams were not a single entity, the Court noted that although they may share certain common interests, "they are still separate, profit-maximizing entities, and their interests . . . are not necessarily aligned."[75] The vertical nature of an agreement, such as a standard distribution agreement between separate firms at different levels of the supply chain, does not transform the parties into a single economic entity for antitrust purposes.

Likewise, the fact that the agreements involve patented products does not automatically trigger the single-entity doctrine. Actelion cites two cases involving exclusive patent licenses, but neither involves a distribution agreement.[76] Courts have reasoned that an exclusive license is fundamentally different from other kinds of vertical agreements because the "grant of an exclusive license excludes even the patent holder himself from exercising the rights conveyed by the license."[77] As a result, only one entity has economic control over the patent. Even in the context of an exclusive license, "the relationship between a patent holder and its licensee *could* be a conspiracy in violation of the antitrust laws if the relationship 'deprived the marketplace of

[73] *See Leegin*, 551 U.S. at 924 (Breyer, J., dissenting) (noting that Section 1 has been applied to vertical restraints for over 100 years).

[74] 130 S. Ct. at 2212.

[75] *Id.* at 2213.

[76] Actelion Br. at 23-24 (citing *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 2550835, at *5 (D. Del. June 10, 2011), and *Levi Case Co., Inc. v. ATS Prods., Inc.*, 788 F. Supp. 428, 430 (N.D. Cal. 1992)/TT pa

independent actors.'"[78] Finally, under the patent exhaustion doctrine, when a patent holder sells, rather than licenses, a patented product, restrictions on re-sale can be anticompetitive.[79]

IV. Conclusion

In considering Actelion's motion, the FTC respectfully requests that the Court carefully consider the unique regulatory framework governing the pharmaceutical industry and the potential ramifications for consumers of prescription drugs. The FTC would be pleased to address any questions the Court may have, including participating at any hearing, should the Court find it useful.

Dated: March 11, 2013

Respectfully submitted,

/s/ Timothy J. Slattery

RICHARD A. FEINSTEIN
Director
Bureau of Competition

PETER J. LEVITAS
Deputy Director
Bureau of Competition

DAVID C. SHONKA
Acting General Counsel
Federal Trade Commission

MARKUS H. MEIER
BRADLEY S. ALBERT
MICHAEL J. PERRY
JAMES E. RHILINGER
DANIEL W. BUTRYMOWICZ
TIMOTHY J. SLATTERY
Attorneys for *Amicus Curiae*
Federal Trade Commission
600 Pennsylvania Avenue N.W.
Washington, D.C. 20580
Telephone: (202) 326-3364
Facsimile: (202) 326-3384
tslattery@ftc.gov