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

ACTELION PHARMACEUTICALS LTD. and ACTELION CLINICAL RESEARCH, INC., *Plaintiffs*, v. APOTEX INC., APOTEX CORP., ROXANE LABORATORIES, INC., and ACTAVIS ELIZABETH LLC *Defendants*.	Case No. 1:12-cv-05743-NLH-AMD

FEDERAL TRADE COMMISSION'S BRIEF AS *AMICUS CURIAE*

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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 their generic formulation against the reference brand drug, which requires access to a limited amount of the brand product. These generic firms allege that Actelion has implemented distribution restrictions that prevent them from purchasing samples of Actelion's brand products through customary distribution channels, and that Actelion refuses to sell them the products directly, thereby precluding them from meeting Food and Drug Administration (FDA) requirements for developing generic versions of these drugs. Among other claims, the generic firms assert that this conduct violates the federal antitrust laws. Actelion argues in response that antitrust law places virtually no limit on its ability to block generic access to its brand product, and it seeks a broad declaration that it is under "no duty or obligation" to sell its products to potential competitors. Although Actelion contends that its distribution restrictions are required by the FDA, it argues that its right to refuse to sell to the generic firms is nearly absolute and would apply even without any FDA mandate.

Actelion's legal position, if adopted, could prove costly for consumers of prescription drugs. Competition from lower-priced generic drugs saves American consumers billions of dollars a year. But the unique regulatory framework that facilitates development and adoption of generic drugs depends on generic firms' ability to access samples of brand products. In order to receive FDA approval, generic firms must conduct bioequivalence testing to demonstrate that a generic formulation is therapeutically equivalent to the reference brand drug; such testing

requires access to a limited amount of the brand product. Actelion's position that it has a virtually absolute right to block generic access to its products therefore poses a significant threat to competition in the pharmaceutical industry.

Although the Supreme Court has expressed caution about imposing antitrust liability based on a monopolist's unilateral refusal to deal, the Court continues to recognize that under certain circumstances such conduct may violate Section 2 of the Sherman Act. The Supreme Court has also held that vertical agreements, like those between a manufacturer and its distributors, may violate Section 1. In both contexts, antitrust analysis requires a careful application of general legal principles to the specific factual circumstances and regulatory setting. The Federal Trade Commission submits this brief as *amicus curiae* to assist this Court with its analysis. The Commission presents background information on the unique regulatory framework that applies to the pharmaceutical industry and evaluates how actions to prevent generic access to brand product may violate the antitrust laws.

I. Interest of the Federal Trade Commission

The FTC is an independent agency charged by Congress with protecting the interests of consumers by enforcing competition and consumer protection laws.[1] It exercises primary responsibility over federal antitrust enforcement in the pharmaceutical industry.[2] The Commission has substantial experience evaluating the framework for generic drug development and competition under the Hatch-Waxman Act and corresponding state laws.

Over the past several years, the FTC has investigated allegations that restrictions on the distribution of certain brand drugs are preventing generic firms from offering competing generic

[1] 15 U.S.C. §§ 41-58.

[2] For a summary of the FTC's antitrust actions in the pharmaceutical industry, see *Overview of FTC Antitrust Actions in Pharmaceutical Services and Products* (September 2012), *available at* http://www.ftc.gov/bc/healthcare/antitrust/rxupdate.pdf.

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,"[3] we begin by explaining how certain features of the regulatory setting may be exploited by brand firms to foreclose competition in this industry.

A. Bioequivalence and the Hatch-Waxman Framework

Generic drugs play a crucial role in containing rising prescription drug costs by offering consumers therapeutically equivalent alternatives to brand drugs at a significantly reduced cost. With the Hatch-Waxman Act, Congress created a mechanism for accelerated approval of generic drugs through an Abbreviated New Drug Application (ANDA) based on a showing of bioequivalence.[4] A generic drug is considered bioequivalent or "AB-rated" if it contains the same active pharmaceutical ingredient as the brand drug, is the same dosage and form, and

[3] *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004).

[4] 21 U.S.C. § 355(j).

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

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[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] William H. Shrank et al., *The Consequences of Requesting "Dispense as Written,"* 124 Am. J. Med. 309, 311 (2011).

[9] Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.* (4th ed. 2012) at 2.

[10] Actelion Br. at 2.

[11] H.R. Rep. No. 98-857, Pt. 1, p. 14-17 (1984); *see also Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012); *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 204 (3d Cir. 2012).

[12] *See Eli Lilly and Co v. Medtronic, Inc.*, 496 U.S. 661, 669-71 (1990) (describing patent-term restoration provisions).

[13] 21 U.S.C. § 355(j)(5)(B)(iii).

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 patented invention . . . solely for uses reasonably related to the development and submission of information" for FDA approval.[16] This provision, known as the *Bolar* Amendment,[17] reflects Congress's concern that if generic firms could not begin the testing necessary to submit an ANDA until the brand's patents had expired, "the patentee's *de facto* monopoly would continue for an often substantial period until regulatory approval was obtained," amounting to an "effective extension of the patent term."[18] The *Bolar* Amendment addresses that problem by allowing generic firms to conduct testing with brand product before patent expiration.

C. Improper Use of Restricted Distribution Programs May Impede Generic Competition

Certain brand drugs are subject to distribution restrictions that may be used to prevent generic firms from accessing samples of the brand product. In many instances, these restricted distribution programs are implemented as part of FDA-mandated risk management programs known as Risk Evaluation and Mitigation Strategies (REMS). The FDA's authority to require

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[14] Alfred B. Engleberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA J. L. & Tech. 389, 402 (1999).

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

[16] 35 U.S.C. § 271(e)(1).

[17] The provision overruled *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984), in which the Federal Circuit had held that testing conducted to develop a generic drug was an act of infringement.

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

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]

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[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 preserve a brand firm's monopoly indefinitely.

III. Actions that Block Generic Access May Violate the Antitrust Laws

Actelion asserts that it is entitled to declaratory relief, and dismissal of the antitrust counterclaims, as a matter of law. Actelion relies on two general principles of antitrust law: first, that a private firm is ordinarily free to choose with whom it does business; and second, that vertical agreements, such as those between a manufacturer and its distributors, rarely pose any competitive concern. But these general principles are not absolute. Under certain circumstances, potentially including those alleged in the counterclaims here, a monopolist's refusal to sell to its rivals may violate Section 2 of the Sherman Act, and vertical agreements may violate Section 1. As detailed in the previous section, the unique regulatory framework governing the pharmaceutical industry may create conditions that increase the potential for anticompetitive conduct that prevents or delays generic competition. While the evidence may not ultimately support any of the Sherman Act claims in this case, the FTC respectfully submits that they are

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obtain approval of an [ANDA]"); Axelrad Statement, *supra* note 21, at 271 (expressing FDA's willingness to issue letters stating that REMS should not be a barrier to generic access).

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 affirmed the district court's finding that defendant Otter Tail had used its monopoly in power transmission to foreclose competition in retail power distribution by denying its potential rivals access to its power transmission infrastructure.[25] The towns that chose to compete with Otter Tail by offering their own retail power service were dependent on Otter Tail's transmission network. Otter Tail provided transmission services to non-competing customers, and no technical limitations would have prevented it from offering the same services to the towns seeking to establish their own competing retail systems. The Supreme Court therefore affirmed the district court's finding that Otter Tail's refusals were "solely to prevent municipal power systems from

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[23] *Trinko*, 540 U.S. at 408-10; *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601-11 (1985); *Otter Tail Power Co. v. United States*, 410 U.S. 366, 378 (1973).

[24] The FTC takes no position in this brief on the generic firms' other theories of exclusionary conduct, including the claims that Actelion has denied access to an essential facility, *see* Joint Br. at 39, and the argument that Actelion's actions, considered together, provide evidence of an overall monopolization scheme, *see id.* at 24.

[25] 410 U.S. at 370-72, 377-78.

eroding its monopolistic position."[26] Notably, the Court's decision was not based on a prior course of dealing between Otter Tail and the towns, and the Court recognized that Section 2 applies to conduct aimed at foreclosing even "potential entrants."[27]

In *Aspen Skiing*, the Supreme Court upheld liability based on defendant Ski Co.'s decision to terminate a joint four-mountain ski pass with plaintiff Highlands, combined with Ski Co.'s refusal either to sell its tickets to Highlands at full retail price or to honor vouchers from Highlands' customers. In analyzing Highlands' Section 2 claim, the Court began by noting that a firm's general right to refuse to deal with other firms is not "unqualified."[28] The Court then evaluated whether Ski Co.'s conduct was exclusionary, noting that if "a firm has been 'attempting to exclude rivals on some basis other than efficiency,' it is fair to characterize its behavior as predatory."[29] The Court further explained that "exclusionary" conduct is identifiable by its tendency to "impair the opportunities of rivals" and "either does not further competition on the merits or does so in an unnecessarily restrictive way."[30] Applying these standards, the Court went on to conclude that Ski Co.'s refusal to accept compensation at full retail price "supports an inference that Ski Co. was not motivated by efficiency concerns and that it was willing to sacrifice short-run benefits . . . in exchange for a perceived long-run impact on its smaller rival."[31] The Court emphasized the lack of evidence that Ski Co.'s conduct was supported by a

[26] *Id.* at 378.

[27] *Id.* at 377.

[28] 472 U.S. at 601.

[29] *Id.* at 605 (quoting Robert Bork, *The Antitrust Paradox* 138 (1978)).

[30] *Id.* at 605, n.32 (quoting Phillip Areeda & Donald F. Turner, *Antitrust Law* 79 (1978)).

[31] *Id.* at 610-11.

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]

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[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.[40]

Moreover, a prior voluntary course of dealing is not the only way to show that refused sales would have been profitable. In fact, under certain circumstances a prior course of dealing alone may not necessarily provide particularly reliable evidence that a subsequent refusal is anticompetitive. Indeed, some courts and commentators have cautioned against focusing on the termination of a voluntary course of dealing in *Aspen Skiing*, reasoning that a monopolist may choose to terminate a once-profitable arrangement for legitimate, pro-competitive reasons. For example, Judge Posner has explained that it would be "perverse" to make the "encouraging

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should focus on the economic significance of a refusal rather than the specific form it takes. Like the Supreme Court in *Trinko*, the Third Circuit described the termination of the joint ticket in *Aspen Skiing* as evidence of "the defendant's willingness to forego short-run profits for anticompetitive purposes." *Id.*

[39] *See Trinko*, 540 U.S. at 409.

[40] Actavis Counterclaims ¶ 31; Apotex Counterclaims ¶¶ 31-32; Roxane Counterclaims ¶¶ 118, 139, 150.

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 decision to adopt one business model" should not "lock the resort into that approach and preclude adoption of the other at a later time."[43] In the Tenth Circuit's view, the "critical fact" from *Aspen Skiing* was not the termination of the joint pass itself, but the fact that the defendant had sacrificed short-term profits without a valid business justification.[44]

This interpretation is further supported by the second distinguishing feature the *Trinko* Court highlighted when addressing *Aspen Skiing*: Ski Co.'s "unwillingness to renew the ticket *even if compensated at retail price*."[45] This fact provided additional evidence of Ski Co.'s willingness to forgo profitable sales in the short run, "suggesting a calculation that its future monopoly retail price would be higher."[46] Since Verizon would have been compensated at a statutory cost-based rate of compensation rather than at its market rates, its refusal did not necessarily provide evidence that its conduct was anticompetitive. In this case, however, the generic firms' allegations that they would be willing to compensate Actelion at full retail price

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[41] *Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d 370, 376 (7th Cir. 1986).

[42] *Id.* at 377; *see also Trinko*, 540 U.S. at 410 (describing *Otter Tail* as a case where "the defendant was already in the business of providing a service to certain customers . . . , and refused to provide the same service to other customers").

[43] *Christy Sports LLC v. Deer Valley Resort Co., Ltd.*, 555 F.3d 1188, 1196 (10th Cir. 2009).

[44] *Id.* at 1197; *see also* Susan A. Creighton and Jonathan M. Jacobson, *Twenty-Five Years of Access Denials*, 27 Antitrust 50, 52 (2012) (criticizing the requirement of a prior course of dealing and explaining that *Christy Sports* and *Olympia Equipment* both interpret *Aspen Skiing* as a case "where the refusal to deal was supported by no business justification").

[45] *Trinko*, 540 U.S. at 409 (emphasis in original).

[46] *Id.*

support an inference, like in *Aspen Skiing*, that the refused sales would have been profitable.[47]

As a third distinguishing factor, the *Trinko* Court explained that in both *Aspen Skiing* and *Otter Tail*, the defendant refused to sell something it was "already in the business of providing," rather than new services or products that are "not otherwise marketed or available to the public."[48] *Trinko* involved allegations that Verizon had failed to fulfill its statutory obligations under the 1996 Telecommunications Act, which required the company to design and implement new systems to enable interconnection with its rivals. In this case, by contrast, Actelion is in the business of selling Tracleer and Zavesca, and the generic firms are requesting access to samples of these products in the same form, and at the same price, as they are sold to the public.[49] Notably, Roxane has alleged that Actelion has provided Tracleer and Zavesca to non-competitor research organizations and brand drug companies to conduct clinical studies using the drugs, outside the restricted distribution networks used to distribute the drugs to patients.[50] These allegations—that Actelion is willing to provide access to non-competitors, despite its distribution restrictions, but refuses to provide access to its potential competitors, even if compensated at full retail price—support a viable theory of exclusionary conduct under existing precedent.

In addition, the relief sought in this case does not seem to raise the policy concerns with "enforced sharing" the Court described in *Trinko*: (1) reducing the incentive for the monopolist and its rivals to invest in the shared asset; (2) setting the terms and conditions on which the monopolist must deal; and (3) inadvertently encouraging collusion between the monopolist and

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[47] Actavis Counterclaims ¶ 57; Roxane Counterclaims ¶ 118. Apotex alleges Actelion has refused to sell Tracleer at "market prices." Apotex Counterclaims ¶¶ 63-66.

[48] *Trinko*, 540 U.S. at 410.

[49] Actavis Counterclaims ¶ 4; Apotex Counterclaims ¶ 66; Roxane Counterclaims ¶¶ 85-90.

[50] Roxane Counterclaims ¶¶ 86-90.

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]

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[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.

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[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

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[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

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[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.

possibility that a brand firm may unilaterally impose distribution restrictions that block generic access to brand product, even without any safety requirement from the FDA. Given the regulatory context, distribution agreements implementing such a strategy could pose significant competitive concerns and would be properly evaluated under the rule of reason.

Actelion's second argument depends on an interpretation of the single-entity doctrine that would extend it well beyond the bounds of existing case law. In *Copperweld*, the Supreme Court held that when the parties to an agreement are part of a single economic entity rather than "separate economic actors pursuing separate economic interests," they cannot, as a matter of law, be liable under Section 1.[70] Though *Copperweld* itself addressed a parent company and its wholly-owned subsidiary, some courts have extended the doctrine to include legally separate entities that have completely unified economic interests.[71]

Actelion argues that its distribution agreements are shielded by this doctrine because "the distributors participate in the sale of Tracleer and Zavesca only because of their appointment by Actelion to sell its patented products," and, "absent the distribution agreement with Actelion, the distributors would [not] be competitors of Actelion or . . . potential independent sources of Tracleer or Zavesca."[72] This expansive reading of *Copperweld*—that two entities cannot be liable under Section 1 unless they are potential horizontal competitors—is inconsistent with

[70] *Copperweld*, 467 U.S. at 769.

[71] *See, e.g., City of Mt. Pleasant, Iowa v. Assoc. Elec. Coop., Inc.*, 838 F.2d 268, 275-76 (8th Cir. 1988) (finding that electrical utility cooperative, owned by a large number of individuals and comprising several distinct corporate entities, was a single entity); *see also American Needle, Inc. v. Nat'l Football League*, 130 S.Ct. 2201, 2211-12 (2010) (rejecting claim that NFL teams were a single entity, while noting that economic realities, rather than legal relationships, control the single-entity analysis).

[72] Actelion Br. at 23-24.

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)).

[77] *Levi Case*, 788 F. Supp. at 431.

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,

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[78] *Townshend v. Rockwell Int'l Corp.*, No. C99-0400, 2000 WL 433505, at *6 (N.D. Cal. Mar. 28, 2000) (quoting *Levi Case*, 788 F. Supp. at 431).

[79] *See United States v. Univis Lens Co., Inc.*, 316 U.S. 241, 250-51 (1942) (holding that Sherman Act applies once a patent holder has sold the patented product).