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

MYLAN PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	Case No. 2:14-CV-2094-ES-MAH
v.	)	
CELGENE CORPORATION,	)	
Defendant.	)	

FEDERAL TRADE COMMISSION'S BRIEF AS *AMICUS CURIAE*

DEBORAH L. FEINSTEIN
Director
Bureau of Competition

STEPHEN WEISSMAN
Deputy Director
Bureau of Competition

JONATHAN E. NUECHTERLEIN
General Counsel
Federal Trade Commission

MARKUS H. MEIER
BRADLEY S. ALBERT
JAMES E. RHILINGER
DANIEL W. BUTRYMOWICZ
KARA L. MONAHAN
Attorneys for *Amicus Curiae*
Federal Trade Commission
600 Pennsylvania Avenue N.W.
Washington, D.C. 20580
Telephone: (202) 326-2018
Facsimile: (202) 326-3384

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

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. Mylan seeks to offer competing generic versions of Celgene's brand drug products, Thalomid and Revlimid, 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. Mylan alleges that Celgene has implemented distribution restrictions that prevent it from purchasing samples of Celgene's brand products through customary distribution channels, and that Celgene refuses to sell it the products directly, thereby precluding it from meeting Food and Drug Administration (FDA) requirements for developing generic versions of these drugs. Among other claims, Mylan asserts that this conduct violates the federal antitrust laws. Celgene argues in response that antitrust law places virtually no limit on its ability to block generic access to its brand product, and it seeks dismissal of Mylan's claims.

Celgene'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. Celgene's view that it has a virtually absolute right to block access to the samples generic firms need to compete threatens to foreclose these cheaper alternatives, perhaps indefinitely.

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 thwart generic access to a brand's 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 versions of those drugs. 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 to monitor legal and regulatory developments in this area. 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.

---

[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* (March 2013), *available at* http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/rxupdate.pdf.

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. The first generic competitor's product is typically offered at a 20% to 30% discount to the brand product.[4] Subsequent generic entry creates greater price competition, with discounts of 85% or more off the price of the brand name drug.[5] 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.[6]

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 exhibits a similar

---

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

[4] 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.

[5] 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.

[6] 21 U.S.C. § 355(j).

rate and extent of absorption as the brand product.[7] 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. 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

[7] *Id.* §§ 355(j)(2)(A)(ii), (iii), (iv).

where no generic existed.[8] In 2012 alone, the use of generic drugs generated an estimated $217 billion in total consumer savings.[9]

B. The Hatch-Waxman Act Balances Innovation and Competition

The Hatch-Waxman Act is a carefully calibrated regulatory framework to facilitate the introduction of lower-cost generic drugs while preserving incentives for innovation.[10] 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.[11] 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.[12] Through these provisions, "patent owners received statutory assurance that there would be no generic competitor on the market unless and until their patent rights were adjudicated."[13]

Congress coupled these protections for brand drugs with provisions directed at another "unintended distortion" created by the FDA approval process.[14] Because generic firms must conduct bioequivalence testing with brand product before submitting an ANDA, the Act

---

[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.* (5th ed. 2013) at 1.

[10] 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), vacated, *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013).

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

[12] 21 U.S.C. § 355(j)(5)(B)(iii).

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

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

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.[15] This provision, known as the *Bolar* Amendment,[16] 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."[17] 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 REMS was codified in the 2007 Food and Drug Administration Amendments Act (FDAAA).[18] 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, a brand firm may restrict how the drug is distributed to patients.

---

[15] 35 U.S.C. § 271(e)(1).

[16] The provision overruled *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *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.

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

[18] 21 U.S.C. § 355-1.

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.[19] Consistent with subsection f(8), the FDA has stated publicly that REMS programs should not be used to block or delay generic competition.[20] In appropriate circumstances, the FDA has issued letters clarifying that a particular brand firm – including Celgene itself – may sell REMS drugs subject to restricted distribution programs to particular generic firms for bioequivalence testing without violating the REMS.[21]

Distribution restrictions associated with a REMS can, in fact, 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 the product directly from the brand firm, allowing brand firms to prevent

[19] 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.

[20] *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").

[21] *See* Verified Compl., Exh. A, *Lannett Co. v. Celgene Corp.*, No. 08-cv-3920 (E.D. Pa. Aug. 15, 2008) (letter from FDA to Celgene Corp. 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 obtain approval of an [ANDA]"); Axelrad Statement, *supra* note 20, at 271 (expressing FDA's willingness to issue letters stating that REMS should not be a barrier to generic access).

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

Celgene seeks dismissal of Mylan's antitrust claims as a matter of law, relying 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 Mylan alleges 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. Moreover, Celgene's claims of patent protection for its products fails to demonstrate a lack of antitrust injury. 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 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.[22] Mylan's allegations in this case support a plausible theory of exclusionary

[22] *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).

conduct under this established precedent.[23] Moreover, the only two district courts to rule on similar allegations have denied motions to dismiss, allowing the refusal to deal claims to proceed, including an earlier case against Celgene involving the same drugs, Thalomid and Revlimid.[24] While neither court issued written opinions, in *Actelion*, Judge Hillman explained his ruling from the bench, explicitly stating that his decision to deny the motion to dismiss was based on his reading of Supreme Court precedent.[25]

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 precedent 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.[26] 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

---

[23] The FTC takes no position in this brief on Mylan's other theories of exclusionary conduct, including the claims that Celgene has denied access to an essential facility. *See* Mylan Compl. ¶¶ 231, 248.

[24] Order, *Lannett Co., Inc. v. Celgene Corp.*, No. 08-cv-3920 (E.D. Pa. March 20, 2011) (Docket No. 42); Order, *Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 12-cv-5743 (D.N.J. Oct. 17, 2013) (Docket No. 90).

[25] Tr. at 115, *Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 12-cv-5743-NLH (D.N.J. Oct. 17, 2013) ("When I read *Trinko* and *Aspen Highlands*, I look at those cases through the lens of -- the case now almost a hundred years old, *Colgate* and *Otter Tail*, it suggests to me that the proper application of the antitrust laws is almost always a fact-specific one and, indeed, an industry-specific one.").

[26] 410 U.S. at 370-72, 377-78.

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 eroding its monopolistic position."[27] 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."[28]

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."[29] 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."[30] 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."[31] 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

[27] *Id.* at 378.

[28] *Id.* at 377.

[29] 472 U.S. at 601.

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

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

rival."[32] The Court emphasized the lack of evidence that Ski Co.'s conduct was supported by a legitimate, pro-competitive justification.[33]

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.[34] 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.[35] But the Court identified three distinguishing circumstances supporting liability in *Aspen Skiing* and *Otter Tail* that were lacking in *Trinko*.[36] Mylan's allegations in this case meet all three of these circumstances.

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."[37] Celgene argues that both "prior dealings *and* profit sacrifice are necessary to allege a duty to deal."[38] Although some courts in other circuits have interpreted *Trinko* to require a prior course of dealing,[39] neither the Supreme Court

---

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

[33] In this case, Celgene may ultimately demonstrate that its refusal to sell to Mylan is supported by a legitimate business justification. While Celgene raises several justifications in its brief, *see* Celgene Brief at 17-18, for purposes of this Motion Mylan's contrary allegations are accepted as true. *See* Mylan Compl. ¶¶ 164, 170.

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

[35] *Id.* at 408.

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

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

[38] Celgene Br. at 16 (emphasis added).

[39] *See, e.g., In re Adderall XR Antitrust Litig.*, __ F.3d __, 2014 WL 2565832, at *5 (2d Cir. June 9, 2014); *Covad Commc'ns Co. v. BellSouth Corp.*, 374 F.3d 1044, 1049 (11th Cir. 2004).

nor the Third Circuit has ever held that a prior course of dealing is an essential element of a refusal to deal claim.[40] Rather, the Court in *Trinko* recognized the termination of prior dealing as evidence suggesting profit sacrifice, but not an independent element of the claim itself.

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 Celgene'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.[41] 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, Mylan has asserted plausible allegations that Celgene 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.[42]

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

---

[40] 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 should focus on the economic significance of a refusal rather than the specific form it takes. While Celgene cites *Broadcom* for the proposition that both prior dealing and profit sacrifice are required to allege an illegal refusal to deal, Celgene Br. at 16, the case does not support that position. 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." 501 F.3d at 316.

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

[42] Mylan Compl. ¶¶ 10, 233.

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 gestures" of a prior course of dealing the "fulcrum of an antitrust violation."[43] 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."[44] 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."[45] 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.[46]

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*."[47] This fact provided additional evidence of Ski Co.'s willingness to forgo profitable sales in the short run, "suggesting a calculation that its future

---

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

[44] *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").

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

[46] *Id.* at 1197.

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

monopoly retail price would be higher."[48] 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, Mylan's allegations that it would be willing to compensate Celgene at full retail price support an inference, like in *Aspen Skiing*, that the refused sales would have been profitable.[49]

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."[50] *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, Celgene is in the business of selling Thalomid and Revlimid, and Mylan is requesting access to samples of these products in the same form, and at the same price, as they are sold to the public.[51] Notably, Mylan has alleged that Celgene has provided Thalomid and Revlimid to non-competitor research organizations to conduct clinical studies using the drugs, outside the restricted distribution networks used to distribute the drugs to patients.[52] These allegations—that Celgene 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.

---

[48] *Id.*

[49] Mylan Compl. ¶¶ 88, 143.

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

[51] *See* Mylan Compl. ¶¶ 88, 143.

[52] *Id.* ¶¶ 161-63.

In addition, the relief sought in this case does not seem to raise the policy concerns with "enforced sharing" the Court identified 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 its would-be rivals.[53] 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 Celgene retains the ability to exert its patent rights. Second, as Celgene already routinely sells the products to retail and wholesale customers and provides access to research organizations, a one-time sale of a limited quantity to Mylan would not entail the potential expense and effort the Court feared might be required of Verizon in *Trinko*.[54] 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

Celgene makes two arguments grounded in food and drug law to support its position that it has no antitrust duty to deal with potential generic competitors. It claims that the Court should not impose a duty to deal under antitrust law because: (1) Congress has considered and failed to include an explicit duty as part of FDAAA; and (2) Mylan could just develop new drugs rather than generic versions of Celgene's.[55] Both arguments ignore the aim of the broader statutory

[53] 540 U.S. at 407-08.

[54] *Id.* at 410; *see* Mylan Compl. ¶ 143.

[55] Celgene Br., at 20, 22.

framework described earlier, with Congress passing the Hatch-Waxman Act at least in part to encourage the development of generic drugs.

Regarding Celgene's first argument, FDAAA included a clear statement that REMS should not be used to "block or delay approval" of an ANDA.[56] And as for Congress's failure to create an explicit duty to sell samples, *Otter Tail* is directly on point. There, Congress had considered legislation that would have created an explicit statutory obligation for Otter Tail to supply transmission services, but did not include that requirement in the final legislation.[57] The Supreme Court 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.[58] Under these circumstances, the ordinary principles of antitrust law apply, and a regulated monopolist's refusal to deal may violate the Sherman Act.[59]

Regarding Celgene's second argument, Mylan's ability, in theory, to develop brand drugs rather than generic versions of Celgene's drugs is irrelevant and certainly does not immunize an otherwise exclusionary refusal to deal. Congress created a mechanism in the Hatch-Waxman Act to spur generic entry, thereby increasing price competition in prescription drug markets. The Supreme Court in *Trinko* noted that antitrust analysis should "reflect the distinctive economic and legal setting of the regulated industry to which it applies."[60] 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

---

[56] 21 U.S.C. § 355-1(f)(8).

[57] *Otter Tail*, 410 U.S. at 374.

[58] *Id.* at 375.

[59] *Id.* at 374,-75.

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

for competition."[61] 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."[62] 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.

B. Distribution Agreements Are Not Immune from Antitrust Scrutiny

In addition to its Sherman Act Section 2 claims, Mylan also alleges that restrictions in Celgene'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.[63]

Courts have held that when the parties to an agreement are 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.[64] Celgene argues that this doctrine shields its distribution agreements because its distributors have no "competitive interest in excluding

---

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

[62] *Id.* at 217.

[63] *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).

[64] *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 769-71 (1984); *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 form, control the single-entity analysis).

Mylan" and the agreement does not "bring together economic power that was previously pursuing divergent goals."[65] But there is no requirement "that vertically aligned co-conspirators must share an identical anticompetitive motive."[66] Instead, as the Supreme Court recently articulated in *American Needle*, the single-entity doctrine examines not whether parties to an agreement have a specific interest in the anticompetitive end, but rather whether the agreement "joins together separate decisionmakers,"[67] 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."[68] 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.

Celgene's related argument—that its agreements are immune because its distributors are its "agents" with "no independent interest in reducing competition"—fares no better.[69] Courts have recognized that an agency relationship may exist where the second entity is "in effect, an inseparable part of [the principal's] structure" such that they "constituted one economic unit."[70] But Celgene cannot plausibly contend—let alone establish as a matter of law—that large

---

[65] Celgene Br. at 25-27.

[66] *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 213 (3d Cir. 1992); *see also* P. Areeda & H. Hovenkamp, *Antitrust Law* ¶1408d at 48 (2d ed. 2003) ("[T]he legal convention of treating express promises in the vertical context as § 1 contracts or conspiracies is well established, notwithstanding an unwilling dealer.").

[67] 130 S. Ct. at 2212.

[68] *Id.* at 2213.

[69] Celgene Br. at 26.

[70] *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125, 1135 (3d Cir. 1995).

pharmaceutical distributors and retailers, such as CVS/Caremark, are "in effect, an inseparable part of [Celgene's] structure."[71]

Finally, as to Celgene's argument that FDA's REMS process mandates the restrictions contained in its distribution agreements, this claim involves disputed questions of fact. Mylan has alleged that Celgene has used the REMS restrictions as a "pretext" to prevent generic firms from acquiring samples.[72] According to Mylan, FDA has informed Celgene that it will exercise its discretion to allow Celgene to sell samples to Mylan.[73] In those circumstances, Mylan may be able to show that FDA would also allow Celgene to sell samples to Mylan through its distributors.

C. Celgene's Patents Alone Do Not Demonstrate a Lack of Antitrust Injury

Finally, Celgene argues that Mylan cannot demonstrate antitrust injury on the ground that "the antitrust laws do not protect infringing competition" and "Celgene's patents stand in the way" of lawful competition.[74] At this stage of the approval process, however, Mylan merely seeks to perform the testing with the brand product needed to seek FDA approval, an activity that is explicitly exempted from patent infringement liability.[75] Indeed, as discussed above, 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."[76] The Hatch-Waxman Act paired certain benefits for brand firms with offsetting provisions designed to facilitate generic competition. If a brand firm can effectively block generic firms from accessing brand

[71] *Id.*

[72] Mylan Compl. ¶ 7.

[73] Mylan Compl. ¶ 91.

[74] Celgene Br. at 6.

[75] 35 U.S.C. § 271(e)(1).

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

product for bioequivalence testing, it may be able to continue 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.

If Mylan is able to file an ANDA, and that ANDA includes a certification that a Celgene patent is invalid or not infringed, Celgene may properly seek to enforce its patent rights by filing an infringement action. At that point, Celgene's patents *may* stand in the way of lawful competition. But they may not. As the Supreme Court recently recognized in *FTC v. Actavis*, "[t]he patent here may or not be valid, and may or may not be infringed."[77] Thus, "to refer. . . simply to what the holder of a valid patent could do does not answer the antitrust question."[78] Thus, Celgene's assertions that it holds valid patents for Thalomid and Revlimid do not by themselves demonstrate a lack of antitrust injury.

IV. Conclusion

In considering Celgene's motion, the FTC respectfully requests that this 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.

[77] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2231 (2013).

[78] *Id.* at 2230 (reversing and remanding allegations of collusive patent settlement, even though the patent holder might be able to exclude competition until patent expiration and the settlement did not exclude competition beyond that point).

Dated: June 17, 2014

Respectfully submitted,

/s/

DEBORAH L. FEINSTEIN
Director
Bureau of Competition

STEPHEN WEISSMAN
Deputy Director
Bureau of Competition

JONATHAN E. NUECHTERLEIN
General Counsel
Federal Trade Commission

MARKUS H. MEIER
BRADLEY S. ALBERT
JAMES E. RHILINGER
DANIEL W. BUTRYMOWICZ
KARA L. MONAHAN
Attorneys for *Amicus Curiae*
Federal Trade Commission
600 Pennsylvania Avenue N.W.
Washington, D.C. 20580
Telephone: (202) 326-3759
Facsimile: (202) 326-3384