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

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The allegations in this case highlight a troubling phenomenon: the possibility that

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 violatrkgene(t)-3841(o)-6otund3 Tw 4.6 m329(o)-623157(e)1(r)15(i)85(c)19 ie scı

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

rate and extent of absorption as the brand product.

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

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[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

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

Recognizing that certain REMS programs could

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

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]

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 Buu uk a .9sdJ /TT(B)42(u)62(.9sf1( )85(cvJ /Td57(

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*

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

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.

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B. Distribution Agreements Are Not Immune from Antitrust Scrutiny m

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

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[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).

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Respectfully submitted,

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