CPI COMPETITION POLICY INTERNATIONAL

CPI Antitrust Chronicle
April 2014 (2)

When Does Sharing Make Sense?:
Antitrust & Risk Evaluation and Mitigation Strategies

Jan M. Rybnicek
U.S. Federal Trade Commission

www.competitionpolicyinternational.com

When Does Sharing Make Sense?: Antitrust & Risk Evaluation and Mitigation Strategies

Jan M. Rybnicek[1]

I. INTRODUCTION

There exists a new front in the battle to define the precise circumstances under which a monopolist's refusal to deal with a rival constitutes exclusionary conduct that violates Section 2 of the Sherman Act. The latest clash arises in the context of a brand-name drug manufacturer's decision not to sell samples of a patented drug that is subject to certain government-mandated restricted distribution protocols to a potential generic rival seeking to use those samples to conduct bioequivalence testing necessary to develop a generic version of the product.[2] Without access to these pharmaceutical samples, the generic firm may be unable to develop, manufacture, and ultimately sell a generic version of the drug to consumers at a significantly lower price than the branded product.[3]

Against the compelling backdrop of a health care system afflicted by rapidly rising costs, some now argue that the antitrust laws should be used to force brand-name drug companies to share samples of their products with generic rivals to further competition and reduce the cost of prescription drugs.[4] Although significant ambiguity remains about the exact contours of "refusal-

[1] The author is an Attorney Advisor to Commissioner Joshua D. Wright of the Federal Trade Commission. Any views expressed in this article are his own and do not necessarily represent the views of the Commission or any Commissioner.

[2] Some also have argued that the Federal Trade Commission ("FTC") can prosecute such conduct as a standalone "unfair method of competition" under Section 5 of the FTC Act. *See, e.g.*, David Balto, *Can Antitrust Laws Prevent Abuse of FDA Risk Programs?*, LAW360 (Sept. 4, 2013), *available at* http://www.law360.com/articles/468192/can-antitrust-laws-prevent-abuse-of-fda-risk-programs. Although the precise boundaries of Section 5 remain unclear, it is well accepted that Section 5 should not be used to circumvent standards established by the federal courts to evaluate claims under Section 2 of the Sherman Act. *See* Boise Cascade Corp. v. FTC, 637 F.2d 573, 581-82 (9th Cir. 1980) (rejecting a Section 5 claim where there is "well-forged" case law under the traditional federal antitrust laws).

[3] *See* Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii (2011), *available at* http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf (finding early generic drugs are offered on average at a 20 to 30 percent discount to the branded products); Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-offs Cost Consumer Billions* 8 (2010), *available at* http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (finding generic entry immediately benefits purchasers because of savings from lower drug prices).

[4] There have been at least four cases filed in federal court in the United States challenging such conduct. Mylan Pharm. Inc. v. Celgene Corp., No. 2:33-av-00001 (D. N.J. filed May 3, 2014); Lannett Co. Inc. v. Celgene Corp., No. 2:08-cv-03920 (E.D. Pa. filed Aug. 15, 2008); Accord Healthcare, Inc. v. Acorda Therapeutics, Inc., No. 0:13-cv-60742 (S.D. Fla. filed Apr. 1, 2013); Actelion Pharm. Ltd. v. Apotex Inc., No. 1:12-cv-05743 (D. N.J. filed Sept. 14, 2012). The FTC filed an *amicus* brief in *Actelion Pharmaceuticals Ltd.* opposing the defendant's motion for a

to-deal" law in the United States, it is unlikely that this problem can or should be remedied through the blunt instrument of the antitrust laws. A better approach might be to rely instead on existing regulatory tools that are better tailored to addressing potential problems arising in the pharmaceutical industry. Another option would be to seek Congressional action establishing an appropriate process for the development of generic versions of branded drugs with restricted distribution protocols.[5]

II. REGULATORY AND INDUSTRY BACKGROUND

The potential antitrust issue outlined above stems from the intersection of two aspects of the unique regulatory regime that overlays the pharmaceutical industry:

1. First, in order to ensure that a drug's benefits outweigh its risks, the Food & Drug Administration ("FDA") is authorized to mandate risk management programs known as Risk Evaluation and Mitigation Strategies ("REMS") for certain high-risk pharmaceuticals that raise significant safety concerns.[6] REMS can consist of a variety of safety measures beyond routine labeling requirements, including special training for prescribers and patients, patient monitoring, and restricted distribution through specific certified pharmacies. REMS programs therefore can prevent access to a drug through customary distribution channels, such as wholesale distributors.

   An example of a drug subject to a FDA-mandated REMS program is Thalomid. In the late 1950's and early 1960's, thalidomide was marketed and sold to pregnant women to relieve symptoms of morning sickness. Tragically, it was discovered later that thalidomide led to the death of thousands of children whose mothers had prolonged exposure to the drug during pregnancy, and caused serious birth defects in several thousands more.[7] As a result, the drug was withdrawn from the market. In 1998, the FDA approved thalidomide under the brand-name Thalomid to treat symptoms associated with leprosy and, in 2006, to treat multiple myeloma patients.[8] Significantly, the FDA approved Thalomid only on

---

declaratory judgment. Without taking a position on the merits of the underlying case, the FTC asserted that a refusal by a branded manufacturer to sell samples to a generic drug company could, under certain specific circumstances, violate Section 2 of the Sherman Act. Brief for Fed. Trade Comm'n as Amicus Curiae, Actelion Pharm. Ltd. v. Apotex Inc., No. 1:12-cv-05743 (D. N.J. Mar. 11, 2013), *available at* http://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et-al.v.apotex-inc./130311actelionamicusbrief.pdf.

[5] For additional discussion about the the issues raised by the application of the antitrust laws to this scenario, *see* Darren S. Tucker, Gregory F. Wells & Margaret E. Sheer, *REMS: The Next Pharmaceutical Enforcement Priority*, 28 ANTITRUST 74 (2014).

[6] 21 U.S.C. § 355-1 (2012). For additional background on the FDA's authority to require REMS, *see* U.S. FOOD & DRUG ADMIN., *FDA Basics Webinar: A Brief Overview of REMS*, http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf.

[7] *See, e.g.*, *The Thalidomide Disaster*, TIME (Aug. 10, 1962).

[8] *See, e.g.*, Sheryl Gay Stolberg, *Thalidomide Approved to Treat Leprosy, With Other Uses Seen*, NY TIMES (July 17, 1998), http://www.nytimes.com/1998/07/17/us/thalidomide-approved-to-treat-leprosy-with-other-uses-seen.html; Sheryl Gay Stolberg, *Thalidomide, Once Banned, Is in Demand*, NY TIMES (Nov. 28, 1997), http://www.nytimes.com/1997/11/28/us/thalidomide-once-banned-is-in-demand.html; Sheryl Gay Stolberg, *Thalidomide, Long Banned, Wins Support*, NY TIMES (Sept. 6, 1997), http://www.nytimes.com/1997/09/06/us/thalidomide-long-banned-wins-support.html.

the condition that the drug manufacturer would restrict the distribution of the drug and implement a REMS program to prevent the risk of embryo-fetal exposure.[9]

2. Second, under the Hatch-Waxman Act, generic drug manufacturers can obtain accelerated approval of a generic drug through an Abbreviated New Drug Application ("ANDA") by showing bioequivalence with the branded version of the product.[10] This process reduces the development costs for generic drugs and expedites generic drug approval by allowing generic manufacturers to rely on safety and efficacy studies conducted for the branded product. Significantly, in order to conduct the bioequivalence testing necessary to file an ANDA successfully, the generic drug manufacturer must acquire samples of the branded pharmaceutical.

A REMS program potentially can have significant implications for the ability of a generic manufacturer to develop a generic product, successfully file an ANDA, and introduce the generic product into the market. When a REMS prevents distribution of a drug through customary channels, a brand-name drug manufacturer's decision not to sell a limited quantity of the product directly to a potential generic rival may foreclose the only means for accessing the branded product and theoretically can thwart generic competition.

Recognizing this possibility, Congress granted the FDA the authority to ensure that REMS do not "block or delay approval" of an ANDA.[11] The FDA can enforce this provision through monetary penalties or by withdrawing the branded product from the market.[12] Furthermore, the FDA has the authority to craft procedures that would help make REMS-restricted drugs available to generic drug companies for bioequivalence testing.[13]

III. POTENTIAL ANTITURST IMPLICATIONS OF REMS

Some have asserted that a brand-name drug manufacturer's decision not to provide samples of a REMS-restricted drug to a generic firm so that the potential rival can develop a generic version of the drug represents an anticompetitive "refusal to deal" that violates Section 2 of the Sherman Act. However, the Supreme Court has long held that "the Sherman Act does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal," suggesting that such claims face significant obstacles.[14]

Indeed, although "the high value . . . placed on the right to refuse to deal with other firms does not mean that the right is unqualified," the antitrust laws only require firms with monopoly power to assist their rivals under very narrow circumstances.[15] The Supreme Court has been

[9] *See* U.S. FOOD & DRUG ADMIN., *Thalomid Risk Evaluation and Mitigation Strategy (REMS)* (Nov. 2013), http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM222649.pdf.

[10] 21 U.S.C. § 355(j).

[11] 21 U.S.C. § 355(f)(8).

[12] 21 U.S.C. § 333(f)(4)(A).

[13] 21 U.S.C. § 355-1(f)(2), (g)(4).

[14] Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 408 (2004) (quoting United States v. Colgate & Co., 250 U.S. 300, 307 (1919)).

[15] *Id.* (quoting Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585 (1985)).

cautious in recognizing such circumstances "because of the uncertain virtue of forced sharing and the difficulty of identifying and remedying anticompetitive conduct by a single firm."[16] Moreover, compelling firms to share "may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities" and "requires antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing—a role for which they are ill suited."[17]

So when do the antitrust laws require a monopolist to assist a rival?

Many have read the Supreme Court's guidance in this area, and chiefly its decisions in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*[18] and *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko*,[19] as imposing a "prior course of dealing" requirement for any successful refusal to deal claim under Section 2. Under this approach, a firm cannot be held liable under the antitrust laws for refusing to deal unless it is first shown that the firm terminated a voluntary course of dealing with the rival. Many lower courts have endorsed this view, requiring plaintiffs to proffer evidence of a "prior course of dealing" to establish that a refusal to deal has the potential to violate Section 2.[20] Under this interpretation, a brand-name drug manufacturer's decision not to provide samples of a REMS-restricted drug to a potential generic rival would not violate Section 2 unless it could be shown that the branded firm terminated an existing supply contract for a REMS-restricted drug. This can be a very demanding requirement as there often may be no "prior course of dealing."

But as others have pointed out, a "prior course of dealing" requirement finds little actual support in either *Aspen Skiing* or *Trinko*.[21] Indeed, central to the Supreme Court's conclusion in *Trinko* that Verizon's refusal to share its telephone network with a local phone service competitor did not violate Section 2 was not the absence of a prior course of dealing, but rather the absence of more general evidence demonstrating that Verizon's conduct was "prompted not by competitive zeal but by anticompetitive malice."[22]

Although a "unilateral termination of a voluntary (and thus presumably profitable) course of dealing" can suggest a "willingness to forsake short term profits to achieve an anticompetitive end," and thus can shed light "upon the motivation of [a firm's] refusal to deal," a prior course of dealing is not the only means for identifying exclusionary conduct that violates Section 2. In fact, in *Otter Tail Power Co. v. United States*, an earlier "refusal to deal" decision that remains good law and is cited favorably by the Supreme Court in *Trinko*, the Supreme Court held

[16] *Id.*

[17] *Id.* at 407.

[18] 472 U.S. 585 (1985).

[19] 540 U.S. 398 (2004).

[20] *See, e.g.*, In re Elevator Antitrust Litig., 502 F.3d 47, 54 (2d Cir. 2007); Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 316 (3d Cir. 2007); Covad Commc'ns Co. v. BellSouth Corp., 374 F.3d 1044, 1049 (11th Cir. 2004).

[21] *See* Christy Sports, LLC v. Deer Valley Resort Co., 555 F.3d 1188 (10th Cir. 2009) ("The critical fact in *Aspen Skiing* was that there were no valid business reasons for the refusal."); Susan A. Creighton & Jonathan M. Jacobson, *Twenty-Five Years of Access Denials*, 27 ANTITRUST 50 (2012), *available at* http://www.wsgr.com/publications/PDFSearch/creighton-jacobson-fall12.pdf (arguing that a fair reading of the refusal to deal precedent does not compel a prior course of dealing requirement).

[22] *Trinko*, 540 U.S. at 409.

that the defendant's refusal to carry electricity produced by rival power companies over the defendant's power lines violated Section 2 despite the absence of a prior course of dealing because the defendant did so "solely to prevent municipal power systems from eroding its monopolistic position."[23]

The case law therefore suggests that the relevant inquiry for determining whether a refusal to deal is exclusionary conduct that violates Section 2 is not whether the defendant engaged in a "prior course of dealing" but instead whether the defendant's refusal can only be explained by its negative impact on the rival and the resulting harm to competition.[24]

Moreover, although a "prior course of dealing" screen might be easy to apply, and thus is attractive to practitioners seeking to offer clear guidance to clients and avoid fact-intensive inquiries requiring costly and lengthy litigation, the rule also has the very real potential to distort a firm's incentives away from welfare maximization.[25] For example, a "prior course of dealing" requirement may steer a firm away from a potentially profitable contract for fear that if it later decides to withdraw from the arrangement it might be exposed to antitrust liability. Indeed, cautious antitrust counsel may advise a brand-name drug manufacturer not to supply a REMS-restricted drug to a generic drug company—even if it is in the branded firm's interest—for fear that doing so may obligate the branded firm to provide all REMS-restricted drugs requested by the generic in the future.

A better approach to analyzing whether a brand-name drug manufacturer's refusal to supply REMS-restricted drugs to a generic drug company that wants to develop a generic alternative is to apply the "no economic sense" test.[26] Consistent with *Trinko*, *Aspen Skiing,* and *Otter Tail*, under this approach a refusal to deal could result in antitrust liability only in those rare circumstances where the sole justification for the refusal is the negative impact the conduct could have on the rival and the benefits conferred by eliminating competition. Although less of a bright line than the "prior course of dealing" requirement, the "no economic sense" test remains relatively easy to apply in a vast majority of cases and has the added benefit of better identifying refusals to deal that are likely to be anticompetitive while minimizing the risk to consumers associated with false positives.[27]

Even under the somewhat relaxed "no economic sense" approach, a challenge to a brand-name drug manufacturer's refusal to supply limited quantities of REMS-restricted drugs to a generic drug company would face significant obstacles. As the history of thalidomide demonstrates, REMS-restricted drugs carry an inherent and serious risk that—through either use or misuse—the drug may significantly harm individuals handling or taking the drug. If either the brand or generic product caused such harm, the branded firm likely would face significant

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

[24] *See* Creighton & Jacobson, *supra* note 21, at 53.

[25] *Id.*

[26] For a detailed analysis of the benefits of the "no economic sense" test, *see* Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The "No Economic Sense" Test*, 73 ANTITRUST L.J. 413 (2006).

[27] For a criticism of applying the "no economic sense" test to exclusive dealing cases under Section 2 of the Sherman Act, *see* Jonathan M. Jacobson & Scott A. Sher, *"No Economic Sense" Makes No Sense for Exclusive Dealing*, 73 ANTITRUST L. J. 779 (2006).

expenses in the form of regulatory costs, litigation costs, and harm to the branded firm's reputation. Under such circumstances, it is easy to imagine a brand-name drug manufacturer reasonably opting to forgo the relatively small profits earned from the sale of samples of REMS-restricted drugs in order to maintain exclusive control of the product and be able to limit the likelihood that the drug is used or misused in a way that causes harm.

This calculus likely holds true regardless of (i) how sophisticated the generic manufacturer is, (ii) whether the generic firm promises to indemnify the branded firm, or (iii) whether the FDA has blessed the sale of samples of the REMS-restricted products to the generic manufacturer. This is because, given the significant costs associated with an adverse event, the economic rationale for selling a limited quantity of drugs to a generic drug company (*i.e.*, the profits from the sale of the drugs) will almost always be dwarfed by the probabilistic value of harm even as the probability of harm approaches nearly zero.

It therefore appears that a brand-name drug manufacturer often will be able to present a legitimate business justification explaining why it has refused to supply a generic drug company with a limited supply of its REMS-restricted drug. As a result, even under the "no economic sense" test, it would seem that a branded firm's refusal to provide samples of REMS-restricted drugs to generic rivals ordinarily will not lead to antitrust liability under Section 2 of the Sherman Act. There of course may be exceptions to this more general result, and each case should be evaluated individually, but the antitrust laws do not appear to be the best avenue for furthering generic drug development of REMS-restricted drugs.

IV. CONCLUSION

It seems unlikely, whether analyzed for a "prior course of dealing" requirement or under the "no economic sense" test, that a brand-name drug manufacturer's refusal to sell samples of a REMS-restricted product to a potential generic rival that seeks to develop a generic alternative should constitute exclusionary conduct that violates Section 2 of the Sherman Act. A better approach than relying on the antitrust laws to solve the potential problem created by the unique regulatory framework that overlays the pharmaceutical industry, and a solution that finds support in *Trinko*, is to rely more heavily on the existing tools available to the FDA to help make REMS-restricted products accessible to interested generic companies.[28] Doing so would avoid turning the courts into regulators tasked with crafting and monitoring detailed supply contracts between branded and generic firms. Alternatively, Congress could step in to amend the current regulatory regime and create an appropriate process for encouraging generic development of REMS-restricted drugs.

[28] *Trinko*, 540 U.S. at 412 (holding that antitrust liability under Section 2 was not warranted, in part, because of "the existence of a regulatory structure designed to deter and remedy anticompetitive harm").