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Early Lessons From The REMS Battlefield

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Generic pharmaceuticals save consumers billions of dollars each year. To be sure, the Generic Pharmaceutical Association estimates that in the past decade alone, generic pharmaceuticals saved the United States health system approximately $1.46 trillion dollars.[1] Considering the enormous cost savings afforded by generic drugs, it comes as no surprise that brand name pharmaceutical companies have historically employed highly aggressive, and in some instances, unlawful tactics to prevent competing generic drugs from entering the market. These unlawful tactics range from fraudulently obtaining patents and initiating sham litigation, to providing large and unjustified payments to would-be rivals to stay out of the market, to product-hopping (also known as evergreening), where a branded manufacturer releases a new version of a pre-existing drug with only minor or no substantive improvements to prevent consumers from switching to lower-priced generic competitors.

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In their latest ploy to evade competition, brand name pharmaceutical companies are increasingly invoking their "risk evaluation and mitigation strategies" (REMS) to delay or preclude competition from generic pharmaceutical companies. While there is a dearth of case law addressing the legality of invoking REMS to deny generic companies access to drug samples, the limited rulings to date indicate that this latest tactic by branded pharmaceutical companies may violate the antitrust laws in certain circumstances. These decisions also reveal two important early lessons for antitrust lawyers: a generic pharmaceutical company may likely not need to allege a prior course of dealing to state a legally sufficient refusal-to-deal claim (at least in the Third Circuit) and a branded pharmaceutical company's ostensible reliance on safety concerns as a legitimate business justification to deny rivals access to drug samples will likely be rejected.

Background and Regulatory Framework

The U.S. Food and Drug Administration requires REMS for particularly dangerous drugs. REMS is a set of measures above and beyond professional labeling that the FDA requires a branded manufacturer to design and implement to inform patients of a drug's health and safety risks. Under the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), the FDA may require a branded manufacturer to formulate and implement a REMS if "necessary to ensure that the benefits of the drug outweigh the risks of the drug."[2] REMS may include, for example, a guided plan to convey the drug's risks to patients or restrictions on the

drug's distribution. According to several recently filed complaints, branded drug manufacturers have co-opted REMS requirements to inappropriately deny generic competitors' access to drug samples needed to conduct bioequivalence testing, a predicate for FDA approval to market generic drugs.[3] Branded drug manufacturers argue that selling samples of REMS-protected drugs to generic competitors violates the terms of their REMS and may subject them to legal liability if the generic manufacturers do not take adequate safety precautions.

Government Oversight and Enforcement

The FDAAA states that no brand name manufacturer of a REMS-covered drug shall use any portion of the REMS to "block or delay approval" of a generic manufacturer's ANDA.[4] And, in late 2014, the FDA issued draft guidance describing the process whereby a generic manufacturer may request the FDA to inform its branded rival that providing the generic manufacturer with enough of the brand drug to perform bioequivalence testing would not be considered a violation of the branded manufacturer's REMS. The FDA appears to disavow bringing any enforcement actions however, and has asserted that "issues related to ensuring that marketplace actions are fair and do not block competition would be best addressed by the [Federal Trade Commission] ("FTC")."[5]

As of this date, the FTC has not filed any enforcement actions against branded drug companies for invoking the REMS process to preclude or delay generic competition. The FTC has, however, announced that REMS misuse is an enforcement priority and it has filed an amicus brief in private antitrust litigation to express its concerns about the practice.

Private Enforcement

Generic drug manufacturers have brought several actions alleging that the refusal to supply samples for REMS-restricted drugs violates the antitrust laws. In an interesting twist, brand name drug manufacturers have also gone on the offensive by filing actions for a declaratory judgment that they have no obligation to supply drug samples to generic competitors. While there are few dispositive rulings, several decisions to date — all in the Third Circuit — provide some insight into how courts analyze whether REMS misuse amounts to an antitrust violation and illuminate the following two important lessons.

Lesson 1: A Prior Course of Dealing May Not Be Needed To State A Monopolization Claim

Determining the circumstances in which a monopolist has a duty to deal with rivals is "one of the most unsettled and vexatious in the antitrust field."[6] And when it comes to a branded drug manufacturer's refusal to supply product to would-be generic rivals, the law is even less settled. In one of the few decisions to address refusals to deal in the REMS context, Mylan Pharmaceuticals Inc. v. Celgene Corp.[7], a federal district court in New Jersey recently upheld Mylan's complaint that Celgene, the branded manufacturer of Thalomid and Revlimid, denied it access to samples of these two REMS-protected drugs in violation of Section 2 of the Sherman Act. In so holding, the court rejected Celegene's argument that a duty to deal only arises when there is a prior course of dealing between the parties and the alleged monopolist irrationally forsakes short-term profits for long-term anti-competitive gains.[8] Instead, the court declared that "the cases in our circuit that have considered the scope of the affirmative duty to deal suggest that a 'prior course of dealing' is relevant but not dispositive in determining whether such a duty applies."[9] Because Mylan pled there was no legitimate business reason for Celegene's refusal, which Mylan alleged was solely motivated by Celegene's desire to further its monopoly, the court concluded that the complaint "may give rise to a plausible § 2 claim."[10]

In another decision, Actelion Pharmaceuticals Ltd. et al. v. Apotex Inc., et al[11], Actelion took a different approach by preemptively suing generic-drug makers and seeking a declaratory judgment that the antitrust

laws did not compel it to do business with its potential generic rivals. At issue was the request by several generic drug manufacturers for access to samples of Tracleer, a treatment for lung hypertension that has been linked to severe liver problems. The generic manufacturer defendants asserted antitrust counterclaims and Actelion responded with both a motion for judgment on the pleadings as to its claims and a motion to dismiss the generics' antitrust counterclaims. The court denied Actelion's motions, refusing to find on the "scant record" before it that Actelion's refusal to sell samples to its rivals amounted to "protected and lawful conduct."[12] The court further held that, when the Supreme Court's seminal refusal-to-deal decisions were read together, such cases are almost always "fact-specific" and "industry-specific" so that mere reliance on Trinko[13] does not provide a "simple answer to the issue that's been presented to this Court." Relying on Aspen Skiing,[14] the court further noted that other exclusionary conduct could substitute for a prior course of dealing, such as the "refusal to sell at retail."[15] The fact that the generic drug companies did not plead a prior course of dealing, therefore, did not preclude a monopolization claim because they alleged other facts demonstrating exclusionary conduct.

Thus, in light of Mylan and Actelion, it is highly unlikely that courts (at least those in the Third Circuit) will require a prior course of dealing to uphold a complaint alleging that a branded drug manufacturer's refusal to deal in the REMS context violates the antitrust laws[16].

Lesson 2: Branded Drug Companies will Find it Increasingly More Challenging to Rely on Safety Concerns as a Legitimate Business Justification

In any refusal to deal case under Section 2 of the Sherman Act, a defendant has an opportunity to offer a legitimate business justification for its decision to deny product to the plaintiff. In REMS litigation, branded drug companies consistently argue that their refusals to supply samples to generics are a legitimate business decision to ensure the safe distribution of their products. These arguments will be more difficult to make going forward given the FDA's recent guidance that providing samples to generics will not violate a branded company's REMS program. Additionally, in Mylan, the plaintiff had offered to indemnify the branded drug company for any liability arising from the sale of product samples to it — and that company's refusal to agree to an indemnification would certainly appear to mitigate any argument that a refusal to deal is based on safety concerns. Furthermore, at the heart of the dispute in Actelion was the company's proffered business justification for its refusal to deal — "government-mandated safety concerns" — and its generic competitors' argument that these safety concerns were a beard to mask Actelion's true motivation of extracting monopolistic profits.[17] There, the court specifically stated during oral argument that, if it could be shown that the branded manufacturer was motivated not by safety concerns but by a desire to use REMS to maintain and extend its monopoly, the plaintiffs might "very well" make out a Section 2 claim.[18]

Conclusion

If anything, the early decisions emanating from the REMS battlefield indicate just how unsettled the law is on refusals to deal. For the time being, however, courts in the initial stages of such actions have indicated that there is no antitrust immunity for a blanket refusal to deal with a generic rival merely because the companies never engaged in any prior course of dealing. Similarly, while proper consideration of any legitimate business justification for a refusal to deal should be reserved for later stages of litigation, recent decisions at the dismissal stage of litigation, coupled with the latest regulatory guidance, indicate that safety concerns are not likely to shield branded drug companies from antitrust liability.

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[1] Generic Pharmaceutical Association, Generic Drug Savings in the U.S. (6th ed. 2014).

[2] 21 U.S.C. § 355-1(a).

[3] In 1984, Congress enacted the Hatch-Waxman Act to expedite generic drug approval. Under the Hatch-Waxman Act, a generic manufacturer seeking to file an abbreviated new drug application ("ANDA") for FDA approval must demonstrate that its generic formulation is bioequivalent to the brand drug. To perform the necessary bioequivalence testing, the generic manufacturer needs access to a sample of the brand drug.

[4] 21 U.S.C. § 355-1(f)(8).

[5] Partial Petition Approval & Denial at 7, No. FDA-2009-P-0266 (Aug. 7, 2013).

[6] Byars v. BluffCity News Company, Inc., 609 F.2d 843, 846 (6th Cir. 1979).

[7] Transcript of Oral Opinion, Mylan Pharmaceuticals Inc. v. Celgene Corp., No. 2:13-cv-02094-ES (D.N.J. Dec. 22, 2014).

[8] Id. at 10.

[9] Id. at 12.

[10] Id. at 17.

[11] Transcript of Motions Hearing, Actelion Pharm. Ltd. V. Apotex, Inc., 1:12-cv-05743 (D.N.J. Oct. 21, 2013).

[12] Id. at 115.

[13] Verizon Communs, Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004).

[14] Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 606, 611 (1985).

[15] Actelion at 13-14.

[16] See also Lannett Co., Inc. V. Celgene Corp., No. 08-3920, slip op. (E.D. Pa. Mar. 31, 2011).

[17] Actelion at 116.

[18] Mylan at 14-15, (quoting Actelion at 117).
