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Antitrust Alert

District Court Permits Section 2 Claim to Proceed Against Pharmaceutical Manufacturer for Denying Generic Rival Access to Branded Drug Samples

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On December 22, 2014, a federal district court in New Jersey found that Mylan Pharmaceuticals, Inc. ("Mylan") alleged facts sufficient to plead an antitrust claim under Section 2 of the Sherman Act against defendant, Celgene Corporation ("Celgene"), for denying a generic rival access to samples of its branded drugs (Thalomid® and Revlimid®) that are distributed pursuant to a Risk Evaluation and Mitigation Strategies ("REMS") program. Citing the Supreme Court's decisions in *Otter Tail Power Co. v. United States*[1] and other relevant cases that discuss the scope of an affirmative duty to deal with rivals, the district court preserved the Plaintiff's Section 2 claim by finding that Celgene's conduct fit within one of the limited exceptions to the general rule that there is no duty to deal with competitors, concluding that antitrust liability could be found without allegations of a prior course or history of dealing with the Plaintiff. However, the court dismissed the Plaintiff's conspiracy claims, concluding that the Complaint did not contain sufficient facts to support allegations of an unlawful conspiracy between Celgene and its distributors that would give rise to liability under Section 1 of the Sherman Act. Oral Opinion, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.*, No. 2:13-cv-02094-ES (D.N.J. Dec. 22, 2014).

This decision comes at a time when refusals to provide access to drugs distributed pursuant to REMS programs are under close scrutiny by the Federal Trade Commission ("FTC"). According to Commissioner Maureen Ohlhausen, "the refusal to sell restricted distribution drugs to potential generic manufacturers can constitute exclusionary conduct under Section 2 of the Sherman Act."[2] Although the FTC has filed an amicus brief in a similar case in the District of New Jersey, the Commission has not yet filed a complaint challenging such conduct. As such, this case is noteworthy because it is one of the few cases to address potential liability under Section 2 in connection with FDA-required REMS programs and is likely to be instructive on such issues as litigation in this area unfolds. The court's analysis also adds to the continuing debate over the application of Section 2 to situations involving a refusal to deal with a rival, as lower courts continue to adopt disparate interpretations of the Supreme Court's 2004 decision in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko*.[3]

Background

Mylan's complaint centers on its inability to procure samples of Thalomid® and Revlimid® from Celgene in order to conduct the bioequivalence testing required for FDA approval of its proposed generic product. An Abbreviated New Drug Application ("ANDA") contains data and information that provides for the review and ultimate approval of a generic drug product by the FDA, generally including test results comparing the bioavailability of its proposed generic product with that of its branded counterpart, the reference listed drug ("RLD"). This comparison allows the generic manufacturer to avoid extensive human testing and provides a pathway to faster generic availability. The FDA does not allow a generic manufacturer to test its product and compare on paper with the results of the brand's own testing — the bioequivalence testing must simultaneously test samples of the branded RLD, which generic drug manufacturers often obtain through wholesale distribution channels.

Certain restricted distribution programs are implemented as part of FDA-mandated risk management programs known as REMS. The FDA is authorized to require a REMS program when necessary to ensure that a drug's benefits outweigh its risks. Aimed to ensure patient safety, these distribution restrictions may prevent generic drug manufacturers from obtaining branded drug samples through customary distribution channels. In this case,

the FDA mandated that Celgene restrict the distribution of Thalomid® and Revlimid® due to the serious risk of significant birth defects. Due to these restrictions, Mylan was unable to procure samples through its normal methods and, instead, sought to purchase samples directly from Celgene. After several rounds of negotiation, Mylan had not obtained the RLD samples from Celgene, and filed suit.

Mylan alleged two antitrust violations: (1) Celgene's unilateral refusal to deal was anticompetitive in violation of Section 2 of the Sherman Act; and (2) Celgene's exclusive distribution agreements with its wholesalers unreasonably restrained trade under Section 1 of the Sherman Act by preventing Mylan access to the branded samples it requires for FDA approval. The court held that Mylan's Section 2 claims could proceed, but dismissed its Section 1 claims.

The District Court's Analysis

Antitrust claims under Section 2 of the Sherman Act require a Plaintiff to plead: (1) monopolization; and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident (i.e., anticompetitive or exclusionary conduct). Celgene argued that its conduct was not exclusionary as a matter of law because Section 2 only imposes an affirmative duty to deal with competitors when (a) there is a prior course of dealing between the parties; and (b) the alleged monopolist irrationally sacrificed short-term profits for long-term anticompetitive gains. Celgene maintained that both of those exceptions were inapplicable.

The court disagreed. While acknowledging the Supreme Court's long-held rule that the antitrust laws generally do not impose a duty upon a firm to deal with competitors, the judge found that Mylan plausibly alleged a Section 2 violation because Celgene's conduct could fit within an exception to the general rule.

In dissecting the scope of the exception to the "no duty to deal" rule, the judge analyzed the facts in light of the Supreme Court's seminal cases on the issue, *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*[4] and *Trinko,*[5] and concluded that the Supreme Court did not require any prior course of dealing as dispositive of whether a duty applies, but considered those facts as evidence of the defendant's willingness to forgo short-run profits for long-run anticompetitive results – it was "relevant to the § 2 inquiry insofar as it served as a proxy for the larger inquiry of whether the defendant's conduct was anticompetitive." [6] According to the judge, the *Trinko* court "considered these facts not for their independent significance, but rather for what they *suggest*: A willingness to engage in irrational, anticompetitive conduct." *Id.* Third Circuit precedent supported this interpretation, including three other REMS-related cases brought by generic manufacturers against their branded counterparts. The court stated, "[T]he 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."[7] On these grounds, the court allowed Mylan's Section 2 claims to survive.

The court, however, dismissed Mylan's Section 1 allegations that Celgene devised an anticompetitive scheme to prevent Mylan from filing ANDAs for generic versions of Thalomid® and Revlimid® and entered into unlawful agreements with wholesale distributors and pharmacies to unreasonably restrain trade. The court noted that a plaintiff asserting a Section 1 claim must assert four elements: (1) that there were concerted actions by the defendant; (2) that they produced anticompetitive effects within the relevant product and geographic markets; (3) that the concerted actions were illegal; and (4) that the plaintiff was injured as a proximate result of the concerted action. The judge concluded that Mylan made no allegations that the distributors shared a common purpose or would otherwise benefit from the allegedly anticompetitive implications of the distribution agreements. Mylan argued that it met its pleading burden by "directly alleging the existence of restrictive distribution contracts between Celgene and downstream entities," arguing that it did not need to plead unity of purpose in support of its Section 1 claim. The court disagreed, noting that the Third Circuit has not eliminated the requirement that a plaintiff alleging a §1 violation must plead an agreement to a common scheme or design.[8]

Conclusion

Branded drug manufacturers should not assume that a refusal to supply branded samples will be impervious to antitrust attack under a "no duty to deal" theory. As cases of this nature are brought against branded drug manufacturers, it will be instructive to observe the extent to which Section 2 claims survive motions to dismiss

and the grounds upon which they do so. These cases also serve as an early test of the antitrust ramifications of the FDA's REMS requirements and may pose a bit of a dilemma for branded drug manufacturers that seek to abide by REMS programs while simultaneously complying with the antitrust laws.

If you have any questions about this topic, please contact the author(s) or your principal Mintz Levin attorney.

Endnotes

[1] 410 U.S. 366 (1973) (upholding liability of a wholesale supplier of electricity that refused to supply power to rival power systems where the competing power systems had no other source of supply).
[2] S*ee A Discussion with FTC Commissioner Maureen K. Ohlhausen*, ANTITRUST HEALTH CARE CHRONICLE, Nov. 2013, at 3.

[3] 540 U.S. 398, 409 (2004) (raising the bar significantly on Section 2 claims finding, that without a prior course of dealing, there was no antitrust violation for Verizon's refusal to adequately share its telephone network with competitors).

[4] 472 U.S. 585 (1985) (holding that a defendant violated Section 2 when it terminated a long-running, profitable business relationship in which the parties offered joint ski passes to both parties' resorts). According to the Supreme Court, Section 2 liability was supported by the suggestion that the defendant's conduct was not "justified by any normal business purpose." *Id*. at 608.

[5] In *Trinko*, the Supreme Court described *Aspen Skiing* as "at or near the outer boundary of § 2 liability." 540 U.S. at 409. The court also 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." *Id.* (emphasis in original).

[6] Slip Op. at 12.

[7] *Id.* at 12-13.

[8] Slip Op. at 21, 22 (further noting that Section 1 liability in the Third Circuit requires "a unity of purpose or a common design and understanding or meeting of the minds in an unlawful arrangement").

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