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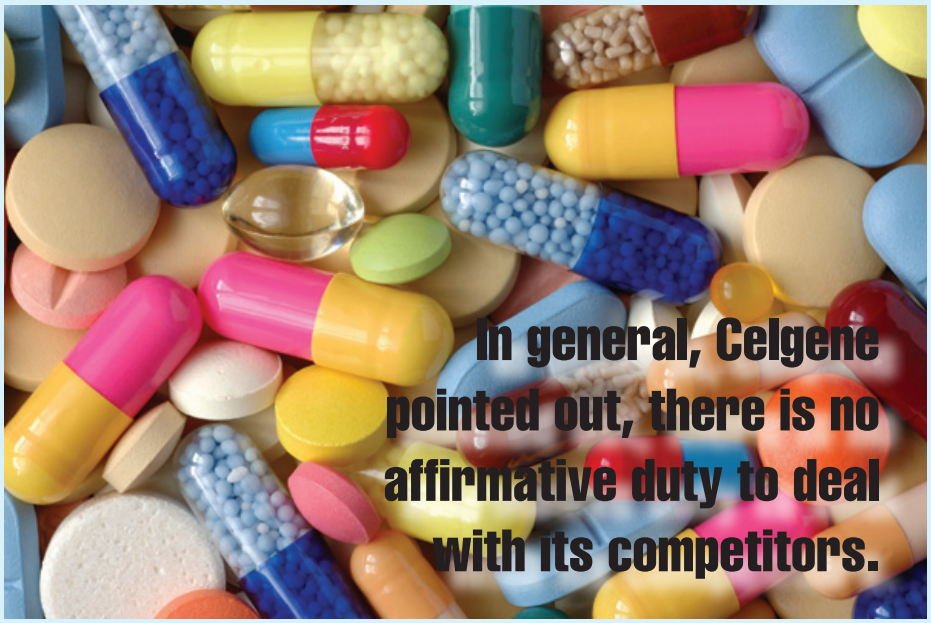
Refusals to Deal Still at Issue in 'Celgene' Case

By Carl W. Hittinger and Lesley Grossberg

When a patent owner relies on FDA drug-distribution regulations to withhold samples of a branded product to a would-be generic manufacturer, resulting in that generic manufacturer's inability to conduct bioequivalence testing required for an Abbreviated New Drug Application under the Hatch-Waxman Act, does it amount to an antitrust violation?

In broader terms, is a prior course of dealing between the parties a prerequisite to asserting a Sherman Act claim for refusal to deal? A case raising these questions is currently pending before Judge Esther Salas in the U.S. District Court for the District of New Jersey (*Mylan Pharmaceuticals v. Celgene Corp.*, case no. 2:14-cv-02094). The U.S. Court of Appeals for the Third Circuit declined to weigh in on the issue, by way of denial of a petition for an interlocutory appeal of the District Court's denial of Celgene's motion to dismiss. (Appeal No. 15-8017, March 5, 2015, Order.)

Celgene manufactures and sells Thalomid and Revlimid, branded drugs covered by various patents for the Revlimid compound, as well as the composition of matter and method of use for both products. Thalomid is approved for treatment of lesions resulting from Hansen's Disease, and both products are indicated for treatment of multiple myeloma and subsets thereof. Because the products contain thalidomide, a compound whose risks for causing birth defects are well-known, the products are subject to Risk Evaluation and Management Strategies (REMS) pursuant to FDA regulations, and cannot be obtained from pharmaceutical wholesalers.



Celgene also owns patents covering the REMS aimed at minimizing the risk of fetal exposure to Thalomid and Revlimid. The REMS require certification, training and monitoring of health-care providers who prescribe the products and the pharmacies who dispense them, as well as patient monitoring, in order for Celgene to track the delivery of every dose of the drugs to every patient.

Mylan, unable to purchase the drugs on the market due to Celgene's REMS, sought to obtain samples of Thalomid and of Revlimid directly from Celgene as part of its efforts to develop generic versions of those products. Celgene asserted that it declined to provide these samples because Mylan did not provide sufficient information showing how it would comply with the REMS requirements. Mylan filed suit in April 2014, alleging that Celgene's refusal to provide it samples of Thalomid and Revlimid amounted to unlawful monopolization under Section 2 of the Sherman Antitrust Act, and that Celgene had "used REMS as a pretext to prevent Mylan from acquiring the necessary samples to conduct bioequivalence studies."

Celgene moved to dismiss the complaint, arguing that as the owner of patents covering both the compositions and the methods for distribution of the products at issue, it is a lawful monopolist. Celgene also noted that in other instances where generic drug manufacturers sought samples of Thalomid and Revlimid, Celgene provided the samples to them where they abided by Celgene's risk mitigation policies (and ANDA litigation followed

Hittinger is a partner with Baker Hostetler in Philadelphia. He focuses his practice on complex commercial and civil rights litigation. Grossberg is an associate at the firm, focusing her IP practice on trademark and copyright litigation.

in both cases). In contrast, Celgene argued, Mylan refused to abide by the REMS that would, in Celgene's view, adequately protect Celgene from the substantial products liability exposure it could face if the REMS are not strictly adhered to.

In general, Celgene pointed out, there is no affirmative duty to deal with its competitors. *United States v. Colgate & Co.*, 250 U.S. 300 (1919). The Supreme Court has recognized limited exceptions to this rule. In *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), the court upheld a jury verdict of Section 2 liability, where the defendant "elected to forgo short-run benefits because it was more interested in reducing competition in the Aspen market over the long run."

Twenty years later, however, the court in *Verizon v. Trinko* observed that *Aspen Skiing* "is at or near the outer boundary of Section 2 liability," and found the fact of a unilateral termination of a voluntary and presumably profitable course of dealing in *Aspen Skiing* to be a distinguishing factor for declining to find liability based on Verizon's alleged refusal to deal. In its motion to dismiss, Celgene argued that in light of *Aspen Skiing* and *Trinko*, Mylan should be required to allege both a prior course of dealing, *and* that Celgene intentionally forsook short-run profits in favor of long-term anticompetitive gain, in order to invoke the exception to the general rule against affirmative antitrust duties.

Mylan argued in opposition to the motion to dismiss that the fact that Celgene makes samples available to non-competitors and Mylan has offered to pay full retail value for the samples indicate that Celgene's sole reason for refusing to provide the samples was to keep Mylan from entering the market. Mylan also observed that by withholding the samples, Celgene had "immunized" itself from a Hatch-Waxman challenge to the validity of its patents. The Federal Trade Commission filed a brief as amicus curiae regarding Celgene's motion to dismiss, arguing that Mylan's allegations stated a plausible claim for antitrust liability and suggesting that refusing to sell to generic rivals may constitute illegal exclusionary conduct that would undermine the objectives of the Hatch-Waxman Act.

At the oral argument on the motion to dismiss, the district court indicated that it is likely a factual question whether Celgene is creating a pretext, in the form of its safety requirements, for refusing to sell the products directly to Mylan, referring to two other district court cases from within the Third Circuit that had denied similar motions to dismiss on that basis. (*Actelion Pharm. v. Apotex*, No. 12-5743, dkt. 90 (D.N.J. Oct. 21, 2013); *Lannett Co. v. Celgene Corp.*, No. 08-3920, dkt. 42 (W.D. Pa. Mar. 20, 2011).)

Celgene argued that just because the pro-competition policy of the Hatch-Waxman procedures for generic entry to the market might be frustrated in a case such as this, where a brand owner relies upon FDA regulations limiting distribution of dangerous drugs to would-be competitors, that should not create a new species of antitrust liability.

In an oral opinion delivered on Dec. 22, 2014, the District Court dismissed several of Mylan's claims, but denied Celgene's motion as to, inter alia, the Sherman Act Section 2 refusal to deal claims. The District Court held that there is "no question" that the existence, vel non, of a prior course of dealing between the parties is relevant to the question of Section 2 liability, but that in the absence of a Third Circuit opinion requiring a plaintiff to allege such a prior course of dealing, she would not impose that requirement at the motion to dismiss stage. Celgene sought certification to petition for interlocutory review of that decision as to the question, "Whether a prior, voluntary course of dealing is required to allege an actionable refusal to deal under Section Two of the Sherman Act, 15 U.S.C. § 2." The district court certified the question to the Court of Appeals, but in a summary order, the Third Circuit denied the petition for interlocutory appeal, leaving the parties to continue litigating in the District Court.

While this particular issue, as framed in this case, may not be particularly susceptible to repeated litigation insofar as there are only about 70 individual products subject to FDA-approved REMS protocols, it is of note that the Third Circuit declined the opportunity to join its sister circuits in addressing the legal significance of the presence or absence of a prior course of dealing in Sherman Act, Section 2 cases.

Whereas several Circuit Courts of Appeals have interpreted *Verizon v. Trinko*, 540 U.S. 398 (2004) to require a prior course of dealing in refusal-to-deal cases—(*In re Adderall XR Antitrust Litig.*, 754 F.3d 128 (2d Cir. June 9, 2014) ("the sole exception to the broad right of a firm to refuse to deal with its competitors comes into play only when a monopolist seeks to terminate a prior (voluntary) course of dealing with a competitor"); *Covad Communications v. BellSouth Corp.*, 374 F.3d 1044, 1049 (11th Cir. 2004)—the Third Circuit has not ruled directly on the issue.

The Third Circuit's denial of interlocutory review on the question suggests that it will tacitly condone district courts' denial of motions to dismiss that are predicated solely on a plaintiff's failure to allege a prior course of dealing, but will not join a burgeoning circuit split at this time. In the meantime, however, Celgene faces increased exposure on the antitrust front, in the form of a now-consolidated proposed class action alleging monopolization through anticompetitive interference for refusing to sell its products to generic manufacturers. *In re Thalomid and Revlimid Antitrust Litigation*, Civ. No. 14-6997). Celgene, once again, has moved for dismissal of refusal-to-deal claims. Stay tuned. ■