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FDA Publishes List of Drug Companies Accused of Hindering Generic Entry: Antitrust Implications

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On May 17, as part of the Trump Administration's stated goal to lower drug prices, the Food and Drug Administration (FDA) published a list of pharmaceutical companies that have allegedly refused to sell samples of their drugs to generic manufacturers. Secretary of Health and Human Services Alex Azar and FDA Commissioner Scott Gottlieb contend that refusals to provide generic manufacturers with samples needed to perform the bioequivalence testing required for generic approval hinder competition and lead to higher prices. Commissioner Gottlieb said that the agency has received 150 complaints from generic manufacturers relating to 20 to 30 drugs and is encouraging the Federal Trade Commission (FTC) to take enforcement action. The FDA's publication could also expose those on the list to enforcement actions by state attorneys general and to private class action lawsuits, and it implicates the unsettled question of whether innovator drug companies have a duty under the antitrust laws to deal with prospective generic rivals. We provide below an overview of the state of the law.

Background

Most “duty to deal” antitrust cases relating to sample sharing have involved drugs that are subject to FDA-mandated Risk Evaluation and Mitigation Strategies (REMS) Programs. The REMS process—which Congress created as part of the Food and Drug Administration Amendments Act of 2007—is designed to address issues involving the safety, abuse and diversion of selected pharmaceutical drugs. REMS programs often restrict drug distribution, for example by requiring pharmacies or wholesalers to distribute drugs only to certain qualified physicians or healthcare facilities. These restrictions become operative when the FDA concludes they are “necessary to ensure that the benefits of the drug outweigh the risks of the drug.”[1]

In many cases, REMS distribution restrictions can complicate a generic drug manufacturer's path to approval. The Hatch-Waxman Act sought to streamline that path by providing an abbreviated application process for generic drugs. Under those provisions, the generic manufacturer filing an Abbreviated New Drug Application (ANDA) need not prove that the drug is safe and effective for its intended use. Instead, the generic applicant need only show that its product is bioequivalent to a reference listed drug that has already satisfied the rigorous FDA clinical trial requirements. To

demonstrate bioequivalence, the generic manufacturers must obtain samples of the branded drug and provide comparative data on bioavailability. With no REMS restrictions in place, generic manufacturers normally purchase drug samples from wholesalers.

If the drug at issue is subject to a REMS distribution restriction, however, the generic manufacturer may be unable to do so. In these circumstances, the generic manufacturer will request that the branded drug company itself provide it with samples, squarely raising the question of whether the branded company has an antitrust duty to do so. Not surprisingly, many innovator companies object to giving a potential rival samples because doing so would aid that rival's efforts to challenge the innovator's patents and to free ride off the innovator's massive research and development investment. While some innovators have also expressed concerns about violating mandatory REMS requirements, the ability to refuse based on those safety or legal concerns is limited if the generic obtains a “safety determination letter” from the FDA, a process through which the FDA declares that sales of the branded drug to a generic company do not violate or implicate FDA regulations regarding distribution. (For 20 of the branded drugs about which the FDA said it has received complaints, the FDA had issued a safety determination letter.)

Caselaw

There is limited caselaw addressing whether innovator drug companies must deal with generic challengers under Section 2 of the Sherman Act. The Supreme Court has long resisted imposing on market participants, including monopolists, duties to aid rivals for fear that such rules would dampen, rather than enhance, competition.[2] To date, however, the few district courts that have considered the issue have refused to adopt the broad proposition that brands have no antitrust duty to provide samples. Defendants in those cases argued that there could be no such duty because there was no preexisting voluntary course of dealing between the innovator and the generic, which they argued was a prerequisite for the limited antitrust duty to deal recognized by the Supreme Court in Aspen Skiing and Trinko.[3] The district courts have held instead—as the FTC advocated—that a prior course of dealing is not a requisite for antitrust liability, and it can be sufficient that the innovator sacrificed short-term profits by refusing to sell the drug to the generic at market prices with no valid business justification.[4] Whether these decisions are consistent with the relevant Supreme Court authority is debatable, and it remains to be seen whether other courts, including appellate courts, will follow suit.[5]

While these initial district court opinions have opened the door to antitrust claims based on refusals to sell samples to generics, such claims still face significant obstacles. First, the plaintiff must plead and prove an actual refusal to deal and the unavailability of the samples through other means. For example, one court recently granted a motion to dismiss because the generic company did not adequately plead it was unable to obtain the samples without undue burden, such as by partnering with a qualified physician performing clinical studies.[6] Moreover, the plaintiff still needs to prove the basic elements of a monopolization claim under Section 2, including that the innovator company possesses monopoly power. As the Third Circuit's decision in Doryx demonstrates, this is a case-by-case, fact-intensive analysis.[7]

Private litigants seeking damages face still another important hurdle: causation. To satisfy the

requirements of Section 4 of the Clayton Act, the plaintiff must prove that but for the alleged refusal, the generic product would have reached the market earlier, leading to lower prices for consumers.[8] As an initial matter, given that brand-name drugs enjoy various periods of marketing exclusivity, it may be difficult for a plaintiff to establish that any delay in getting access to a sample was the proximate cause of a delay in generic entry. In addition, the Third Circuit's decision in Wellbutrin suggests that antitrust plaintiffs may also need to prove that it was more likely than not that the generic challenger would have succeeded in its challenge to the relevant patents covering the brand drug.[9]

Conclusion

Given the absence of any appellate law on point, and the relative paucity of district court law, Commissioner Gottlieb's list may encourage the FTC, state attorneys general and private plaintiffs to pursue litigation. Assessing exposure to such claims requires a careful analysis to determine (1) whether the drug is truly unavailable to the generic, (2) whether market conditions likely show the brand has monopoly power, and (3) whether private antitrust plaintiffs would be able to establish the requisite causation to support a treble damages claim.

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1. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 505.1, 121 Stat. 823, 926 (codified as amended at 21 U.S.C. § 355-1(a)).

2. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 600 (1985); *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, L.L.P.*, 540 U.S. 398, 407 (2004).

3. *Id*.

4. *See e.g.*, Brief for Fed. Trade Comm'n as Amicus Curiae, *Mylan Pharmaceuticals, Inc. v. Celgene Corporation* (FTC Amicus), No. 14-2094 (D.N.J. June 17, 2014); *see also*, Order of Dismissal, Actelion, No 1:12-cv-05643 (D.N.J. Feb. 28, 2014); Transcript of Proceedings, Actelion, No. 1:12-cv-05743 (D.N.J. Oct. 17, 2014) and *Helicopter Trans. Servs., Inc. v. Erickson Air-Crane Inc.*, No. 06-3077-PA, 2008 WL 151833, at *9 (D. Or. Jan. 14, 2008) (holding that the fact of no prior course of dealing was “immaterial” as “the Supreme Court has never held that termination of a preexisting course of dealing is a necessary element of an antitrust claim.”).

5. Moreover, although some courts have effectively immunized refusals to supply a patent-protected product, In re Independent Service Organizations Antitrust Litig., 203 F.3d 1322, 1328 (Fed. Cir. 2000), the Bolar Amendment immunizes from infringement claims testing necessary to support ANDAs, which some contend undermines arguments that an innovator's prerogative to exercise its patent rights immunizes refusals to supply patented drug samples for testing. Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271(e)(1)). The Bolar Amendment overruled *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d (Fed. Cir. 1984), which had held that a generic company's use of a patented article for testing purposes constituted infringement. *See also* FTC Amicus at 19-20 (arguing that the Bolar Amendment reinforces an antitrust duty to deal).

6. *Natco Pharma Ltd. v. Gilead Sciences, Inc.*, No. 14-3247, 2015 WL 5718398, at *5 (D. Minn. Sept. 29, 2015).

7. *Mylan Pharms. Inc. v. Warner Chilcott Pub Ltd. Co.*, 838 F.3d 421, 435 (3d Cir. 2016).

8. In re Wellbutrin XL Antitrust Litig., 868 F.3d 132, 153 (3d Cir. 2017).

9. *Id*. at 169.

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