Beyond Pay-for-Delay: Three Pharma Antitrust Cases To Watch In 2017

By Chad J. Peterman, Evan D. Diamond & Edwin Mok

While courts continue to grapple with the implications of the Supreme Court’s landmark decision in *FTC v. Actavis, Inc.*,¹ the potential for antitrust scrutiny in the pharmaceutical context is not confined to so-called “pay-for-delay” situations. As exemplified by the following three cases to watch for 2017, there are a wide variety of alleged activities that are drawing the antitrust attention of both private litigants and government entities.

**Exclusive API Supply Agreements: Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC, No. 16-4544 (D.N.J.)**

On February 10, 2017, the district court for the U.S. District of New Jersey refused to dismiss Fresenius’s allegations that Par unlawfully restricted the supply of vasopressin — the active pharmaceutical ingredient (“API”) in Intravenous Vasopressin Injection (“IVI”) products — by entering into exclusive deals with Drug Master File (“DMF”) holders for vasopressin API. Both Fresenius and Par had previously marketed IVI as an unapproved drug, but after the FDA encouraged unapproved drug-makers to comply with approval provisions, Par was the first to obtain approval. As alleged by Fresenius, Par then campaigned the FDA to force Fresenius’s unapproved version off the market, and due to Par’s alleged exclusive deals with two of the three available DMF holders for vasopressin API, Fresenius was unable to submit an ANDA for approval of its IVI product.²

The district court has thus far allowed Fresenius’s case to move forward, finding that its allegations of monopolization, attempted monopolization, conspiracy, unlawful exclusive dealing, and unlawful group boycott, as well as a state tortious interference claim, were sufficiently well-pled to survive Par’s motion to dismiss.³

**Pharmaceutical Testing Standards: Amphastar Pharmaceuticals, Inc. v. Momenta Pharmaceuticals, Inc., No. 16-2113 (1st Cir.)**

In July 2016, antitrust defendants Momenta Pharmaceuticals and Sandoz prevailed when the district court for the U.S. District of Massachusetts granted their motion to dismiss the plaintiffs’ claims under the Sherman Act⁴ and California state law regarding alleged restraint of trade in the manufacture and sale of generic enoxaparin, an anticoagulant.⁵ The alleged anticompetitive conduct arose when the U.S. Pharmacopeial Convention (“USP”), a pharmaceutical standards-setting organization, started a process to establish standards for testing enoxaparin products. Momenta Pharmaceuticals participated in this process through an employee representative — but allegedly failed to disclose to the USP that it owned a pending patent application covering part of the testing method that was proposed and
ultimately accepted. The FDA subsequently made enoxaparin approval contingent upon adoption of the USP standard. Shortly after Amphastar obtained approval for and began marketing its enoxaparin product, Momenta and its exclusive licensee Sandoz sued for infringement of the patent covering the USP standard testing process, and obtained a preliminary injunction against Amphastar.\textsuperscript{6}

In dismissing Amphastar’s antitrust case, the district court held that because Amphastar’s alleged injuries flowed from government action — the FDA’s adoption of the USP standard — rather than directly from Momenta’s alleged nondisclosure of its pending patent application to the USP or its agreement with Sandoz, the antitrust claims were barred by the Noerr-Pennington doctrine.\textsuperscript{7}

Amphastar appealed in September 2016, arguing that the district court inappropriately expanded the scope of Noerr-Pennington immunity, whereas Momenta has countered that the doctrine was properly applied. The First Circuit heard oral argument on February 9, 2017.

**Generic Drug Pricing Collusion: Connecticut v. Aurobindo Pharma USA, Inc., No. 16-2056 (D. Conn.)**

On December 15, 2016, twenty states filed a complaint against six generic manufacturers in the district court for the U.S. District of Connecticut, alleging that, in violation of Section 1 of the Sherman Act, drug-makers Heritage, Mylan, and Mayne had conspired to divide the market for generic doxycycline, an antibiotic, and that Heritage, Teva, Aurobindo, and Citron had conspired to fix prices for glyburide, a diabetes drug.\textsuperscript{8} The complaint came on the heels of the U.S. Department of Justice’s December 14, 2016 unsealing of felony charges against two of Heritage’s former top executives for criminal conspiracy under the Sherman Act in relation to the same two drugs (the two accused pled guilty on January 9, 2017). On February 14, 2017, the district court granted the parties’ joint motion allowing the plaintiffs to file an amended complaint adding additional plaintiff states and claims.\textsuperscript{9}

Each of these three cases arose from alleged interactions between drug-makers and various industry players: API suppliers; a standard-setting body and the FDA; and numerous drug-makers. The cases highlight the need for pharmaceutical companies to be aware of the possible antitrust implications of their interactions and strategies with players across the industry — especially important in light of today’s competitive environment. We will be tracking these antitrust cases (and others) with interest over the course of this year.

If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings New York lawyers:

<table>
<thead>
<tr>
<th>Name</th>
<th>Phone Number</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chad J. Peterman</td>
<td>1.212.318.6797</td>
<td><a href="mailto:chadpeterman@paulhastings.com">chadpeterman@paulhastings.com</a></td>
</tr>
<tr>
<td>Evan D. Diamond</td>
<td>1.212.318.6004</td>
<td><a href="mailto:evandiamond@paulhastings.com">evandiamond@paulhastings.com</a></td>
</tr>
</tbody>
</table>

Patent and antitrust trial lawyer in the Paul Hastings New York office
1 133 S.Ct. 2223 (2013).
3 Id. at 6-10.
7 “The [Noerr-Pennington] immunity doctrine protects valid efforts to elicit favorable government action from antitrust liability even if the ultimate purpose or incidental consequence of the efforts is an anti-competitive restraint on trade.” 2016 WL 4033107, at *4-6 (citing Eastern R. R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 137 (1961) and Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 499 (1988)).
8 Connecticut v. Aurobindo Pharma USA, Inc., No. 16-2056, D.I. 1, Complaint at 34-35 (D. Conn.).
9 See Connecticut v. Aurobindo Pharma USA, Inc., No. 16-2056, D.I. 144, Order (D. Conn.).