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Life Sciences & Antitrust: Cases to Watch in 2018

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The intersection of complex drug competition frameworks and the antitrust laws continues to grow. With increased collaboration between the Food and Drug Administration and the Federal Trade Commission on the horizon, acts taken in the life sciences industry may be under greater scrutiny.¹ In this article, we discuss three cases to watch in 2018 as antitrust principles impacting pharmaceutical companies continue to develop.

Antitrust Meets the Biosimilars Market

In the first antitrust case between a biologic sponsor and biosimilar maker, Pfizer filed suit in the U.S. District Court for the Eastern District of Pennsylvania on September 20, 2017 alleging that Johnson & Johnson (“J&J”)—sponsor of the blockbuster biologic Remicade[®] (infliximab)—engaged in a plan to keep Pfizer’s biosimilar version of the product off the market.² After Pfizer’s Inflectra[®] (infliximab-dyyb) became the second biosimilar approved under the Biologics Price Competition and Innovation Act (“BPCIA”), J&J commenced its “Biosimilars Readiness Plan” to protect market share. According to Pfizer, the plan involves exclusive contracts with insurance companies consisting of reimbursement schemes, explicit promises not to cover Inflectra[®], and bundling arrangements. Pfizer asserts that the contracts have resulted in Inflectra[®] not appearing on the insurance company’s medical policy or, in the alternative, being designated as a “fail first” product—i.e., only reimbursed if Remicade[®] was first tried, but failed.

In a motion to dismiss filed on November 28, 2017, however, J&J argues the complaint fails because, *inter alia*, Pfizer has alleged no facts showing it has attempted to compete for insurance company reimbursements through multi-product bundling incentives or by offering net prices for Inflectra[®] that are lower than Remicade[®]. J&J further argues that any delay in market uptake for Inflectra[®] is not due to anticompetitive acts, but rather, market forces that cut against immediate adoption for a biosimilar to Remicade[®], such as competition in approved indications, lack of interchangeable designation, and the possibility that physicians are not as familiar with biosimilars. In response, Pfizer argues it need not allege an inability to employ its own bundles and that it has sufficiently alleged a multifaceted scheme by J&J to foreclose Inflectra[®] biosimilar competition through exclusive dealings.

While the Supreme Court and Federal Circuit have interpreted various provisions of the BPCIA, courts have yet to grapple with the economic nuances in the nascent biosimilars market. As this case develops, the court is likely to address how the intricacies of biosimilar competition impact the application of the antitrust laws.



FTC Scrutinizes Citizen Petition Process

In a case that Acting Chairwoman Maureen Ohlhausen has long been interested to pursue,³ the FTC filed a first-of-its-kind lawsuit based on serial petitioning. On February 7, 2017, the FTC alleged that, in violation of Section 5(a) of the FTC Act, Shire ViroPharma Inc. (“ViroPharma”) engaged in unfair competition by serially petitioning the FDA in an attempt to delay generic approval of Vancocin[®] HCl Capsules used to treat colitis.⁴ Seeking to invoke its power to enjoin ViroPharma from filing additional petitions, the FTC’s complaint highlights 43 regulatory filings and 3 lawsuits against the FDA within a six-year span. In a still-pending motion to dismiss filed on April 10, 2017, however, ViroPharma argues that its 46 petitions are constitutionally protected speech under the First Amendment’s *Noerr-Pennington* doctrine, which immunizes petitioning activity from antitrust scrutiny.⁵ While there has long been a sham exception to *Noerr-Pennington*, the ViroPharma case raises a core issue at the intersection of product development, life cycle management strategies, competition, and free speech: whether a brand company’s strategy to challenge the approvability of a proposed generic transitions from constitutionally protected speech to anticompetitive behavior merely based on the numerical volume of petitions filed, regardless of the petition’s content.

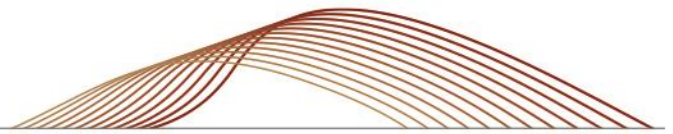
Given the ever changing regulatory system and ongoing changes at the FDA under Commissioner Scott Gottlieb’s leadership, life sciences companies with expertise on specific matters may wish to petition the agency. Moving into 2018 and beyond, the ViroPharma case is likely to illustrate whether certain petitioning strategies will fall outside the scope of traditional *Noerr-Pennington* protections and illuminate the extent to which current FTC leadership will pursue FDA-related issues.

Settlements, States, and the Eleventh Amendment

In *In re Flonase Antitrust Litigation*, the U.S. Court of Appeals for the Third Circuit ruled the Eleventh Amendment shielded Louisiana from GlaxoSmithKline’s efforts to enforce a prior settlement with a class of private indirect purchasers to which Louisiana did not opt out.⁶ After years of litigation, GSK settled antitrust claims brought by a class of private indirect purchasers in 2013. During that process, Louisiana—an indirect purchaser of Flonase[®]—had received notice of the class certification as required by the Class Action Fairness Act of 2005 (“CAFA”), but declined to opt out. In December 2014, however, Louisiana’s Attorney General filed suit against GSK in state court alleging the same antitrust claims resolved in the prior class settlement. In response, GSK filed suit in federal court to enforce that settlement.

On December 22, 2017, the Third Circuit declined GSK’s motion, reasoning that by attempting to enjoin Louisiana from pursuing a claim in its own state court, this qualified as a suit seeking an equitable remedy against a state, thereby implicating Louisiana’s sovereign immunity protections under the Eleventh Amendment. Moreover, although Louisiana was notified of the 2013 indirect purchaser settlement and declined to opt out of the class, the Third Circuit held Louisiana’s silence was insufficient to waive sovereign immunity, as failing to opt out was not a clear intention of waiver given that class notifications under CAFA impose no duties on state officials.

GlaxoSmithKline filed for en banc review on January 5, 2018, arguing, *inter alia*, that the panel’s ruling invites all 50 states to re-litigate settled claims. The development of this issue is important because class-action defendants in the life sciences industry are now routinely facing multiple waves of antitrust plaintiffs: from purchasers, to competitors, to the FTC, to State Attorneys General. Under the Third Circuit’s holding in *In re Flonase*, life sciences companies may now be exposed to antitrust claims brought by all 50 State Attorneys General in their respective states, even though the state had been notified of a class to which it belongs is in the process of settling, but did not opt out.



In all three cases, important antitrust issues are developing that will impact the life sciences industry. Whether the application of antitrust principles in the context of biosimilar competition, *Noerr-Pennington's* protection of a multi-petition strategy, or the potential for costly waves of antitrust cases brought by State Attorneys General despite a prior settlement, these cases highlight the need for pharmaceutical companies to assess the antitrust implications of their strategies. Paul Hastings 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 the following Paul Hastings New York lawyer:

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¹ See FTC Workshop, *Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics* (Nov. 8, 2017), <https://www.ftc.gov/news-events/events-calendar/2017/11/understanding-competition-prescription-drug-markets-entry-supply>.

² *Pfizer Inc. v. Johnson & Johnson*, Case No. 17-4180 (E.D. Pa. Sept. 20, 2017).

³ Maureen Ohlhausen, Remarks, *The First Wealth is Health: Protecting Competition in Healthcare Markets* 4-5 (Nov. 16, 2017), https://www.ftc.gov/system/files/documents/public_statements/1275573/mko_fall_forum_2017.pdf.

⁴ *FTC v. Shire ViroPharma Inc.*, Case No. 17-0131 (RGA) (MPT) (D. Del. Feb. 7, 2017).

⁵ *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965).

⁶ 2017 WL 6544107 (3d Cir. Dec. 22, 2017) (precedential).

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