

Alert Memo: Fifth Circuit Upholds FTC’s Impax Decision in First Fully Litigated Post-Actavis Reverse Payment Decision

April 23, 2021

On April 13, the U.S. Court of Appeals for the Fifth Circuit affirmed the Federal Trade Commission’s decision that Impax Laboratories entered an anticompetitive “reverse payment” settlement with Endo Pharmaceuticals. This case was the FTC’s first fully litigated reverse payment case since the Supreme Court’s 2013 decision in *FTC v. Actavis* holding that reverse payment settlements can violate the antitrust laws.

Background

In 2016, the FTC alleged that Impax entered an illegal “reverse payment” settlement agreement with Endo in 2010 that delayed generic entry by more than two years in exchange for payments worth over \$100 million. Specifically, the FTC alleged that Impax could have entered with a generic version of extended-release oxymorphone to compete with Endo’s Opana ER product in mid-2010, but instead agreed to delay entry until January 1, 2013. In return, Endo agreed (1) to not sell an authorized generic version of Opana ER for 180-days after Impax launched its generic; (2) to pay Impax in cash if revenues for Opana ER fell by more than 50% prior to Impax’s launch; and (3) to make up to \$40 million in payments to Impax in connection with a purported collaboration to develop a treatment for Parkinson’s disease. The FTC also alleged that during the period of delayed entry, Endo sought to “product hop” by switching patients from Opana ER to a reformulated version. Endo had previously settled FTC charges. Impax did not settle, and instead argued that the FTC had failed to meet its burden under the rule of reason.

If you have any questions concerning this memorandum, please reach out to your regular firm contact or the following authors

WASHINGTON

Kenneth Reinker
+1 202 974 1743
kreinker@cgsh.com

Bruce Hoffman
+1 202 974 1784
bhoffman@cgsh.com

Kathleen Bradish
+1 202 974 1686
kbradish@cgsh.com

George Cary
+1 202 974 1920
gcary@cgsh.com



The FTC brought suit in the FTC’s internal administrative courts. In the initial proceeding, an Administrative Law Judge (“ALJ”) found that the settlement restricted competition but held that the procompetitive benefits outweighed anticompetitive effects. Specifically, the ALJ credited the fact that the settlement ended litigation and gave consumers access to generic Opana ER starting in January 2013, nine months before expiration of the initial patents and sixteen years before the expiration of Endo’s after-acquired patents. Further, the ALJ noted that Endo could have asserted its later-acquired patents against Impax, as it had enjoined other unlicensed generic manufacturers. The ALJ characterized the anticompetitive harms alleged by the FTC as “largely theoretical,” and found in favor of the “substantial” procompetitive benefits.

The FTC staff appealed the decision to the Commission. The Commission reversed after it determined that Impax failed to show the settlement had any procompetitive effects because the purported benefits of the settlement could have been achieved by settling without a reverse payment for delayed entry.

Impax’s Appeal to the Fifth Circuit

Impax appealed. An appellant from an FTC decision can appeal to the circuit court of its choice, and Impax chose to appeal to the Fifth Circuit. Still, the Fifth Circuit ruled against Impax and affirmed the Commission’s decision in all respects.

Standard of Review. The Fifth Circuit held that while the Commission’s legal findings were granted “some deference,” its factual findings would be affirmed so long as they are supported by “substantial evidence,” which the Court described as “even less than a preponderance” standard and similar to review for a jury verdict. In this case, it does not seem that the standard of review drove the Court’s decision and Impax seems likely to have lost even if a less deferential standard were applied. It is important to

note, however, that the highly deferential standard of review to FTC fact-finding reiterated in the Fifth Circuit’s decision could be outcome-determinative. That is especially likely in merger cases or unilateral conduct cases that will often be factually complex and where the legal conclusions are likely to depend on debatable factual judgments and the weighing of legitimate procompetitive benefits against potential anticompetitive effects.

Existence of a Large Reverse Payment. Impax did not challenge the determination that there was a large reverse payment. The Court noted it was obvious that there was a reverse payment in light of Endo’s commitment “to not market an authorized generic, which increased Impax’s projected profits by \$25.5 million.”¹ The Court also considered Endo’s commitment to pay Impax cash credits for the shrunken market Impax could have inherited if Endo’s “product hop” to reformulated Opana ER succeeded, and noted “[t]he \$102 million Endo ultimately paid is likely a good approximation of the parties’ expected value for these credits.”² Regarding the research collaboration for the treatment of Parkinson’s, the Court observed that “even assuming that the collaboration is relevant and that the \$10 million Parkinson’s research agreement constituted payment for services, over \$100 million of Endo’s payment remains unjustified.”³ The Court concluded that “[t]he size of these payments is comparable to other cases where courts have inferred anticompetitive effect.”⁴

Anticompetitive Effects. Impax argued that any anticompetitive effects were reduced by the fact that Endo’s attempted “product hop” failed when the reformulated product was taken off the market due to safety concerns. The Court first noted the “basic antitrust principle” that the impact of an agreement is assessed as of the time it was entered into and thus that subsequent developments were not relevant to the liability determination. Examining the facts “as they existed when the parties adopted the settlement,” the

¹ *Impax Labs., Inc. v. FTC*, 2021 U.S. App. LEXIS 10555, at *18-19 (5th Cir. 2021).

² *Id.*

³ *Id.* at *20.

⁴ *Id.*

Court determined that “Endo agreed to make large payments to the company that was allegedly infringing its patents,” and that “[i]n exchange, Impax agreed to delay entry of its generic drug until two-and-a-half years after the FDA approved the drug.”⁵

Lack of Procompetitive Benefit Given a Less Restrictive Alternative. Finally, the Court found it did not need to assess whether there were procompetitive benefits because any of the purported procompetitive benefits from Endo granting licenses to Impax could have been achieved with a less restrictive alternative. The Court noted any reverse payment would normally be expected to result in a later entry date and held that Endo and Impax could instead have simply negotiated a settlement with an earlier entry date without a reverse payment.

Takeaways

The *Impax* case is important as the first fully litigated FTC decision following *Actavis*. The Fifth Circuit’s holdings are consistent with the holdings of other courts of appeal, including for example the Third Circuit’s recent holding in *FTC v. AbbVie* that a favorable supply agreement could be a reverse payment under *Actavis*⁶ and the First Circuit’s holding in *In re Loestrin 24 Fe Antitrust Litig.* that “no-AG” agreements or licenses can be reverse payments.⁷

The *Impax* cases and other recent precedent provide some takeaways:

- The best way to eliminate antitrust risk in a patent settlement is to negotiate solely over early entry that reflects the strength of the patents.
- Any reverse payment will likely be viewed as delaying entry, unless limited to litigation costs. Thus, when there is a large reverse payment, it is

extremely difficult for defendants to argue that competition was not eliminated.

- Any exchange of value regardless of the form might be actionable as a reverse payment. That includes “no-AG” agreements,⁸ payments for purported collaboration agreements, favorable supply agreements, agreements to settle damages claims at substantially less than they are worth,⁹ and more.
- The argument that reverse payment settlements are procompetitive because they provide a date for generics to enter and provide the patent licenses to the generic is unlikely to succeed. There is a readily-available less restrictive alternative in negotiating only over the entry date without a payment. What requires a procompetitive justification is not the entry date or the licenses, but rather the reverse payment itself.
- As to liability, whether an agreement is procompetitive or anticompetitive is assessed at the time of the agreement. However, note that to recover damages, private plaintiffs must also demonstrate that they suffered an injury, causation, and damages. The *Impax* opinion thus should not prevent defendants from raising these arguments in defense in private cases. For example, in *In re Wellbutrin XL Antitrust Litigation*, the Third Circuit denied plaintiffs antitrust standing on a reverse payment claim where the evidence showed that the generic would still have been blocked by other patents.¹⁰

Conclusion

As the first fully litigated FTC reverse payment case, *Impax* represents the culmination of FTC efforts to challenge “reverse payments” that have been ongoing

⁵ *Id.* at *25.

⁶ *FTC v. AbbVie Inc.*, 976 F.3d 327, 356 (3d Cir. 2020).

⁷ *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 551-52 (1st Cir. 2016).

⁸ See e.g., *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 404 (3d Cir. 2015).

⁹ See *In re Lipitor Antitrust Litig.*, 46 F.Supp.3d 523, 543 (D.N.J. 2014), *rev’d on other grounds*, 868 F.3d 231 (3d Cir. 2017).

¹⁰ *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 165 (3d Cir. 2017).

for over a decade. In that time, the FTC has achieved many of its goals: The FTC won a significant Supreme Court victory in *Actavis*, reverse payments have largely disappeared from pharmaceutical settlements,¹¹ and the FTC has secured major settlements and now a major litigation victory. The FTC's success has also generated a large number of private lawsuits concerning reverse payments. The FTC continues to litigate a reverse payment in the *FTC v. AbbVie* case, but it is otherwise unclear whether reverse payment cases will continue to comprise a large part of the FTC's health care enforcement docket.

...

CLEARY GOTTLIB

¹¹ See e.g., FTC BUREAU OF COMPETITION, OVERVIEW OF AGREEMENTS FILED IN FY 2017.