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The US Court of Appeals for the Fifth Circuit upholds the FTC's ruling regarding an unlawful pay-for-delay agreement in the pharmaceutical sector *(Endo / Impax)*

ANTICOMPETITIVE PRACTICES, AGREEMENT (NOTION), BURDEN OF PROOF, PHARMACEUTICAL, JUDICIAL REVIEW, EFFECT ON COMPETITION, UNITED STATES OF AMERICA, PAY-FOR-DELAY

US Court of Appeals for the Fifth Circuit, *Endo / Impax*, Case no. 19-60394, 13 April 2021
US FTC, *Endo / Impax*, Press release, 13 April 2021

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On April 13, 2021, the U.S. Court of Appeals for the Fifth Circuit upheld the Federal Trade Commission's ("FTC" or "Commission") ruling that the "reverse-payment" settlement agreement between Endo Pharmaceuticals Inc. ("Endo") and Impax Laboratories LLC ("Impax") violated federal antitrust laws. The Fifth Circuit's decision—which upholds the FTC's first fully-litigated reverse-payment case since the Supreme Court's landmark 2013 ruling in *FTC v. Actavis* ("*Actavis*")—found the FTC's findings that Endo and Impax entered into an unlawful "pay-for-delay" agreement to be supported by "substantial evidence." Significantly, the panel also rejected Impax's primary argument that the FTC needed to do more under the rule of reason to balance the anticompetitive conduct against procompetitive justifications—namely that the FTC needed to evaluate the strength of the patents at issue and assess whether it was likely Impax would have entered the market earlier absent the settlement. The court "disagree[d] that *Actavis* requires the Commission to assess the outcome of the patent case in order to find anticompetitive effects"—focusing heavily on the mere size of the alleged payment—and found the fact that generic competition was "possible" absent the settlement, combined with the large payment, was enough to infer anticompetitive effect under the framework outlined in *Actavis*.

The Fifth Circuit's decision leaves in place the FTC's cease-and-desist order enjoining Impax from entering similar reverse-payment settlements going forward (as the decision noted, the FTC did not invalidate Impax's agreements with Endo or impose any monetary sanctions). But the impact of the decision on the industry as a whole—and courts' treatment of patent settlements—may be widespread. Indeed, according to the FTC's acting chair Rebecca Slaughter, the panel's decision represents an "important milestone in the decades of work by FTC staff to stop pay-for-delay agreements." And while it remains to be seen how courts (particularly courts in other circuits) will

view this decision—and in particular, the Fifth Circuit's interpretation of the guidance set out in *Actavis*—the ruling here will certainly have an impact on how parties approach settlement agreements to resolve Hatch-Waxman suits in the future.

Background and FTC Decision

Endo, the brand-name pharma company in this case, began selling an extended-release formulation of oxymorphone (an opioid) called Opana ER in 2006. In 2007, Impax filed the first application to market generic extended-release oxymorphone. At the time, two of Endo's patents for Opana ER would not expire until September 2013, and Endo sued Impax for patent infringement in January 2008. Under the Hatch-Waxman Act, this would delay any FDA approval of the generic for 30 months—until June 2010—unless the litigation concluded earlier in Impax's favor.

Early settlement talks between the two companies failed, and Endo purportedly projected that generic entry would cut Opana ER sales by 85 percent and cost it approximately $100 million in revenue within six months. Separately, Endo also planned to move customers to a new reformulated version of Opana ER that would be protected by new patents and not be therapeutically equivalent to Impax's generic, thus precluding pharmacists from automatically substituting the generic in place of the brand when filling prescriptions—a move known as a product transition or "product hop." But the success of Endo's product hop depended on the reformulated Opana ER getting to market sufficiently in advance of Impax's generic product.

Endo also allegedly projected that the reformulated Opana ER would generate about $200 million in annual sales by 2016 if the market transitioned to the reformulated product before the generic entered, but only $10 million annually if the generic entered first. In June 2010, with the possible launch date for Impax's generic imminent, the parties settled the patent litigation shortly after the patent infringement trial began and less than a week before the FDA granted final approval to Impax's generic product.

Under the settlement, Impax agreed to delay launching its generic until January 2013—two and a half years after it otherwise could have entered at risk, but several months before certain patents for Opana ER expired. In return, Endo agreed not to market its own generic version of extended-release oxymorphone until after Impax's 180-day Hatch-Waxman exclusivity period expired in July 2013, and it agreed to pay Impax a credit if sales revenue for the original formulation of Opana ER fell by more than 50 percent between the dates of settlement and the date of Impax's entry. The agreement to provide Impax with the credit protected Impax if Endo transitioned its customers to the reformulated Opana ER; which Endo did in March 2012, resulting in a $102 million credit to Impax.

In January 2017, the FTC brought separate actions against Endo and Impax alleging that the settlements was an "unfair method of competition" in violation of Section 5 of the FTC Act and an unreasonable restraint of trade under the Sherman Act. Endo settled, but Impax chose to litigate. The case proceeded in the FTC's administrative court.

In May 2018, following a three-week trial with 37 witnesses and over 1,250 exhibits, the FTC's administrative law judge ("ALJ") D. Michael Chappell concluded that although the reverse-payment agreement restricted competition, it was nonetheless lawful because "as a whole" its procompetitive benefits outweighed the anticompetitive effects because it allowed Impax to enter the market before the Opana ER patents would have expired. Specifically, he found that "the evidence proves that consumers have benefitted from the [Endo-Impax agreement] by having uninterrupted and continuous access to generic Opana ER since January 2013," and that the "real-world

effect procompetitive benefits of the Endo-Impax Settlement are substantial." Judge Chappell also found that any anticompetitive harm was "largely theoretical" because there was little chance of Impax entering the market earlier absent a settlement, and Impax would not have launched "at risk."

The full Commission reviewed the ALJ's decision de novo and reached an entirely different conclusion. The Commission unanimously reversed the ALJ, finding that to be procompetitive, the benefits of the "pay-for-delay" agreement must be directly linked to the restraint of competition to outweigh the proof that the restraint harms competition—which the Commission held was not the case here. The Commission further held that Impax's procompetitive justifications failed because there were less restrictive ways of achieving the purported benefits. Impax's appeal to the Fifth Circuit followed.

Fifth Circuit Decision

On appeal, the Fifth Circuit upheld the Commission's ruling, holding that the FTC had "substantial evidence" to conclude that the reverse payments replaced "the possibility of competition with the certainty of none." The panel found that the over $100 million in payments from Endo to Impax did not represent the fair value of services rendered or avoided litigation expenses, nor was it otherwise linked to the restraint of competition in a way that would outweigh the proof that the agreement harmed competition.

The opinion also rejected Impax's argument that the rule of reason required the FTC to do more to balance the harm with the procompetitive justifications—specifically, Impax contended that the FTC should have looked at the strength of the patents and assessed whether Impax could have entered the market earlier absent the settlement. The court held that *Actavis* does not require Impax's proposed analysis, and the fact that generic competition was "possible," combined with the large payment, was enough to infer anticompetitive effect. Indeed, in evaluating the parties' arguments, the panel placed great emphasis on the size of the payment in evaluating the settlement. And despite holding that the FTC was not required to assess the strength of the patents or predict the outcome of the patent infringement action, the panel nonetheless reasoned that if Endo was actually "highly likely" to prevail in the infringement suit, then Impax would have likely settled for early market entry only—without any payment at all. The more than $100 million Endo ultimately paid to Impax would have been a "windfall" if Impax was likely to lose the infringement suit. The court held that the "need [for Endo] to add that substantial enticement" indicates that at least some portion of the payment was for exclusion beyond the point that would have resulted from litigating the case to conclusion. In other words, the court found the objective of the payment to Impax was to delay its product so Endo could maintain supra-competitive prices for Opana ER, the profits from which it then shared with Impax rather than face a competitive market.

Impax also argued that, in hindsight, the settlement was not anti-competitive for two primary reasons. *First*, Endo obtained additional patents after the fact and has proven their validity in court. And *second*, Endo's alleged "product hop" ultimately failed because in 2017 Endo voluntarily withdrew the reformulated Opana ER from the market due to safety concerns. Impax's generic version of extended-release oxymorphone—which it began marketing in January 2013—is the only version available on the market today. But the Fifth Circuit rejected this argument as well, holding that it is "a basic antitrust principle that the impact of an agreement on competition is assessed at the time it was adopted," and that principle applies equally in reverse payment cases. So, the focus of the inquiry is on the facts as they existed when the parties adopted the settlement.

The panel concluded that because the payments at issue were unquestionably "large" and "[n]either the saved costs of forgoing a trial nor any services Endo received justified these payments," "[s]ubstantial evidence supports the Commission's finding that the reverse payment settlement threatened competition."

The panel next addressed the question of whether Impax could show procompetitive benefits, which the Commission concluded it could not. Although the ALJ concluded that the settlement benefitted competition, the Commission found that the procompetitive benefits did not "flow from the challenged restraint—the reverse payments themselves." As a result, the Commission did not treat Impax's ability to enter the market nine months before the patents expired as benefits to be weighed against the anticompetitive effects of the reverse payments. The Commission assumed *arguendo* that Impax could connect the settlement's purported procompetitive effects with the challenged restraint, but nonetheless determined that even if that was the case, there was a "less restrictive alternative" because "Impax could have obtained the proffered benefits by settling without a reverse payment for delayed entry."

Given the Commission's assumption, the panel reviewed only the "less restrictive alternative" finding—i.e., whether "substantial evidence" supports the Commission's conclusion that FTC's Complaint Counsel had established a less restrictive alternative. Impax argued that the evidence the FTC relied on was not probative of whether it in fact ever had the opportunity to enter in a no-payment settlement or could have done so. The panel nonetheless found that the FTC's findings—relying on "industry practice," as well as fact and expert witness testimony—would "allow a reasonable factfinder to conclude that the no-payment settlement was feasible." And because there was "more than enough evidence" to uphold the Commission's view that a less restrictive alternative was viable," the panel held that it "must uphold" the Commission's conclusion that the reverse-payment settlement was an agreement to preserve and split monopoly profits and amounted to an unreasonable restraint of trade.

Conclusion

The Fifth Circuit's opinion handed both the FTC and private plaintiffs a huge win in the years-long battle against purported "pay-for-delay" settlements. But the panel's interpretation of the guidance set out in *Actavis*—particularly the Supreme Court's guidance that only "large and **unjustified** payments" should be subject to antitrust scrutiny—potentially places outsized importance on the size of the alleged payment (and in effect treats the payment itself as the restraint), regardless of the strength of the patents at issue or the parties' valuations of the patent infringement action. This interpretation goes beyond what *Actavis* and other courts have held. And while the court's decision may have been impacted by the highly deferential and highly nebulous "substantial evidence" standard which the FTC is accorded in its appeals, the opinion will inevitably have a significant impact on future patent settlements.

In any event, this case may be a prime candidate for the Supreme Court to finally revisit *Actavis* and provide further clarification to the lower courts, as well as the pharmaceutical industry, regarding the balancing act courts must engage in as it concerns patent settlement agreements that may give rise to antitrust scrutiny. And with growing calls for antitrust reform, as well as the FTC's recently announced pharmaceutical mergers working group, these and other conduct challenges in the pharmaceutical sector are unlikely to leave the spotlight anytime soon.

See also Walid Chaiehloudj, Les Accords de Report d'Entrée, Concurrences, 2019