The Federal Trade Commission Slams Impax/Endo Reverse Payment Settlement

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On March 28, 2019, the Federal Trade Commission (the "Commission") issued a landmark opinion in the agency's case against Impax Laboratories Inc. regarding its patent settlement with Endo Pharmaceuticals Inc., marking the first time that the Commission has weighed in on the proper application of the Supreme Court's *Actavis* antitrust evaluation framework for "reverse payment" settlements.[i] Highlighting multiple *Actavis* "red flags," the Commission concluded that the settlement raised the precise antitrust concerns that led the Supreme Court to subject these types of agreements to antitrust scrutiny, which provided guidance to lower courts confronting these challenging and nuanced issues in future cases.

Factual Background

Endo received FDA approval and launched Opana ER in 2006. In 2007, Impax filed the first ANDA and paragraph IV certification for generic Opana ER. Under the provisions of the Hatch-Waxman Act, Endo sued Impax for statutory patent infringement, automatically staying FDA approval of Impax's ANDA for 30 months. After expiration of the stay in May 2010, the FDA tentatively approved Impax's ANDA. Endo's patent litigation against Impax continued, and the trial commenced June 3, 2010.

During the trial, the parties entered into two separate agreements, which settled the case.[2] In one agreement (the SLA), Impax agreed not to market generic Opana ER until January 2013, and Endo agreed: (1) not to sell an authorized generic during Impax's 180-day first-filer exclusivity period ("No-AG Commitment"); (2) to make a cash payment to Impax if the sales volume of Opana ER dipped below a certain level before January 2013 ("Endo Credit");[3] and (3) to license its current and future patents covering Opana ER to Impax and not to sue Impax for infringement of those patents. In the other agreement (the DCA), Endo agreed to make a $10 million payment to Impax within five days, plus up to $30 million in additional "Milestone Payments" for collaboration regarding the development and marketing of a potential Parkinson's disease treatment (and allocated profits if the drug was successfully marketed). Impax received final approval to market Opana ER days after Impax and Endo entered into these agreements.

Legal Standard

Reverse payment settlements are examined under the rule of reason, and the burden shifts between the plaintiff and the defendant. Because the *Actavis* Court explicitly left the task of structuring the rule of reason inquiry in the reverse payment context to lower courts,[4] *Impax Labs* allowed the Commission to weigh in on the proper analysis for the first time, and it took advantage of that opportunity to provide clear guidance for future cases.[5]

Under the rule of reason, the plaintiff first has the burden to prove that "the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market."[6] If the "plaintiff demonstrates anticompetitive harm, [then] the burden shifts to the defendant to show a procompetitive rationale for the restraint."[7] "If the defendant does so, the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could reasonably be achieved through less anticompetitive means." [8] If the plaintiff succeeds, the analysis ends, and the plaintiff prevails. If the plaintiff fails to meet this final burden, "the adjudicator proceeds to weigh the harms and benefits against each other to judge whether the challenged behavior is, on balance, reasonable."[9]

The Administrative Law Judge ("ALJ") Decision

The ALJ who tried the case for the Commission concluded that the No-AG Commitment plus the Endo Credit constituted a large and unjustified reverse payment, which when combined with Endo's market power constituted anticompetitive harm. [10] The ALJ also recognized that Impax's entry prior to patent expiration constituted a procompetitive benefit.[11] The ALJ weighed the procompetitive benefits (early entry) with the anticompetitive harm (which he concluded was "largely theoretical" because it was "unlikely" that Impax would have launched at-risk), and concluded that the settlement was not an unreasonable restraint of trade.[12]

The Commission Decision

Reviewing the ALJ's decision *de novo*, in a 5-0 decision written by Commissioner Noah Phillips, the Commission overturned the ALJ decision and found that the settlement constituted an unreasonable restraint of trade.

Anticompetitive Harm

In its analysis of whether the FTC Staff had demonstrated anticompetitive harm, the Commission first recognized that a large, unjustified payment made in exchange for deferring entry into the market or for abandoning a patent suit raises an inference of anticompetitive harm.[13] Such a payment may "provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim," as a reverse payment "would be an irrational act unless the patentee believed that generic production would cut into its profits."[14]

In determining whether a payment is large, the Commission held that all value that the branded drug manufacturer transfers to the generic through the settlement—"includ[ing] side agreements that contemporaneous timing or other circumstances indicate should be considered part of the same transaction"—must be considered as part of the payment. [15] Here, the value exchanged included: the No-AG Commitment (valued at $23-33 million to Impax), the Endo Credit (which ultimately resulted in Endo paying Impax $102 million), the cash payments under the DCA ($10 million upfront and up to $30 million later), and the value of the patent licenses granted to Impax.[16] The parties agreed that the patent licenses were procompetitive and therefore not part of the reverse payment. The Commission (in a partially redacted portion of its decision) decided not to include the DCA in its valuation of the reverse payment because it was not needed to reach its ultimate decision.[17] Thus, the reverse payment was the combined total value of the No-AG Commitment, the Endo Credit, and the cash payments under the DCA. The Commission found that this payment was unjustified because it exceeded the value of avoided litigation costs and fair value for services.[18]

But a large and unjustified reverse payment only raises an *inference* of anticompetitive harm, and the Commission went further. Because *Actavis* makes clear that anticompetitive harm occurs not just when competition is *actually* eliminated, but also when the *risk* of competition is eliminated, the Commission held that there was no need to evaluate whether it was "likely" that Impax would have entered before January 2013 (the date it agreed with Endo).[19] Instead, the question was whether the *risk* of competition had been eliminated by the agreement. Of course, when evidence establishes that the generic drug would have been brought to market earlier but for the agreement, there is clear anticompetitive harm.[20] In contrast, if the evidence reveals a clear impediment to generic launch, then something other than the agreement would have eliminated the risk of competition, and there would be no anticompetitive harm.[21]

Here, the Commission concluded that the evidence fell into a middle ground (no clear evidence that entry would have been earlier and no evidence of intervening causes delaying generic entry).[22] The Commission emphasized that "the relevant anticompetitive harm occurs when the branded manufacturer and its generic competitor *replace the possibility of competition with the certainty of none*."[23] Noting that there was "ample evidence" of a "real threat" of competition, including evidence that senior management had considered launching at risk and that Impax had taken steps to prepare to launch, the Commission found that the settlement agreement eliminated a plausible risk of competition from Impax.[24]

Procompetitive Justification

Having found anticompetitive harm, the Commission turned to the procompetitive justification – that Impax was permitted to enter the market with generic Opana ER nine months before the expiration of Endo's original patents and was protected from liability for infringement of later obtained patents.[25] However, the Commission rejected Impax's proffer of procompetitive benefits because it failed to link those benefits to the challenged restraint.[26] Importantly, the Commission reasoned that:

"because both the payment and the license… were benefits flowing to Impax, Impax readily could have accepted the license without also accepting a payment. Endo certainly would have been willing to give less…. The only reasonable explanation for the payment was that it prevented Impax from demanding an even earlier entry date, which demonstrates that the payment was anticompetitive, not procompetitive.[27] So, "[t]he appropriate question is whether Endo and Impax could have reached a similar licensing agreement without a reverse payment for delayed generic entry."[28]

Because Impax failed to meet its burden to show procompetitive benefits resulting from the reverse payment, the Commission found that the settlement agreement was anticompetitive,[29] and enjoined Impax from entering into any agreement that included either a No-AG Commitment by a brand manufacturer *or* a payment by a brand manufacturer to a generic manufacturer, in combination with an agreement by the generic company not to research, develop, manufacture, distribute, market, or sell a generic for any period of time.[30]

Analysis

Before counsel for pharmaceutical companies swoon into their chair cushions, it bears reminder that the settlement between Endo and Impax was reached in 2010, years before the Supreme Court's 2013 decision in *Actavis*. So, although the Supreme Court's decision in *Actavis* merely explained how "pay for delay" settlements could infringe existing antitrust laws under the rule of reason, counsel for these companies did not have the *Actavis* guidelines to settling pharmaceutical patent cases at the time of the Endo-Impax settlement.

That said, after *Actavis*, the Commission's decision in *Impax* should not be a surprise.[31] The Commission closely followed the Supreme Court's guidance in *Actavis* in coming to its decision. Payments *by* the patent holder (whether in the form of cash or agreements not to compete with an authorized generic) *to* the patent challenger remain inherently suspect.[32] A large, unjustified payment made in exchange for deferring entry into the market or for abandoning a patent suit raises an inference of anticompetitive harm.[33] And a decision to end a patent infringement lawsuit with an agreement to allow the alleged infringer to bring its alleged infringing generic drug to market prior to the expiration of the patent holder's patents is still procompetitive.[34]

What the Commission's decision in *Impax* makes clear is that an agreement to permit generic entry prior to patent expiration – a procompetitive allowance of competition – does not automatically render a settlement beyond scrutiny. As the Commission pointed out, if a patent holder is willing to allow competition despite its patents, then it should be willing to authorize just that – without *also* transferring value to the alleged infringer in the form of cash or an agreement not to compete with an authorized generic.[35] Impax's argument to the contrary underscores exactly why this logic holds: Impax twice proposed a settlement in which Endo would allow Impax to sell generic Opana prior to the expiration of the patents-in-suit, but without the no-AG and Endo Credit reverse payment provisions, and Endo rejected the proposal both times.[36] So Impax proposed that it enter prior to expiration of Endo's patents, and Endo's counterproposal was entry on the same date *plus* more value for Impax? Clearly not. Impax had proposed entry in July 2011, December 2011, or January 2012.[37] Endo rejected that, insisting on a later entry date (January 2013), but with a reverse payment to make up the difference to Impax. These facts evidence the very reason that reverse payments are suspect – "payments flowing in the 'wrong' direction signal that a settling party is being compensated for not competing when it otherwise might."[38] Combined with "ample evidence" of a "real threat" of competition, the reverse payment signals an agreement to eliminate that risk of competition.

Importantly, in overturning the ALJ's decision, the Commission also made clear that the party challenging the settlement does not need to prove that competition was *actually* eliminated – only that *the risk* of competition was eliminated.[39] FTC staff were not required to prove that Impax would have marketed generic Opana earlier but for the settlement agreement: "Requiring a fact-finder later to conclude whether and on what date competition would have occurred asks too much."[40] The point was that "[a]ntitrust liability can thus attach even where the parties entered into the settlement without knowing for certain that they were, in fact, eliminating competition…."[41]

Just as settlement is encouraged in other industries to avoid the costs and risks of ongoing litigation, the Commission made clear that procompetitive settlement agreements allowing earlier generic entry are common in the pharmaceutical industry,[42] and absent a reverse payment, they are not considered suspect. In fact, the Commission suggested that the entire premise behind *Actavis* is that there are feasible, less restrictive, and less anticompetitive ways to settle patent lawsuits. Thus, this line of case law does not stand for the proposition that pharmaceutical patent litigation should not be settled; if anything, the Commission emphasized that parties can settle patent lawsuits without triggering antitrust scrutiny.

Finally, the Commission's decision instructs that creative settlement terms that disguise a reverse payment are subject to scrutiny. The Commission followed a line of federal court decisions in finding that the payment does not need to be in cash form to raise *Actavis* concerns,[43] explaining that "[a]ny other result would ignore the economic realities of the settlement by disregarding forms of consideration that the brand conveyed. This could create a perverse incentive for settling parties to shield the sharing of the brand's monopoly profits through non-cash value transfers."[44] All value flowing in the "reverse" direction to the generic should be examined as potentially suspicious, including value exchanged through separate agreements, so long as the agreements are sufficiently linked.[45] Indeed, "peculiar circumstances" surrounding a contemporaneous side agreement may suggest the parties are trying to mask "value transferred in exchange for eliminating the risk of competition."[46]

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