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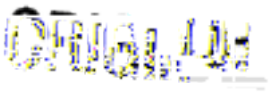

Markus H. Meier
Assistant Director

Bradley S. Albert
Deputy Assistant Director

Charles A. Loughlin
Chief Trial Counsel

Daniel W. Butrymowicz
Alpa D. Davis
Nicholas A. Leefer
Synda Mark
Lauren Peay
J. Maren Schmidt
Eric M. Sprague
Jamie Towey
James H. Weingarten
Rebecca E. Weinstein
Counsel Supporting the Complaint

Federal Trade Commission
Bureau of Competition
600 Pennsylvania Ave., NW
Washington, DC 20580
Telephone: (202) 326-2114
Email: cloughlin@ftc.gov

Cases

Other Authorities

Endo obtained additional patents claiming Opana ER beginning in late 2012 and started asserting them against other generic drug manufacturers. (FF.575-83). In 2015 and 2016, some of these patents were upheld and prevented other companies from marketing generic Opana ER. (FF.578, 585-87).

Despite obtaining the license to future patents, Impax did not avoid further litigation. In May 2016, Endo sued Impax for breach of the settlement agreement, contending that Impax had violated its obligation to negotiate a royalty for the later-acquired patents. (CCF ¶1421). Endo also claimed infringement of these patents. (CCF ¶1421).

In July 2017, Endo announced that it would comply with an FDA request that it voluntarily withdraw reformulated Opana ER from the market. (CCF ¶1429; F.111). Shortly thereafter, Endo and Impax settled the breach of contra

The Commission's January 2017 complaint charges that Impax agreed not to compete with Endo's Opana ER for 2½ years in return for a share of Endo's monopoly profits.[2] It further alleges that this agreement did not further any legitimate, procompetitive objective.

Following a three-week trial, Chief Administrative Law Judge D. Michael Chappell issued an initial decision on May 11, 2018. He found that Endo agreed to make a large reverse payment to Impax, "the purpose and effect of which was to induce Impax to give up its patent

challenge and agree not to launch generic Opana ER until January 2013." ID 6-7. But the ALJ ruled that the settlement agreement as a whole was procompetitive because it provided a license enabling Impax to sell its generic product even when Endo subsequently acquired additional patents and successfully enforced them against other generic drug companies. ID 7, 144-46, 157-58.

The ALJ's rule-of-reason analysis acknowledged that the relevant anticompetitive harm in a reverse-payment case is the branded drug firm's use of a large payment to prevent the risk of competition. ID 100. He then assessed the No-AG's value as of the settlement date, looking to contemporaneous evidence reflecting Impax's profit expectations as the sole generic seller for six months. ID 104-06. He concluded that the No-AG was worth $23-$33 million in additional profits. ID 106. He also determined that the Endo Credit was designed to "backstop" the value of the No-AG in case of an Endo reformulation. ID 107-10, 114. As a result, he deemed it unnecessary to estimate a separate monetary value for the Endo Credit. The ALJ concluded that the size of the No-AG/Endo Credit reverse payment was large relative to the estimated saved litigation costs. ID 114-15.

The ALJ also found that at the time of settlement Endo ha s c[( )B at at the ti

because the expert had not calculated the DCA's net present value to Endo at the time of the settlement. ID 137-38.

Having found a prima facie case of competitive harm, the ALJ turned to the second step of the rule-of-reason framework, where "the burden shifts to the defendant to prove procompetitive justifications for the challenged restraint." ID 91. The ALJ explained that the challenged restraint in a reverse-payment case is "the use of the payment to restrain potential generic competition." ID 99. But despite the well-established principle that, at this second step, the antitrust defendant's burden is "to show that the restraint in fact serves a legitimate objective," (Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1504b (3d and 4th Eds. 2010-2017) ("Areeda")), the ALJ did not require Impax to make such a showing.

Instead, relying on post-settlement events, the ALJ concluded that the SLA as a whole had procompetitive benefits because of the license to future patents. ID 141-46 (describing Endo's acquisition of patents more than two years after the settlement; subsequent court rulings in 2015 and 2016 upholding some of these patents; Endo's withdrawal of its original Opana ER product; and its 2017 withdrawal of reformulated Opana ER at the FDA's request). He concluded that the "real-world effect" of the SLA's provision covering future patents is that "there is a product on the market and available to consumers today that would not be there had Impax not had the foresight to negotiate licenses to future patents." ID 146.

The ALJ then undertook to balance the harms and benefits of the settlement agreement as a whole. His balancing analysis again focused on events occurring years after the June 2010 settlement. ID 7, 156-58. In light of these subsequent events, he found the "real world procompetitive benefits" of the SLA were "substantial." ID 157.

against other generic companies; (3) Endo's 2012 discontinuation of Original Opana ER; and (4) the FDA's 2017 request that Endo withdraw reformulated Opana ER from the market. ID 7, 143-46, 157-58.

The rule-of-reason anticompetitive effects inquiry focuses on whether an agreement, by its nature, "promotes competition or . . . suppresses competition." Nat'l Soc'y of Prof'l Eng'rs, 435 U.S. at 691; see also Cal. Dental Ass'n v. FTC, 526 U.S. 756, 770-81 (1999) (examining "the principal tendency of a restriction" to interfere with competition). As Judge (now Justice) Breyer explained, "anticompetitive" has a "special meaning" under the antitrust laws, referring "not to actions that merely injure individual competitors, but rather to actions that harm the competitive process." Clamp-All Corp. v. Cast Iron Soil Pipe Inst., 851 F.2d 478, 486 (1st Cir. 1988) (internal quotations omitted).[11]

Anticompetitive effects can be established by demonstrating an actual increase in price or decrease in output, because those effects reveal the underlying anticompetitive character of the agreement. See, e.g., Sullivan v. Nat'l Football League, 34 F.3d 1091, 1097 (1st Cir. 1994). But that is not the only way to prove antitrust harm. The Supreme Court also has condemned restraints because they "impede[d] the ordinary give and take of the market place." Nat'l Soc'y of Prof'l Eng'rs, 435 U.S. at 692, or were "likely enough to disrupt the proper functioning of the price-setting mechanism of the market . . . even absent proof that [they] resulted in higher prices." Ind. Fed'n of Dentists, 476 U.S. at 461-62.

The use of a large reverse payment to eliminate the risk of competition harms the competitive process by distorting the bargaining process that ordinarily would protect consumer interests. Actavis, 570 U.S. at 153-54; see also supra Part I.B. Antitrust law "does not condone

the purchase of protection from uncertain

challenged agreements actually delayed entry" and holding that "FTC only needs to prove that the Defendants entered into the settlements in order to avoid the risk of a competitive market" (emphasis in original)). This distinction between private parties and government enforcers reflects policy: while the interest of a private plaintiff is to "remediate an injury," the interest of the government is "to prevent and restrain violations of the antitrust laws along with the attendant social costs such violations can cause." *Nexium*, 842 F.3d at 60 (quoting Brief of Amicus Curiae FTC in Support of No Party at 9-10, *In re Nexium Antitrust Litig.*, Nos. 15-2005, 15-2006, 15-2007 (1st Cir. Mar. 10, 2016)).

As the ALJ correctly held, "the evidence proves that the Endo-Impax Settlement included payment to prevent the risk of competition." ID 156. Endo would not have paid to prevent competition from Impax if Impax did not pose a real threat of competing before January 2013.

Indeed, Impax had strong financial incentives to launch its generic product "as early as possible" to prevent Endo from destroying Impax's market opportunity with a reformulated product. (CCF ¶¶121-26). Successfully launching oxymorphone ER in 2010 was a "key" Impax goal, and Impax consistently forecasted a launch as early as June 2010. (CCF ¶¶127-30, 137, 148-67, 188). Impax's generics president had informed the Board of Directors that oxymorphone ER "was a good candidate for an at-risk launch" and presented a June 2010 at-risk launch as the "Current Assumption" in May 2010 board materials. (CCF ¶¶139, 145-47). Impax invested significant resources preparing for a June 2010 launch, including obtaining additional quota from the DEA, manufacturing product for launch, and getting customer commitments to purchase the product upon launch. (CCF ¶¶168-213). Absent the settlement, Impax would have been "ready to launch [on the] same day" as ANDA approval in June 2010. (CCF ¶204). Following the settlement, Impax was forced to discard approximately $1.4 million in manufactured

oxymorphone ER product and was left with more than $1.6 million in oxymorphone API with a 2011 expiration date. (CCF ¶¶208-12).

Impax might also have been able to enter risk-free before 2013 even if it waited until an appellate decision in the patent case. In that scenario, Endo believed that Impax's launch would "likely happen around June [2011]." (CCF ¶¶65, 370). Impax had the same expectation, modeling a mid-2011 entry date as a "base case" scenario. (CCF ¶¶166, 592, 597). Impax's patent expert predicted an appellate decision in November 2011. (CCF ¶1377).

The Initial Decision largely ignored this evidence. Instead, it made much of the fact that Impax's management never sought board authorization for an at-risk launch and that Impax could have faced potentially significant damages liability if it launched. ID 150-54. But the question is not whether Impax necessarily would have launched in the absence of the settlement; that is aninjury question. Instead, to establish an antitrust violation, the questions are whether Impax posed a competitive risk to Endo and whether Endo made a large payment to avoid that risk. The answer to both questions is yes.

The Initial Decision's weighing analysis gets things exactly backwards. The record shows a certain and significant anticompetitive harm: the elimination of the risk of competition from Impax for 2½ years—the vast majority of the remaining term for Endo's asserted patents. In comparison, the procompetitive benefit of a license to possible future patents (if counted at all) was "largely theoretical" at the time of the settlement. The parties did not know whether any subsequent patents would even issue, let alone whether they would be effective in blocking Impax's generic. The balancing is thus straightforward: a certain harm outweighs a speculative benefit.

But there is a more fundamental problem with the Initial Decision's "balancing" approach. The Initial Decision simply looked at whether the length of time Impax was permitted to be on the market prior to expiration of the licensed patents exceeded the length of time Impax agreed to stay off the market. ID 141-48, 156-58. This approach would automatically bless any agreement that allows generic entry for more than 50% of the remaining life of the last possible expiring patent (whether asserted or not), even if the brand used a large, unjustified (even naked) reverse payment. The scope-of-the-patents test *Actavis* rejected would be replaced by a "51%-of-the-remaining-patent-life" test. *See Actavis*, 570 U.S. at 147-48. And if parties could measure the benefit based on a license to potential future patents with an uncertain (but far away) expiration date, there may be no realistic limit to how long they can agree to restrain entry. Indeed, the agreement in this case kept Impax out of the market for about 79% of the remaining life of the patents asserted in the patent litigation.[13] But the ALJ nonetheless found the agreement procompetitive because it allowed Impax to enter before expiration of patents that Endo obtained years later. Such a result cannot stand under *Actavis*.

Actavis teaches that, in assessing a reverse payment, "the relevant antitrust question" is: what is "the basic reason" for the payment?

> Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of

> some other justification, the antitrust laws are likely to forbid the arrangement.

570 U.S. at 158. A payment may merely reflect "compensation for other services that the generic has promised to perform"; if so, "there is not the same concern that a patentee is using its monopoly profits to avoid of the risk of patent invalidation or a finding of noninfringement." *Id.* at 156. Thus, the "fair value for services" inquiry focuses on the "basic reason" for the payment: Did the brand company make the payment as compensation for goods or services it received, or did it make the payment to "induce the generic challenger to abandon its claim with a share of its monopoly profits"? *Id.* at 154.

The Initial Decision, however, failed to assess the "basic reason" for Endo's $10 million upfront payment under the DCA. While this error did not alter the Initial Decision's conclusion that Endo made a large, unjustified payment to Impax, the Commission should clarify the proper justification analysis for reverse payments that take the form of side business transactions. Such side deals are a common form of compensation and will likely arise in future cases. The evidence in this case shows that the "basic reason" for Endo's $10 million DCA payment was to induce Impax to stay off the market.

Rather than examine the "basic reason" for Endo's $10 million payment, the ALJ focused on whether the DCA was "a good deal for Endo." ID 132. By focusing on the wrong question, the ALJ erroneously rejected much of the relevant evidence concerning the reason for Endo's payment. For example, Complaint Counsel presented testimony from Dr. John Geltosky, an expert in pharmaceutical business development with over 35 years of experience. Dr. Geltosky testified that the negotiation, due diligence, strategic fit, and payment terms of the DCA were inconsistent with Endo's and the industry's usual approach. (CCF ¶¶1085-1255). This testimony

supported Complaint Counsel's position that Endo was not paying for the benefits of this deal, but rather to induce Impax to stay out of the market. The ALJ, however, disregarded this testimony because Dr. Geltosky failed to offer an opinion on the "actual value of the DCA," which, in his view, "incurably undermine[d]" Dr. Geltosky's opinions. ID 137-38.

Actavis, though, does not require establishing a precise financial value, or determining that the side deal was a sham. Instead, a court should assess the basic reason for the payment based on the totality of the circumstances. Lower courts applying Actavis have followed this

First, the ALJ credited trial testimony of Dr. Cobuzzi (the executive in charge of Endo's DCA evaluation) that Endo had adequate time to negotiate and evaluate the DCA. (FF.337-45). But, in contemporaneous documents Dr. Cobuzzi complained that there was "very little time for this evaluation." (CCF , 290 (

The DCA was negotiated from start to finish in only three weeks, far quicker than industry standard (6-12 months) and Endo's own documented process ("6 months-1 year from initial evaluation to deal close") (CCF ¶¶1105-06, 1110, 1121-30), with only three

By crediting Dr. Cobuzzi's testimony that the DCA was a "good deal," the ALJ ignored these numerous critical flaws in the analysis underlying this testimony.

Third, the ALJ concluded, based solely on Dr. Cobuzzi's testimony, that the $10 million upfront payment for the DCA was typical in the pharmaceutical industry. (FF.369-70); ID 132. But Endo has never paid any upfront money for any other product in early stage development. (CCRF ¶453). As Dr. Geltosky explained, a deal for a pre-clinical product like IPX-203 would normally involve little if any guaranteed money, but instead would provide increasing milestone payments as the product showed potential in development. (CCF ¶¶1224-26). Yet here, Endo offered to pay $10 million without even knowing what it was getting in return. (CCRF ¶¶397, 422; CCF ¶1083).

Fourth, the ALJ relied on Mr. Nestor's testimony about the promising development of a product with the same IPX-203 code name to support his conclusion that the DCA was fair value for Endo's $10 million payment. (FF.378-395); ID 129-31.

Indeed, outside the context of the patent settlement, Endo consistently demonstrated that it was not actually interested in Impax's Parkinson's disease drugs. (CCF ¶¶1090-92, 1267).

Taken in its entirety, the record shows that Endo agreed to pay $10 million not to obtain potential profit-sharing rights in IPX-203, but instead to secure Impax's agreement not to sell generic Opana ER before 2013. Impax described the $10 million payment as

And Endo acknowledged that the DCA "adds significant topline revenue for Opana," not from IPX-203 itself. (CCF ¶1084).

Rule-of-reason analysis follows a well-established burden-shifting framework: (1) the plaintiff must make a *prima facie* showing of anticompetitive harm; (2) the burden then shifts to the defendant to demonstrate a procompetitive justification for the restraint; and (3) the burden shifts back to the plaintiff to show that the restraint is not reasonably necessary to achieve the procompetitive objective.[15] The Initial Decision correctly found that Complaint Counsel proved an anticompetitive effect and that the "payment conferred to Impax by the no-AG and Endo Credit provisions . . . was unjustified." ID 116. But it departed from the established rule-of-

reason framework by assessing Impax's proffered justifications for the reverse payment at the initial stage of the analysis.

Although this approach did not alter the outcome of the first-step analysis, it is unwarranted and unwise, and nothing in *Actavis* endorses it. In any rule-of-reason case, a

defendant's case. Contrary to the ALJ's supposition, however,

the conclusion that Endo made a large payment to Impax to eliminate the risk of competition, the Commission should clarify that Professor Noll's calculations should have been considered. Economic analyses are likely to play an important role in future cases because reverse payments increasingly involve more complex forms of non-cash compensation.

From an ex ante perspective, the ultimate size of the combined No-AG/Endo Credit payment depended critically on an uncertain factor: original Opana ER's eventual sales in the last quarter of 2012. Professor Noll therefore calculated the range of the payment's potential values given plausible changes in original Opana ER sales between June 2010 (the agreement date) and the end of 2012:

(1) if original Opana ER sales remained flat;

(2) if original Opana ER sales grew;

(3) if original Opana ER sales declined, but not enough to trigger the Endo Credit; and

(4) if original Opana ER sales had essentially disappeared by the time Impax entered.

(CX5000 at 159-60, 169-70 (Noll Report)).[18] Relying on Impax's contemporaneous documents and Opana ER sales data, Professor Noll calculated that the ex ante values of the No-AG and Endo Credit provisions under these plausible outcomes ranged from $16.5 million to at least $62 million. (CCF ¶¶461-71).

The Initial Decision appears to fault Professor Noll's analysis because he did not calculate a mathematical "expected value" of the payment at the time of the settlement. ID 35,

38. An expected value is the "probability-weighted sum of every conceivable event." (CCRF ¶1423). But even Impax's own expert conceded that such a calculation is not "in any practical sense doable." (CCF ¶479). Indeed, Impax's expert offered no criticism of Professor Noll's calculations. (CCF ¶479). Nor did Impax challenge or rebut any of Professor's Noll's calculations.

Professor Noll's calculations are well supported and demonstrate that at the time the No-AG/Endo Credit payment was large under all plausible outcomes. They confirm what Impax's CFO told investors at that time: that Impax would receive a large payment "almost no matter what happened." (CCF ¶438). The Commission should clarify that consideration of this expert evidence is appropriate in assessing whether Impax received a large payment from Endo.

The Commission has "wide discretion" in crafting an appropriate remedy. Jacob Siegel Co. v. FTC, 327 U.S. 608, 611 (1946). The Supreme Court has emphasized that the Commission "is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past." FTC v. Ruberoid Co., 343 U.S. 470, 473 (1952).[19] Instead, "those caught violating the Act must expect some fencing in." FTC v. Nat'l Lead Co., 352 U.S. 419, 431 (1957).[20]

Respectfully submitted,

Dated: July 10, 2018

/s/ Charles A. Loughlin
Charles A. Loughlin
Federal Trade Commission
Bureau of Competition
600 Pennsylvania Ave., NW
Washington, DC 20580
Telephone: (202) 326-2114
Facsimile: (202) 326-3384
Email: cloughlin@ftc.gov

Appendix A

Notice of Electronic Service

I hereby certify that on July 10, 2018, I filed an electronic copy of the foregoing Complaint Counsel's Appeal o the Initial Decision, with:

D. Michael Chappell
Chief Administrative Law Judge
600 Pennsylvania Ave., NW
Suite 110
Washington, DC, 20580

Donald Clark
600 Pennsylvania Ave., NW
Suite 172
Washington, DC, 20580

I hereby certify that on July 10, 2018, I served via E-Service an electronic copy of the foregoing Complaint Counsel's Appeal of the Initial Decision, upon:

Bradley Albert
Attorney
Federal Trade Commission
balbert@ftc.gov
Complaint

Daniel Butrymowicz
Attorney
Federal Trade Commission
dbutrymowicz@ftc.gov
Complaint

Nicholas Leefer
Attorney
Federal Trade Commission
nleefer@ftc.gov
Complaint

Synda Mark
Attorney
Federal Trade Commission
smark@ftc.gov
Complaint

Maren Schmidt
Attorney
Federal Trade Commission
mschmidt@ftc.gov
Complaint

Eric Sprague
Attorney
Federal Trade Commission
esprague@ftc.gov
Complaint

Jamie Towey
Attorney
Federal Trade Commission
jtowey@ftc.gov

rweinstein@ftc.gov
Complaint

Garth Huston
Attorney
Federal Trade Commission
ghuston@ftc.gov
Complaint

I hereby certify that on July 10, 2018, I served via other means, as provided in 4.4(b) of the foregoing Complaint Counsel's Appeal of the Initial Decision, upon:

Markus Meier
Attorney
Federal Trade Commission
mmeier@ftc.gov
Complaint

Rebecca Weinstein
Attorney