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UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 19-60394

IMPAX LABORATORIES, INC.,
Petitioner,
v.
FEDERAL TRADE COMMISSION,
Respondent.

Filed: April 13, 2021

Before: SOUTHWICK, COSTA, and DUNCAN, *Circuit Judges*.

OPINION

COSTA, *Circuit Judge*:

Normally, when lawsuits settle the defendant pays the plaintiff. That makes sense as the defendant is the party accused of wrongdoing.

But when a generic drug is poised to enter the market and threaten the monopoly enjoyed by a brand-name pharmaceutical, federal law can incentivize a different type of settlement. The Hatch-Waxman Act delays the entry of the generic drug if the brand-drug manufacturer files a patent infringement

suit against the generic. Those patent suits are sometimes settled with the brand-drug plaintiff paying the allegedly-infringing generic. In return for the payment, the generic agrees to delay its market entry beyond the date when the FDA would allow it to compete. The result is an extension of the brand drug's monopoly.

Given the counterintuitive flow of money in this scenario—to, rather than from, the alleged wrongdoer—such deals are called "reverse payment settlements." The Supreme Court has held that these settlements that extend the brand drug's monopoly can have anticompetitive effects that violate the antitrust laws. *FTC v. Actavis*, 570 U.S. 136, 158 (2013). Reverse payment settlements, however, are not automatically invalid; they are subject to the rule of reason. *Id.* at 159.

In its first post-*Actavis* reverse payment case, the Federal Trade Commission charged Impax Laboratories with antitrust violations for accepting payments ultimately worth more than $100 million to delay the entry of its generic drug for more than two years. The resulting administrative hearing included testimony from 37 witnesses and over 1,200 exhibits. Based on that record, the Commission conducted a rule-of-reason analysis and unanimously concluded that Impax violated antitrust law.

On appeal, we face a narrower task: determining whether the Commission committed any legal errors and whether substantial evidence supported its factual findings. Concluding that the Commission's ruling passes muster on both fronts, we DENY the petition for review.

I.

A.

Anyone who buys pharmaceuticals knows that generic drugs are cheaper than their brand counterparts. The first generic to enter the market typically costs 10 to 25 percent less than the branded drug; those discounts grow to between 50 and 80 percent once other generics enter.

To bring competition to the drug market, the Hatch-Waxman Act promotes entry for these generics. *Actavis*, 570 U.S. at 142. Rather than undergoing the lengthy and costly approval process that a new drug faces, generics can file an Abbreviated New Drug Application with the Food and Drug Administration. *Id.* at 142; 21 U.S.C. §355(j). If the generic drug is biologically equivalent to a brand drug the FDA has already approved, then the generic can essentially "piggy-back on the pioneer's approval efforts." *Actavis*, 570 U.S. at 142; 21 U.S.C. §355(j)(2)(A)(i)-(iv). The Act offers an additional carrot to the first generic applicant: it can market its generic drug for 180 days without competition from any other generic manufacturer. *Actavis*, 570 U.S. at 143-44; 21 U.S.C. §355(j)(5)(B)(iv). During this period of exclusivity, the newly approved generic only faces competition from the brand drug or a generic sold by the brand manufacturer. *Actavis*, 570 U.S. at 143-44. In effect, the statute allows a duopoly during those 180 days. A firstto- file generic often realizes most of its profits, potentially "several hundred million dollars," during this initial six-month period. *Id.* at 143 (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical*

Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1579 (2006)).

Generic entry is not so easy when there is a patent for the brand drug. The Hatch-Waxman Act also addresses this common situation. If the brand manufacturer asserts a patent in its initial drug application, then the generic manufacturer must certify in its application that the patent is invalid or that its drug will not infringe the patent. 21 U.S.C. §355(j)(2)(A)(vii)(IV). If the brand manufacturer disagrees (it likely will), it may file a patent infringement suit. 35 U.S.C. §271(e)(2)(A). And if it does so within 45 days, the FDA is stayed from approving the generic application until either 30 months have passed or the patent litigation concludes. 21 U.S.C. §355(j)(5)(B)(iii); *see also Actavis*, 570 U.S. at 143 (describing these procedures). This delay for the first generic's entry also postpones the potential entry of other generics. They must wait for the same 30-month stay and then for the expiration of the first generic's 6-month exclusivity period before entering the market.

What happens if the patent suit against the first generic settles? The brand manufacturer no longer faces an immediate threat of competition from new generic entrants. The 30-month statutory stay restarts if the brand maker brings a patent suit against another generic that wishes to enter the market. *Actavis*, 570 U.S. at 155 (citing 21 U.S.C. §355(j)(5)(B)(iii)). Plus, any subsequent generic is not entitled to the exclusivity period. *Id.* That greatly reduces the potential benefit of challenging the brand maker's patent. *Id.* (noting that subsequent generics

"stand to win significantly less than the first if they bring a successful" challenge to the patent).

These features of the Hatch-Waxman Act—the period of exclusivity for the first generic; the 30-month stay of the generic's FDA application when the brand maker sues for infringement; and the reduced incentive a subsequent generic has to challenge the brand maker's patent—can lead the brand maker to pay large sums for delaying entry of the first generic maker. *Actavis*, 570 U.S. at 155 (recognizing that these Hatch-Waxman "features together mean that a reverse payment settlement with the first filer ... 'removes from consideration the most motivated challenger, and the one closest to introducing competition" (quoting Hemphill, *Paying for Delay*, *supra*, at 1586)).

B.

The facts of this case show those incentives in action. The drug at issue is a type of oxymorphone, which is an opioid. Endo, the brand-name drug maker in this case, started selling an extended-release formulation of oxymorphone called Opana ER in 2006. An extended-release pain reliever provides medication to the bloodstream over several hours, as opposed to immediate-release opioids which are short-acting. When it entered the market, Opana ER was the only extended-release version of oxymorphone.

In late 2007, Impax filed the first application to market generic extended-release oxymorphone. The application did not result in prompt approval of the generic, however, because Endo held patents for Opana ER that would not expire until 2013. Endo sued Impax for patent infringement in January 2008,

delaying any FDA approval of the generic for 30 months—until June 2010—unless the litigation concluded earlier.

Early settlement talks failed, with Endo rejecting Impax's proposed entry dates of January 2011, July 2011, December 2011, or January 2012.

The June 2010 expiration of the Hatch-Waxman stay loomed. Delaying Impax's entry beyond the stay period would save Endo millions. Endo had projected that generic entry would cut Opana ER sales by 85 percent within three months and cost it $100 million in revenue within six months.

But extending the period in which it could sell Opana ER without competition was just one of Endo's priorities. The drug maker had something else in the works: It planned to move consumers to a new brandname drug that would not face competition for years. Endo would remove the original Opana ER from the market, replace it with a crush-resistant version of the drug, and obtain new patents to protect the reformulated drug. While Impax's generic would still eventually reach the market, it would not be therapeutically equivalent to Endo's new branded drug and thus pharmacists would not be able to automatically substitute the generic when filling prescriptions. This automatic substitution of brand drug prescriptions, promoted by state laws, is the primary driver of generic sales. So, if Endo succeeded in switching consumers to its reformulated drug, which would be just different enough from the original formulation to preclude substitution, the market for Impax's generic would shrink dramatically, preserving Endo's monopoly profits.

The success of this "product hop"[1] depended on the reformulated Opana ER reaching the market sufficiently in advance of Impax's generic entry to allow patients to move away from the original drug before pharmacists started substituting the generic version. This transition period to the reformulated drug would take roughly six to nine months. A successful transition to the reformulated Opana ER before generic entry would mean millions to Endo. The company projected that the reformulated Opana ER would generate about $200 million in annual sales by 2016 if the market transitioned to the new drug before the generic entered. But if the generic launched first, then 2016 sales of the new formulation would fall to $10 million.

The date when Impax could start selling its generic was thus critical. The FDA tentatively approved Impax's application in May 2010. The Hatch-Waxman stay would expire the next month. There were signs that Impax was planning to launch its generic soon thereafter.[2]

With the possible launch date for generic entry imminent, Endo restarted settlement negotiations

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[1] Product hopping can itself be anticompetitive. *See generally New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 643 & n.2, 652-59 (2d Cir. 2015); Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 MICH. ST. L. REV. 631, 657-673 (crediting Professor Hovenkamp with the "product hop" term).

[2] If Impax entered the market before resolution of the patent litigation, it would risk paying any damages for its sales in the event Endo later proved infringement. This is called "at risk" entry. *See In re Lipitor Antitrust Lit.*, 868 F.3d 231, 241 (3d Cir. 2017).

just three days after the FDA's tentative approval of the generic. The parties settled the patent litigation in June 2010, just a few days after the patent trial began and less than a week before the FDA fully approved Impax's application.

C.

Under the settlement, Impax agreed to delay launching its generic until January 1, 2013—two and a half years after Impax otherwise could have entered "at-risk." In turn, Endo agreed to not market its own generic version of extended-release oxymorphone until Impax's 180-day Hatch-Waxman exclusivity period concluded in July 2013. Additionally, Endo agreed to pay Impax a credit if sales revenues for the original formulation of Opana ER fell by more than 50 percent between the dates of settlement and Impax's entry. This credit served as an insurance policy for Impax, preserving the value of the settlement in case Endo undermined the generic oxymorphone market by transitioning consumers to the reformulated Opana ER. Endo also provided Impax with a broad license to Endo's existing and future patents covering extended-release oxymorphone. Finally, Endo and Impax agreed to collaboratively develop a new Parkinson's disease treatment, with Endo paying Impax $10 million immediately and up to $30 million in additional payments contingent on achieving sufficient development and marketing progress.

Impax's delayed entry allowed Endo to execute the product hop. In March 2012, Endo introduced its reformulated drug and withdrew the original drug. It publicly stated that the original drug was unsafe, though the FDA later disagreed that safety concerns

motivated the withdrawal. Predictably, the market for the original Opana ER shriveled. So Endo had to pay Impax $102 million in credits. Endo subsequently succeeded in securing additional patents, and in 2015 and 2016 secured injunctions that prevented all manufacturers, including Impax, from marketing generic versions of the reformulated drug. But in 2017, the FDA asked Endo to voluntarily withdraw the reformulated Opana ER from the market due to safety concerns, and it did.

For its part, Impax began marketing original formulation generic oxymorphone in January 2013, despite the damaged market Endo left behind. Because of the injunctions Endo secured against other generics and because Endo eventually withdrew the reformulated Opana ER from the market, Impax's generic is the only extended-release oxymorphone available to consumers today.

D.

The FTC brought separate actions against Endo and Impax alleging that the settlement was an unfair method of competition under the FTC Act and an unreasonable restraint on trade under the Sherman Act. Endo settled. Impax fought the charge and successfully argued that the case should proceed in an administrative proceeding rather than in federal district court where the Commission had first filed.

An administrative law judge determined that the agreement restricted competition but was nevertheless lawful because its procompetitive benefits outweighed the anticompetitive effects. Reviewing both the facts and law *de novo*, 16 C.F.R. §3.54(a), the Commission reached a different

conclusion. It found that Impax had failed to show that the settlement had any procompetitive benefits. Moreover, it determined that the purported benefits Impax identified could have been achieved through a less restrictive agreement. The Commission did not impose any monetary sanctions. It did not even invalidate Impax's agreements with Endo or other drug makers. Instead, it issued a cease-and-desist order enjoining Impax from entering into similar reverse payment settlements going forward.

Impax now petitions for review of the FTC's order.

II.

We review the Commission's ruling, not the ALJ's. *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 354 (5th Cir. 2008); *cf. Shaikh v. Holder*, 588 F.3d 861, 863 (5th Cir. 2009) (noting that we review the decision of the BIA in immigration cases). Any legal conclusions are reviewed *de novo*, though we "are to give some deference to the [FTC]'s informed judgment that a particular commercial practice is to be condemned as 'unfair.'" *N. Tex. Specialty*, 528 F.3d at 354 (quoting *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986)).

The "findings of the Commission as to the facts, if supported by evidence, shall be conclusive." 15 U.S.C. §45(c). That statutory command is "essentially identical" to the substantial-evidence standard that often governs judicial review of agency factfinding. *Ind. Fed'n of Dentists*, 476 U.S. at 454. Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id.* (quoting *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477 (1951)). We must accept

findings supported by such evidence "even if 'suggested alternative conclusions may be equally or even more reasonable and persuasive." *N. Tex. Specialty*, 528 F.3d at 354 (quoting *Colonial Stores, Inc. v. FTC*, 450 F.2d 733, 739 (5th Cir. 1971)). This deferential review should be no more searching than if we were evaluating a jury's verdict. *See District of Columbia v. Pace*, 320 U.S. 698, 702 (1944) (explaining that substantial evidence review is less intrusive than clear error review); 3 Steven Alan Childress & Martha S. Davis, Federal Standards of Review §15.04 (same); Robert L. Stern, *Review of Findings of Administrators, Judges and Juries: A Comparative Analysis*, 58 Harv. L. Rev. 70, 84-86 (1944) (analyzing Justice Jackson's opinion in *Pace*).

III.

A reverse payment settlement is a settlement of patent litigation in which the patentholder gives the alleged infringer cash or other valuable services or property and the alleged infringer agrees not to market its allegedly infringing product until some later date. *See Actavis*, 570 U.S. at 140. These horizontal agreements unlawfully restrain trade, *see* 15 U.S.C. §1, if they cause anticompetitive effects that outweigh any procompetitive benefits.[3] *See Actavis*, 570 U.S. at 156-59.

This rule-of-reason inquiry uses a burden-shifting framework. *See Ohio v. Am. Express*, 138 S. Ct. 2274,

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[3] Reverse-payment settlements are also sometimes called "pay for delay" agreements. *See FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1301 (11th Cir. 2012), *rev'd sub nom. FTC v. Actavis*, 570 U.S. 136 (2013). Following the Supreme Court's lead, we use the term "reverse payment."

2284 (2018). The initial burden is on the FTC to show anticompetitive effects. *Id*. If the FTC succeeds in doing so, the burden shifts to Impax to demonstrate that the restraint produced procompetitive benefits. *Id*. If Impax successfully proves procompetitive benefits, then the FTC can demonstrate that any procompetitive effects could be achieved through less anticompetitive means. *Id.* Finally, if the FTC fails to demonstrate a less restrictive alternative way to achieve the procompetitive benefits, the court must balance the anticompetitive and procompetitive effects of the restraint. *Apani Sw., Inc. v. Coca-Cola Enters., Inc.*, 300 F.3d 620, 627 (5th Cir. 2002). If the anticompetitive harms outweigh the procompetitive benefits, then the agreement is illegal. *Id.*

A.

The first question is whether the agreement caused anticompetitive effects or "created the potential for anticompetitive effects." *Doctor's Hosp. of Jefferson, Inc. v. Se. Med. All., Inc.*, 123 F.3d 301, 310 (5th Cir. 1997); *accord Retractable Techs, Inc. v. Becton Dickinson & Co.*, 842 F.3d 883, 895 (5th Cir. 2016) (noting that an antitrust plaintiff must show that a restraint "had the potential to eliminate, or did in fact eliminate, competition"); *see also Actavis*, 570 U.S. at 157 (noting that the "relevant anticompetitive harm" of a reverse payment settlement is "prevent[ing] the risk of competition"). Such effects may be proved "indirectly," with "proof of market power plus some evidence that the challenged

restraint harms competition."[4] *Am. Express Co.*, 138 S. Ct. at 2284.

Anticompetitive effects are those that harm consumers. Think increased prices, decreased output, or lower quality goods. *Id.* Eliminating potential competition is, by definition, anticompetitive. *See, e.g.*, *United States v. Falstaff Brewing Corp.*, 410 U.S. 526, 532-33 (1973) (acquiring potential competitor was anticompetitive both because of current pressure of potential entry and potentially beneficial effects of future entry). Indeed, paying a potential competitor not to compete is so detrimental to competition that normally it is a *per se* violation of the antitrust laws. *See Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 48-49 (1990); *see also Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406, 1415 (7th Cir. 1995) (Posner, C.J.) (suggesting that market allocation agreements are even more pernicious than price-fixing agreements because the former eliminates all forms of competition); Joshua P. Davis & Ryan J. McEwan, *Deactivating* Actavis*: The Clash Between the Supreme Court and (Some) Lower Courts*, 67 Rutgers U.L. Rev. 557, 559 (2015) (calling "an agreement between horizontal competitors not to compete, the *bête noir* of antitrust law").

Actavis concluded that, in contrast to the typical horizontal agreement to divvy up markets, reverse payment settlements might produce both antiand procompetitive effects. On the one hand, a brand

[4] The FTC required that showing of market power to show potential anticompetitive effect under *Actavis*. Impax does not argue that it lacked market power—it held a patent after all—so we need not address that issue further.

maker's paying a generic to delay entry "in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." 570 U.S. at 153-54. In fact, reverse payment settlements may restrict competition even more than typical market allocation agreements because delaying entry of the first generic does not just eliminate one competitor—it prolongs the "bottleneck" that delays entry of other generic competitors. *In re Nexium (Esomeprazole) Antitrust Lit.*, 842 F.3d 34, 41 (1st Cir. 2016). But the existence of patent—a lawful monopoly if valid—points in the other direction. If the patent is valid, then unlike traditional market allocation agreements, a settlement that allows generic entry after the FDA's approval of the drug but still earlier than the patent expiration date may result in more competition than would have existed absent the settlement. *Actavis*, 570 U.S. at 154. Given the potentially countervailing impacts of reverse payment settlements, the Supreme Court applied the rule of reason rather than automatic invalidity. *Id.* at 159.

At this first step of the rule-of-reason analysis, we are just focused on the anticompetitive side of the equation. *Actavis* held that a "large and unjustified" reverse payment creates a likelihood of "significant anticompetitive effects." *Id.* at 158. "[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might

represent payment, and the lack of any other convincing justification." *Id.* at 159.

In many reverse payment cases, the central dispute is whether there was in fact a reverse payment. HERBERT HOVENKAMP ET AL. IP & ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW §16.01 (2018 Supp.); *see, e.g., In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 550-51 (1st Cir. 2016) (citing numerous post-*Actvavis* case addressing whether nonmonetary benefits to a generic are reverse payments). The settling party will often contend that any settlement payments are for services rather than for delayed entry. *Id.* That is not the case here. Impax has not challenged the ALJ's original determination "that a large reverse payment helped induce settlement or that the payment was linked to the January 2013 entry date."

That concession makes sense in light of the valuable consideration Impax received in exchange for delaying entry.[5] We will note two significant items. First, Endo committed to not market an authorized generic, which increased Impax's projected profits by $24.5 million. *See King Drug Co. of Florence*, 791 F.3d 388, 394 (3d Cir. 2015) (holding that brand manufacturer commitments to not market a generic drug during the 180-day exclusivity period are "payments" under *Actavis*); *see also Loestrin 24 Fe Antitrust Litig.*, 814 F.3d at 549-53 (explaining that *Actavis* recognized that a reverse payment could

[5] The Commission also considered the payments to Impax for the Parkinson's research and the licenses Endo granted Impax.

include more than just an exchange of money). Second, Endo would pay Impax credits for the shrunken market the latter would inherit if, as expected, Endo timely executed the product hop to the reformulated Opana ER. The $102 million Endo ultimately paid is likely a good approximation of the parties' expected value for these credits. The size of these payments is comparable to other cases where courts have inferred anticompetitive effect. *See In re Wellbutrin XL Antitrust Lit. Indirect Purchaser Class*, 868 F.3d 132, 162 (3d Cir. 2017) (holding that $233 million paid to three generic manufacturers is large under *Actavis*); *Nexium*, 842 F.3d at 50, 54 (acknowledging jury finding that a $300-$690 million payment was large); *accord Actavis*, 570 U.S. at 145 (brand manufacturer agreed to pay three generic manufacturers $12 million, $60 million, and an estimated $171-270 million over nine years).

The Commission rejected the argument that just showing a large payment was enough to establish anticompetitive harm. It reasoned that "[e]stablishing that the payment is not otherwise justified is necessary for demonstrating that the payment is purchasing an exclusive right and preventing the risk of competition." *See also Actavis*, 570 U.S. at 158 (stating that "a reverse payment, where large and *unjustified*, can bring with it the risk of significant anticompetitive effects" (emphasis added)).

But the Commission correctly found no such justification. A large reverse payment might be justified if it represents "avoided litigation costs or fair value for services." *Id.* at 156. That is not the case here. The FTC estimated the settlement saved Endo

only $3 million in litigation expenses, an amount in the ballpark of the typical cost for litigating pharmaceutical patents. *See* Fed. Trade Comm'n, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact 111-12 & n.27 (2011) (estimating average costs in the $5-10 million range based on research from Morgan Stanley); Michael R. Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 Colum. L. Rev. 1788, 1795 n.41 (2011) (noting that litigation expenses can bring the costs of generic entry to about $10 million). Nor did the agreement involve any services that the generic would provide to Endo that could otherwise justify the large payment. Only the services associated with the Parkinson's collaboration could plausibly provide an appropriate basis for the payments. But 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.

This large and unjustified payment generated anticompetitive effects. The Commission explained that there "was a real threat of competition from Impax" snuffed out by Endo's agreement to make the reverse payments. The FDA had just approved Impax's generic, allowing it to sell the drug. Impax had taken steps to do so, even though its market entry would be "at risk" of infringement liability. Endo's known product-hop plans increased Impax's incentive to quickly enter the market. The Commission thus had substantial evidence to conclude that the reverse

payments replaced the "possibility of competition with the certainty of none."

Impax argues that the Commission needed to do more at this first stage of the rule of reason. Its principal attack on the finding of anticompetitive effect is that the Commission needed to evaluate "the patent's strength, which is the expected likelihood of the brand manufacturer winning the litigation." Impax reasons that if it was highly likely that Endo would win the patent suit, then the reverse payment was not anticompetitive because it allowed the generic to enter the market before the patent expired.

We disagree that *Actavis* requires the Commission to assess the likely outcome of the patent case in order to find anticompetitive effects. The fact that generic competition was possible, and that Endo was willing to pay a large amount to prevent that risk, is enough to infer anticompetitive effect. *Actavis*, 570 U.S. at 157. In fact, *Actavis* squarely rejected Impax's argument: "[T]he size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id*. at 158; *see also id*. at 157 ("[I]t is normally not necessary to litigate patent validity to answer the antitrust question."); *id.* at 158 (reiterating that a court can assess the anticompetitiveness of a reverse payment "without litigating the validity of the patent"); *id*. at 159 (stating yet again that the Commission need not "litigate the patent's validity" to establish anticompetitive effects). The idea is that a large reverse payment "itself would normally suggest that

the patentee has serious doubts about the patent's survival." *Id.* at 157; *see also* Hovenkamp, *supra*, §16.01[D] (explaining that a sizeable reverse payment "raise[s] a strong inference that that the parties believed ex ante that there was a significant chance that the patent was invalid").

Consider this settlement. If the parties thought Endo was highly likely to win the infringement suit, then Impax would have been happy with a deal giving it nothing more than entry months in advance of the likely-valid patent's expiration. *Cf. In re Cipro Cases I & II*, 348 P.3d 845, 865 (Cal. 2015) (noting that a settlement postponing market entry, but not accompanied by a reverse payment, would be a "fair approximation" of the strength of the patent suit). Reverse payments potentially worth nine figures would have been a windfall. The need to add that substantial enticement indicates that at least some portion of that payment is "for exclusion beyond the point that would have resulted, on average, from simply litigating the case to its conclusion." *Id.* at 867; *see also In re Aggrenox Antitrust Lit.*, 94 F. Supp. 3d 224, 240-41 (D. Conn. 2015) (explaining that a plaintiff need not prove that the patent was weak because a "large and unjustified reverse-payment" can show that the parties perceived weakness with the patent that would have made earlier entry likely). "And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what *might have been* a competitive market—the very anticompetitive consequence that

underlies the claim of antitrust unlawfulness." *Actavis*, 570 U.S. at 157 (emphasis added).[6]

Impax also argues that the settlement does not look anticompetitive in hindsight. After all, since the settlement Endo has obtained more patents for Opana ER and proven their validity in court. On top of that, the product hop ended up failing once Endo had to take reformulated Opana ER off the market due to safety concerns. So Impax's generic is now the only version of Opana ER on the market.

But it is a basic antitrust principle that the impact of an agreement on competition is assessed as of "the time it was adopted." *See Polk Bros. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir. 1985) (Easterbrook, J.); *see also* FTC & DOJ, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS §2.4 (2000) (stating that the agencies "assess the competitive effects of a relevant agreement as of the time of possible harm to competition"). That approach also makes sense in reverse payment cases. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003) (refusing to consider postagreement invalidation of patent because "reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are

[6] In addition to crediting these economic implications of a large reverse payment, the Supreme Court recognized the difficulty of trying a patent case within an antitrust case. *Actavis*, 570 U.S. at 157 (discussing the Eleventh Circuit's concern with "litigat[ing] patent validity" in an antitrust case, but explaining that is not needed for antitrust scrutiny). An Eleventh Circuit colleague apparently familiar with Cajun cuisine called this the "turducken" problem. *Watson*, 677 F.3d at 1315.

entered into"); *Cipro*, 348 P.3d at 870 ("Just as later invalidation of a patent does not prove an agreement when made was anticompetitive, later evidence of validity will not automatically demonstrate an agreement was procompetitive."); 12 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶2046e1, at 399 (4th ed. 2019) (explaining that the "reasonableness of a patent settlement agreement cannot be made to depend on an *ex post* determination" of validity or infringement).

So the focus is on the following facts as they existed when the parties adopted the settlement. Endo agreed to make large payments to the company that was allegedly infringing its patents. In exchange, Impax agreed to delay entry of its generic drug until two-and-a-half years after the FDA approved the drug. Neither the saved costs of forgoing a trial nor any services Endo received justified these payments. Substantial evidence supports the Commissions' finding that the reverse payment settlement threatened competition.

B.

The next rule-of-reason question is whether Impax can show procompetitive benefits. *Am. Express*, 138 S. Ct. at 2284. The Commission concluded it could not. Although the ALJ had recognized that the settlement's license and covenant-not-to-sue provisions benefited competition, the Commission concluded that these procompetitive effects 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, and the protection

Impax secured against other patents Endo might obtain, as benefits to be weighed against the anticompetitive effects of the reverse payments. After the Commission concluded that the reverse payments lacked any procompetitive benefits, it followed that they "constitute[d] an unreasonable restraint of trade."

The parties and amici vigorously contest the Commission's finding of "no nexus" between the restraint and the procompetitive benefits Impax asserts. That dispute turns largely on how to define the restraint. Is it limited to the reverse payments or does it extend to the entire settlement agreement?

We need not resolve this question because of an alternative ruling the Commission made. Although the Commission found the reverse payments generated no procompetitive benefits, it went on to assume *arguendo* that Impax could connect the settlement's purported procompetitive effects to the challenged restraint. Even if that was so, the Commission determined that "Impax could have obtained the proffered benefits by settling without a reverse payment for delayed entry—which is a practical, less restrictive alternative." If we conclude that substantial evidence supported this finding of a less restrictive alternative, we can also assume that Impax has proven procompetitive benefits. So we will turn to our review of the "less restrictive alternative" finding.

C.

A restraint is unreasonable when any procompetitive benefits it produces "could be reasonably achieved through less anticompetitive

means." *Am. Express*, 138 S. Ct. at 2284; *see generally* 11 AREEDA & HOVENKAMP, *supra*, ¶1913, at 395-402; C. Scott Hemphill, *Less Restrictive Alternatives in Antitrust Law*, 116 COLUM. L. REV. 927, 937-42 (2016). The concept traces back to then-Circuit Judge Taft's opinion in *United States v. Addyston Pipe & Steel Co.* Hemphill*, Less Restrictive*, *supra*, at 938 & n.53 (citing 85 F. 271, 282 (6th Cir. 1898) (holding that a restraint of trade is unenforceable unless it is "ancillary to the main purpose of a lawful contract[]and *necessary* to protect the covenantee['s] ... enjoyment of the legitimate fruits of the contract" (emphasis added))). The less-restrictive-alternative standard applies across a range of antitrust claims and is included in model antitrust jury instructions. *Id.* at 929, 938 & n.50 (citing ABA SECTION OF ANTITRUST LAW, MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES A-10 (2005)).[7] The idea is that it is unreasonable to justify a restraint of trade based on a purported benefit to competition if that same benefit could be achieved with less damage to competition. Focusing on the existence of less restrictive alternatives may allow courts to avoid difficult balancing of anticompetitive and procompetitive effects and to "smoke out" anticompetitive effects or pretextual justifications for the restraint. Hemphill, *Less Restrictive*, *supra*, at 947-63. When a less restrictive alternative exists, a party's decision to nonetheless engage in conduct "that

[7] The Fifth Circuit Pattern Jury Instructions does not include circuit-specific antitrust instructions, but refer courts and parties to two sources, including the ABA Antitrust Section's proposed instructions. FIFTH CIRCUIT PATTERN JURY INSTRUCTIONS (CIVIL CASES) §6 (2020).

harms consumers" likely results from a desire "to gain from the resulting consumer harm." *Id*. at 968. The question, in short, is whether "the good [could] have been achieved equally well with less bad." *Id*. at 929.

Actavis recognizes the possibility of less restrictive alternatives to reverse payment settlements. The Court noted that parties to pharmaceutical patent litigation "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without ... paying the challenger to stay out prior to that point." 570 U.S. at 158; *see also* 12 AREEDA & HOVENKAMP, *supra*, ¶2046c2, at 381-82 (observing that *Actavis* recognizes "that there are better, less anticompetitive ways to settle these disputes").

The Commission found that Impax could have achieved just as much and likely more good (an entry date even earlier than 2013) without the bad (Endo's agreement not to sell a competing generic during the exclusivity period and to pay credits to Impax for the decline of the Opana ER market while Endo executed the product hop). The Commission explained that "[h]olding everything else equal, Impax's acceptance of payment would normally be expected to result in a later entry date than what Impax would have accepted based on the strength of the patents alone." To support its view that Impax could have entered into a settlement without reverse payments that would have resulted in greater generic competition, the Commission relied on industry practice, economic analysis, expert testimony, and adverse credibility

findings discounting the testimony of Impax's lead settlement negotiator.

"[T]he existence of a viable less restrictive alternative is ordinarily a question of fact." 11 AREEDA & HOVENKAMP, *supra*, ¶1913b, at 398; *accord O'Bannon v. NCAA*, 802 F.3d 1049, 1074 (9th Cir. 2015) (applying clear-error review to district court's finding of less restrictive alternative). So the substantial deference we owe the Commission's factfinding kicks in, in particular on its determination that a no-payment settlement was feasible.

Impax nonetheless tries to lodge legal objections to the finding of a less restrictive alternative. First, it argues that the Commission only recognized what it considers an equally restrictive alternative—the possibility of a settlement with the same entry date but no reverse payments. But the Commission recognized the feasibility of no-payment settlements with both the same[8] or an earlier entry date. Its ultimate ruling relied on an agreement with an earlier entry date as a less restrictive alternative: "A no-payment settlement allowing *pre-2013 generic entry* would have been a practical alternative for both Impax and Endo, but they chose instead to exchange sizeable

[8] Even if Impax's entry date were the same in a no-payment settlement, the arrangement would be less anticompetitive than the actual agreement because it would not include Endo's "payment" of not selling a generic competitor during Impax's six-month exclusivity period. Thus, in a no-payment settlement, there would have been greater price competition during at least those six months. In any event, because the Commission's ultimate finding relied on the feasibility of a no-payment settlement with an earlier entry date, we only consider that agreement as a less restrictive alternative.

payment for *a later* entry date." (emphasis added). Impax does not dispute that an agreement with an earlier entry date would be less restrictive.

Impax does argue that the Commission "flipped the burden of proof" in finding that such a less restrictive settlement was feasible. We disagree. The Commission concluded that there was a "strong showing" of the possibility of less restrictive settlement, and only then asked whether Impax had rebutted that evidence. That is a normal way of evaluating whether a plaintiff has met its burden of persuasion.

So we turn to whether substantial evidence supports the Commission's conclusion that Complaint Counsel had established a less restrictive alternative. First is the fact that most settlements between brand and generic makers do not include reverse payments. The Commission relied on an expert witness who analyzed industry practice and studies showing that from 2004-2009 "only 30 percent of the patent settlements filed with the FTC involved both compensation from the branded firm to the generic firm and restrictions on generic entry." In recent years, reverse payment settlements may have become even rarer; over 80 percent of brand-generic settlements reached within the year following *Actavis* did not include a reverse payment.

Impax suggests this evidence of industry practice is not probative of whether it had the opportunity to enter in a no-payment settlement. But leading scholars have recognized that other parties' "actual experience in analogous situations" can help establish the feasibility or practicality of a less restrictive

alternative. 11 AREEDA & HOVENKAMP, *supra*, ¶1913b, at 398; *accord* Hemphill, *Less Restrictive*, *supra*, at 984 ("One useful indicia of practicality is that the alternative has been implemented by this or other firms in similar circumstances."); *see also Ind. Fed'n of Dentists*, 476 U.S. at 454 (recognizing the FTC's expertise about commercial practices). Showing that the alternative is "rooted in real commercial experience" may be especially compelling as the defendant often will not want to acknowledge its willingness to enter into an arrangement that would not have included "the illicit profits arising from an anticompetitive effect." *Id.* at 984-85; *see also* Kevin B. Soter, Note, *Causation in Reverse Payment Antitrust Claims,* 70 Stan. L. Rev. 1295, 1336 (2018) (raising concerns about rules that would "tell[] defendants that all they need to do to avoid liability is to insist in settlement talks that the only agreement they would make is an illegal one").

And the Commission did not rely on industry practice alone. It acknowledged but refused to credit the trial testimony of Impax's chief negotiator, who said that Endo was "adamant about preventing pre-2013 entry."[9] The Commission noted that this resolute trial testimony was inconsistent with the witness's prior statements that he could not remember discussing pre-2013 entry dates with Endo. In that earlier testimony, the negotiator said he could not remember if "Impax ever 'tried to get a date earlier than January of 2013'" or whether "Endo ever told

[9] The Commission's consideration of this testimony further dispels Impax's claim that the Commission did not find a settlement with an *earlier* entry date to be a viable alternative.

Impax that it would 'not settle the litigation' with an entry date before 2013." Doubts about the negotiator's newfound certainty allowed the Commission not just to reject his testimony but also to treat it as evidence of the possibility of pre- 2013 entry. *See Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 147 (2000) (discussing the "general principle of evidence law that the factfinder is entitled to consider a party's dishonesty about a material fact as 'affirmative evidence of guilt'"). The Commission further noted that while early on Impax had unsuccessfully sought entry dates during 2011 and even January 2012, a significant time gap exists between those proposed entry dates and the 2013 entry date in the final agreement. The professed failure to consider other possible 2012 entry dates thus casts doubt on the notion that an agreement with pre-2013 entry was unachievable.[10]

Finally, economics support the Commission's finding that Endo would have entered into a settlement with an earlier entry date if it could have could have kept the more than $100 million it ended up paying Impax. Hemphill, *Less Restrictive*, *supra*, at 984 (recognizing that a plaintiff could use "expert testimony based on economic theory" to show a likelihood that the parties would have entered into a less restrictive alternative). If everything has a price,

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[10] The case-specific nature of this aspect of the FTC's ruling undermines Impax's concern that the agency's decision would invalidate all reverse payment settlements. So does the FTC's enforcement record. During the first fifteen years of this century, the agency challenged only 6 of the 1336 brand/generic settlements entered into during that period. FTC BUREAU OF COMPETITION, OVERVIEW OF AGREEMENTS FILED IN FY 2016, at 4.

then those large payments were the price for Impax's delayed entry. *King Drug*, 791 F.3d at 405 n.23; *Cipro*, 348 P.3d at 871. Such "fairly obvious" observations can show the feasibility of a less restrictive alternative. 11 AREEDA & HOVENKAMP, *supra*, ¶1913b, at 398; *see also Ind. Fed'n of Dentists*, 476 U.S. at 454 (holding that deference is due FTC's assessment of business practices).

Three evidentiary legs—industry practice, credibility determinations about settlement negotiations, and economic analysis—thus supported the Commission's conclusion that Endo would have agreed to a less restrictive settlement. 11 AREEDA & HOVENKAMP, *supra*, ¶1914c, at 410 (stating that a finding of less restrictive alternative should be based on alternatives "that are either quite obvious or a proven success"). As for Impax's side of things, of course it would have preferred the settlement that paid it over $100 million. But any reluctance Impax had to agree to a no-payment settlement based on a "desire to share in monopoly rents" cannot undermine the Commission's finding that a less restrictive settlement was viable. *See* Hemphill, *Less Restrictive*, *supra*, at 984-85; *see also* Soter, *supra*, at 1336.

Our question is not whether the Commission could have reached a different result on the less-restrictive-alternative question. It is whether there was evidence that would allow a reasonable factfinder to conclude that a no-payment settlement was feasible. *Ind. Fed'n of Dentists*, 476 U.S. at 454; *see also Ripley v. Chater*, 67 F.3d 552, 555 (5th Cir. 1995) (noting that substantial evidence can even be less than a preponderance). Because there was more than

enough evidence to support that unanimous view of the Commissioners, we must uphold their view that a less restrictive alternative was viable. And that means the reverse payment settlement was an agreement to preserve and split monopoly profits that was not necessary to allow generic competition before the expiration of Endo's patent. As a result, Impax agreed to an unreasonable restraint of trade.

* * *

The petition for review is DENIED.

Appendix B

UNITED STATES FEDERAL TRADE COMMISSION

No. 9373

IN THE MATTER OF IMPAX LABORATORIES, INC.,

Respondent.

Filed: March 28, 2019

Commissioners: SIMONS, Joseph J.; PHILLIPS, Joshua N.; CHOPRA, Rohit; SLAUGHTER, Rebecca K.; WILSON, Christine S.

OPINION

PHILLIPS, J., *Commissioner*:

I. INTRODUCTION

The Constitution empowers Congress to "promote the progress of science and useful arts" by creating intellectual property rights, including patents. U.S. CONST. art I, §8, cl. 8. Congress has done so since the founding of our Republic and, today, the United States leads the world in, among other things, the development and manufacturing of pharmaceutical drugs, which save and enhance lives around the world.

But Americans too often pay more than they should for the prescription drugs they need.

In 1984, Congress sought to address this problem by enacting the DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §355) (1994) ("Hatch-Waxman Act"), which created a specialized process to encourage the market entry of generic prescription pharmaceutical drugs. Generic drugs contain the same active ingredients as branded drugs, but typically at a much lower cost. The Hatch-Waxman Act, together with other legislation at the federal and state levels, has facilitated a "dramatic rise in sales of generic drugs," making them more widely available to Americans who would otherwise be forced to pay higher branded drug prices. *See* CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (July 1998), https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf. Under the Hatch-Waxman Act, generic drugs with the same active pharmaceutical ingredients as, and bioequivalent to, branded drugs already approved by the Food and Drug Administration (FDA) can take advantage of an abbreviated regulatory review. If the generic drug manufacturer is the first to seek approval, the Hatch-Waxman Act can confer upon it six months of exclusive sales. Abbreviating the regulatory process and awarding the first filer an exclusive sales period together have encouraged competition in pharmaceutical drugs and, accordingly, provided greater access to healthcare at lower prices.

As explained below, where a patent protects the underlying drug and a generic manufacturer certifies

that patent is invalid, unenforceable, or will not be infringed,[1] this certification automatically triggers the patent holder's ability to sue the generic. In this way, the Hatch-Waxman Act strikes a balance to encourage generic entry while protecting innovation, by giving the branded drug manufacturer an opportunity to assert its patent rights before the FDA approves the sale of the generic drug. This right allows the innovator to protect the congressionally authorized fruits of its labor (to the extent its patents are valid), maintaining the incentive to innovate that patent protection creates.

For decades, the Federal Trade Commission ("Commission") has prioritized efforts to make pharmaceutical drugs more affordable and accessible to American consumers by fostering competition between generic and branded drugs. That effort has included policing anti-competitive abuses of the regulatory process, and, as is relevant in this case, settlements of litigation brought by branded drug manufacturers against their generic competitors seeking to come to market using the Hatch-Waxman Act process.

This case involves a particular form of patent litigation settlement between a branded patent-holder and a generic challenger known as a "reverse payment" settlement. In a reverse payment settlement, the branded drug maker—the *plaintiff* in the patent infringement action—pays the patent challenger and alleged infringer—the *defendant*—to

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[1] Otherwise known as a Paragraph IV certification. See infra Section II.A.

refrain from offering its generic drug for a period of time as part of a settlement of patent litigation. The value in the settlement flows in the opposite direction of what one would ordinarily expect, where the defendant and alleged infringer might pay the plaintiff intellectual property (IP) rights holder for allegedly violating those rights. *See FTC v. Actavis*, 570 U.S. 136, 152 (2013).

For years, the FTC challenged reverse payment settlements as anticompetitive.[2] Early on, some courts considering these settlements held that, so long as the generic entry date was before the patent expired, the settlement was within the "scope of the patent" and therefore beyond the reach of the antitrust laws. *See, e.g., Schering-Plough Corp. v. FTC,* 402 F.3d 1056 (11th Cir. 2005); *In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 544 F.3d 1323, 1332-1337 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212-213 (2nd Cir. 2006). Other courts agreed with the FTC that such settlements raise valid antitrust concerns, treating them as per se unlawful or subject to truncated "quick look" review. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003); *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214-218 (3d Cir. 2012), *judgment vacated by* 570 U.S. 913, 133 S. Ct. 2849 (2013), *reinstatement granted by* 2013 WL 5180857 (3d Cir. 2013). In *FTC v. Actavis*, 570 U.S. 136 (2013), the Supreme Court addressed

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[2] *See generally,* FTC Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions (Jan. 2010), https://wwwftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

this circuit split and made clear that the magnitude and direction of the reverse value flow in these settlements raise a red flag, suggesting that the parties may be using the settlement to split monopoly rents by paying would-be generic competitors to stay out of the market, and thereby insulating the brand from the risk of competition that would otherwise manifest. That led the Court to hold that reverse payment settlements, even when they limit competition within the scope of the patent, can still violate the antitrust laws, and are to be analyzed under the rule of reason. *Id.* at 158-60. This case provides the Commission our first opportunity to apply Actavis, and to develop the rule of reason analysis that it directs.

As described below, the facts of this case make clear that Respondent Impax Laboratories, Inc. (now Impax Laboratories LLC) ("Impax" or "Respondent") contrived with Endo Pharmaceuticals, Inc. ("Endo") to accomplish precisely what led the Court in *Actavis* to subject reverse payments settlements to antitrust scrutiny—*i.e.*, the elimination of the risk of competition in return for sharing monopoly rents.

On January 19, 2017, the Commission issued an Administrative Complaint alleging that Impax, a generic manufacturer, had entered into an unlawful reverse payment settlement with Endo, the maker of Opana ER, an extended-release formulation of oxymorphone, an opioid used to treat pain.[3] During

[3] Endo is not before us in this case because it has settled the FTC's claims against it regarding its 2010 patent settlement for Opana ER. *See* Stipulated Order for Permanent Injunction, *FTC*

the administrative trial, Complaint Counsel submitted evidence that Endo agreed to pay Impax to abandon its patent challenge and to forgo entering the market with its lower-cost generic version of Opana ER until January 2013. IDF 124, 127, 129; ID at 138; Koch, Tr. 236, 239; RX364 at 0003-08, 0010-11 (definitions, patent settlement and license provisions of the Settlement and License Agreement between Endo and Impax ("SLA")); *see also* CX3164 at 009-11 (Impax's Responses to Requests for Admission No. 15 and 17).[4] Rather than a simple cash payment from Endo to Impax, Complaint Counsel argued that the reverse payment settlement involved an unlawful transfer of value in several forms: (1) freedom from generic competition during Impax's first 180 days on the market by virtue of Endo's agreement to refrain from offering an "authorized generic" version of Opana ER (the "No-AG Commitment");[5](2) a contingent payment—ultimately worth $102 million—designed

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v. Endo Pharm., Inc., No. 17-cv-00312-WHO (N.D. Cal., Feb. 2, 2017).

[4] We use the following abbreviations in this opinion:
Compl.: Complaint
ID: Initial Decision
IDF: Initial Decision Finding of Fact
Stip: Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity
Second Stip: Second Set of Joint Stipulations
CCAB: Complaint Counsel's Brief on Appeal
RB: Respondent's Answering Brief to Complaint Counsel's Appeal Brief
CCRB: Complaint Counsel's Reply Brief on Appeal

[5] An "authorized generic" drug typically refers to an approved brand name drug that is marketed without the brand name on its label. An authorized generic may be marketed by the brand name drug company, or another company with the brand company's permission.

to ensure that Impax recouped the value of the No-AG Commitment, in the event Endo destroyed the market for oxymorphone ER; and (3) a payment to Impax of $10-40 million, purportedly for an independent development and co-promotion deal. RX364 at 0003-08, 0010-11; *see also* Koch, Tr. 234-39, 241; CX0326 (email attaching execution version of the Development and Co-Promotion Agreement).

Complaint Counsel alleged that Impax's conduct denied patients the opportunity to purchase lower-cost generic versions of Opana ER until at least January 2013, and forced them, instead, to pay hundreds of millions of dollars a year more for Endo's branded product. Complaint Counsel concluded that, in so doing, Impax violated Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §45.

Impax denied that Endo agreed to pay or paid Impax to abandon its patent challenge or to forgo entering the market for generic Opana ER. Answer ¶3. Among other defenses, Impax asserted that the conduct had substantial procompetitive justifications, benefited consumers and the public interest, and avoided potential infringement of valid patents. Answer, Affirmative Defenses ¶8.

The case went to a 12-day trial before Chief Administrative Law Judge ("ALJ") D. Michael Chappell. Judge Chappell heard live testimony from 18 witnesses and admitted into evidence over 1250 exhibits. ID at 3. In a 162-page decision issued on May 11, 2018, Judge Chappell found that Complaint Counsel had failed to prove a violation of Section 5 of the FTC Act, and dismissed the Complaint. Complaint

Counsel filed a timely appeal. The Commission heard the parties' oral arguments on October 11, 2018.

For the reasons set out below, the Commission reverses the Initial Decision, concludes that Impax has violated Section 5 of the FTC Act, and enters a cease and desist order.

II. LEGAL AND FACTUAL BACKGROUND

A. The Hatch-Waxman Act and the *Actavis* Decision

Under the Hatch-Waxman Act, when a manufacturer seeks to market a new prescription drug, it must submit a New Drug Application and undergo a long and costly testing process. The manufacturer's application must identify the "number and the expiration date" of any relevant patents. 21 U.S.C. §355(b)(1). Once the FDA has approved the drug, a manufacturer seeking to market a generic version may file an Abbreviated New Drug Application (ANDA) certifying that the product contains the same ingredients as, and is biologically equivalent to, the brand-name drug. 21 U.S.C. §355(j)(2)(A)(ii), (iv). The ANDA process "allow[s] the generic to piggy-back on the pioneer's approval efforts" rather than conducting its own rigorous testing process. *Actavis*, 570 U.S. at 142.

To protect the branded manufacturer's incentive to innovate, when a generic manufacturer submits an ANDA, it must assure the FDA that the generic drug will not infringe any valid patents covering the branded drug (as listed in the FDA's official Orange Book). If the branded manufacturer has listed relevant, non-expired patents, the generic manufacturer may file what is known as a "Paragraph

IV" certification declaring that those patents are "invalid or will not be infringed by the manufacture, use, or sale" of the generic drug.[6] 21 U.S.C. §355(j)(2)(A)(vii)(IV).

Filing a paragraph IV certification "automatically counts as patent infringement" and entitles the brand manufacturer to sue. *Actavis*, 570 U.S. at 143; *see* 35 U.S.C. §271(e)(2)(A). If the branded company files suit within 45 days, the FDA may not approve the generic drug for 30 months, while the parties litigate their patent dispute. *Actavis*, 570 U.S. at 143. If the courts resolve the patent litigation during this 30-month period, the FDA follows that determination. *Id.* If the patent case remains unresolved at the end of 30 months, the FDA may approve the generic. *Id.*; *see* 21 U.S.C. §355(j)(5)(B)(iii). The generic manufacturer would then have the right to launch "at risk,"[7] with the consequence that if the "court proceeding ultimately determines that the patent was valid and infringed, the generic manufacturer will be liable for the brand-name manufacturer's lost profits despite the FDA's approval." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 241 (3d Cir. 2017). These damages can be significant.

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[6] A Paragraph IV certification is not the only avenue; ANDA filers may also utilize Paragraphs I, II or III, certifying, respectively, that: patent information has not been filed, the relevant patent(s) have expired, or the date on which the patent(s) expire. *See* 21 U.S.C. §355(j)(2)(A)(vii)(I)-(III).

[7] An "at risk" launch occurs when a generic firm begins marketing its product before a non-appealable decision in the relevant patent litigation. IDF 451.

In adopting the Hatch-Waxman Act framework, Congress sought to give generic manufacturers a "special incentive" to be the first to file an ANDA challenging a branded drug's patents under paragraph IV. *See Actavis*, 570 U.S. at 143. The first filer "will enjoy a period of 180 days of exclusivity" from other generic competition if it successfully brings the product to market. *Id.* at 143-44; *see* 21 U.S.C. §355(j)(5)(B)(iv). The Hatch-Waxman Act accomplishes this by preventing other ANDA filers from entering the market during the exclusivity period, whenever that occurs. *See* 21 U.S.C. §355(j)(5)(B)(iv). The exclusivity period can be worth hundreds of millions of dollars to a generic manufacturer. *Actavis*, 570 U.S. at 144. Because the Hatch-Waxman Act only prevents other ANDA filers from entering, however, the branded manufacturer may still distribute its own generic equivalent, commonly known as an "authorized generic" or "AG." *See King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 396 (3d Cir. 2015).

In *Actavis*, the Supreme Court considered the antitrust implications of reverse payment settlement agreements in which a branded drug manufacturer pays a generic entrant to abandon its patent challenge under the Hatch-Waxman Act and delay launching its product. The Court held that reverse payment settlements can have "significant adverse effects on competition," even if they allow a generic rival to introduce its product before the end of the patent's term—*i.e.*, within the temporal scope of the patent. *Actavis*, 570 U.S. at 148. These settlements essentially allow a branded manufacturer to buy "the exclusive right to sell its product, a right it already claims but

would lose" were a court to declare the patent "invalid or not infringed." *Id.* at 153-54. The settlement may keep drug prices at monopoly levels while "dividing that return between the challenged patentee and the patent challenger." *Id.* at 154. In the process, "[t]he patentee and the challenger gain; the consumer loses." Id. These "anticompetitive consequences will at least sometimes prove unjustified." *Id.* at 156.

In a lawsuit challenging a reverse payment under *Actavis*, "offsetting or redeeming virtues are sometimes present." *Id.* For example, a reverse payment may "amount to no more than a rough approximation" of the branded company's saved litigation expenses or reflect "compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item." *Id.* at 156; *see also id.* at 159. If a payment reflects such "traditional settlement considerations ... there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Id.* at 156.

But when a branded manufacturer makes a large, unexplained payment to a generic challenger, this "suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness." *Id.* at 157. The payment "likely seeks to prevent the risk of competition," which constitutes the "relevant anticompetitive harm." *Id.* Preventing the risk of competition is the

anticompetitive harm at issue in *Actavis*, and a large and unjustified payment from the plaintiff (the branded manufacturer) to the defendant (the generic manufacturer) triggers antitrust scrutiny because it may reflect the plaintiff's dividing its monopoly profits to accomplish this goal.

The question presented in *Actavis* was whether a reverse payment settlement "can sometimes unreasonably diminish competition in violation of the antitrust laws." *Id.* at 141. The Court held that the answer is yes. In so doing, it rejected abbreviated analysis either for or against liability. The Court rejected the "scope of the patent" test, which essentially held that reverse payment settlements were lawful so long as they did not prolong the life of the patent. *Id.* at 158. And it likewise rejected the Commission's argument that reverse payment settlements should be considered "presumptively unlawful." *Id.* at 158-59. The Court held that reverse payment settlements are to be analyzed under traditional rule of reason analysis. *Id.* Whether a reverse payment is anticompetitive "depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.* at 159. The Court "le[ft] to the lower courts the structuring of the present rule-of-reason antitrust litigation," keeping in mind that the "basic question" in each case is whether a given reverse payment settlement agreement "unreasonably diminish[ed] competition in violation of the antitrust laws." *Id.* at 160, 141.

B. Opana ER and Potential Generic Competition

Impax develops, manufactures, and sells generic drugs. IDF 3. This case considers its settlement of patent litigation initiated by Endo, the manufacturer of branded Opana ER. The settlement included a reverse payment to Impax in exchange for Impax's agreement not to launch a competing generic drug until January 2013. As developed below in Section V.A.3, the reverse payment here consisted of the No-AG Commitment and the "Endo Credit," a payment Endo would make in the event the Opana ER market declined in the two and a half years between the time of settlement and Impax's entry date.[8]

In 2006, Endo received FDA approval for and launched Opana ER, an extended-release formulation of oxymorphone, an opioid used to treat pain. IDF 41-47. In 2007, Impax filed an ANDA to market a generic version of Opana ER and certified under paragraph IV that Endo's patents were invalid, unenforceable, or would not be infringed. IDF 55-60. Impax was the first generic manufacturer to file an ANDA and paragraph IV certification for the five most popular dosage strengths of Opana ER, which comprised over 95 percent of Opana ER sales. IDF 173; Second Stip. ¶7.

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[8] As discussed further *infra* Section V.A.3.c, the circumstances surrounding the development and co-promotion agreement suggest it may also have been a means of masking value transferred in exchange for eliminating the risk of competition; but we need not decide whether the arrangement was a *bona fide* agreement for justified value. To the extent the $10 million upfront payment under the agreement is unjustified, it simply increases the value of the overall reverse payment we find to be large and unjustified.

It was therefore entitled to 180 days of exclusivity from competition with other ANDA filers at those doses. IDF 174.

Endo timely sued Impax in January 2008, claiming that Impax's ANDA infringed two of its patents, which expired in September 2013. IDF 53, 61, 68. The suit triggered the Hatch-Waxman Act's 30-month stay, precluding the FDA from finally approving Impax's ANDA until June 14, 2010 or until the patent dispute was resolved in Impax's favor. IDF 62-63. Endo and Impax first discussed settlement in the fall of 2009, but Endo rejected Impax's proposals for a generic entry date in July 2011, December 2011, or January 2012. IDF 112-18.

Endo reopened settlement talks with Impax on May 17, 2010, approximately three days after learning that the FDA tentatively approved Impax's ANDA, three weeks before the patent trial was scheduled to begin, and one month before the 30-month stay would have expired. IDF 119-23, 283; Koch, Tr. 340-41. Endo recognized the possibility that Impax might launch its generic at risk upon receiving final FDA approval—expected the following month—or that Impax might launch after completing the patent trial and any relevant appeals "around June" of 2011. Stip. at 007 ¶17 (30-month stay set to expire on June 14, 2010); Koch, Tr. 340-41; Snowden, Tr. 417-18; CX4025 (Bingol Dep.) at 26; CX2564 at 094; CX2576 at 0001, 0003 ("If they wait for the appeal to play out, it will happen around June of next year [*i.e.*, 2011]"). Endo sought a commitment from Impax that it would instead refrain from launching its generic until 2013. IDF 132, 147, 154, 156, 158.

Endo had a substantial financial interest in delaying Impax's generic entry. Endo forecast that, if Impax launched its generic at risk, Endo would lose 85 percent of its branded Opana ER sales within three months, and $100 million in sales revenue within six months. IDF 133; *see also* CX1106 at 005 (Endo's July 2009 Strategic Plan: "Each month that generics are delayed beyond June 2010 is worth ~$20 million in net sales per month."). To prevent this, Endo planned to remove original Opana ER from the market, replace it with a reformulated, "crush-resistant" version, and obtain additional patent protection and other advantages for the reformulated drug that would fend off competition. IDF 96-98, 102, 109.[9] Doing so would move consumers to the reformulated version, effectively destroying the market for original oxymorphone ER, extending Endo's market power and negating the effect of Impax's entry. Koch, Tr. 238; CX5007 (Hoxie Rebuttal Report) ¶43 at 023; Mengler, Tr. 527. At the time of the 2010 settlement negotiations, Endo had not yet sought FDA approval for the reformulated product, but was forecasting a launch at some point in late 2010 or in 2011. *See* IDF 105.

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[9] In some circumstances, this strategy of avoiding generic competition, commonly known as "product hopping," can itself violate the antitrust laws. *See, e.g.*, *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 659 (2d Cir. 2015) ("[W]e conclude that the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates §2 of the Sherman Act.").

Endo recognized that its reformulation plan could succeed only if it beat Impax's generic product to the market with enough time to transition patients away from original Opana ER. IDF 99-109. Patients cannot switch long-acting opioids overnight; the process instead requires careful supervision as physicians adjust dosages. IDF 106. Endo understood that it would take six to nine months to transition the market to the reformulated product. *Id.* It sought to protect its sales revenues from generic competition by completing this transition before Impax could launch its generic version of the original product; as developed below in Section II.C, the settlement at issue here was key to realizing this goal. IDF 97, 99-101, 103. Reformulating Opana ER in time would significantly reduce demand for Impax's generic product, since pharmacists would not be able automatically to substitute it for Endo's reformulated product, as they could for the original product. IDF 202, 204.[10]

Endo projected that its reformulation plan, if successful, would generate hundreds of millions of dollars in additional sales revenue for branded Opana ER. It predicted that, if reformulated Opana ER beat generics to the market, its peak-year sales would exceed $199 million by 2016. IDF 99; CX2578 at 0008. By contrast, if generics launched before Endo could transition the market, Endo's peak projected annual

[10] Generics may be automatically substitutable under state law for a branded drug only when they are therapeutically equivalent. Impax's generic was equivalent to the original product (which Endo was planning to withdraw), not the reformulated product. IDF 14, 29, 199-200. Automatic substitution is the primary mechanism for generic companies' sales. IDF 32.

sales in 2016 would be a mere $10 million. IDF 99; CX2578 at 0008.

C. The Impax-Endo Patent Settlement

The trial in the Endo/Impax patent litigation commenced on June 3, 2010. IDF 73. Just a few days later, the parties settled. IDF 74. On June 8, 2010, they simultaneously executed two agreements: a Settlement and License Agreement and a Development and Co-Promotion Agreement ("DCA"), which was incorporated into the SLA. IDF 74, 245; Stip. at 007-08 ¶¶18-19; Second Stip. ¶26. Under the SLA, Impax agreed not to launch its generic Opana ER until January 1, 2013, two and one-half years later. IDF 124; RX364 at 0001-02, 0009 (SLA §§1.1, 4.1(a)). The settlement thus gave Endo a "clear path (until January 2013) to establish ... demand" for the reformulated product. RX007 at 001 (Endo narrative for 3Q 2010 Earnings Call).

In return, Endo agreed to the No-AG Commitment, whereby it pledged not to sell an authorized generic to compete with Impax's five dosage strengths of generic Opana ER during its 180-day first-filer exclusivity period. IDF 127; RX364 at 0010-11 (SLA §4.1(c)). That concession would shield Impax from all generic competition (not just the competition from other ANDA filers that the 180-day exclusivity period provides) for six months after its January 2013 launch date. IDF 127, 130, 187. Impax considered the No-AG Commitment to be extremely valuable, since the absence of a generic rival meant that Impax would be able to sell more of its product and charge higher prices. IDF 172, 177, 179-83, 188-91; CX2753-004 (projecting that Impax's profits

during the exclusivity period would be $53 million without an AG competitor but $28.5 million with an AG).

The SLA contained a provision known as the "Endo Credit," which would protect Impax in the event the Opana ER market declined in the two-and-a-half years between the time of settlement and Impax's entry date. IDF 129. Impax feared—correctly, as it turns out—that Endo was planning to shift patients to a reformulated Opana ER before the generic launch date, which would impair the market for Impax's generic product and "subvert the value of the deal." IDF 139-43, 148-49, 204-05. To ensure against that possibility, Impax first sought an acceleration trigger allowing it to enter the market before 2013 should Endo sales fall below a certain threshold. IDF 137-39. The concept was that, in the event sales began dropping, Impax could enter the market early. This would have allowed competition, benefiting consumers. Endo rejected the acceleration trigger, but instead agreed to make a cash payment to Impax (*i.e.*, the Endo Credit) if Endo's sales revenues for original Opana ER fell by more than 50% between their quarterly peak and the fourth quarter of 2012 (the quarter before Impax's launch date). IDF 129, 147, 195; *see* RX364 at 0003-06, 0012 (SLA §§1.1, 4.4).[11] The Endo Credit was designed to "back-up" the value of the No-AG Commitment and provide Impax with the profits it would have earned had Endo not shifted

[11] Conversely, the SLA provided that if Endo's Opana ER sales *grew* by a certain percentage before Impax's entry date, Impax would need to pay royalties to Endo. IDF 128; RX364-0012 (SLA §4.3).

the market away from original Opana ER. IDF 197-215.

The SLA also provided Impax with a license to Endo's current and future patents covering original Opana ER, and a covenant by Endo not to sue Impax for infringing those patents. IDF 125-26, 567-68, 570, 592-93; RX364 at 0001-02, 0009-10 (SLA §§1.1, 4.1(a)-(b)). At the time of the settlement, Impax knew that Endo had additional pending patent applications (whose outcomes were uncertain) and anticipated that Endo could acquire other patents. IDF 167, 569, 572. When negotiating settlements with brand companies, Impax regularly sought licenses to future patents to ensure that Impax's generics had freedom to operate without patent risk. IDF 565-66.

Under the DCA, Endo and Impax agreed to collaborate regarding the development and marketing of a potential Parkinson's disease treatment known as IPX-203. IDF 244, 246; RX365 (executed DCA). Endo agreed to make a $10 million upfront payment to Impax within five days, plus up to $30 million in additional "Milestone Payments" contingent on achieving certain benchmarks in developing and commercializing the product. IDF 247-48; RX365 at 0009 (DCA §3.2). In addition, the parties agreed that Impax would promote IPX-203 to neurologists, while Endo would promote it to non-neurologists. IDF 249; RX365 at 0010-11 (DCA §4.1). Endo would receive a share of the profits—100 percent of gross margins on sales resulting from prescriptions by non-neurologists—if IPX-203 ever reached the market. IDF 250; RX365 at 0009-10 (DCA §3.4).

D. Developments after the Settlement Agreement

On June 14, 2010—six days after finalizing the SLA and DCA—Impax received final FDA approval to market its generic Opana ER at four dosage strengths. IDF 66.[12] Had Impax not settled with Endo, it would have been permitted to launch its generic product at risk as of that date. IDF 451-52. Coupled with the Hatch-Waxman Act, however, the settlement effectively precluded entry by Impax and by other generic manufacturers, which had to wait until Impax, the first filer, entered the market in January 2013 and then completed its six-month exclusivity period. IDF 449. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 41 (1st Cir. 2016) ("[T]he first filer may create a bottleneck, as all other generic manufacturers must wait for the exclusivity period to end before launching their own generics.").

In March 2012, Endo introduced its reformulated Opana ER and stopped selling original Opana ER (as Impax had feared). IDF 110, 229-31. It then attempted to undermine the market for the original formulation. In August 2012, for instance, Endo publicly declared that the original product was unsafe. IDF 233.[13]

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[12] Impax received final approval for a fifth dosage strength on July 22, 2010. IDF 67.

[13] Endo filed multiple citizen petitions with the FDA asking it to: (1) determine that original Opana ER was discontinued for safety reasons; (2) refuse to approve any ANDAs to market a generic version of the drug; and (3) withdraw its approval of Impax's generic. IDF 233; CX3203 (citizen petitions). In response, the FDA determined that Endo did *not* withdraw original Opana ER for safety reasons. IDF 235.

Because these actions effectively eliminated the market for the branded original Opana ER, Endo was required to pay Impax $102 million under the Endo Credit. IDF 236-37.

Between 2012 and 2014, Endo obtained additional patents related to Opana ER and asserted them against generic manufacturers of both the original and reformulated versions. IDF 575-77, 579-84. In 2015 and 2016, Endo won district court rulings enjoining manufacturers other than Impax from selling their generic versions of original Opana ER until as late as 2029, and enjoining all manufacturers, including Impax, from selling generic versions of reformulated Opana ER. IDF 578, 586-87. The Federal Circuit recently affirmed one of those rulings. *See Endo Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F. App'x 962 (Fed. Cir. 2018).

Impax has sold generic Opana ER continuously since January 2013 and is the only generic manufacturer that has not been enjoined from the market. IDF 596-97. Even so, the SLA did not fully protect Impax from the risk of litigation regarding Endo's patents. In May 2016, Endo sued Impax for breaching the SLA by failing to negotiate a royalty for the patents Endo acquired after the SLA and, consequently, for infringing those patents. IDF 589; CX2976 (Endo's Complaint for breach of contract and patent infringement). The parties settled that dispute in August 2017. ID 590-91; CX3275 (Contract Settlement Agreement), in camera.

In September 2017, Endo voluntarily withdrew its reformulated Opana ER from the market in response to a June 2017 FDA request. IDF 111. The FDA had

determined that the benefits of the reformulated product no longer outweighed the risks that consumers would abuse it via injection. CX6048-0001 (June 8, 2017 FDA news release). As a result of that withdrawal and of Endo's decision to withdraw its original Opana ER product, Impax's generic original Opana ER is now the only extended-release oxymorphone product available to consumers. IDF 598.

E. The FTC's Complaint

In January 2017, the FTC issued an administrative complaint against Impax, alleging that its reverse-payment settlement with Endo was an unfair method of competition in violation of Section 5(a) of the FTC Act. Compl. ¶¶101-02. The Complaint charges that Impax agreed to abandon its challenge to Endo's patents and stay off the market for two and a half years in exchange for a payment of at least $47 million (and potentially over $100 million). Compl. ¶¶1, 3, 62, 67. According to the Complaint, a payment of this size could not be justified as either a reasonable measure of saved litigation costs or the value of any services that Impax provided. Compl. ¶¶68, 72-73. The Complaint alleges that the payment was designed to, and did, eliminate the risk that Impax would launch its generic version of Opana ER before January 2013. Compl. ¶94. Endo and Impax allegedly injured competition by splitting Endo's monopoly profits for themselves, while depriving consumers of access to

generic drugs that could have saved them hundreds of millions of dollars. Compl. ¶¶4, 95-97.[14]

F. The Initial Decision

The ALJ held that Endo "provided Impax with a reverse payment, the purpose and effect of which was to induce Impax to give up its patent challenge and agree not to launch a generic Opana ER until January 2013." ID at 6-7. However, he further found that the "procompetitive benefits" of the agreement "outweigh[ed] the anticompetitive harm." *Id.* at 7. The ALJ reached this conclusion by applying the rule of reason burden-shifting framework.

The ALJ held that the first step of the rule of reason analysis placed on Complaint Counsel the burden of showing that the Endo-Impax Settlement produced anticompetitive effects within the relevant market. ID at 91. That, in turn, entailed a showing that Endo provided "payment for delay, or, in other words, payment to prevent the risk of competition." *Id.* at 98 (quoting *Smithkline Beecham,* 791 F.3d at 412). The ALJ observed that, under *Actavis,* the relevant anticompetitive harm from an unexplained reverse payment is the loss of the *risk* of competition. *Id.* at

[14] Prior to the evidentiary hearing before the ALJ, Complaint Counsel moved for partial summary decision to preclude Impax from offering certain procompetitive justifications for the settlement. The Commission denied the motion as premature because Impax had not received a full opportunity to articulate its procompetitive justifications and because the parties had not briefed the question of how the rule-of-reason inquiry should be structured. *See Impax Labs., Inc.*, 2017 WL 5171124, at *6, *9 & n.16 (F.T.C. Oct. 27, 2017).

100 (citing *Actavis,* 570 U.S. at 157) (emphasis supplied).

The ALJ held that the No-AG Commitment of the SLA gave Impax a six month monopoly on generic sales of Opana ER that was worth between $23 and $33 million in additional projected sales revenue to Impax, a value he assigned as part of the reverse payment. ID at 106, 114. As for the Endo Credit, the ALJ acknowledged that the provision eventually resulted in a cash payment of $102 million to Impax; but he held that the Endo Credit should be valued as of the date of settlement. *Id.* at 113. At that point, the value of the Endo Credit was "uncertain … and was contingent on unknown future events that were outside of Impax's control." *Id.* at 110. The ALJ thus did not assign independent value to the Endo Credit;[15] instead, he found that the payment "fulfilled its purpose" of providing Impax the profits that it would have received during the 180-day exclusivity period with no AG in the event of a sharp decline in the market. *Id.* at 114. The ALJ then found that the value of the No-AG Commitment of the SLA, as secured by the Endo Credit, amounted to between $23 and $33 million. *Id.* The ALJ found that this amount substantially exceeded Endo's saved litigation costs,

[15] The ALJ also rejected Complaint Counsel's effort to prove a value for the Endo Credit through testimony of their expert economist, Dr. Roger Noll. ID at 111. Professor Noll calculated values of the Endo Credit and No-AG Commitment under four potential sales scenarios, *id.,* and opined that the value ranged from $16.5 to $62 million. Tr. 1473-77; CX5000 (Noll Expert Report) App. F at 240. The ALJ opined that Professor Noll failed to adequately describe or explain the bases for his assumptions or calculations. ID at 111.

was unjustified, and that the parties agreed to the provision as an inducement to compensate Impax for giving up its patent challenge and committing not to launch a generic Opana ER until January 2013. *Id.* at 116, 138. He found these facts demonstrated that the SLA included a payment to prevent the risk of competition. *Id.* at 138-39.

The ALJ found that the $10 million upfront payment to Impax under the DCA was fair value for the profit-sharing rights given to Endo, and that the DCA was a *bona fide* product collaboration consistent with Endo's business interests. ID at 132, 138. He found that the payment was therefore justified. *Id.* at 138.

The ALJ found that Endo possessed market power. ID at 139. Pharmaceutical patents "by their nature," he explained, "often carry with them market power" because they provide "'the legal right to exclude generic competition and the practical ability to profitably charge higher prices than generic competitors would charge.'" *Id.* (quoting *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 668 (D. Conn. 2016)). He also took the view that, in this case, the "reverse payment settlement itself" was "strong proof of Endo's market power," since a firm lacking such power would have had no incentive to pay others to keep out of the market. *Id.* at 139-40 (discussing *Actavis*, 570 U.S. at 157). The ALJ further observed that regulatory barriers under the Hatch-Waxman Act, such as the 30-month stay on FDA approval of an ANDA, can serve to protect market power. *Id.* at 140. In the unique context of pharmaceutical reverse payments, he ruled, "the appropriate market in which

to assess the anticompetitive effects ... [is] the branded pharmaceutical product and its generic equivalents." *Id.* at 97. At the time of settlement, "Endo had a 100% share of the market for oxymorphone ER," *id.* at 140, and therefore possessed market power in a relevant market so defined. *Id.* at 139-40.

The ALJ held that, because Complaint Counsel had shown anticompetitive harm, the burden shifted to Respondent to demonstrate procompetitive benefits, the second step in the rule of reason analysis. *See generally* ID at 99, 141-47.

The ALJ rejected Complaint Counsel's argument that he should consider only those benefits that justified the anticompetitive reverse payment itself, and held instead that he should assess *all* procompetitive effects of the Impax-Endo settlement agreement. ID at 99-100 (finding that "to condemn an agreement based on the reverse payment term alone is an approach that is too abbreviated to permit proper analysis" (internal quotation marks omitted)). Viewing the settlement as whole, the ALJ concluded that Impax had met its burden to show procompetitive benefits. *Id.* at 146. The agreements settled litigation, and the broad patent license that Impax obtained had provided consumers with uninterrupted and continuous access to generic Opana ER since January 2013. *Id.* Absent the broad license, Endo could have asserted its later-acquired patents against Impax and enjoined Impax from selling generic Opana ER, just as Endo has enjoined other unlicensed generic manufacturers. *Id.* at 145. The ALJ also considered the fact that the SLA enabled Impax to enter the market prior to the expiration of Endo's Opana ER

patents, but noted this fact was "not dispositive." *Id.* at 146. The SLA enabled Impax to enter the market in January 2013, nine months before expiration of the initial Opana ER patents in September 2013, and sixteen years before the expiration of Endo's after-acquired patents in 2029. *Id.* Thus, the ALJ found that Respondent met its burden of proving procompetitive benefits of the SLA. *Id.*

Having found that the Respondent met its burden to demonstrate procompetitive benefits, the ALJ shifted the burden to Complaint Counsel to establish that the benefits could have been achieved with a less restrictive settlement agreement. ID at 146. The ALJ determined that Complaint Counsel failed to meet their burden. *Id.* at 147. He rejected Complaint Counsel's argument that the parties could have agreed to the very same patent license without a payment. *Id.* (finding that Complaint Counsel had not demonstrated that a settlement without a payment would have included the broad patent license). In reaching this conclusion, the ALJ noted that Impax twice proposed a settlement with a 2011 entry date and no reverse payment, and Endo rejected each proposal. *Id.* at 147, n.35.

The ALJ proceeded to assess the extent to which the Endo-Impax settlement harmed competition by actually delaying generic entry. ID at 150-58. He found the anticompetitive effects of the reverse payment to be "largely theoretical" because Impax would have been "unlikely" to launch its generic product before the agreement's January 2013 entry date in any event. *Id.* at 156-57. Impax would not have launched at risk, he found, because it was a relatively

small firm (less than $1 billion in revenues) that could have faced "bet the company" damages in the event of an adverse patent ruling after entry. *Id.* at 150. The ALJ found that Impax had no history of launching at risk in analogous situations, and that its management had not sought the approval of its board of directors required for such a launch. *Id.* at 150-51. Furthermore, he found, Impax's hypothetical entry after completion of the Endo-Impax litigation would not have occurred until "November 2011 at the earliest, and more likely [...] a date close to January 2013," *id.* at 156, even if Impax had been successful. The ALJ based this finding on the opinion of E. Anthony Figg, Respondent's expert, who testified regarding the time likely to be required for a hypothetical district court decision and for resolution of an appeal (and a possible remand) in the Endo-Impax patent litigation. Id. at 155-56.

The ALJ found that the procompetitive benefits of the SLA were, by contrast, "substantial," because the broad patent license has allowed Impax to sell generic Opana ER "without interruption for more than five years" and because Impax's product is now the "only available oxymorphone ER product" for consumers. *Id.* at 157; IDF 596-98. The ALJ concluded that the January 2013 entry date in the SLA, together with the broad patent license, enabled Impax's generic Opana ER to enter the market eight months before Endo's original Opana ER patents expired and sixteen years before Endo's after-acquired patents expired. ID at 157. Impax was able to continue selling its product without threat of patent infringement litigation due to its broad license. *Id.* "These actual consumer benefits," the ALJ concluded, "outweigh the theoretical

anticompetitive harm demonstrated in this case." *Id.* Even if it were assumed that Impax would have entered the market as early as June 2010, the ALJ added, the benefits to consumers of uninterrupted access to generic Opana ER for more than five years (from 2013 through 2018) would still outweigh any harm from two and a half years of delayed generic entry. *Id.*

Accordingly, the ALJ found that the evidence failed to demonstrate that the Endo-Impax settlement was an unreasonable restraint of trade in violation of Section 5 of the FTC Act, and he therefore dismissed the Complaint. ID at 158. Before the Commission, Complaint Counsel challenge the ALJ's conclusions that Impax met its burden to identify cognizable procompetitive benefits and that the settlement at issue was not anticompetitive. Impax challenges the ALJ's findings regarding market definition and power, but it does not challenge the ALJ's finding that it received a large and unjustified payment.

III. STANDARD OF REVIEW

Under the applicable regulations, the ALJ issues an initial decision following administrative trial, 16 C.F.R. §3.51, and the Commission reviews the ALJ's findings of fact and conclusions of law *de novo*, considering "such parts of the record as are cited or as may be necessary to resolve the issues presented." 16 C.F.R. §3.54(a). The Commission may "exercise all the powers which it could have exercised if it had made the initial decision." *Id.*; *see also* 5 U.S.C. §557(b). The *de novo* standard of review applies to both findings of fact and inferences drawn from those facts. *See Realcomp II, Ltd.*, 2007 WL 6936319, at *16 n.11

(F.T.C. Oct. 30, 2009), *aff'd*, 635 F.3d 815 (6th Cir. 2011).

IV. JURISDICTION

Respondent does not dispute that the Commission has jurisdiction over it and over the conduct challenged in the Complaint. Section 5(a) of the FTC Act grants the Commission authority to prevent "unfair methods of competition in or affecting commerce" by "persons, partnerships, or corporations," 15 U.S.C. §45(a)(1)-(2). Impax is a corporation as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. §44, over which the Commission has jurisdiction. *See* Stip. at 001-02 ¶¶4, 7. Impax's acts and practices at issue are subject matter over which the FTC has jurisdiction. *Id.* at ¶¶5, 7.

V. ANALYSIS

The Complaint alleges that the SLA and associated acts and practices are an agreement to restrain competition and constitute an unfair method of competition in violation of Section 5 of the FTC Act. Compl. ¶¶101-102. To determine whether this conduct violates Section 5 of the FTC Act, we follow case law that has developed under Section 1 of the Sherman Act.[16]

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[16] The Commission's authority under Section 5 of the FTC Act extends to conduct that violates the Sherman Act. *See,* FTC, Statement of Enforcement Principles Regarding "Unfair Methods of Competition" Under Section 5 of the FTC Act (Aug. 13, 2015), https://www.ftc.gov/system/files/documents/public_statements/735201/150813section5enforcement.pdf; *see also Actavis,* 570 U.S. at 145; *Cal. Dental Ass'n,* 526 U.S. at 762 & n.3; *FTC v. Motion Picture Advert. Serv. Co.,* 344 U.S. 392, 394-95 (1953); *Fashion*

In *Actavis*, the Supreme Court held that the rule of reason applies to reverse payment settlement cases, but explicitly left to the lower courts the task of structuring the inquiry. 570 U.S. at 160. Citing its holding in *California Dental Association v. FTC*, 526 U.S. 756 (1999), the Court directed trial courts to "avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on […] the presence of significant anticompetitive consequences." *Actavis*, 570 U.S. at 159-60. This case concerns a reverse payment settlement, the restraint within it, and the relationship between the two.

With the Supreme Court's *Actavis* guidance in mind, we apply the burden-shifting analysis that courts have used in other rule of reason cases, as informed by the Supreme Court's reasoning in *Actavis*. Under this framework, the plaintiff has the burden to prove that "the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market." *See Ohio v. American Express,* 138 S. Ct. 2274, 2284 (2018) ("*Amex*"); *Todd v. Exxon Corp.*, 275 F.3d 191, 206 (2d Cir. 2001) ("an actual adverse effect on competition"); *Law v. Nat'l Collegiate Athletic Ass'n,* 134 F.3d 1010, 1019 (10th Cir. 1998) ("substantially adverse effect on competition"); *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993) ("adverse, anti-competitive effects within the relevant product and geographic markets").

Originators' Guild of Am., Inc. v. FTC, 312 U.S. 457, 463-64 & n.4 (1941). In this proceeding, our analysis under Section 5 is the same as it would be under Section 1 of the Sherman Act.

Provided the plaintiff demonstrates anticompetitive harm, the burden shifts to the defendant to show a procompetitive rationale for the restraint. *Amex*, 138 S. Ct. at 2284; *Law*, 134 F.3d at 1019. If the defendant does so, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could reasonably be achieved through less anticompetitive means. *Amex,* 138 S. Ct. at 2284. If the plaintiff carries this burden, it prevails. 7 Areeda & Hovenkamp, ANTITRUST LAW ¶1507c, at 448 (4th ed. 2017). If the plaintiff does not, the adjudicator proceeds to weigh the harms and benefits against each other to judge whether the challenged behavior is, on balance, reasonable. *See Law v. NCAA,* 134 F.3d at 1019 (citing Areeda & Hovenkamp, *supra* ¶1502). Cases do not often reach the balancing stage.

A. Complaint Counsel's *Prima Facie* Case under *Actavis*

Complaint Counsel's first obligation is to make out a *prima facie* case, proving that the challenged restraint has a substantial anticompetitive effect in a relevant market. In the Hatch-Waxman Act litigation context, *Actavis* makes clear that a settlement involving a large and unjustified reverse payment raises a "red flag" that the parties may be agreeing to eliminate the risk of competition. A plaintiff may thus make out a *prima facie* case by proving a large, unjustified payment was made in exchange for deferring entry into the market or for abandoning a patent suit, plus the existence of market power. *See Nexium,* 842 F.3d at 59 (first step of rule of reason framed for the jury as requiring market power plus a

large and unjustified payment). The ALJ found that Impax received a large and unjustified payment as part of the settlement at issue, and Impax does not challenge that finding before the Commission.

We likewise find that Impax received a large and unjustified payment. In addition, we conclude that Complaint Counsel met their burden here. Complaint Counsel successfully raised the inference that Endo and Impax agreed to the large and unjustified payment as an inducement to Impax to give up its patent challenge and to commit not to launch a generic Opana ER until January 2013—thereby eliminating the risk of any generic entry until that time—and they proved the requisite market power. *See Actavis,* 570 U.S. at 154. Complaint Counsel demonstrated that the risk of earlier entry was real: there was a plausible threat that Impax could have entered the market prior to the agreed-upon entry date. *See In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 240 (D. Conn. 2015) (plaintiff must prove large, unjustified payment "as part of [a] settlement in order to shore up *some perceived risk*" of competition (emphasis added)). And *Actavis* makes clear that eliminating the risk of competition is a cognizable harm under the antitrust laws. 570 U.S. at 157. Complaint Counsel further demonstrated that the relevant product market consisted of branded and generic oxymorphone ER, and that Endo held market power.

1. Large, Unjustified Payment Raises Inference of Anticompetitive Harm

The *Actavis* Court described certain inferences that can be drawn from a large, unexplained reverse payment in a patent settlement. Such a payment raises a red flag signaling that the parties may not merely be settling valid claims, but may actually be entering an unlawful agreement to maintain and to share the brand's monopoly profits. As the Court explained, a large and unjustified reverse payment "may ... provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in a competitive market." 570 U.S. at 154. Such payments "would be an irrational act unless the patentee believed that generic production would cut into its profits." Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision,* 15 MINN. J. L. SCI. &TECH. 3, 25 (2014). The presence of a large and unjustified payment may thus signal the presence of an unlawful agreement yielding competitive harm. *See* Aaron Edlin, *et al., The Actavis Inference: Theory and Practice*, 67 RUTGERS U. L. REV. 585, 587, 591 (2015) ("The Court identified a large and unexplained payment as a suspicious act that suggests the patent holder is paying to limit competition."); *see, e.g., Smithkline Beecham,* 791 F.3d at 394 (payment "may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition").

2. Principles of Analysis for Evaluating Large, Unjustified Payments

To make out a *prima facie* case, any antitrust plaintiff must establish the existence or likelihood of substantial anticompetitive harm. *See Amex,* 138 S. Ct. at 2284; *Law,* 134 F.3d at 1019; *Brown Univ.,* 5 F.3d at 668 ("adverse, anti-competitive effects within the relevant product and geographic markets"). Under *Actavis*, this includes a demonstration that a "large and unjustified" reverse payment was made. 570 U.S. at 158.

When analyzing the size of the "payment" in a reverse payment case, factfinders should consider all value—cash and otherwise—that the branded drug manufacturer transfers to the generic through the settlement (including any side agreements that contemporaneous timing or other circumstances indicate should be considered part of the same transaction). *See infra* Section V.A.3; *see generally Smithkline Beecham,* 791 F.3d at 403 (*Actavis* is not limited to payments of cash and includes no-AG clauses).[17] The Endo/Impax settlement included both a cash payment under the DCA and non-cash or contingent forms of value, including the No-AG Commitment, the Endo Credit, and the licenses granted to Impax, all of which should be considered in

[17] As one district court wrote, "[a] settlement agreement may be very simple or tremendously complex, and it may involve all manner of consideration; and if, when viewed holistically, it effects a large and unexplained net transfer of value from the patent-holder to the alleged patent-infringer, it may fairly be called a reverse-payment settlement." *Aggrenox*, 94 F. Supp. 3d at 243.

valuing the reverse payment. *See In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 718 (N.D. Ill. 2016) (court should look at whether, "taken as a whole," the total payment Impax received under the SLA, the No-AG Commitment, and the DCA was large and unjustified). Any 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. *See In re Loestrin 24 Fe Antitrust Litig.,* 814 F.3d 538, 549 (1st Cir. 2016) (holding that non-monetary reverse payments are subject to *Actavis* because the Supreme Court contemplated that "a disguised above-market deal, in which a brand manufacturer effectively overpays a generic manufacturer for services rendered, may qualify as a reverse payment").

Contrary to Complaint Counsel's argument that demonstrating a payment is "large," along with a showing of market power, will establish a *prima facie* case, CCAB at 39-41, plaintiffs also need show that the reverse payment was "unjustified." *Actavis,* 570 U.S. at 158; *Loestrin 24 Fe,* 814 F.3d at 552.

Establishing that the payment is not otherwise justified is necessary for demonstrating that the payment is purchasing an exclusive right and preventing the risk of competition. In other words, it is the basis for attributing anticompetitive harm to the patent settlement, and thus an essential part of plaintiff's case. As explained by *Actavis*, "the potential for genuine adverse effects on competition" arises when the reverse payment "amounts to a purchase by

the patentee of the exclusive right to sell its product," a right that would be lost if the patent proved to be invalid or not infringed. 570 U.S. at 153-54 (internal quotation omitted).

The concepts of "large" and "unjustified" are closely linked, because the size of the payment must be evaluated relative to the legitimate value that may justify it. A "large" payment is one that exceeds the value of the avoided litigation costs, plus any other services the generic drug manufacturer provides to the branded firm. *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). Meanwhile, a payment is justified when it represents "traditional settlement considerations, such as avoided litigation costs or fair value for services." *Actavis,* 570 U.S. at 156. *Actavis* directs us to look not merely at the absolute value of a payment, but also at benchmarks such as "[the payment's] scale in relation to the payor's anticipated future litigation costs [and] its independence from other services for which it might represent payment[.]" *Id.* at 159. *Actavis* thus requires that a plaintiff prove as part of its *prima facie* case that a payment was both large and unjustified. As discussed below, Complaint Counsel made that showing here.

Placing the burden on Complaint Counsel to demonstrate a "large and unjustified" payment in the *prima facie* case also finds support in the limited post-*Actavis* case law. *See*, *e.g., Nexium,* 842 F.3d at 59 (upholding jury verdict form with "large and unjustified" as part of *prima facie* case); *Loestrin 24 Fe,* 814 F.3d at 552 (to survive a motion to dismiss,

plaintiff "must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment"); *Smithkline Beecham,* 791 F.3d at 412 (requiring plaintiff to prove a payment for delay, with the "likelihood of a reverse payment bringing about anticompetitive effects" dependent on the payment's size, its scale in relation to anticipated future litigation costs, and independence from other services); *In re Cipro Cases I & II ("Cipro")*, 348 P.3d 845, 865-66 (Cal. 2015) (requiring plaintiff to show that the value of the reverse payment exceeded the value of collateral products or services provided by the generic to the brand, plus anticipated future litigation costs); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.,* 2015 WL 5458570, at *7 (D. Mass. Sept. 16, 2015) (plaintiff bears "initial burden" to show a large and unjustified payment).

Complaint Counsel need not negate every conceivable justification for the payment, nor pre-emptively refute evidence of value not in their possession or control, to satisfy their *prima facie* burden.[18] *Cf. Lipitor,* 868 F.3d at 255 (noting that in *Actavis,* the FTC's complaint "did not preemptively

[18] The shifting burdens of production characteristic of antitrust adjudication can address both plaintiffs' information problem and defendants' right to adduce evidence of justification. *See, e.g.*, *Cipro*, 348 P.3d at 867; *K-Dur*, 2016 WL 755623, at *13 (once plaintiff shows that the payment was "large" in comparison to the expected future litigation costs, the burden of production shifts to the respondent to come forward with evidence that the value of collateral products and services suffices to bring the settlement's value up to the value of the payment without reference to the delayed entry).

negate justifications for the reverse payments"); *Cipro,* 348 P.3d at 867 (a party's own litigation costs and the existence and value of any collateral products or services provided in the settlement are "matters about which the settling parties will necessarily have superior knowledge"); *In re K-Dur Antitrust Litig.*, 2016 WL 755623, at *13 (D.N.J. Feb. 25, 2016) (same). It suffices to show that the size of the payment exceeded the payor's anticipated saved litigation costs plus the value to be rendered under the agreement and that no other clear justification presents itself. *See In re Androgel Antitrust Litig. (No. II) ("Androgel II"),* 2018 WL 2984873, at *9 (N.D. Ga. June 14, 2018) (plaintiff's burden is to show that "the settlement payments are ... larger than what could reasonably be expected to cover such traditional settlement concerns as future litigation costs or the value of services rendered").

3. Analyzing the Value Flow and Determining the Reverse Payment

The Initial Decision found that the No-AG Commitment of the SLA secured by the Endo Credit was an "unjustified reverse payment," ID at 138, "the purpose and effect of which was to induce Impax to give up its patent challenge and agree not to launch a generic Opana ER until January 2013." ID at 7. Impax has not appealed the ALJ's conclusion that a large reverse payment helped induce settlement or that the payment was linked to the January 2013 entry date, *see* RB at 4 n.1, and we agree that Complaint Counsel have borne their burden.

We reiterate that, to determine in the first instance whether a settlement involves a suspicious

reverse payment, the factfinder should consider all value flowing in the "reverse" direction, *i.e.*, to the generic. Not all of this value may properly be attributed as part of a "large and unjustified" payment, but whether it should be attributed as such can only be discerned after examining it in the light of the facts at hand. The value flowing to Impax in this case came in several forms, discussed in turn below.

a. The No-AG Commitment

First, Endo agreed to the No-AG Commitment, which obligated Endo not to market an "authorized generic" of Opana ER during the six months of Impax's exclusivity. Koch, Tr. 235-36; Snowden, Tr. 392-93. In the wake of *Actavis*, several federal courts have held that the rule of reason governs both cash and in-kind payments—including no-AG commitments—arising in reverse payment settlements. Such concessions can be of "great monetary value" to the first-filing generic drug manufacturer, which would then enjoy a "generic monopoly instead of a generic duopoly" for those six months. *Smithkline Beecham*, 791 F.3d at 404-05; *see also Loestrin 24 Fe*, 814 F.3d at 549-52.

The No-AG Commitment here would allow Impax to obtain greater revenues from its generic sales than it would if Endo entered and competed with an authorized generic. IDF at 187-89, 191. Impax valued this commitment between $23-33 million in projected revenue, IDF 193, and Endo approximated the revenues it forwent to be $25 million. IDF 192. As Complaint Counsel demonstrated, this value range exceeded substantially a reasonable estimate of costs saved from litigation ($5 million, $3 million of which

was attributable to Endo).[19] CX5000 (Noll Expert Report) at ¶375; Noll, Tr. 1463; IDF 77-81; ID at 115 (value of the reverse payment "substantially exceeded the estimated saved litigation costs").[20]

b. The Endo Credit

Second, the reverse payment settlement provided Impax significant value in the form of the Endo Credit, which Impax would receive if Endo moved the market away from original formulation Opana ER before Impax entered. The evidence at trial demonstrated that, at the time the parties entered the settlement, Endo was planning a "product hop" that would destroy the market for original Opana ER before Impax could bring its generic to market. IDF 96-107; Koch, Tr. 236-37; CX3205 at 001 (December 13, 2007 Endo memo: "There is also a life cycle management (LCM) imperative for Endo's Opana ER franchise ... . To ensure we continue to protect the franchise in the face of loss of regulatory exclusivity in June 2009, a [tamper resistant] formulation of ER will be important

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[19] *Actavis* indicates it is appropriate to compare the size of the payment to the *payor's* expected saved litigation costs, not the combined savings, *see* 570 U.S. at 159 ("[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs ... ."). This makes sense because it is the excess of Endo's payment over its other savings or justified benefits that should be understood as directed toward buying market exclusivity. Whether we utilize the projected savings of Endo alone or the joint savings of the parties, however, the size of the reverse payment is unquestionably "large" by comparison.

[20] The parties have not pled, and therefore we do not reach, the separate question of whether all no-AG commitments are large and unjustified payments under *Actavis*.

to secure. Without this LCM strategy, Opana ER is expected to lose about 70% of its sales within six months if generic entry occurs"); CX4010 (Mengler, Investigative Hearing Transcript ("IHT")) at 21 (Impax feared "that Endo had a strategy in place that would have led to the elimination of the Opana ER market, destroying ... all of [its] value and [its] ability to sell the generic."). Evidence suggests that Endo negotiated for a later entry date to give it time to execute this scheme. *See* CX4014 (Hsu Dep.) at 156-57 ("Obviously that's their goal" to transfer the market to a reformulated version before Impax could enter under the SLA); CX2724 (Endo's plan to reformulate Opana ER and transition the market to the new product would be adversely affected if Impax launched its generic in June 2010). The evidence also showed that Impax suspected the plot and, fearful that Endo planned to destroy the value it had secured itself through the No-AG Commitment, demanded what became the Endo Credit. Mengler, Tr. 528, 531-35, 568. The credit would compensate Impax in the event Endo's Opana ER dollar sales fell by more than 50 percent of their quarterly peak prior to Impax's entering the market. RX364 at 0003-06, 0012 (SLA §§1.1, 4.4). This dynamic underscores the fact that Impax sought to share in the value created by agreeing with Endo to eliminate the risk of competition. In the event it launched as planned, there would be no authorized generic. In the event plans went awry, and any sale of Opana ER was foreclosed or minimized, Impax still would profit from less competition. The credit ultimately resulted in Endo paying Impax $102 million.

c. The DCA

Impax and Endo also entered into the DCA, a distinct written agreement that was negotiated and executed simultaneously with the SLA and incorporated into it. IDF 244-45, 284, 306, 308; *see also* ID at 124. Under the DCA, Endo agreed to make a $10 million upfront payment to Impax, with the possibility of making $30 million more in milestone payments, for the development of an early-stage Parkinson's disease drug known as IPX-203. IDF 244, 246-48. Under the DCA, Impax and Endo agreed to share promotional responsibilities for IPX-203 and Endo would be entitled to a share of the profits if the drug were successfully commercialized. IDF 249-50. The legal and temporal links between the DCA and the SLA led the ALJ to dete1mine that the DCA's value to Impax should be included as pali of the payment from Endo to Impax, and we agree. ID at 114; *see also In re Niaspan Antitrust Litig.,* 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) ("the Licensing Agreement must be read in conjunction with the CoPromotion and Manufacturing Agreements executed that same day").

The ALJ found, however, that the $10 million payment in the DCA was fully justified by the benefits to Endo that the agreement conferred.[21] In addition to

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[21] The ALJ found that the DCA was a *bona fide* product development collaboration, and that the $10 million payment was justified by the profit-sharing rights that the agreement gave to Endo, ID at 132, relying on, *inter alia,* evidence that: (1) both companies had a history of interest in Parkinson's disease treatments, *id.;* (2) Impax needed outside funding to advance the development ofIPX-203, *id.;* (3) Endo did not consider the $10 million upfront payment to be uncharacteristically large, and projected a rate of retum of [redacted] percent on that payment,

the contemporaneity of the two agreements and the DCA's incorporation into the SLA, several additional facts in the record call into question this conclusion. *First,* the IPX-203 deal was evaluated on a timeline shortened to line up with the settlement negotiations, including an abbreviated analysis by Endo that ignored obvious risks. *See, e.g.,* Cobuzzi, Tr. 2592 (Endo group had two days to complete initial evaluation); CX2625 at 001 (Impax recognized that Endo was "on a tight time table" to complete the DCA "if the wished to settle prior to June 17."; RX072 at 0004, *in camera* [redacted] *Secon*, evidence suggests that Endo was only willing to enter into the deal as part of the settlement negotiations. *See* CXI 005 at 064 (in 2008, a third party market research group engaged by Endo specifically rejected Impax's relevant Parkinson's disease products from the list of potential opportunities because generic versions of products were already on the market). *Third,* Endo had never previously made an upfront payment for a product on such an abbreviated timeline. Cobuzzi, Tr. 2565.[22]

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nearly [redacted] Endo's minimum requirements for a co-development deal, *id.;* and (4) Impax continued its development efforts regarding IPX-203 for years after executing the DCA, investing over [redacted] employee hours in work on the compound. *Id.* at 129.

[22] Through the testimony of a pharmaceutical expert, Dr. John Geltosky, Complaint Counsel describe numerous other irregularities in the DCA, including, for example: (i) that Endo's financial analysis did not assess the circumstances specific to the compound actually agreed upon, IPX-203, instead using commercial terms that related to a different compound in later-stage development, IPX-066, that Impax had originally considered but then declined to offer, CX5003 (Geltosky Expert Report) at ¶37; (ii) that Endo did not conduct a risk adjustment

Finally, in its business documents, Endo noted that the license deal for the DCA added significant topline revenue for Opana ER. CX1701-005. For its part, Impax's budget documents attribute the $10 million it received under the DCA as [redacted] CX2701 at 004.

The peculiar circumstances surrounding the DCA suggest that the agreement may have been a means of masking value transferred in exchange for eliminating the risk of competition. To the extent that the $10 million upfront payment is unjustified, however, it simply increases the value of the overall reverse payment that we have found already to be large and unjustified.[23] We thus need not decide whether the DCA was a *bona fide* agreement for justified value.

d. The Freedom to Operate License

Endo also granted Impax a broad patent license with respect to the oxymorphone ER products covered by Impax's ANDA. IDF 169-70; Figg, Tr. 1951-52. This license covers "any patents and patent applications owned by or licensed to Endo ... that cover or could

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when calculating the net present value of the IPX-203 opportunity, Geltosky, Tr. 1084-85; (iii) that Endo failed to compare the pharmacokinetic data ofIPX-203 with IPX-066, and thus did not analyze whether the newer compound would offer any benefits over the earlier one, CX5003 (Geltosky Expert Report) at ¶42; and (iv) that Endo failed to conduct a freedom-to-operate analysis of IPX-203 that would have revealed the level of intellectual property risk posed by the compound, *id.* at ¶¶49-50.

[23] As explained below, *infra* Section V.B, because Impax failed to meet its burden to connect the alleged procompetitive justifications to the restraint at issue, leaving no need to balance competitive harms and benefits, whether we include any value from the DCA payment does not affect our ultimate conclusion.

potentially cover" Impax's generic oxymorphone ER product. IDF 169-70. Complaint Counsel did not plead this term as part of the unlawful consideration for the settlement (Compl. ¶62), nor submit evidence attempting to value the license agreement. Noll, Tr. 1648.

Because the license granted Impax freedom to operate once the January 2013 date was past and thus provided value to Impax, it is correctly incorporated in an initial assessment of whether the settlement contained suspicious reverse payments. Although the Commission will look at all aspects of the transaction together for purposes of determining the size and justification of the value flow, we recognize the inherently procompetitive nature of the freedom to operate conferred by patent licenses. Hatch-Waxman Act patent litigation cannot be settled procompetitively without both an entry date and a license for the generic, so a payment consisting only of a license to operate in the relevant market—alone or with other clearly procompetitive terms—will not ordinarily trigger antitrust scrutiny, and so should not be considered part of a "large and unjustified" payment. *See Actavis,* 570 U.S. at 154 (distinguishing between "settlement on terms permitting the patent challenger to enter the market before the patent expires" which, alone, would bring about competition "to the consumer's benefit," and "payment in return for staying out of the market [which] simply keeps prices at patentee-set levels"); *accord In re Actos End Payor Antitrust Litig.,* 2015 WL 5610752, at *15-19 (S.D.N.Y. Sept. 22, 2015), *rev'd in part on other grounds,* 848 F.3d 89 (2d Cir. 2017) (holding that reverse payment did not include (i) acceleration

clauses that allowed the generic to enter the market upon the entry of any other generic, and (ii) a license to enter as an authorized generic on a date certain). The parties have not argued that the licenses are part of such a payment, and nothing in the record suggests that it operated to enable Impax and Endo to split monopoly rents.

4. Restraint of Trade

The "large and unjustified payment" that triggers antitrust scrutiny under *Actavis* is consideration in exchange for a restraint of trade—which itself is a requirement of any claim under Section 1 of the Sherman Act. 15 U.S.C. §1. The ALJ concluded that any competitive harm was "largely theoretical" because, for a variety of reasons,[24] Impax was unlikely to have introduced a generic Opana ER before January 2013, the agreed-upon entry date under the SLA. ID at 156-57. Complaint Counsel argue that the ALJ answered the wrong question—i.e., that the harm Actavis recognizes is the elimination of the risk of competition, not proof that entry would actually or probably have occurred earlier. CCRB at 14. They also argue that the ALJ lacked a factual basis to draw the conclusion he did regarding the likelihood of generic competition. Id. Impax argues that Complaint Counsel must prove that entry earlier than January 2013 was reasonably probable in the absence of the challenged agreement; and it contends that the risk of launching

[24] The ALJ pointed to the length of time necessary to resolve the patent litigation (ID at 156), the financial risk associated with launching "at risk" (*id.* at 150), the fact that Impax's board had not approved doing so (*id.* at 151), and the company's track record of not doing so (*id.* at 150-51).

"at risk" coupled with the litigation delay made competition before January 2013 unlikely. RB at 35-37.

We agree with Complaint Counsel. The Hatch-Waxman Act context is unique, as are the reverse payment settlements that arise within it. These payments flowing in the "wrong" direction signal that a settling party is being compensated for not competing when it otherwise might. The Supreme Court thus instructs us to inquire into whether and how such reverse payments distort competition. In *Actavis*, the Court recognized the inherently probabilistic nature of the underlying facts surrounding the settlement of Hatch-Waxman Act litigation: patent validity; patent infringement; the outcome of patent litigation; the willingness and ability of the generic drug manufacturer to launch at risk; and so on. Requiring a fact-finder later to conclude whether and on what date competition would have occurred asks too much. That is why *Actavis* makes clear that the relevant anticompetitive harm in a reverse payment case is "prevent[ion of] the *risk* of competition." *Actavis,* 570 U.S. at 157 (emphasis added); *see also Smithkline Beecham,* 791 F.3d at 408 (the "antitrust problem" in *Actavis* "was that, as the Court inferred, entry *might* have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered" (emphasis added)).

Antitrust liability can thus attach even where the parties entered into the settlement without knowing for certain that they were, in fact, eliminating competition:

> The patent here may or may not be valid, and may or may not be infringed. A valid patent excludes all except its owner from the use of the protected process or product. ... But an *invalidated* patent carries with it no such right. ... The paragraph IV litigation in this case put the patent's validity at issue, as well its actual preclusive scope. The parties' settlement ended that litigation.

Actavis, 570 U.S. at 147 (internal quotation and citation omitted). The Court considered eliminating even a small risk of generic entry to be a cognizable harm. *See id.* ("The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm."). *See also Cipro,* 348 P.3d at 864 ("Every restraint of trade condemned for suppressing market entry involves uncertainties about the extent to which competition would have come to pass.").

Three corollaries flow from the *Actavis* approach. *First*, where the evidence establishes that competition actually was eliminated—that a generic drug would have been brought to market earlier but for the agreement—*a fortiori* that establishes an antitrust harm. *Second*, a clear impediment to generic launch, such as a finding that the FDA had disapproved the generic firm's ANDA, would mean that no risk of competition was lost and therefore that no liability should lie. *Third,* and between those two poles, in a

reverse payment settlement case, the "relevant anticompetitive harm," occurs when the branded manufacturer and its generic competitor replace the possibility of competition with the certainty of none. *Actavis*, 570 U.S. at 157. To establish such a harm in this case, then, Complaint Counsel bear the burden of proving that there was a risk of competition to eliminate—*i.e.*, that Impax would compete with Endo for sales of branded Opana ER. They must demonstrate facts to support that risk, but need not prove—as the ALJ required—that competition was likely. Put differently, our test for Sherman Act liability is whether the generic drug manufacturer might plausibly have entered the marketplace prior to the agreed entry date. *See Androgel II,* 2018 WL 2984873, at *10 ("[Defendants] argue[d] that the FTC failed to show that the settlements *actually* delayed entry. That may well be true, but that is not what the FTC needs to prove in order to show an antitrust harm. As discussed above, the FTC only needs to prove that the Defendants entered into the settlements in order to avoid the risk of a competitive market.").

In this case, ample evidence supports the proposition that there was a real threat of competition from Impax. The FDA approved the Impax ANDA in June 2010, meaning Impax was permitted to launch a generic Opana ER at risk. Senior management had considered launching "at risk," and the company had taken a number of steps to prepare.[25] Impax's

[25] Impax executives identified a 2010 launch as a "key goal," repeatedly forecasting it. *See, e.g.,* CX2562-002 (2010 Company Key Goals); CX2824-001 and tab "Jan Forecast Bottles" (Jan. 2010 Monthly Forecast indicating launch date of June 2010);

incentive to do so was likely bolstered by Endo's plans to product hop. *See* Mengler, Tr. 527; Hoxie, Tr. 2707. A large payment would be an "irrational act" unless the patentee believed such a payment would preserve its profits. Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision,* 15 MINN. J. L. SCI. &TECH. 3, 25 (2014). *See also Androgel II,* 2018 WL 2984873, at *9 ("Rather than having to litigate the merits of any underlying patent suits or establish a theory of causation, the Supreme Court said that courts can look to the 'size of the payment ... [to] be able to assess its likely anticompetitive effects ... .'"). We therefore find there was a plausible risk that Impax could have entered earlier than January 2013 but for the agreement.[26]

The record makes clear that the SLA eliminated a risk of competition from Impax. How likely it was to launch, when, and precisely how much competition

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CX2829 at tab "may 10 Forecast bottles" (May 2010 Monthly Forecast - same); CX5000 (Noll Expert Report) at ¶371 and App. D (summarizing 27 forecasts). Company executives repeatedly presented "at risk" launch in June 2010 to the Board of Directors. *See* CX2662-012; CX2663-001. And the company took steps to prepare, getting DEA approvals, manufacturing product, obtaining letters of intent, and completing process validation. CX2882-001; IDF 537-40; Engle, Tr. 1758-62. The company obtained "Quota"—the amount of a controlled substance, like oxymorphone, that the DEA permits a company to purchase in a particular year—from the DEA. *See* Camargo, Tr. 965-66.

[26] This is not to say that Impax *would* have entered earlier but for the agreement. As explained, the ALJ erred in asking whether Impax would have entered earlier. The relevant question is whether it was plausible Impax *could* enter earlier, which tells us whether a risk of entry—the harm *Actavis* instructs us to guard against—was eliminated.

was eliminated are difficult questions that may require much speculation to resolve. Because we resolve this case before reaching the weighing of anticompetitive harms and procompetitive benefits, we need not do so.

5. Market Power

Under the rule of reason a plaintiff must generally prove that the defendant possessed market power in the relevant market.[27] *See, e.g., Leegin Creative Leather Prods., Inc. v. PSKS, Inc.* 551 U.S. 877, 885-6 (2007) (rule of reason includes inquiry into the existence of market power) (citations omitted); *United States v. Visa U.S.A., Inc.,* 344 F.3d 229, 237 (2d Cir. 2003) (plaintiff "must demonstrate that the defendant conspirators have 'market power' in a particular market for goods or services"); *Gordon v. Lewistown Hosp.,* 423 F.3d 184, 213 (3d Cir. 2005) (market power necessary in order for court to presume anticompetitive effects). We find, as did the ALJ, that Endo possessed the requisite market power and, accordingly, that Complaint Counsel met their burden. *See* ID at 139-41.

a. General Principles

Market power is the ability to charge prices above what would prevail in a competitive market by

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[27] However, "[s]ince the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, 'proof of actual detrimental effect, such as a reduction of output,' can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effect.'" *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986) (quoting Areeda & Hovenkamp, *supra* ¶1511).

restricting output below competitive levels. *See Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Okla. ("NCAA")*, 468 U.S. 85, 109 n.38 (1984) (citing, *inter alia*, *Jefferson Parish Hosp. Dist. No. 2 v. Hyde,* 466 U.S. 2, 27 & n.46 (1984)); *Ball Mem'l Hosp., Inc. v. Mutual Hosp. Ins.*, 784 F.2d 1325, 1335 (7th Cir. 1986) (Easterbrook, J.) ("Market power comes from the ability to cut back on the market's total output and so raise price"); 2B PHILLIP E. AREEDA, ET AL., ANTITRUST LAW ¶501 at 109 (4th ed. 2014) ("Market power is the ability to raise price profitably by restricting output."). Relatedly, courts have defined "monopoly power" as the "power to control prices" by limiting output or to "exclude competition." *See, e.g., United States v. E.I. du Pont de Nemours & Co.,* 351 U.S. 377, 391 (1956); *Broadcom Corp. v. Qualcomm Inc.,* 501 F.3d 297, 307 (3d Cir. 2007) (citing *United States v. Grinnell Corp.,* 384 U.S. 563, 571 (1966)).

A plaintiff can prove market power directly through evidence of control over prices and output or the exclusion of competition; a court also can infer such power from proof of a firm's large percentage share of the relevant market. *Broadcom,* 501 F.3d at 307; *Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.,* 386 F.3d 485, 500 (2d Cir. 2004) (citing *Tops Mkts., Inc. v. Quality Mkts., Inc.,* 142 F.3d 90, 98 (2d Cir. 1998)); *New York ex rel. Schneiderman v. Actavis PLC,* 787 F.3d 638, 652 (2d Cir. 2015); *United States v. Microsoft Corp.,* 253 F.3d 34, 51 (D.C. Cir. 2001) (*per curiam*).

A valid patent may confer market power, but does not always do so. *See Ill. Tool Works Inc. v. Independent Ink, Inc.*, 547 U.S. 28 (2006). There may

be so many equivalent substitutes for the patented article that the patentee cannot exercise market power. U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY §2.2 (Jan. 2017). Alternatively, there may be few economically close substitutes such that ownership of the patent allows the patentee to extract durable monopoly profits during the patent's life. *See* HERBERT HOVENKAMP, ET AL., IP AND ANTITRUST, §4.02 (Nov. 2017).

To establish market power, a plaintiff typically first defines the relevant antitrust market. *See, e.g., City of New York v. Grp. Health Inc.,* 649 F.3d 151, 155 (2d Cir. 2011); *Worldwide Basketball & Sport Tours, Inc. v. NCAA,* 388 F.3d 955, 962 (6th Cir. 2004). The *Actavis* Court did not conduct a rule of reason analysis, and did not define a relevant market. But its decision recognized that a branded drug and its generic equivalents could—and, in the reverse payment context, often would—together constitute an antitrust-relevant market. The Court noted that the large size of a payment is a "strong indicator of power" over prices, because a firm "without that power [is unlikely] to pay 'large sums' to induce 'others to stay out of *its* market.'" *Actavis*, 570 U.S. at 157 (emphasis added) (quoting 12 HERBERT HOVENKAMP, ANTITRUST LAW ¶2046 at 351 (3d ed. 2012)); *see also King Drug Co. of Florence v. Cephalon, Inc.,* 88 F. Supp. 3d 402, 414 (E.D. Pa. 2015). As the district court in *Aggrenox* observed, although it is "conceivable that the patented drug faced such fierce competition from therapeutically similar drugs that it could not be sold at supracompetitive prices," it is "vanishingly

unlikely" that a large reverse payment would be made in such a case. 199 F. Supp. 3d at 666.

b. Analysis and Conclusions Regarding Market Power

Based on a thorough review of the factual record, we find that the relevant product market in this case consists of branded and generic oxymorphone ER, not all long acting opioids ("LAOs"), as Impax claims.[28] We further find, as did the ALJ, that Endo possessed market power.[29] *See* ID at 139-41.

The determination of what constitutes the relevant product market "hinges ... on a determination of those products to which consumers will turn, given reasonable variations in price." *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA,* 296 F. Supp. 3d 1142, 1167 (N.D. Cal. 2017) (quoting *Lucas Auto. Eng'g, Inc. v. Bridgestone/Firestone, Inc.*, 275 F.3d 762, 767 (9th Cir. 2001)). Specifically, our goal in this market definition exercise is to determine whether sufficient users would switch away from oxymorphone ER in response to a small but significant, non-transitory

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[28] The parties do not dispute that the relevant geographic market is the United States.

[29] Market definition and market power are always fact-intensive questions. Although in most cases arising in the *Actavis* context, a brand and its generics will constitute the relevant product market, this is not to suggest that a brand and its generics will, in every case or context, necessarily constitute the relevant product market. *See, e.g.*, *Mylan Pharms. Inc. v. Warner Chilcott PLC,* 838 F.3d 421, 437 (3d Cir. 2016) (finding the relevant market consisted of all oral tetracyclines used to treat acne).

price increase [a "SSNIP"] to make the increase unprofitable. *See FTC v. Whole Foods Mkt., Inc.*, 548 F.3d 1028, 1038 (D.C. Cir. 2008). This requires examining whether products are close economic substitutes.[30] *See* Areeda & Hovenkamp, *supra* ¶562a at 390-92 (relevant market includes "close substitutes" that exhibit high cross-elasticity of demand). In conducting this examination, the relevant question is how consumers respond to increases from competitive pricing levels.[31] Evidence of competitive effects may help to inform the inquiry. U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES §4 (2010).

Complaint Counsel argued that branded and generic oxymorphone ER comprise the antitrust-relevant market. In an effort to shed light on cross-elasticities between various LAO products, Complaint Counsel's expert, Professor Noll, examined whether events that affected prices and quantities in the sale of one product were reflected in changes in prices and quantities for the other product. Noll, Tr. 1374. If they were not, he reasoned, then the products were not in the same relevant market. *Id.* at 1375. Professor Noll

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[30] Due to data limitations, neither side's economic expert was able to conduct a SSNIP test directly or to measure cross-elasticities through econometrics. *See* Noll, Tr. 1514-17; Addanki, Tr. 2476-77.

[31] If the allegedly anticompetitive conduct is already permitting supracompetitive pricing, a larger percentage of consumers might turn to alternatives in the face of *additional* price increases than would do so if prices increased from a competitive level—thereby artificially and erroneously inflating the apparent size of the product market. *See* Areeda & Hovenkamp, *supra* ¶539.

examined the effects of entry of the generic drug on the branded product at the time that entry occurred. *Id.* at 1377. His review established that the entry of the former correlated to a drop in the quantity sold of the latter. *Id.* at 1380. Based on these results, he found that generic and branded oxymorphone ER were in the same relevant market. Professor Noll repeated the process of examining entry effects for other candidate LAOs (including extended release versions of oxycodone, hydromorphone, morphine, tapentadol, buprenorphine, fentanyl, and hydrocodone ER) on Opana ER's sales to determine if they were part of the relevant market. Noll, Tr. 1386-87; CX5000-194 at Exh. 4. In each case, he found that the abrupt rise and fall in sales of Opana ER in 2010-2012 did not reflect a parallel fall and rise in the sales of the other LAOs and determined that the latter were not part of the relevant market. CX5000 at ¶183; *see also id.* at ¶¶158, 161-64, 166-67, 169, 172, 175, 177, and 179. Based on this analysis Professor Noll concluded that oxymorphone ER (both generic and branded versions) is a relevant product market.

Impax, on the other hand, argued the appropriate market consists of all LAOs. Unlike Professor Noll, Impax's expert, Dr. Addanki, did not study the effects that brand or generic entry in other LAOs had on quantities sold of oxymorphone ER or *vice versa*. Rather, Dr. Addanki based his view on other sources of information including, *inter alia*: (1) clinical guidelines for treatment of chronic pain, including FDA labels and other resources such as data showing that multiple LAOs are used for the same indication, Addanki, Tr. 2241-43, 2247; (2) business documents from Endo and other industry participants suggesting

that they viewed other LAOs as being in the same market as Opana ER, *id.* at 2257-66; and (3) evidence suggesting that competition existed between and among various LAOs at the three levels of the market: physicians, insurers, and patients, *id.* at 2253.

Professor Noll's sales volume analysis addressed economic substitution more directly than did Dr. Addanki's approach. Oxymorphone ER sales exhibited large share shifts and price reductions in response to generic entry—but not in response to entry by other LAOs. Sales of Opana ER declined when generic oxymorphone was introduced and as generic sales increased. CX5000 (Noll Expert Report) at ¶119 and Exhs. 2A1, 2A3, 2A5, 2A6 and 2A7. Sales of other LAOs were either far less responsive, or not responsive at all, to the introduction of oxymorphone ER. *Id.* at ¶¶162-64 (OxyContin), ¶169 (hydromorphone ER, a.k.a. Exalgo), ¶172 (buprenorphine ER, a.k.a. Butrans), ¶175 (fentanyl ER), ¶179 (tapentadol ER, a.k.a. Nucynta ER). When Professor Noll examined whether sales of other LAOs affected sales of Opana ER (or *vice versa*), he found that the drugs' sales generally did not exhibit negative correlations, suggesting that—unlike generic oxymorphone ER—they did not take sales from each other. *Id.* at ¶¶162-63 (sales of OxyContin and oxymorphone ER generally "rose and fell in parallel"), ¶169 (introduction of Exalgo had "no apparent effect" on sales of Opana ER), ¶172 [redacted]; ¶175 (availability of generic fentanyl ER did not inhibit rapid growth of Opana ER sales through the end of 2011); ¶177 (entry of Zohydro did not substitute for sales of oxymorphone ER); ¶179 [redacted]. The sales volume evidence thus supports the proposition that

generic oxymorphone ER, but not other LAOs, is in the same relevant market as branded oxymorphone ER.[32]

This evidence is consistent with economic research showing that generic entry is, by far, the most important source of price competition for pharmaceuticals—generally far more important than

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[32] Impax would disregard this evidence as reflecting mere "visual inspection" of LAO sales trends. RB at 34. But courts have accepted exactly this type of analysis in other pharmaceutical cases. *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 363 F. Supp. 2d 514, 522-23 (E.D.N.Y. 2005), *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008); *Teikoku Pharma,* 296 F. Supp. 3d at 1174-75; *SmithKline Corp. v. Eli Lilly & Co.,* 427 F. Supp. 1089, 1118-19 (E.D. Pa. 1976), *aff'd*, 575 F.2d 1056 (3d Cir. 1978). Where, as here, patterns of generic substitution are clear, "we do not need to do economic gymnastics to determine whether the defendant had market power[.]" *Aggrenox,* 199 F. Supp. 3d at 668; *see also McWane,* 2014 WL 556261, at *14 (F.T.C. 2014), *aff'd*, *McWane, Inc. v. FTC*, 783 F.3d 814 (11th Cir. 2015); ABA Section of Antitrust Law, *Mergers and Acquisitions* 55 (3d ed. 2008).

In contrast, Impax gives considerable weight to evidence that utilization of alternatives to OxyContin increased when the University of Pittsburgh Medical Center health plan eliminated coverage of OxyContin while maintaining coverage of Opana ER, morphine sulfate ER, fentanyl patches, and methadone. *See* RX087 and discussion at Addanki, Tr. 2302-09. However, the participants' shift from OxyContin to the remaining drugs still covered by the formulary may reflect little more than a tendency of participants in a particular health plan to keep that health plan and to maintain in-formulary coverage. Dr. Addanki does not explain why this experience would generalize to reflect the likely competitive effects of changes in price or product availability involving consumers at large nor did he know the amount of the price increase at issue, which might have been far larger than the SSNIP usually considered when defining a market. Addanki, Tr, 2505.

different compounds in the same therapeutic class. *See* CX5000 (Noll Expert Report) at ¶¶76-79 (citing, *inter alia*, Fiona Scott Morton & Margaret Kyle, *Markets for Pharmaceutical Products*, *in* 2 HANDBOOK OF HEALTH ECONOMICS, 763-823 (M. Pauly, et al., eds., 2011); Ernst Berndt & Joseph Newhouse, *Pricing and Reimbursement in U.S. Pharmaceutical Markets*, *in* OXFORD HANDBOOK ON THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY (P. Danzon & S. Nicholson, eds., 2012); Ernst Berndt, *Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price*, 16:4 J. ECONOMIC PERSPECTIVES 45-66 (2002)). Where generic entry occurs, it tends to displace a large share of branded sales and to do so at a much lower price, as occurred here. *Id.* at ¶¶77-78. Consequently, it is not surprising that courts frequently define product markets to encompass a single active ingredient. *See, e.g., Barr Labs.*, 386 F.3d at 496 (defining a market for generic warfarin sodium); *Teikoku Pharma*, 296 F. Supp. 3d at 1176 (defining a market for 5% lidocaine patches, *i.e.,* Lidoderm and its generic equivalents); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 389 (D. Mass. 2013) (concluding that the relevant market consisted of the brand and generic alone); *In re Cardizem CD Antitrust Litig.,* 105 F. Supp. 2d 618, 680-81 (E.D. Mich. 2000) (accepting plaintiffs' pleadings that a single brand of a drug and its generic bioequivalents constituted the relevant market). *But cf. Mylan Pharms. Inc. v. Warner Chilcott PLC,* 838 F.3d 421, 437 (3d Cir. 2016) (finding a relevant market for all oral tetracyclines used to treat acne).

Impax's argument that the relevant market includes all LAOs has both factual and analytical

limits. From a factual perspective, as Complaint Counsel's medical expert, Dr. Seddon Savage, testified, opioids differ according to their biological receptors, pharmacokinetic profiles, and adverse side effects, including adverse interactions with other drugs. Savage, Tr. 689-92, 702; CX5002 (Savage Expert Report) ¶¶51, 115-16. Of significance for this case, oxymorphone is one of the few opioids that is not metabolized by the CYP450 enzyme. Savage, Tr. 716; *see also* CX5000 (Noll Expert Report) at ¶¶142-43. This means that oxymorphone is less likely to cause adverse interactions with the many other drugs that *are* metabolized by that same enzyme, such as some antibiotics, anticoagulants, beta blockers, statins, and tranquilizers. *See* Savage, Tr. 716-18; CX5000 (Noll Expert Report) at ¶143. Oxymorphone also has a longer half-life than oxycodone, hydrocodone, morphine, and other LAOs, resulting in longer duration of action. Savage, Tr. 720. Switching a patient from Opana ER to generic oxymorphone would yield much more predictable results than switching to a different opioid molecule, because the generic oxymorphone would operate on the patient's pain receptors in the same manner and with the same side-effect profile. *Id.* at 715. In any event, while functional interchangeability is certainly relevant to market definition, it is not the end of the analysis. *See, e.g., Meijer, Inc. v. Barr Pharms., Inc.,* 572 F. Supp. 2d 38, 58 (D.D.C. 2008) (functional interchangeability is probative but "certainly not dispositive"); *see also Barr Labs.,* 386 F.3d at 496 (defining market for generic warfarin sodium alone, despite functional interchangeability with branded version); *United States v. Archer-Daniels-Midland Corp.,* 866 F.2d 242,

248 (8th Cir. 1988) (functionally interchangeable sweeteners were separate product markets because "a small change in the price of [one] would have little or no effect on the demand for [the other]").

Dr. Addanki's evidence of product marketing and discounting does not convince us to place all LAOs in the same relevant market. Even a monopolist might engage in the sorts of brand-building and product differentiation activities that Dr. Addanki catalogues, such as visiting potential customers (*i.e.,* doctors) and advertising in medical journals. That is because even a monopolist may benefit from stimulating demand through promotional activities and because, at a sufficiently high price, it faces some substitutes to which it will want to avoid losing sales. The relevant question is the *degree* of constraint that these other products offer.[33] Dr. Addanki failed to undercut Professor Noll's showing that generic oxymorphone ER was a far more effective constraint on Opana ER than were the other LAOs. For example, his limited evidence of direct-to-patient discounting lacks data about the size of these programs and provides no showing that the programs had a significant effect on either average net prices or sales of the products. *See* CX5004 (Noll Rebuttal Report) at ¶66.[34]

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[33] *See Coal Exps. Ass'n v. United States,* 745 F.2d 76, 92 n. 20 (D.C. Cir. 1984) ("[A]ll firms, even the pure monopolist ... are subject to limits established by market forces. The issue is how effective are the limits.").

[34] Impax's citation to our settlement and relevant market definition in *King Pharm., Inc. & Alpharma, Inc.*, No. C- 4246 (F.T.C. Feb. 2, 2009), buttresses rather than undercuts our relevant market definition here. RB at 50. As Impax mentions, the Commission's settlement identified a relevant market for oral

Consequently, we find that Complaint Counsel adequately proved a relevant market confined to branded and generic oxymorphone ER.

We find that Endo clearly held market power in this highly concentrated market. Prior to entry by Actavis in 2011, Endo was the only player on the market—in other words, it had a monopoly. *See* CX5000 (Noll Expert Report) ¶189. After Actavis entered for two generic, lowsales dosages and prior to generic entry by Impax, Endo held more than a [redacted] percent market share, and the Herfindahl-Hirschman Index ("HHI") exceeded [redacted] *Id.* at ¶189 & Exhs. 6A and 6B. Thus, during the critical period when Endo and Impax entered the SLA and during which the parties' agreement prevented Impax from entering, Endo held shares sufficient to support market power. *Id.* at ¶192.[35]

LAOs. Impax does not mention, however, that the Commission proceeded in the same sentence to identify a "narrower market for oral long-acting morphine sulfate in which [the respondents' products] compete directly with each other." Complaint, ¶11. The Commission intervened in King Pharmaceuticals' proposed acquisition of Alpharma because the transaction would have joined the two leading producers of morphine sulfate oral LAOs, unacceptably raising concentration in that relevant market, and the Commission obtained a divestiture of King's morphine sulfate product. FTC Press Release, FTC Intervenes in King Pharmaceuticals Acquisition of Rival Alpharma Inc. (Dec. 29, 2008) https://www.ftc.gov/news-events/press-releases/2008/12/ftc-intervenes-king-pharmaceuticals-acquisition-rivalalpharma (attaching Commission Complaint and Decision and Order).

[35] Using net sales revenue, Endo's market share between 2013 and the end-date of available data in Q1 2017 always exceeded [redacted] percent and usually was around [redacted] percent.

Additional evidence supports our market power findings. Generic oxymorphone ER entry caused Opana ER to lose market share and the average price of oxymorphone ER to fall. CX5000 (Noll Expert Report) at ¶122. [redacted] *Id.* at ¶120. [redacted] *Id.* That indicates pre-entry prices were above the competitive level. Noll, Tr. 1381- 82; *see Aggrenox*, 199 F. Supp. 3d at 667 ("if competitive prices were being charged before the patented drug had a generic competitor, then the entry of new [generic] competitors would not result in a substantial change in price"). Endo's documents and testimony further support the conclusion that generic entry caused substitution and price reductions. *See, e.g.,* CX1106-005 ("Each month that generics are delayed beyond June 2010 is worth about $20 million in net sales per month."); CX1320-007 (2010 revenue forecast incorporating the working assumption that after generic entry in July 2011, "15% brand volume remains after 3 months"); CX4004 (Engle, IHT) at 245 (indicating that Actavis' entry caused some lowering of prices and that Actavis won some business from Endo).

The substantial evidence of Endo's market power is consistent with the inference permitted by *Actavis*: that the presence of a large and unjustified payment may itself signal market power. 570 U.S. at 157

CX5000 (Noll Expert Report) at ¶191 & Exh. 6. Throughout that period, HHI based on net sales revenue exceeded [redacted] , and HHI based on total prescriptions was above [redacted]; both figures substantially exceed the Horizontal Merger Guidelines' threshold of HHI 2,500 denoting a highly concentrated market. *Id.* at ¶191.

(finding that a firm "without that power [is unlikely] to pay large sums to induce others to stay out of its market"). If the payor-patentee lacked market power before generic entry due to competition from other drugs, prices for the brand drug already would have been competed down to the competitive level and there would be no monopoly profits left to protect by a large reverse payment. *See Aggrenox,* 199 F. Supp. 3d at 667.

Strong record evidence further demonstrates that Endo's market power was durable and protected by substantial entry barriers. IDF 90-95. Endo's patents could be (and were effectively) used to exclude competitors who wished to market and sell oxymorphone ER. *See Aggrenox,* 199 F. Supp. 3d at 668. The Hatch-Waxman Act's regulatory procedures build in timing constraints affecting generic entry, as described above. First, if a branded drug company files a patent infringement suit against a Paragraph IV ANDA filer, the Hatch-Waxman Act provides a 30-month stay before the FDA can approve the ANDA. IDF 93-94. Second, non-first-filer Paragraph IV ANDA applicants have to wait at least 180 days after the first filer has entered before they can enter a market. *Id.* Thus, Endo had the power to delay entry to the market even if its patents were eventually found to be invalid or not infringed. IDF 95. These barriers are in addition to more general barriers such as brand loyalty and DEA regulation of opioids, (CX5000 (Noll Expert Report) at ¶¶15, 63, 195-96; IDF 508, 522-26), not to mention the need to develop a product suitable for receiving FDA approval and to build up the necessary launch inventory. Noll, Tr. 1409-10; IDF 12, 513. In the pharmaceutical industry, manufacturing and

production issues can seriously impact a company's ability to enter and remain on the market. In this very case, Novartis Consumer Health, Inc. ("Novartis"), the company that manufactured Opana ER for Endo, experienced a plant shutdown by the FDA that resulted in a full-blown "supply chain crisis" for Endo. CX4017 (Levin Dep.) at 136-38. Endo's high share in the market for oxymorphone ER, combined with the presence of substantial entry barriers, lead to the conclusion that Endo possessed market power.

We find significant record evidence demonstrating the relevant market consists of branded and generic oxymorphone ER and that Endo commanded market power.

B. Procompetitive Justifications

Because Complaint Counsel have established a *prima facie* case showing that Impax harmed competition, "the burden shifts to [Impax] to show a procompetitive rationale for the restraint." *Amex*, 138 S. Ct. at 2284. As discussed, the ALJ found that the No-AG Commitment and Endo Credit had the "purpose and effect" of "induc[ing] Impax to give up its patent challenge and agree not to launch a generic Opana ER until January 2013." ID at 6-7. Impax does not challenge that finding on appeal. *See* RB at 4 n.1.

The ALJ concluded that while the *reverse payment for delay* impaired generic competition, *other provisions* of the settlement between Impax and Endo benefited competition and salvaged the entire agreement from antitrust condemnation. The settlement included a broad license and covenant-not-to-sue covering all patents related to original Opana ER that Endo owned or might acquire. ID at 142-44;

IDF 567-70, 592-93. According to the ALJ, these provisions allowed Impax to enter nine months before expiration of Endo's original patents and protected Impax when Endo acquired additional patents and asserted them to enjoin other drug manufacturers from marketing generic versions of Opana ER. ID at 143-44, 146; IDF 573-81, 588, 596. Although other manufacturers were barred from the market until 2029, the broad license has shielded Impax from the "threat of patent infringement litigation relating to original Opana ER." ID at 144, 146; IDF 594, 596. The ALJ thus found that, on balance, the settlement promoted competition by ensuring that consumers have continued access to generic Opana ER. ID at 144, 146; IDF 594, 596. Impax urges us to sustain these findings.

We disagree with the ALJ because we find that Impax did not sustain its burden of linking the procompetitive benefits to the challenged restraint. Impax failed adequately to link the alleged procompetitive justifications to the challenged restraint, which—as the ALJ acknowledged—was the use of a reverse payment to eliminate the risk of generic entry before January 2013. ID at 100-02; *Actavis,* 570 U.S. at 157. Impax does not make any argument that the No-AG Commitment or Endo Credit (or any portion of the $10 million DCA payment) have *themselves* protected Impax from the threat of patent litigation or that it needed to accept these payments in order to enjoy the procompetitive benefits of the patent license. Impax thus fails to overcome the anticompetitive effect, which *Actavis* anticipated, from reverse payments "independen[t] from other services for which it might represent

payment," and "lack[ing] [] any other convincing justification." 570 U.S. at 159.

1. Impax Has Failed to Show that the Restraint Furthered any Procompetitive Justifications

After Complaint Counsel made a *prima facie* case of anticompetitive harm, it became Impax's burden to show that the "*challenged restraint* enhances competition." *NCAA*, 468 U.S. at 104 (emphasis added). For purposes of procompetitive justifications, we look at the specific restraint, not the agreement as a whole. Even if an agreement between competitors generally benefits competition, this does not validate a restraint that "makes no significant contribution to the alleged justification." Areeda & Hovenkamp, *supra* ¶1505a. For example, in *NCAA*, the Supreme Court held that even though the NCAA's member institutions had a legitimate interest in adopting rules to promote "competitive balance" among football teams, the NCAA's specific restrictions on telecasts were "not even arguably tailored" to serve that interest. 468 U.S. at 117- 19. Thus, to justify a challenged restraint, Impax must "articulate the specific link between the challenged restraint and the purported justification," and demonstrate that the restraint in fact "advance[s] procompetitive goals." *Polygram Holding, Inc.*, 136 F.T.C. 310, 347 (2003), *enforced*, *Polygram Holding, Inc. v. FTC*, 416 F.3d 29 (D.C. Cir. 2005); *see also N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 368-69 (5th Cir. 2008) (defendant must show that the restraint bears a "logical nexus to [the] claimed efficiencies," meaning that the efficiencies either "result from or are in any

way connected to" the restraint); *Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 835 (6th Cir. 2011) (affirming FTC's finding that the respondent had not "demonstrated a connection" between the restraint and the proffered rationale); *Visa*, 344 F.3d at 238, 243 (explaining that defendants "must provide a procompetitive justification for the challenged restraint," and sustaining district court's finding that "no evidence" showed that the restraint advanced the proffered justifications).

As explained below, we hold that the relevant restraint here is the payment in exchange for the elimination of the risk of entry, *Actavis,* 570 U.S. at 157, and that defendant must adduce facts tying any cognizable procompetitive benefits to the elimination of this risk. Impax points to the fact that the payments coincided in the SLA with the broad license, the entry date, and other terms, and argues that any benefits deriving from a reverse payment settlement as a whole are cognizable, and therefore that it need not prove any link between the actual restraint and the benefits. That is wrong, and Impax has failed to meet its burden. Even if Impax had established a link, Complaint Counsel can prevail by showing that the restraint was not reasonably necessary to achieve the alleged procompetitive benefits, which they have accomplished by identifying a less restrictive alternative. *See* Areeda & Hovenkamp, *supra* ¶1505; *North Texas*, 528 F.3d at 368-69; *Realcomp*, 635 F.3d at 835; *Polygram*, 136 F.T.C. at 347.

a. What is the Restraint Impax Must Justify?

The parties cross swords on the foundational question of what constitutes the challenged "restraint" in this case. The ALJ, like Complaint Counsel, defined the restraint as "the payment in conjunction with a restriction on the generic's ability to compete." CCRB at 6; *see* ID at 99 (defining the restraint as "the use of the payment to restrain potential generic competition"), 141 (similar). Impax, on the other hand, argues that when a plaintiff challenges a specific agreement, "all aspects of that agreement are at issue"; and, therefore, maintains that it can offer any procompetitive benefit arising from the agreement, even if that benefit is not tied to, or does not derive from, the specific restraint within the larger agreement. RB at 18-19. We conclude that the ALJ's and Complaint Counsel's interpretation is more consistent with *Actavis*, which instructs that the commitment not to enter in exchange for a large and unjustified payment constitutes the relevant restraint.

In *Actavis*, the Supreme Court recognized the large and unjustified payment in exchange for not entering the market was the red flag that put such settlements into the rule of reason analysis. It referred to the "specific restraint at issue" as "a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed." 570 U.S. at 153-54. Such a "payment in return for staying out of the market" would "keep[] prices at patentee-set levels," allowing

the brand and generic manufacturers to "divid[e]" the profits of the branded drug's continued monopoly. *Id.* at 154. The Court conceded that patent licenses "permitting the patent challenger to enter the market before the patent expires" bring about competition; but, recognizing the need to scrutinize the "specific restraint" within the settlement, stressed that competitive harm arises when the patentee makes a reverse payment to preclude the risk of *even earlier* competition. *Id.*

The *Actavis* Court recognized the defendant has the burden to explain and justify the payment itself, not the settlement as a whole: "[A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it." *Id.* at 158; *accord Lipitor*, 868 F.3d at 256 (on motion to dismiss, noting the "defendants have the burden of justifying the rather large reverse payment here, and they offer no reason why those other elements of the settlement agreement do so"). Thus, an antitrust defendant cannot salvage an anticompetitive reverse payment merely by pointing to unrelated terms in the same settlement agreement, but must justify "the presence of the *challenged term* and show[] the lawfulness of *that term* under the rule of reason." *See Actavis*, 570 U.S. at 156 (emphasis added). The "likelihood of a reverse payment bringing about anticompetitive effects depends upon," inter alia, "its independence from other services for which it might represent payment and the lack of any other convincing justification." *Id.* at 159.

Impax argues that a "payment alone" is not a restraint. RB at 13-14. We agree. But nor can we decouple the payment from the agreement not to enter. As we have explained, *Actavis* instructs that a large and unjustified payment is the red flag signaling anticompetitive harm. 570 U.S. at 154. A generic manufacturer's commitment to stay out of the market until the licensed entry date *in exchange for* such a payment is, accordingly, the relevant restraint. *Id.*

Despite *Actavis*'s focus on the payment for not entering, Impax contends it is a basic principle of antitrust law that a restraint of trade consists of the "sum total" of the parties' contractual relationship, rather than the specific provisions alleged to be anticompetitive. RB at 14.[36] But, as Impax itself notes, the Supreme Court has explained that a restraint of trade "refers *not* to a particular list of agreements, but to a particular *economic consequence*." *Id.* at 13 (quoting *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 731 (1988)) (emphasis added by Impax). Here, *Actavis* defines the relevant "*anticompetitive consequence*" as the sharing, through a reverse payment, of supracompetitive prices between the patentee and the generic challenger "rather than face what might have been a competitive market." *See* 570 U.S. at 157 (emphasis added). That consequence

[36] Impax derives the "sum total" language from a treatise which explained that "the content of the restraint is the sum total of everything that the parties have 'agreed' about *and that is alleged to injure competition*." PHILLIP E. AREEDA & HERBERT HOVENKAMP, FUNDAMENTALS OF ANTITRUST LAW §15.02[D] (rev. ed. 2018) (emphasis added). Impax appears to misread this passage, which makes clear that the restraint only consists of the portions of an agreement that are alleged to injure competition.

cannot be justified by unrelated terms that merely happen to coincide in the same contract. Rather, the defendant must adduce facts, beyond mere assertion, to link the benefits to the restraint.

The Court in *Actavis* instructed us to apply the rule of reason to determine whether an apparently anticompetitive payment to stay out of the market can be justified. 570 U.S. at 159. Impax has offered no such justification. None of the cases Impax cites supports its position that we should consider the competitive effects of the parties' entire contract rather than the allegedly anticompetitive terms. In *NCAA*, the Court, applying the rule of reason, "assume[d] that most of the regulatory controls of the NCAA are justifiable" and "procompetitive," but held that the NCAA had failed to justify its specific restrictions on TV broadcasts. 468 U.S. at 99, 117. Likewise, in *National Society of Professional Engineers v. United States*, 435 U.S. 679 (1978), the Court evaluated the effects of a professional association's "ban on competitive bidding" rather than the association's code of ethics as a whole. *Id.* at 695. Most recently, in *Amex*, the Supreme Court treated the restraint as Amex's "antisteering provisions in its contracts with merchants," rather than the entire contracts. 138 S. Ct. at 2283.[37]

We have followed this approach in our own cases. In *Polygram*, we evaluated the effects of joint venture

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[37] *See also Cal. Dental Ass'n*, 526 U.S. at 778 (evaluating the effects of a professional association's advertising restrictions rather than its entire ethics code); *Ind. Fed'n of Dentists*, 476 U.S. at 451 (analyzing a dental federation's rule prohibiting members from submitting x-rays to dental insurers when making claims for benefits).

members' agreement not to discount their separate competing products, rather than the effects of the venture at large. 136 F.T.C. at 353. And, in Realcomp, we explained that while the "creation and operation" of a real estate multiple-listing service benefitted competition, the specific restraints on listings by lower-priced and limited-service brokers did not. 2007 WL 6936319, at *21-43.

Impax also invokes post-*Actavis* pharmaceutical cases (RB at 15, 17-19), but nearly all of them support Complaint Counsel's position that the restraint is the commitment not to enter, made in exchange for a large and unjustified payment, rather than the entire agreement. For example, the California Supreme Court, applying *Actavis* to state antitrust law, described the restraint as a "limit on the settling generic challenger's entry into the market" in exchange for "cash or equivalent financial consideration flowing from the brand to the generic challenger." *Cipro*, 348 P.3d at 865. "That payment for delay is condemned ... by federal antitrust law, and its purchase as part of a settlement agreement is an unlawful restraint of trade." *Id.* at 871. *See also Aggrenox*, 94 F. Supp. 3d at 243 (noting that defendants might be able to "explain the apparent 'missing' value for the patent-holder in a procompetitive way ... in which case the reverse payment may turn out to be justified, or to be entirely illusory"); *Lipitor*, 868 F.3d at 256.

Impax misinterprets *In re Loestrin 24 Fe Antitrust Litigation*, 261 F. Supp. 3d 307 (D.R.I. 2017), in which the district court declared that it was "looking at the whole of the settlement to determine its alleged effect

on competition." *Id.* at 331. The court in that case adopted this "holistic look" at the motion to dismiss stage for the purpose of determining whether the various forms of compensation to the generic company "amounted to a large and unjustified reverse payment." *Id.*; *accord Niaspan*, 42 F. Supp. 3d at 752. The *Loestrin* court did not hold (or even suggest) that a defendant could successfully have a case dismissed by relying on provisions *unrelated to* the payment in exchange for eliminating competition.

Impax cites only to one case holding, on summary judgment, that the court would "evaluate the settlement as a whole, and not in a piecemeal, provision-by-provision approach." *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 753 (E.D. Pa. 2015). We decline to follow *Wellbutrin*, to the extent it is inconsistent with *Actavis*'s instruction that the burden is on the defendant to justify the restraint itself.[38]

Impax argues that we should treat the entire settlement as the restraint because Complaint Counsel "challenge the settlement (and separate DCA) as a whole, engaging in an unbounded effort to establish anticompetitive impact." RB at 16. But this mischaracterizes Complaint Counsel's allegations,

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[38] *Wellbutrin* was, factually, a very different case. It did not involve the core harm about which *Actavis* warns us, namely, the elimination of the risk of competition. *Id.* at 754. Rather, the "Wellbutrin Settlement specifically contemplated that the generic manufacturer would continue its patent challenge and allowed the generic to enter immediately upon a finding of patent invalidity, maintaining the risk of patent invalidation or a finding of non-infringement even after the settlement." *Id.* at 754.

which clearly challenge specific attributes of the settlement. Compl. ¶¶74-75. And as explained above, this argument is incorrect as a matter of law.

Impax then accuses Complaint Counsel of attempting to "have it both ways," arguing they seek to "gerrymander respondents' defenses" by failing to allege that the broad patent license, a "value-conveying term," was part of the restraint, and thereby precluding Impax from citing the license as a justification. RB at 16. But Actavis defines the restraint and, as discussed above in Section V.A.3.d, there is no evidence in the record here, let alone convincing evidence, to indicate that this license—which facilitated entry—was itself part of a suspicious reverse payment.

Complaint Counsel and the ALJ correctly defined the restraint as the use of the reverse payment to restrain generic competition, *i.e.*, payment for delayed entry. We next consider whether Impax bore its burden to demonstrate that this restraint significantly aided any procompetitive objectives.

b. Did the Restraint Produce any Procompetitive Effects?

An antitrust defendant cannot simply cite procompetitive benefits in the abstract, but must show that those benefits bear a "logical nexus" to the restraint. *North Texas*, 528 F.3d at 368-69; *Realcomp*, 635 F.3d at 835; *Polygram*, 136 F.T.C. at 347. A defendant's purported justifications are "entirely immaterial" unless they "are actually promoted significantly by the restraint." Areeda & Hovenkamp, *supra* ¶¶1505a, 1511c; *see NCAA*, 468 U.S. at 114 (upholding lower court's finding that the restraint

"produced [no] procompetitive efficiencies" because "NCAA football could be marketed just as effectively without the [restraint]"); *Graphic Prods. Distribs. v. ITEK Corp.*, 717 F.2d 1560, 1576 (11th Cir. 1983) ("[M]erely offering a rationale for a ... restraint will not suffice; the record must support a finding that the restraint ... . does indeed have a pro-competitive effect."); *O'Bannon v. NCAA*, 802 F.3d 1049, 1072 (9th Cir. 2015) (concluding what while "a restraint that broadens choices [is] procompetitive ... we fail to see how the restraint at issue in this particular case ... widens recruits' spectrum of choices"). Under *Actavis*, in the context of a reverse-payment settlement, the defendant needs to show that the reverse payment leads to more competition than would have resulted without the payment. *See* 570 U.S. at 156, 158.

The Initial Decision did not require a link between the reverse payment and the purported procompetitive benefits. After properly defining the restraint as the use of a reverse payment to eliminate the risk of earlier generic competition, it held that "procompetitive benefits arising in connection with the *settlement agreement as a whole* are properly considered as part of a well-structured rule of reason analysis." ID at 141 (emphasis added).[39] This was an

[39] Although the ALJ cited our October 2017 order denying Complaint Counsel's motion for summary decision in this proceeding, we held only that it was too early for decisions regarding the admissibility and utility of purported procompetitive benefits. We deemed Complaint Counsel's motion "premature" pending "development of a record, ordering of that record under a proposed rule-of-reason framework, and ultimately briefing of disputed issues concerning the

incorrect statement of law. The rule of reason properly credits only justifications promoted by the challenged restraint in reverse-payment settlement cases.[40] Impax bears the burden to demonstrate this link.

We must therefore ask whether Impax has established that the restraint—a large and unjustified reverse payment to prevent pre-2013 entry—advanced any procompetitive objectives. The ALJ found that the settlement agreement contained a broad patent license allowing Impax to introduce its generic in January 2013, shielding it from lawsuits claiming infringement of patents that Endo acquired after the settlement, and thereby providing consumers continuous access to Opana ER since 2013. ID at 141, 144-46. Even if these benefits were realized, however, Impax still would need to tie those benefits to the challenged restraint.

Impax never attempts to make that showing. Impax does not claim that the No-AG Commitment and Endo Credit (or any portion of the $10 million

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appropriateness of that framework and of its application to the facts presented." *Impax*, 2017 WL 5171124, at *10.

[40] A contrary rule would allow parties to skirt liability for anticompetitive behavior by inserting unrelated provisions into their contracts and claiming that those provisions benefited competition. Requiring that the challenged restraint itself further any alleged procompetitive benefits is also consistent with the ancillary restraints doctrine. "To qualify as an 'ancillary' restraint, 'an agreement eliminating competition must be subordinate and collateral to a separate, legitimate transaction,' and it must also 'be related to the efficiency sought to be achieved.'" *Polygram*, 136 F.T.C. at 366 (quoting *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 224 (D.C. Cir. 1986)).

DCA payment) *themselves* protected Impax from the threat of patent infringement suits. Nor does Impax argue that it needed to accept these payments in order to achieve a settlement containing the broad patent license. Instead, Impax asserts that it "would not have entered the challenged [settlement] without the broad patent license." RB at 17. But that does not address the right question. The appropriate question is whether Endo and Impax could have reached a similar licensing agreement without a *reverse payment* for delayed generic entry.[41]

As Complaint Counsel explain, because "both the payment and the ... license were benefits flowing to Impax," Impax readily could have accepted the license without also accepting a payment. CCAB at 20. For Endo's part, "because [it] was willing to give both the large payment and the license to Impax, it certainly would have been willing to give *less* (*i.e.*, just the license and not the payment)." *Id.* Thus, Complaint Counsel posit, the "only reasonable explanation" for the payment was that it prevented Impax from

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[41] In a pre-*Actavis* decision, we recognized the "hypothetical" possibility that a "cash-starved" generic company might argue that it can "enter earlier and more effectively if it receives some up-front support from the pioneer manufacturer." *See Schering-Plough Corp.*, 136 F.T.C. 956, 1001 (2003), *vacated, Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *abrogated by Actavis*, 570 U.S. at 153. Similarly, we acknowledged other possibilities such as that "[a] judgment-proof generic manufacturer may be willing to hold out for 'unreasonable' settlement terms because its downside risks of damage exposure are small." *Id.* at 1002. Impax makes no such claims here. Nor, for that matter, does it claim it would not have pursued a Paragraph IV filing without the prospect of obtaining a No-AG Commitment.

demanding an even earlier entry date, which demonstrates that the payment was *anticompetitive*, not procompetitive. *Id.* at 21. Impax does not attempt to rebut Complaint Counsel's reasoning or argue that it needed to accept a payment in order to receive a patent license. Indeed, Impax does not appeal the ALJ's finding that the payment had the "purpose and effect" of delaying entry. ID at 6-7. And, as we further explain in Section V.C below, even if Endo and Impax *preferred* to settle by sharing Endo's monopoly profits in exchange for delayed entry, this does not show that a less-anticompetitive settlement was unattainable.

We do not hold today that a defendant cannot adduce facts linking procompetitive benefits within a settlement to a payment for delayed entry. Beyond coincidence with the SLA, however, Impax has simply not done so.

Rather than attempting to demonstrate how the reverse payment furthered its procompetitive justifications, Impax offers a series of legal arguments attempting to bypass this requirement. Impax posits that the rule of reason does not require *any* connection between the challenged restraint and its proffered justifications, provided the justifications coincide in an agreement with the restraint. RB at 19. It seeks to distinguish our *Polygram* decision—where we ruled that the respondent must "articulate the specific link between the challenged restraint and purported justification"—by observing that we were only applying "quick look" review, not the full-blown rule of reason. RB at 19 (discussing *Polygram*, 136 F.T.C. at 347). But quick-look review only affects the showing required for plaintiff to demonstrate anticompetitive

harm, not the defendant's burden to assert procompetitive justifications. *See, e.g.*, *Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 831 (3d Cir. 2010). In *Polygram*, we held that a procompetitive justification is not even "plausible" unless it bears a "specific link" to the restraint. 136 F.T.C. at 347; *accord Actavis*, 570 U.S. at 153 (noting the potential for the "specific restraint at issue" to harm competition). Under quick-look review, it is only when the defendant meets this "plausibility" standard (and the proffered justification is cognizable under the antitrust laws) that the factfinder will conduct a "more searching inquiry into whether the restraint may advance procompetitive goals." *Id.* at 345-47. Here, by contrast, Impax received a full opportunity to demonstrate procompetitive effects under the rule of reason, and still failed to argue any link existed between the specific restraint and its procompetitive goals.

Impax also suggests that the Supreme Court's 2018 decision in *Amex* marked a sea change in the law by "look[ing] at the record as a whole, including procompetitive benefits arising from factors other than the [restraint]." RB at 19-20. But the Court in fact declared the opposite, explaining that once the plaintiff makes a showing of anticompetitive effects, the defendant must "show a procompetitive rationale *for the restraint*." *Amex*, 138 S. Ct. at 2284 (emphasis added). The *Amex* Court did not actually reach the stage of analyzing procompetitive benefits, explaining that the sole issue on appeal was "whether the plaintiffs have carried their initial burden of proving that Amex's antisteering provisions have an anticompetitive effect." *Id.* at 2284, 2287, 2290.

Impax claims it should not be required to link the restraint to its procompetitive justifications at the second step of the rule of reason because "it is the *plaintiff's* burden to establish the absence of any connection" at the third step, which considers the existence of a less-restrictive alternative. RB at 19. Impax again misunderstands its duties at the second step. At this stage, Impax has the burden to show that the restraint "*furthers* ... legitimate objectives" and "*promotes* a legitimate goal." *Brown Univ.*, 5 F.3d at 679 (emphasis added). A restraint cannot "further" or "promote" a procompetitive goal unless it has a clear "connection" to it. Coincidence within a settlement is not enough. It is only when a defendant makes that connection that the burden shifts back to the plaintiff to show a less restrictive alternative. *Id.* That the plaintiff is entitled to offer rebuttal evidence does not relieve defendant of making the initial showing.

For the same reasons, we reject the contention that the early entry facilitated by the reverse payment settlement should be weighed against the competitive harm identified here. Impax has not tied the freedom-to-operate license, which facilitated entry prior to expiration of the after-acquired patents, to the restraint, as discussed above. And, as discussed, the nine month early entry on the initial Opana ER patents almost surely would have been longer absent the reverse payments.

Finally, we find the general policy favoring settlements cannot save this anticompetitive reverse payment settlement. While settling litigation is typically favored under the law, it is not a trump card. As *Actavis* teaches, the mere fact that a reverse

payment settles litigation does not immunize otherwise anticompetitive conduct. 570 U.S. at 153-58. Given that Impax has failed to identify any other cognizable efficiencies,[42] we conclude that the policy favoring settlements does not, on its own, save the anticompetitive conduct at issue here.

In sum, Impax does not argue that: (1) the No-AG Commitment, the Endo Credit, or any portion of the DCA payment have *themselves* allowed Impax to sell its generic product free of patent-infringement claims; (2) a settlement including the broad license was only available because Impax accepted a payment; or (3) the reverse payment furthered the procompetitive objectives of the license in some other way. Because it has not linked the payment for deferred entry that constitutes the challenged restraint to an asserted justification, Impax has not identified a procompetitive benefit that could offset the restraint's anticompetitive harm.

2. Conclusions Drawn from Impax's Failure to Demonstrate Procompetitive Benefits

Accordingly, we conclude that Impax has failed to establish any procompetitive justifications for its acceptance of a large reverse payment to delay generic entry. In combination with our conclusion that

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[42] For clarity, we define "cognizable efficiencies" here to mean those procompetitive justifications that meet all the requirements to be considered legitimate and thus to be counted against any anticompetitive effects, which includes that they be sufficiently related to the restraint at issue. *See* U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS §3.36.

Complaint Counsel have established that the reverse payments caused anticompetitive harm, the failure to establish a procompetitive justification brings the rule-ofreason analysis to its end. Because Impax's conduct had significant anticompetitive consequences and Impax has not established any cognizable procompetitive justifications for these consequences, this conduct constitutes an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. §1, and an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. §45(a).

C. Even if Impax's Procompetitive Justifications Were Valid, Complaint Counsel Have Shown a Less Restrictive Alternative

Had Impax borne its burden to connect creditable procompetitive justifications to the restraint at issue (for example, if Impax had proven the broad patent license offered cognizable efficiencies), the burden would then shift to Complaint Counsel to demonstrate "that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means." *Amex*, 138 S. Ct. at 2284. *See also Brown Univ.*, 5 F.3d at 678-79; *Law*, 134 F.3d at 1019; *Visa*, 344 F.3d at 238; Areeda & Hovenkamp, *supra* ¶1505; U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS §3.36(b). We hold that Complaint Counsel have demonstrated that Impax could have obtained the proffered benefits by settling without a reverse payment for delayed entry—which is a practical, less restrictive alternative.

The Initial Decision devoted a single paragraph to this issue. *See* ID at 146-47. The ALJ found that Complaint Counsel failed to show that a "hypothetical [alternative] settlement could have, or would have, included the broad patent license," noting that Endo had twice rejected Impax's simple settlement proposals with 2011 entry dates and no reverse payments. ID at 147 & n.35. We disagree.

The *Actavis* Court repeatedly recognized that settling without a reverse payment is often a feasible, less anticompetitive alternative. *See* 570 U.S. at 158 ("[P]arties may well find ways to settle patent disputes without the use of reverse payments."). Imposing antitrust liability for reverse payments "does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without ... paying the challenger to stay out prior to that point." *Id.* at 158. The "premise" behind *Actavis*, a leading treatise recognizes, "is that there are better, less anticompetitive ways to settle these disputes." Areeda & Hovenkamp, *supra* ¶2046c3 (3d ed. Supp. 2017).

Additional evidence confirms this insight. Complaint Counsel's expert, Professor Max Bazerman, testified that "[t]he empirical evidence supports the conclusion that settlements are very viable without reverse payments." CX5001 (Bazerman Expert Report) at ¶20; *see also id.* at ¶¶21, 23. Professor Bazerman pointed to, *inter alia*, Commission studies—covering more than a decade—that demonstrate the feasibility of these settlements.

Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires pharmaceutical companies to file with the FTC and the Department of Justice agreements between branded and generic manufacturers regarding the manufacture, marketing, and sale of generic versions of brand-name drugs. *See* Pub. L. No. 108-173, 117 Stat. 2066 (codified in relevant part at 21 U.S.C. §355 note). Professor Bazerman found that for fiscal years 2004-2009 these studies showed that only 30 percent of the patent settlements filed with the FTC involved both compensation from the branded firm to the generic firm and restrictions on generic entry. CX5001 (Bazerman Expert Report) at ¶21, citing FTC Staff Report, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2009 (Apr. 2011), https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/mmareport2009.pdf. Similarly, in the first full fiscal year after *Actavis*, the FTC learned of 160 final agreements resolving patent disputes between branded and generic manufacturers, and found that over 80 percent involved no compensation flowing from the branded to the generic firm. *Id.*, citing FTC Staff Report, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2014 (Jan. 2016), https://www.ftc.gov//reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement-0. The testimony

demonstrates that branded and generic pharmaceutical companies routinely—and far more often than not—settle patent litigation disputes without reverse payments, consistent with the Supreme Court's statements in *Actavis*.

Here, Complaint Counsel argue that a less anticompetitive settlement along the lines suggested in *Actavis* was obvious as a matter of "[b]asic common sense." CCAB at 25. Since Endo "was willing to trade money for its preferred 2013 entry date," it certainly would have been willing to offer the same license and entry date (or possibly an earlier date) without also making a large payment to Impax. *Id.* Thus, according to Complaint Counsel, there is no basis in the record to conclude that Impax needed to receive a multi-million dollar payment in order to obtain the procompetitive benefits of a broad patent license and pre-expiration entry date. *Id.*; CCRB at 11; *see Smithkline Beecham*, 791 F.3d at 412.

Impax responds by charging that Complaint Counsel's proffered alternative was not "possible." RB at 25-26. Impax further responds that Complaint Counsel's no-payment alternative would be "no less restrictive of competition" because "Impax would still have launched its product on the exact same date and given up its patent challenge in the exact same manner." RB at 14, 25 (emphasis omitted). *See also* Oral Arg. Tr. 59:10-59:12; 63:17-63:21 (counsel arguing Impax received "the earliest date that Endo was willing to offer").[43] Impax's argument boils down

[43] The record does not support Impax's assertion. After Endo rebuffed Impax's specific proposals for earlier entry dates (including a 2011 entry date and one as late as January 2012),

to the assertion that the proffered alternative was not offered or agreed to, and that the combination of Endo's desire to further delay competition and Impax's desire to share in monopoly rents prevented this alternative from arising.

Given, however, the Supreme Court's analysis in *Actavis* and the decades of evidence indicating that firms can and do—frequently and successfully—settle Hatch-Waxman patent litigation without reverse payments, Impax needed to support its assertion that a no-payment settlement was impossible with *evidence* rebutting Complaint Counsel's strong showing. *See* Areeda & Hovenkamp, *supra* ¶1914c. It may do so by "showing that the proffered alternative is either unworkable or not less restrictive" based on the facts in evidence. *Id.* ("The defendant's own business expertise and experience is the likely source of information concerning the viability of proffered less restrictive alternatives.").[44] In this specific

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Impax acceded to Endo's proposals for a much later, 2013, entry date and a large reverse payment. IDF 116, 155. Although Impax's lead settlement negotiator, Christopher Mengler, asserted at trial the Endo was adamant about preventing pre-2013 entry (Mengler, Tr. 565-67), in his previous sworn testimony he admitted that he did not remember discussing entry dates prior to 2013 with Endo. *See* CX4010 (Mengler, IHT) at 45-54. Specifically, Mengler professed no recollection of (1) whether Impax ever "tried to get a date earlier than January of 2013"; (2) how Endo reacted to the prospect of an earlier date; or (3) whether Endo ever told Impax that it would "not settle the litigation" with an entry date before 2013. *Id.*

[44] *See also* C. Scott Hemphill, *Less Restrictive Alternatives in Antitrust Law*, 116 COLUM. L. REV. 927, 982 (2016) ("If plaintiffs have the burden of persuasion, defendants ought to bear a burden of production. Defendants have better access to information

context, where Supreme Court jurisprudence and decades of agency experience highlight the viability of the alternative, we need more in order to dismiss it. Other facts showing the impossibility of such terms in a given case might suffice, but such facts are not in this record.

A restraint is unlikely to survive scrutiny where, as here, it appears the parties' desire to preserve and split between themselves monopoly profits is the only impediment to their settling on terms that other parties routinely use to settle similar litigation. *See Actavis*, 570 U.S. at 158. The facts that are before us make it hard to imagine that, if apparently material contract terms—worth at least $23 million—were removed, Impax's key restriction under the settlement, *i.e.*, the entry date, would not have altered. As the ALJ found, and as we have discussed, it is "unlikely" that a brand company would pay a generic "anything more than saved litigation costs, only to obtain entry on the date the [generic] would have entered anyway." IDF 446. Holding everything else equal, Impax's acceptance of payment would normally be expected to result in a later entry date than what Impax would have accepted based on the strength of the patents alone. *See* CX5001 (Bazerman Report) at ¶17; *Cipro*, 348 P.3d at 865, 871; *Smithkline Beecham*,

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about their reasons for adopting a particular practice."); *Wilk v. Am. Med. Ass'n*, 671 F. Supp. 1465, 1483 (N.D. Ill. 1987) (faulting defendant for failing to establish that an alternative was impractical or unworkable), *aff'd*, 895 F.2d 352 (7th Cir. 1990). *Cf. United States v. H & R Block, Inc.,* 833 F. Supp. 2d 36, 91 (D.D.C. 2011) (finding a proffered efficiency not merger-specific when defendant had failed to present evidence showing why an alternative would not be feasible).

791 F.3d at 405 n.23. Furthermore, a no-payment settlement with an earlier entry date would clearly be less restrictive of competition because it would give consumers earlier access to generic drugs at substantial discounts from the branded drug price. IDF 31, 442.

We therefore conclude that Complaint Counsel have demonstrated an alternative to the reverse payment settlement that would have achieved the procompetitive benefits Impax proffered (had Impax proven them cognizable) through significantly less anticompetitive means. A no-payment settlement allowing pre-2013 generic entry would have been a practical alternative for both Impax and Endo, but they chose instead to exchange sizeable payment for a later entry date. They destroyed the risk of competition and enriched themselves at the expense of consumers.

* * *

For the foregoing reasons, we hold that: (1) Complaint Counsel satisfied their *prima facie* burden to demonstrate harm to competition arising from the reverse payment settlement at issue; (2) Impax failed to show that the challenged restraint furthered any cognizable procompetitive justifications; and (3) even if Impax had satisfied this burden, Complaint Counsel identified a viable less restrictive alternative that has been used to settle hundreds of similar pharmaceutical patent litigations. Because the record provides two independent bases to reject Impax's procompetitive justifications, we do not need to reach the balancing stage of the rule of reason.

Impax has thus engaged in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. §1, and an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. §45(a).

VI. REMEDY

Having found a violation of Section 5, we are empowered to enter an appropriate order to prevent a recurrence of the violation. 15 U.S.C. §45(a)(2). The Commission has wide latitude to fashion a remedy, provided that the remedy chosen has a reasonable relation to the unlawful practices found to exist. *See, e.g., FTC v. Colgate-Palmolive Co.,* 380 U.S. 374, 394-95 (1965); *FTC v. Nat'l Lead Co.,* 352 U.S. 419, 429 (1957); *Jacob Siegel Co. v. FTC,* 327 U.S. 608, 612- 13 (1946). The scope of the remedial order is not strictly limited to the respondent's past transgressions but can effectively "close all roads to the prohibited goal, so that [the Commission's] order may not be by-passed with impunity." *FTC v. Ruberoid Co.,* 343 U.S. 470, 473 (1952).

Complaint Counsel have requested that we enter a cease and desist order that contains three major prohibitions against specified conduct by Impax. Specifically:

- Paragraph II.A of Complaint Counsel's Proposed Order would enjoin Impax from entering into a reverse payment patent settlement that includes an agreement not to compete by the generic filer plus a payment by the NDA holder to the generic filer. It covers all potential forms of reverse payments, including no-AG commitments

and business transactions entered within 45 days of a patent settlement. Proposed Order, Paragraph I.W. It carves out payments that are unlikely to be anticompetitive, such as saved litigation expenses, rights to market generic products, or provisions facilitating the regulatory approval of the generic's product. *Id.*

- Paragraph II.B of the Proposed Order would bar Impax from "entering any agreement that prevents, restricts, or in any way disincentivizes competition between oxymorphone ER products." This provision would not affect existing agreements.
- The parties' First Amendment to the 2010 SLA ("2017 Amendment") [redacted]. CX3275-013. Paragraph II.C of the Proposed Order requires Impax to pay royalties to Endo regardless of whether another oxymorphone ER product enters the market. [redacted]

Impax argues that no relief is needed (even assuming that the SLA is found to violate the Act), and further argues that each of the specific prohibitions identified above is overbroad and unwarranted. We reject several of Impax's arguments but find that others have merit. As discussed below, we include Complaint Counsel's first proposed prohibition and part of their second proposed prohibition in our Final Order but decline to include the third prohibition.

A. The Need for a Remedy

Respondent argues that Complaint Counsel have failed to show there is a "cognizable danger" that Respondent will repeat the condemned conduct, and therefore asserts that the Commission cannot enter prospective relief. *See* RB at 62-64, citing, *inter alia, United States v. W.T. Grant Co.,* 345 U.S. 629, 633 (1953). We disagree and find that Complaint Counsel have shown the requisite danger of recurrence.

Impax's motivation to enter the reverse-payment settlement with Endo arose from the parties' joint incentive to split the monopoly profits that Endo could earn from Opana ER rather than see those profits competed away by generic entry. *Actavis,* 570 U.S. at 154. This incentive is enduring and is not limited to the oxymorphone ER market. It is, unfortunately, a feature of infringement litigation under the Hatch-Waxman Act statutory framework generally. *See* C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1560 (2006) (because only the first generic ANDA filer can receive the "bounty" of 180-day exclusivity, the brand's strategy of "buying off" the first generic challenger is effective in heading off the most potent threat to entry); Cipro, 348 P. 2d at 854 (Hatch-Waxman Act legal regime means that, "regardless of the degree of likely validity of a patent, the brand and first-filing generic have an incentive to effectively establish a cartel" through a reverse payment settlement) (citing Hovenkamp, supra ¶2046 at 351). Although the number of settlements involving reverse payments has decreased following the Supreme Court's Actavis decision, as discussed above

in Section V.C, the data also reveal that this practice has not disappeared. The persistence of this incentive supports the grant of prospective relief here. See Polygram, 416 F.3d at 38-39 (upholding FTC cease and desist order because the condition that gave rise to the unlawful agreement - namely, the record company's fear that a new release by an artist may lose sales to an artist's older albums owned by a competitor - is recurrent in the record industry and would give the respondent the same incentive to enter future unlawful agreements).

Moreover, Impax remains an active participant in the pharmaceutical industry and regularly engages in patent infringement litigation. *See* CX3271-030 (Impax 2015 Annual Report describing Impax as "routinely subject" to patent infringement litigation brought by branded pharmaceutical manufacturers). Thus, settling patent litigations will likely continue to be a significant part of Impax's business. *See FTC v. Accusearch Inc.,* 570 F.3d 1187, 1202 (10th Cir. 2009) (court upheld prospective relief in part because respondent remained in the business and had the capacity to engage in similar unfair acts or practices in the future). Given the persistent nature of the incentives for reverse payment settlements, and Impax's likely continued participation in patent infringement litigation, we consider the prospective relief to be warranted here.[45]

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[45] In fact, although our ruling is not dependent on this point, Impax's claim that it has no history of similar violations may be questioned; Impax has entered into at least one other patent settlement with a branded firm alleged to include a large, unjustified reverse payment. *See In re Solodyn (Minocycline*

B. The Asserted Overbreadth of the Order

We next turn to Respondent's specific concerns with the terms of the Proposed Order. Respondent contends that the prohibition on reverse payment settlements in Paragraph II.A is overbroad in that its coverage of "any Payment" would prevent Impax from purchasing materials or services from a branded company for fair value. RB at 64-65. As the dispute in this proceeding over the DCA milestone payments illustrates, whether a payment is for fair value can be a topic of intense debate. The Proposed Order here appropriately short-circuits future argument: having violated the law, a respondent "must expect some fencing in." *Nat'l Lead,* 352 U.S. at 431. Moreover, the Proposed Order does not ban all sales of goods and services, but only those that are either (i) expressly contingent on entering a brand/generic settlement agreement, or (ii) occur within 45 days before or after such a settlement. Proposed Order, Paragraph I.W. Respondent does not explain why, if there were independent business reasons for a fair value transaction, it could not enter such a transaction outside of these restrictions.

Next, Respondent argues that the provision banning "any agreement that prevents, restricts, or in any way disincentivizes competition between Oxymorphone ER Products" is problematic. Proposed Order, Paragraph II. B. Respondent first contends, erroneously, that this provision relates only to the challenged *product* and not the challenged *practice.*

Hydrochloride) Antitrust Litig., 2018 WL 563144 (D. Mass. Jan. 25, 2018).

RB at 65, citing *Nat'l Lead*, 352 U.S. at 428 (improper remedy if "no reasonable relation to the unlawful practices found to exist"). In fact, the provision relates to both the product and the practice. Here, the gravamen of our holding is that Impax and Endo entered into an agreement that "prevent[ed]" and "restrict[ed]" competition for sales of oxymorphone ER. There is thus an amply close nexus between the condemned conduct and the agreements that the Proposed Order forbids. *See FTC v. Mandel Bros., Inc.*, 359 U.S. 385, 393 (1959) (the Commission "may fashion its relief to restrain other like or related unlawful acts") (quotation omitted).

We do agree, however, with Impax to the limited extent that we find the proposed ban on agreements that "disincentivize[]" competition to be vague and potentially overbroad. For example, if Impax entered a procompetitive agreement that increased the supply of oxymorphone ER products, this might be seen as "disincentivizing" third-party entry into the market because it would make such entry less profitable. Yet such an agreement is obviously not the intended target of the remedial order. The Order that we enter has language barring agreements that "prevent[] or restrict[]" competition in oxymorphone ER products but omits the term "disincentivizes." We also accept Complaint Counsel's suggestion to add the following underlined text to clarify the meaning of the Order:

- Paragraph II.B: Respondent shall not enter any agreement with another <u>Oxymorphone ER Manufacturer or Applicant</u> that prevents or restricts competition between Oxymorphone ER Products.

- Paragraph I Definitions: "Oxymorphone ER Manufacturer or Applicant" means any company that has an Oxymorphone ER NDA or ANDA, has filed an Oxymorphone ER NDA or ANDA, or is preparing to file an Oxymorphone ER NDA or ANDA.

Finally, Impax opposes Complaint Counsel's proposal to nullify Impax's rights under the 2017 Amendment to the SLA while maintaining its royalty obligation to Endo. [redacted] CX3275 at 013-014, §§1(h)-(i), 4(a). [redacted] The Proposed Order would require Impax to pay royalties [redacted] until Endo's additional patents expire, regardless of whether Endo or another firm actually enters the market.

Impax raises three concerns about Complaint Counsel's proposal. First, Impax argues that the 2017 Amendment is not a reverse payment but is exactly the kind of "commonplace settlement form" that *Actavis* leaves untouched. RB at 66, quoting *Actavis,* 570 U.S. at 152. Second, Impax argues that Complaint Counsel have not investigated the 2017 Amendment, taken discovery regarding it, adduced evidence at trial regarding it, or formally challenged it. *Id.* Thus, says Impax, it would violate basic notions of administrative law to condemn it as anticompetitive. *Id.* at 67. Third, Impax argues that Complaint Counsel did not suggest until after the trial that they intended to invalidate the 2017 Amendment. Thus, Impax asserts, it would violate due process to enter an adverse finding against the 2017 Amendment at this stage. *Id.*

We do not share Impax's confidence that the 2017 Amendment is an ordinary settlement unremarkable under *Actavis.* As noted in Section II.D above, Endo

has now exited the market for oxymorphone ER. [redacted] This could continue the sharing of monopoly profit on sales of the Opana ER formulation, with Impax now in the role of a monopolist and Endo in the role of a potential entrant paid to stay out of the market. Nonetheless, the fact remains that the contractual provision at issue was neither investigated nor litigated below. Under these circumstances, we believe it would be unwise and inequitable to strip Impax of its rights under the 2017 Amendment, while leaving it with its obligations.[46] We accordingly omit this provision from our Final Order.

ISSUED: March 28, 2019

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[46] Below, Complaint Counsel first sought, at the conclusion of the administrative trial, to nullify the 2017 Amendment in its entirety. CC Post-Trial Br. at 76. Facing what could have been the elimination of its royalties, Endo successfully moved to intervene in the ALJ proceeding for the limited purpose of participating in post-trial briefing to protect what it described as its "due process rights[] and its contract rights" under the August 2017 settlement agreement. Non-Party Endo Pharmaceuticals Inc.'s Unopposed Motion for Limited Intervention and Memorandum in Support, Docket No. 9373 (Jan. 2, 2018). Endo argued that Complaint Counsel's request to nullify the 2017 Amendment "violate[d] the most basic principles of due process and [was] a brazen attempt at governmental overreach." Intervenor Endo Pharmaceuticals, Inc.'s Opposition to Complaint Counsel's Findings and Proposed Relief Regarding the Endo-Impax 2017 Settlement Agreement 1 (Jan. 16, 2018). On this appeal, Complaint Counsel modified their remedial request to require. [redacted] *See* Proposed Order, Paragraph II.C.

Appendix C

UNITED STATES FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

No. 9373

IN THE MATTER OF IMPAX LABORATORIES, INC.,
Respondent.

Filed: May 18, 2018

Chief Administrative Law Judge:
Chappell, D. Michael

INITIAL DECISION

I. INTRODUCTION

A. Summary of Complaint and Answer

The Administrative Complaint in this case ("Complaint"), issued by the Federal Trade Commission ("FTC" or "Commission") on January 19, 2017, alleges that a reverse payment settlement agreement between Respondent Impax Laboratories, Inc. ("Impax" or "Respondent") and Endo Pharmaceuticals Inc. ("Endo") was an anticompetitive agreement in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. §45 ("FTC Act"). Complaint ¶¶1, 3. The Complaint alleges that,

through a settlement agreement entered into in June 2010 (the "Challenged Agreement" or the "Endo-Impax Settlement"), Impax, a generic drug manufacturer, agreed to abandon its legal challenge to patents held by Endo for a branded drug manufactured by Endo (Opana ER) and to forego launching its generic version of Opana ER until January 2013, in exchange for a large, unjustified "reverse payment" from Endo. Complaint ¶¶1, 3. According to the Complaint, the purpose and effect of the Endo-Impax Settlement was to ensure that Endo would not face generic competition for Opana ER until January 2013. Complaint ¶4. Respondent filed its Answer and Defenses ("Answer") to the Complaint on February 7, 2017. Respondent denied most material allegations in the Complaint and further asserted ten affirmative defenses, including its Eighth Defense, which averred that the challenged conduct had substantial procompetitive justifications, benefited consumers, and avoided infringement of valid patents, and that these procompetitive justifications have outweighed any alleged anticompetitive effects. Answer at 21.

B. Procedural History

Although the Complaint challenges an agreement between Impax and Endo, Endo is not a party to this enforcement action. As a result of a federal court action against Endo and others arising from a patent settlement in connection with Lidoderm, another product manufactured by Endo, Endo settled with the FTC and agreed to a stipulated order and permanent injunction that apparently resolved any FTC concerns regarding the conduct of Endo in this case. *See Federal*

Trade Commission v. Endo Pharms, No. 17-cv-00312 (N.D. Cal. Feb. 2, 2017). Accordingly, this litigation proceeded only against Impax.

On August 10, 2017, Complaint Counsel filed a motion for partial summary decision with the Commission, requesting that the Commission declare that certain procompetitive justifications are not legally cognizable defenses to the conduct challenged in the Complaint, pursuant to the Supreme Court's decision in *FTC v. Actavis,* 133 S. Ct. 2223 (2013). *In re Impax Labs, Inc.*, 2017 FTC LEXIS 130, at *11. Specifically, Complaint Counsel sought to preclude three arguments as to procompetitive benefits: (1) that the Endo-Impax Settlement enabled Impax to enter prior to expiration of various existing and future Endo patents; (2) that the Endo- Impax Settlement provided Impax with certainty that it could launch its generic products free from the risk of infringing Endo's existing and future patents; and (3) that the Endo-Impax Settlement enabled Impax to continue selling its generic product, while other potential generic sellers of Opana ER were enjoined due to a court ruling that two Endo patents obtained after the Endo-Impax Settlement were valid and infringed by such sellers. *Id.* at *15 (Oct. 27, 2017). Complaint Counsel sought an order foreclosing Impax from making arguments to justify or otherwise defend the Endo-Impax Settlement on those bases. *Id.*

Under the Commission's Rules of Practice, the motion was not decided by the Administrative Law Judge ("ALJ"), but by the Commission.[1] By Order

[1] The Commission amended Rule 3.22 of its Rules of Practice in 2009 to allow "the Commission to decide legal questions and

issued October 27, 2017, the Commission denied Complaint Counsel's motion. *Id.* at *33. The Commission reasoned that the motion was premature because: (1) Respondent had not yet fully articulated the bases for its assertion of procompetitive justifications, *Id.* at *15-18; and (2) the structure of the rule of reason for a reverse-payment settlement should be determined based on briefing and a factual record at trial. *Id.* at *18, *26-27. The Commission stated: "Without the facts before us, and an understanding of how the parties intend to marshal

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articulate applicable law when the parties raise purely legal issues." Proposed rule amendments; request for public comment, 73 Fed. Reg. 58,832, 58,836 (Oct. 7, 2008). "[C]ommenters (including the [Section of Antitrust Law of the American Bar Association ('Section')], criticized the [Commission's] proposed Rule change as unfairly invading the province of the independent ALJ and compromising the Commission's dual roles as prosecutor and adjudicator." Interim final rules with request for comment, 74 Fed. Reg. 1804, 1809 (Jan. 13, 2009). "For example, the Section argued that the proposed changes ... could raise concerns about the impartiality and fairness of the Part 3 proceeding by permitting the Commission to adjudicate dispositive issues, including motions to dismiss challenging the facial sufficiency of a complaint, shortly after the Commission has voted out the complaint finding that it has 'reason to believe' there was a law violation, without the benefit of an opinion by an independent ALJ." *Id.* A joint comment from former FTC Chairman Robert Pitofsky and Michael N. Sohn "similarly argued that the proposed rules, including Rule 3.22, would arguably infringe on the fairness of the Part 3 proceeding if the Commission more frequently 'invades what has heretofore been the province of an independent ALJ.'" *Id.* Dismissing these objections, the Commission amended its Rules of Practice to give to itself the authority to decide "[m]otions to dismiss filed before the evidentiary hearing, motions to strike, and motions for summary decision[.]" 16 C.F.R. §3.22(a).

those facts, a formulation that unnecessarily establishes the law of the case risks straight-jacketing the proceeding in ways that impede effective inquiry and appropriate resolution." *Id.* at *26-27. The Commission concluded: "What is needed at this time is development of a record, ordering of that record under a proposed rule-of-reason framework, and, ultimately, briefing of disputed issues concerning the appropriateness of that framework and of its application to the facts presented." *Id.* at *32-33.

The evidentiary hearing began on October 24, 2017 and was completed on November 14, 2017. The hearing record was closed by Order dated November 17, 2017.[2] Complaint Counsel and Respondent ("the parties") filed concurrent post-trial briefs and proposed findings of fact on December 20, 2017.

By Order issued January 5, 2018, Endo was permitted to intervene in this action for the limited purpose of responding to Complaint Counsel's Post-Trial Brief and Proposed Order and opposing (1) any findings related to the alleged competitive effects of a 2017 settlement agreement between Endo and Impax and (2) any remedy that would order the nullification of that 2017 settlement, or otherwise affect Endo's rights under that agreement. Endo's brief on these issues, filed on January 16, 2018, has been considered.

Rule 3.51(a) of the Commission's Rules of Practice states that "[t]he Administrative Law Judge shall file

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[2] Over 1,250 exhibits were admitted into evidence, 37 witnesses testified, either live or by deposition, and there are 3,066 pages of trial transcript. The parties' post-trial briefs, proposed findings of fact and conclusions of law, reply briefs and replies to proposed findings of fact and conclusions of law total 2,869 pages.

an initial decision within 70 days after the filing of the last filed initial or reply proposed findings of fact, conclusions of law and order ... ." 16 C.F.R. §3.51(a). The parties filed replies to each other's proposed findings of fact, conclusions of law, and post-trial briefs and to Endo's January 16, 2018 brief on February 7, 2018.[3] Closing arguments were held on February 15, 2018.

Seventy days from the last filed reply proposed findings and conclusions and briefs was April 18, 2018, and, absent an order pursuant to Rule 3.51, the Initial Decision was to be filed on or before April 18, 2018. Based on the voluminous and complex record in this matter, an Order was issued on April 6, 2018, finding good cause for extending the time period for filing the Initial Decision by 30 days. Accordingly, issuance of this Initial Decision by May 18, 2018 is in compliance with Commission Rule 3.51(a).

C. Evidence

This Initial Decision is based on a consideration of the whole record relevant to the issues, including the exhibits properly admitted into evidence, deposition transcripts, and the transcripts of testimony at trial, and addresses the material issues of fact and law. The briefs and proposed findings of fact and conclusions of law, and the replies thereto, submitted by the parties, and all contentions and arguments therein were thoroughly reviewed and considered.

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[3] The Commission's January 19, 2018 order extended the deadline for the parties to file their concurrent reply briefs and replies to proposed findings to February 7, 2018.

Proposed findings of fact submitted by the parties but not accepted in this Initial Decision were rejected, either because they were not supported by the evidence or because they were not dispositive or material to the determination of the merits of the case. Similarly, legal contentions and arguments of the parties that are not addressed in this Initial Decision were rejected, because they lacked support in fact or law, were not material, or were otherwise lacking in merit.[4] In addition, all expert opinion evidence submitted in this case has been fully reviewed and considered. Except as expressly relied on or adopted in this Initial Decision, such opinions have been rejected, as either unreliable, unsupported by the facts, or unnecessary to the findings and conclusions herein.

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[4] Ruling upon a decision of the Interstate Commerce Commission, and interpreting language in the Administrative Procedure Act that is almost identical to language in Commission Rule 3.51(c)(1), the United States Supreme Court held that "[b]y the express terms of [that Act], the Commission is not required to make subordinate findings on every collateral contention advanced, but only upon those issues of fact, law, or discretion which are 'material.'" *Minneapolis & St. Louis Ry. Co. v. United States*, 361 U.S. 173, 193-94 (1959). *Accord Stauffer Labs., Inc. v. FTC*, 343 F.2d 75, 82 (9th Cir. 1965). *See also Borek Motor Sales, Inc. v. NLRB*, 425 F.2d 677, 681 (7th Cir. 1970) (holding that it is adequate for the Board to indicate that it had considered each of the company's exceptions, even if only some of the exceptions were discussed, and stating that "[m]ore than that is not demanded by the [APA] and would place a severe burden upon the agency"). Furthermore, the Commission has held that ALJs are not required to discuss the testimony of each witness or all exhibits that are presented during the administrative adjudication. *In re Amrep Corp.*, 102 F.T.C. 1362, 1670, 1983 FTC LEXIS 17, at *566-67 (Nov. 2, 1983).

Under Commission Rule 3.51(c)(1), "[a]n initial decision shall be based on a consideration of the whole record relevant to the issues decided, and shall be supported by reliable and probative evidence." 16 C.F.R. §3.51(c)(1); *see In re Chicago Bridge & Iron Co.*, 138 F.T.C. 1024, 1027 n.4, 2005 FTC LEXIS 215, at *3 n.4 (Jan. 6, 2005). Under the Administrative Procedure Act ("APA"), an ALJ may not issue an order "except on consideration of the whole record or those parts thereof cited by a Party and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. §556(d). All findings of fact in this Initial Decision are supported by reliable, probative, and substantial evidence. Citations to specific numbered findings of fact in this Initial Decision are designated by "F."[5]

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[5] References to the record are abbreviated as follows:

CX - Complaint Counsel's Exhibit

RX - Respondent's Exhibit

JX - Joint Exhibit

Tr. - Transcript of testimony before the Administrative Law Judge

Dep. - Transcript of Deposition

IHT - Transcript of Investigational Hearing

CCB - Complaint Counsel's Post-Trial Brief

CCRB - Complaint Counsel's Post-Trial Reply Brief

CCFF - Complaint Counsel's Proposed Findings of Fact

CCRRFF - Complaint Counsel's Reply to Respondent's Proposed Findings of Fact

RB - Respondent's Post-Trial Brief

RFF - Respondent's Proposed Findings of Fact

The parties' burdens of proof are governed by Commission Rule 3.43(a), Section 556(d) of the APA and case law. Pursuant to Commission Rule 3.43(a), "[c]ounsel representing the Commission ... shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." 16 C.F.R. §3.43(a). Under the APA, "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. §556(d). The APA, "which is applicable to administrative adjudicatory proceedings unless otherwise provided by statute, establishes '... the traditional preponderance-of-the evidence standard.'" *In re Rambus, Inc.*, 2006 FTC LEXIS 101, at *45 (Aug. 20, 2006) (quoting *Steadman v. SEC*, 450 U.S. 91, 95-102 (1981)), *rev'd on other grounds*, 522 F.3d 456 (D.C. Cir. 2008)).

Pursuant to Commission Rule 3.45(b), several orders were issued in this case granting *in camera* treatment to material, after finding, in accordance with the Rule, that its public disclosure would likely result in a clearly defined, serious injury to the entity requesting *in camera* treatment or that the material constituted "sensitive personal information," as that term is defined in Commission Rule 3.45(b). In addition, when the parties sought to elicit testimony at trial that revealed information that had been granted *in camera* treatment, the hearing went into an *in camera* session.

Commission Rule 3.45(a) allows the ALJ "to grant *in camera* treatment for information at the time it is offered into evidence subject to a later determination by the [administrative] law judge or the Commission

that public disclosure is required in the interests of facilitating public understanding of their subsequent decisions." *In re Bristol-Myers Co.*, Nos. 8917-19, 90 F.T.C. 455, 457, 1977 FTC LEXIS 25, at *6 (Nov. 11, 1977). As the Commission later reaffirmed in another leading case on *in camera* treatment, since "in some instances the ALJ or Commission cannot know that a certain piece of information may be critical to the public understanding of agency action until the Initial Decision or the Opinion of the Commission is issued, the Commission and the ALJs retain the power to reassess prior *in camera* rulings at the time of publication of decisions." *In re General Foods Corp.*, No. 9085, 95 F.T.C. 352, 356 n.7; 1980 FTC LEXIS 99, at *12 n.7 (March 10, 1980). Thus, in instances where a document or trial testimony had been given *in camera* treatment, but the portion of the material cited to in this Initial Decision does not in fact require *in camera* treatment, such material is disclosed in the public version of this Initial Decision, pursuant to Commission Rule 3.45(a) (the ALJ "may disclose such *in camera* material to the extent necessary for the proper disposition of the proceeding"). Where *in camera* information is used in this Initial Decision, it is indicated in bold font and braces ("**{ }**") in the *in camera* version and is redacted from the public version of the Initial Decision, in accordance with Commission Rule 3.45(e).

D. Summary of Initial Decision

This decision arises from the first Part III administrative trial involving a reverse payment patent settlement agreement since the Supreme Court's decision in *FTC v. Actavis*, 133 S. Ct. 2223

(2013). The evidence shows that, under the Challenged Agreement, Endo provided Impax with a reverse payment, the purpose and effect of which was to induce Impax to give up its patent challenge and agree not to launch a generic Opana ER until January 2013. Payment by a patent holder to a generic challenger to induce the generic challenger to drop its challenge and agree to stay out of the market, rather than face the risk of patent invalidation and resulting generic competition, is an anticompetitive harm under *Actavis*.

Under the facts of this case, however, the magnitude and extent of any anticompetitive harm is largely theoretical, based on an inference that, absent the Challenged Agreement, Impax's entry date, and therefore generic competition, would have been earlier than January 2013. The evidence shows that such earlier entry was unlikely. Moreover, even if, absent the Challenged Agreement, Impax would have entered the market substantially earlier than January 2013, the evidence demonstrates that the Challenged Agreement provided real and substantial procompetitive benefits to consumers that outweigh any anticompetitive effect. Among other things, the Challenged Agreement granted Impax a broad patent license covering Endo's existing and subsequently-acquired Opana ER-related patents, which has enabled Impax to sell generic Opana ER without interruption since launching its product in January 2013, while all other potential generic drug manufacturers have been enjoined by patent litigation. Indeed, Impax's product is not only the sole generic oxymorphone ER product available to

consumers, but the only available oxymorphone ER product.

Weighing the anticompetitive harm and the procompetitive benefits, the evidence fails to prove that the Challenged Agreement was anticompetitive on balance. Rather, the evidence proves that the procompetitive benefits of the Challenged Agreement outweigh the anticompetitive harm. Thus, the evidence fails to demonstrate that the Challenged Agreement constituted an unreasonable restraint of trade. Accordingly, the evidence fails to prove a

II. FINDINGS OF FACT

A. Background

1. Jurisdiction

1. Impax Laboratories, Inc. ("Impax") is a for-profit corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-001 ¶1).

2. In addition to its Hayward, California headquarters, Impax operates out of its facilities in Middlesex, New Jersey, among other locations. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-001 ¶2).

3. Impax engages in the business of, among other things, developing, manufacturing, and marketing generic pharmaceutical drugs ("generics" or "generic drugs"). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-001 ¶3).

4. Impax is a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission

Act, 15 U.S.C. §44. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-001 ¶4).

5. Impax has engaged in, and continues to engage in, commerce and activities affecting commerce in each of the fifty states in the United States and the District of Columbia, as the term "commerce" is defined by Section 1 of the Federal Trade Commission Act, 15 U.S.C. §44. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-001- 02 ¶5).

2. Hatch-Waxman framework

6. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§355(b)(2) and 355(j) and 35 U.S.C. §271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-002-03 ¶12).

7. A company seeking to market a new pharmaceutical product must file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") demonstrating the safety and efficacy of the new product. 21 U.S.C. §355. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003 ¶13).

8. NDA-based products generally are referred to as "brand-name drugs," "branded drugs," or "brand drugs." (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001- 003 ¶14).

9. The FDA requires NDA holders to identify patents that the NDA holder believes could reasonably be asserted against a generic company that makes, uses, or sells a generic version of the branded drug. 21 C.F.R. §314.53. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003 ¶15).

10. The NDA holder must submit these patents for listing in an FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) within 30 days of issuance of the patent or within 30 days after approval of the NDA. 21 C.F.R. §314.53. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003 ¶16).

11. A company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application ("ANDA") with the FDA. 21 U.S.C. §355(j). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003 ¶17).

12. The generic applicant must demonstrate that its generic drug is therapeutically equivalent to the brand-name drug that it references and for which it seeks to be a generic substitute. 21 U.S.C. §355(j)(2)(A)(iv). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003 ¶18).

13. Upon showing that the generic drug is therapeutically equivalent to the approved branded drug, the generic company may rely on the studies submitted in connection with the approved branded drug's NDA to establish that the generic drug is safe and effective. 21 U.S.C. §355(j)(2)(A). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003-04 ¶19).

14. The FDA assigns a generic drug an "AB" rating if it is therapeutically equivalent to a brand-name drug. An AB-rated generic drug is the same as a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. A generic drug must also contain identical amounts of the same active ingredient(s) as the brand-name drug, although its inactive ingredients may vary. FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations*, Preface §1.7. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-004 ¶20).

15. When a brand-name drug is covered by one or more patents listed in the Orange Book, a company seeking to market a generic version of that drug before the patents expire must make a "Paragraph IV certification" in its ANDA certifying that the patents are invalid, unenforceable, and/or will not be infringed by the generic drug. 21 U.S.C. §355(j)(2)(A)(vii)(IV). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-004 ¶21).

16. If an ANDA filer makes a Paragraph IV certification, it must notify the patent holder of its certification and the factual and legal bases for its assertion(s) that the relevant patent is invalid, unenforceable, and/or not infringed. 21 U.S.C. §355(j)(2)(B). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-004 ¶22).

17. If the patent holder initiates a patent infringement suit against an ANDA filer within 45 days of receiving such notice (F. 16), the FDA may not grant final approval of the ANDA until the earliest of: (1) patent expiration date; (2) district court resolution

of the patent litigation in favor of the generic company; or (3) the expiration of an automatic 30-month stay. 21 U.S.C. §355(j)(5)(B)(iii). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-004 ¶23).

18. When a generic drug otherwise meets the FDA's criteria for approval but final approval is blocked by statute or regulation, such as the Hatch-Waxman 30-month stay, the FDA may tentatively approve the relevant ANDA. 21 U.S.C. §355(j)(5)(B)(iv). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶24).

19. Tentative approval of an ANDA by the FDA does not permit an ANDA filer to market its generic version of the drug. 21 U.S.C. §355(j)(5)(B)(iv)(II)(dd)(BB). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶25).

20. The FDA can issue final approval of a tentatively-approved drug once the 30-month stay expires. 21 U.S.C. §355(j)(5)(B)(iii). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶26).

21. The Hatch-Waxman Act provides the first generic company or companies filing an ANDA containing a Paragraph IV certification ("first filer") to a particular branded drug with a period referred to as the "180-day exclusivity" or "first-filer exclusivity" period. During this 180-day exclusivity period, no other generic manufacturer can sell its version of that particular branded drug. 21 U.S.C. §355(j)(5)(B)(iv). (Joint Stipulations of Jurisdiction, Law, Fact, and

Authenticity, JX001-005 ¶27; Second Set of Joint Stipulations, JX003 ¶7).

22. A brand drug company can market a generic version of its own brand product at any time, including during the first filer's exclusivity period. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶28).

23. For a brand drug company to market a generic version of its own brand product, no ANDA is necessary because the brand company already has approval to sell the drug under its NDA. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001- 005 ¶29).

24. Brand drug companies' generic versions of their own brand products commonly are known as "authorized generics" ("AGs"). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶30).

25. An authorized generic is chemically identical to the brand drug, but is sold as a generic product, typically through either the brand company's subsidiary or through a third party. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶31).

3. Competition between brand and generic manufacturers

26. A patient can obtain a prescription drug only if a doctor (or someone who is authorized to write prescriptions) writes a prescription for that drug. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶11).

27. Doctors who select the medications they prescribe for their patients do not pay for the medications. Generally, when selecting appropriate medications for patients, doctors' primary concerns are efficacy and safety, rather than the cost of medications. (CX5002 (Savage Expert Report at 063-64 ¶177, 180); Savage, Tr. 770-71; Michna, Tr. 2187-88; CX4046 (Michna, Dep. at 148-49)).

28. The patient, or in most cases a third-party payor such as a public or private health insurer, pays for the drug. These purchasers often have little input over what drug is actually prescribed, because physicians ultimately select and prescribe appropriate drug therapies. (CX5000 (Noll Expert Report at 031 ¶67); CX5002 (Savage Expert Report at 063 ¶177)).

29. All 50 states and the District of Columbia have drug substitution laws that encourage and facilitate substitution of lower-cost AB-rated generic drugs for branded drugs. When a pharmacist fills a prescription written for a branded drug, these laws allow or require the pharmacist to dispense an AB-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise. Conversely, these laws generally do not permit a pharmacist to substitute a non-AB-rated generic for a branded drug unless the physician specifically prescribes it by writing the chemical name of the drug, rather than the brand name, on the prescription. (Second Set of Joint Stipulations, JX003 ¶72).

30. Because of the price advantages of generic drugs over branded drugs, many third-party payors of prescription drugs (e.g., health insurance plans and

Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. (CX5000 (Noll Expert Report at 030-32 ¶¶65, 67-69); CX6052 at 084-85).

31. Generic manufacturers typically charge lower prices than branded drug sellers. The first one or two generic products are typically offered at a 10% to 25% discount off the price of the branded product. Subsequent generic entry creates greater price competition which typically leads to discounts between 50% to 80% off the brand price. (CX5000 (Noll Expert Report at 048 ¶104); CX2607 (Lortie Decl. at 012 ¶29); CX6055 at 010).

32. Automatic substitution of the generic drug for the branded drug is the primary way that generic companies make their sales. (Mengler, Tr. 522; Engle, Tr. 1703).

4. Opiods

33. Opioid medications ("opioids") are prescription drugs indicated for the treatment of moderate to severe pain. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶2; Savage, Tr. 700-01).

34. Opioids are derived from opium. (Michna, Tr. 2104).

35. There are three types of opioids: ultra-fast-acting, immediate-release, and extendedrelease. (Michna, Tr. 2105; *see* Savage, Tr. 693).

36. Ultra-fast-acting opioids are medications that are absorbed through the mouth and have an initial onset of pain relief in about fifteen minutes. They are

used to treat pain that comes on very suddenly and that may dissipate within an hour. (Michna, Tr. 2105).

37. Immediate-release ("IR") opioids are short-acting pain medications that take effect within 30 to 45 minutes of ingestion and tend to last 3 to 6 hours. They are used to treat acute, short-lived pain as well as chronic pain. (Michna, Tr. 2106, 2118; Savage, Tr. 693, 702, 705).

38. Extended-release ("ER") opioids provide continuous levels of medication in a patient's blood over several hours, with effects lasting from 8 to 24 hours, and in the case of transdermal applications - patches that deliver medication through the skin - up to 7 days. (Michna, Tr. 2106; *see* Savage, Tr. 702).

39. Extended-release opioids have been pharmacologically formulated to provide gradual release of the opioid medication. In particular, the physical chemical structure of the tablet, capsule, or bead provides for slower release of the medication and, in turn, more gradual absorption by the body. (Savage, Tr. 693, 704-05).

40. Extended-release opioids generally are used for patients with sustained pain lasting longer than 12 to 24 hours, as well as chronic pain that requires relief 24 hours a day. (Savage, Tr. 705).

B. Context for the Endo-Impax Litigation and Settlement

1. Opana ER

41. Oxymorphone belongs to the class of drugs known as opioids. It is a semi-synthetic opioid used to relieve pain. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶¶1-2).

42. The FDA first approved oxymorphone to relieve pain in 1960. (Second Set of Joint Stipulations, JX003 ¶1).

43. Opana ER is an extended-release formulation of oxymorphone. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶3).

44. Opana ER is used to treat pain for a wide variety of conditions, ranging from chronic back problems to pain caused by cancer. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶5).

45. Endo Pharmaceuticals Inc. ("Endo") and Penwest Pharmaceuticals ("Penwest") collaborated on the development and commercialization of Opana ER. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶47).

46. The FDA approved Endo's NDA for Opana ER (NDA No. 021610) in June 2006 "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶4).

47. In July 2006, Endo announced the commercial availability of Opana ER. At the time of launch in 2006, Opana ER was the only extended-release version of oxymorphone on the market.[6] (Second Set of Joint Stipulations, JX003 ¶3).

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[6] As set forth in F. 110, Endo introduced a reformulated version of Opana ER in 2012. Unless otherwise specified, the term "Opana ER" as used herein refers to original Opana ER.

48. Endo ultimately offered Opana ER in seven dosage strengths (5, 7.5, 10, 15, 20, 30 and 40 milligram ("mg")). (Second Set of Joint Stipulations, JX003 ¶3).

2. Endo's initial patents for Opana ER

49. When Endo launched Opana ER in 2006, it listed a single patent in the Orange Book as covering Opana ER: U.S. Patent No. 5,128,143 ("the '143 patent"). (CX3242 at 003).

50. The '143 patent was set to expire in September 2008. (Second Set of Joint Stipulations, JX003 ¶4; CX3242 at 003).

51. In October 2007, Endo listed three additional patents in the Orange Book as covering Opana ER: U.S. Patent Nos. 7,276,250 ("the '250 patent"), 5,662,933 ("the '933 patent"), and 5,958,456 ("the '456 patent") ("the initial patents"). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶9).

52. Endo listed the '250 patent in the Orange Book on October 2, 2007. The '250 patent will expire in February 2023. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶¶9-10; Snowden, Tr. 351).

53. Endo listed the '933 and '456 patents on October 19, 2007. The '933 and '456 patents expired in September 2013. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶¶9-10; Snowden, Tr. 351).

54. The '250, '933, and '456 patents all pertain to the controlled-release mechanism of the oxymorphone

formulation. (Second Set of Joint Stipulations, JX003 ¶6).

3. Overview of Endo-Impax litigation and settlement

a. Impax's Abbreviated New Drug Applications

55. In June 2007, Impax filed an Abbreviated New Drug Application (No. 79-087) for a generic version of Opana ER, also referred to as generic oxymorphone ER.[7] (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶11; Second Set of Joint Stipulations, JX003 ¶4).

56. As of June 2007, the '143 patent was the only patent listed in the Orange Book as covering Opana ER. (Second Set of Joint Stipulations, JX003 ¶4; CX2967 at 014, 017).

57. Impax's June 2007 ANDA utilized a Paragraph III certification for the '143 patent. A Paragraph III certification meant that Impax's ANDA would be eligible for FDA approval upon the '143 patent's expiration in September 2008. (Second Set of Joint Stipulations, JX003 ¶4; CX2967 at 017).

58. Following Endo's listing of additional patents in the Orange Book in October 2007 (F. 51-53), Impax amended its ANDA to include Paragraph IV certifications for the '250,'933, and '456 patents. With respect to the '250, '933 and '456 patents, Impax certified that, "in its opinion and to the best of its

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[7] Endo and Impax both refer to a generic version of Endo's Opana ER as either "generic Opana ER" or "generic oxymorphone ER" interchangeably.

knowledge," those patents were "invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the oxymorphone hydrochloride extended-release tablets for which" Impax's ANDA had been submitted. Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30, and 40 mg dosages strengths of Opana ER. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶¶12, 13; Second Set of Joint Stipulations, JX003 ¶7; Snowden, Tr. 355).

59. On November 23, 2007, the FDA accepted Impax's ANDA with an amendment to include Paragraph IV certifications for the '250, '933, and '456 patents. (Second Set of Joint Stipulations, JX003 ¶7).

60. On December 13, 2007, Impax sent Endo notice of its Paragraph IV certifications for the'250, '933, and '456 patents. In its notice, Impax asserted that its product did not infringe these patents. (Second Set of Joint Stipulations, JX003 ¶8; Snowden, Tr. 355, 413; CX2714).

b. The filing of the Endo-Impax patent litigation and FDA approval of Impax's ANDA

61. On January 25, 2008, Endo and Penwest filed a patent infringement lawsuit against Impax in the federal district court in Delaware, alleging that Impax's ANDA for generic oxymorphone ER infringed Endo's '456 and '933 patents ("Endo-Impax patent litigation"). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶15; Snowden, Tr. 413-14).

62. The filing of the Endo-Impax patent litigation triggered a statutory 30-month stay, meaning that the FDA could not approve Impax's ANDA until the earlier of the expiration of 30 months or resolution of the patent dispute in Impax's favor. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶15).

63. The 30-month stay was set to expire on June 14, 2010. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶16).

64. The FDA granted tentative approval to Impax's ANDA on May 13, 2010. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶17).

65. Tentative FDA approval is effectively the last step in an ANDA filer's approval efforts. (Koch, Tr. 340-41; *see* Snowden, Tr. 417-18 (tentative approval from FDA "suggest[s] that Impax was almost certain to get final approval at the conclusion of the 30-month stay")).

66. Impax received final approval for Impax's generic oxymorphone ER product on the 5, 10, 20, and 40 mg dosage strengths on June 14, 2010, upon expiration of the statutory 30- month stay. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-008 ¶21).

67. The FDA granted final approval to Impax's ANDA for the 30 mg dosage strength of generic oxymorphone ER on July 22, 2010. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-008 ¶22).

c. Summary of proceedings

68. In the Endo-Impax patent litigation, Endo alleged that Impax's generic oxymorphone ER infringed Endo's '456 and '933 patents. Endo did not allege that Impax's generic oxymorphone ER infringed Endo's '250 patent. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶15; Snowden, Tr. 415-16; CX0304 at 002 ¶5).

69. Impax sought to transfer the Endo-Impax patent litigation from the federal district court in Delaware to the federal district court in New Jersey because the Delaware court was overloaded and Impax hoped the case would move faster in New Jersey. The court granted Impax's request and transferred the case to the federal district court in New Jersey. (Snowden, Tr. 357-58).

70. The district court presiding over the Endo-Impax patent litigation held claim construction hearings on December 21, 2009 and March 19, 2010. (Second Set of Joint Stipulations, JX003 ¶18).

71. On April 5, 2010, the court in the Endo-Impax patent litigation issued an amended order on claim construction. The court adopted the constructions for "hydrophobic material" and "sustained release" proposed by Endo, and the parties stipulated to the construction of "homopolysaccharide." (Second Set of Joint Stipulations, JX003 ¶19).

72. On May 19, 2010, the court scheduled the Endo-Impax patent infringement trial to begin on June 3, 2010 and continue through June 17, 2010. (Second Set of Joint Stipulations, JX003 ¶22).

73. The trial in the Endo-Impax patent litigation began on June 3, 2010. (Second Set of Joint Stipulations, JX003 ¶24; Figg, Tr. 1906; Hoxie, Tr. 2767).

74. On June 8, 2010, the Endo-Impax patent litigation was settled and the parties entered into the Settlement and License Agreement ("SLA") and the Development and Co-Promotion Agreement ("DCA"). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007-08 ¶¶18-19; Second Set of Joint Stipulations, JX003 ¶26).

75. The SLA incorporates the DCA. (Second Set of Joint Stipulations, JX003 ¶69). The SLA and the DCA are referred to collectively in this Initial Decision as the "Challenged Agreement" or the "Endo-Impax Settlement."

76. At the time that Endo and Impax settled their patent litigation, the outcome of Endo's patent infringement suit was uncertain. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-008 ¶20; Second Set of Joint Stipulations, JX003 ¶26).

4. Costs of litigation

77. Although litigation costs vary substantially among cases, a survey by the American Intellectual Property Lawyers Association estimated that the median litigation cost for all patent cases with more than $25 million at stake averages about $5.5 million for each party. When such a case is handled by firms with more than 76 attorneys, the median litigation cost averages approximately $7 million for each party. (CX5000 (Noll Expert Report at 108 ¶247 & n.278)).

78. At the time of the Endo-Impax Settlement, which occurred during trial, Endo had spent between $6 and $7 million and Impax had spent about $4.7 million on litigation in the infringement case. (CX2696 at 013-14; CX3212 at 009-10; CX5000 (Noll Expert Report at 108 ¶247)).

79. The top end of the range that Impax uses in its budgeting process to estimate costs for a generic patent litigation is about $3 to $4 million per litigation. This $3 to $4 million estimate represents total expenses from the start of litigation to completion and is based primarily on expenses for outside counsel, such as hourly attorneys' fees. Impax might also allocate some expenses for its internal legal department's work on patent litigation, but those are minor amounts. (Reasons, Tr. 1221-22).

80. During a public earnings conference call in November 2011, Impax's then-chief financial officer ("CFO") stated that Impax had "lowered [its] patent litigation expense guidance for the full year for 2011 from $13 million to $10 million primarily due to recent settlements" and that Impax was going to save $3 million in litigation expenses because of settlements, including the Endo settlement. (Koch, Tr. 262-63; CX2703 at 004).

81. A reasonable estimate of the combined saved litigation costs for both Endo and Impax for settling the patent litigation in June 2010 is approximately $5 million. (F. 77-80; Noll, Tr. 1463).

5. Other Endo litigation on initial Opana ER patents

82. Eight companies submitted ANDAs seeking approval to market a generic version of Opana ER.

Each company included a Paragraph IV certification asserting that its proposed generic product did not infringe Endo's patents and/or that Endo's patents were invalid or unenforceable. (Second Set of Joint Stipulations, JX003 ¶5; CX2607 at 008- 09 (Lortie Decl. ¶24)).

83. In addition to suing Impax (F. 61), Endo sued all other Opana ER ANDA filers, alleging infringement of one or more of Endo's initial patents. Those suits settled, with the generic companies receiving patent licenses covering only the patents-in-suit. (Snowden, Tr. 440; RX441; RX442; RX443; CX3192).

84. Actavis South Atlantic LLC ("Actavis") filed its ANDA on February 14, 2008 covering all dosage strengths of Opana ER. Actavis was the first to file an ANDA for the 7.5 and 15 mg dosages of Opana ER. (Second Set of Joint Stipulations, JX003 ¶12; Snowden, Tr. 370; CX6039 at 003).

85. In March 2008, Endo sued Actavis, alleging that Actavis' ANDA covering the 5, 10, 20, and 40 mg dosages of generic oxymorphone ER infringed the '456 and '933 patents. (Second Set of Joint Stipulations, JX003 ¶13).

86. In July 2008, after Actavis amended its ANDA to include the 7.5, 15, and 30 mg dosages of generic oxymorphone ER, Endo filed a second suit against Actavis, alleging that Actavis' ANDA for those dosages infringed the '456 and '933 patents. (Second Set of Joint Stipulations, JX003 ¶14).

87. Effective February 20, 2009, Actavis settled the patent litigation with Endo relating to generic Opana ER and received a license to the litigated

patents starting no later than July 15, 2011. (Second Set of Joint Stipulations, JX003 ¶15; CX3383 (Actavis settlement); Snowden, Tr. 370-71).

88. Actavis launched its 7.5 and 15 mg generic Opana ER products, for which it possessed first-filer exclusivity, in July 2011. (CX4034 (Rogerson, Dep. at 13)).

89. Actavis launched its 5, 10, 20, 30, and 40 mg generic Opana ER products on September 17, 2013, several months after the expiration of Impax's first-filer exclusivity. (CX2973; *see* CX4034 (Rogerson, Dep. at 13)).

6. Endo's market power

90. At the time Endo entered into the Endo-Impax Settlement in June 2010, Endo had 100% of the market share for oxymorphone ER. (CX5000 (Noll Expert Report at 083 ¶189)).

91. In the pharmaceutical industry, brand-name drug patent holders have the ability to exclude firms from the market in the sense that they are entitled by law to delay competitive entry by generic manufacturers. (CX5000 (Noll Expert Report at 086 ¶199)).

92. Barriers to entry in the pharmaceutical industry include intellectual property rights, such as patents, and regulatory impediments, such as provisions of the Hatch-Waxman Act (F. 93). (Noll, Tr. 1408; CX5000 (Noll Expert Report at 084-85 ¶194)).

93. The regulatory procedures imposed by the Hatch-Waxman Act allow a brand-name drug to be protected against entry in two ways. First, if a branded drug company files a patent infringement

suit against a Paragraph IV ANDA filer, the Hatch-Waxman Act provides a 30-month stay before the FDA can approve the ANDA. Second, non-first-filer Paragraph IV ANDA applicants have to wait at least 180 days after the first filer has entered before they can enter a market. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-004 ¶23; CX5000 (Noll Expert Report at 084-85 ¶194)).

94. The 30-month stay imposed by the Hatch-Waxman Act (F. 93) benefited Endo in the form of a regulatory entry barrier to the market for oxymorphone ER. (CX5000 (Noll Expert Report at 086-87 ¶194)).

95. Because the Paragraph IV procedures of Hatch-Waxman prevent entry by the first-filer generic for up to 30 months after a generic firm files an ANDA and by other generics for another 180 days, the patents at issue in the Impax infringement case gave Endo the power to exclude competitors even if its patents eventually were found not to be valid or infringed. (CX5000 (Noll Expert Report at 086-87 ¶199)).

7. Endo's plan to reformulate Opana ER

96. Since 2007, Endo had been working on a reformulated "crush-resistant" version of Opana ER ("reformulated Opana ER") to replace the original version. Reformulated Opana ER was also referred to internally by Endo as EN3288 and Revopan. (CX3214 at 015; CX3199 at 046; RX007 at 0001).

97. Introducing a reformulated Opana ER was a potential way for Endo to preserve the value of its Opana ER franchise even after generics became

available for original Opana ER. (CX3205 at 001 ("There is also a life cycle management (LCM) imperative for Endo's Opana ER franchise. ... To ensure we continue to protect the franchise in the face of loss of regulatory exclusivity in June 2009, a TRF [tamper-resistant formulation] of ER will be important to secure. Without this LCM strategy, Opana ER is expected to lose about 70% of its sales within six months if generic entry occurs.")).

98. Reformulating Opana ER would extend the life of the brand through additional patent protection and other possible roadblocks for potential generic competitors. (CX2724 at 005 (forecasting up to four years of "organic exclusivity" and retaining all Opana ER sales if launched with labeling claims and ahead of generics); CX3205 at 001; CX3251).

99. In order to maximize the value of reformulated Opana ER, Endo's goal was to launch the reformulated product before the entry of a generic for original Opana ER, with sufficient time to transition patients from original Opana ER to reformulated Opana ER. Endo forecasted peak-year sales of more than $199 million in 2016 if reformulated Opana ER beat generics and was the first to enter the market. If, however, reformulated Opana ER was launched after generic entry, estimated peak annual sales in 2016 were $10 million. (CX2578 at 008-09 (Dec. 11, 2007 Opana Brand LCM Update, stating that Endo's "Priority #1" was to "Beat Generics by 1 Year")).

100. Endo forecasted that launching reformulated Opana ER ahead of a launch of a generic for original Opana ER would result in an increased demand for the reformulated product because patients will have

been transitioned to the reformulated product. (CX2724 at 006; CX2578 at 008-09; CX4025 (Bingol, Dep. at 95-96)).

101. Endo forecasted significant erosion of its Opana ER franchise if Endo was unable to get reformulated Opana ER approved in a timely manner. If Endo launched reformulated Opana ER at the same time that a generic for original Opana ER came onto the market, reformulated Opana ER would capture at most 30% to 32% of Endo's sales of original Opana ER. (CX1106 at 004; CX2724 at 006 (generic entry would result in steep drop in Opana ER sales unless EN3288 were approved with tamper resistance claims ahead of generic entry); CX1320 at 003 (projecting only $11.9 million in Oxy TRF revenues for 2011); 007 (forecasting rapid generic erosion upon generic entry in July 2011); 024 ("Oxymorphone TRF conversion from OPANA ER base volume: 30% to 32% conversion of base volume; Conversion curve begins at launch (July 2011); Peak conversion (30%) reached in 40 months")).

102. Endo planned to remove original Opana ER from the market after introducing reformulated Opana ER. (CX1108 at 008 (noting that "it is likely that removal of Opana ER will be a condition of Revopan approval by FDA" and assuming launch of Revopan in February 2011 and ending shipment of Opana ER by October 2011)).

103. Launching reformulated Opana ER as far ahead as possible of generic entry on original Opana ER would allow Endo to separate the reformulated brand product from potential generics with a reasonable amount of time to make the conversion and

create the most value. (CX4025 (Bingol, Dep. at 63-64); CX2578 at 009).

104. Endo wanted to introduce reformulated Opana ER as soon as possible. (CX4025 (Bingol, Dep. at 32); Bingol, Tr. 1295 ("the quicker you get to market, the better")).

105. In 2010, Endo forecasted filing its application for approval of reformulated Opana ER with the FDA during the third quarter of 2010 and that the approval process would take between four and ten months. Depending on various assumptions, Endo forecasted launching reformulated Opana ER sometime in 2011. (CX2575 at 004; CX1108 at 008 (assuming launch in February 2011); CX3038 at 001 (projecting range for launch between December 2010 and June 2011); *see also* CX2573 at 004 (projecting May 2011 launch); CX2724 at 005 (projecting range for launch between January and September 2011)).

106. Endo understood that patients cannot be switched immediately from one long-acting opioid to another because physicians are "very careful as they adjust dosages" for patients. Endo sought "an orderly and phased transition from one product to the other so [it] made sure [it wasn't] leaving any current patients in a difficult situation." Such a transition would take about six to nine months. (CX4019 (Lortie, Dep. at 39-42, 156-57); Mengler, Tr. 530-31).

107. Endo's plan to reformulate Opana ER and transition the market to the new product, prior to entry of a generic original Opana ER, would be

adversely affected if Impax launched its generic at risk[8] in June 2010. (CX2724 at 001).

108. If Impax launched a generic Opana ER at risk, Endo planned to launch an authorized generic for original Opana ER. (CX2576 at 003 ("We will launch on word/action of first generic competitor."); CX2581 at 001 ("Endo is prepared to launch an authorized generic if another generic is approved first."); CX2573 at 004 (Endo planned a "[l]aunch of authorized generic" in the event that Impax launched at risk); CX3007 at 003 ("If Impax launches, Endo will launch its authorized generic ...")).

109. Endo did not intend to launch both a reformulated Opana ER and an authorized generic of original Opana ER at the same time. This is because it would have been "very difficult [for Endo] to justify" having a crushable authorized generic on the market at the same time as a crush-proof reformulation. Endo "intended to replace one product with the other, and that would be the only [Opana ER] product that [Endo] had on the market." (CX4019 (Lortie, Dep. at 117-18); Bingol, Tr. 1338-39; *see also* CX1108 at 008 (Endo forecast noting that "it is likely that removal of Opana ER will be a condition of Revopan approval by FDA")).

110. In March 2012, Endo stopped distributing original Opana ER and launched reformulated Opana ER. (Second Set of Joint Stipulations, JX003 ¶33; CX4017 (Levin, Dep. 139)).

111. On June 8, 2017, the FDA publicly requested that Endo voluntarily withdraw its reformulated

[8] An "at-risk launch" is further explained in F. 451-464.

Opana ER product from the marketplace. On September 1, 2017, Endo ceased sales of reformulated Opana ER. (Second Set of Joint Stipulations, JX003 ¶¶55, 57).

C. The Challenged Agreement

1. Preliminary negotiations

112. Impax and Endo first attempted to settle their patent dispute in the fall of 2009, before the claim construction hearing in the Endo-Impax patent litigation. (RX359; RX285; Second Set of Joint Stipulations, JX003 ¶¶16-17).

113. At the time of the settlement negotiations (fall 2009 until settlement on June 8, 2010), Larry Hsu was Impax's chief executive officer ("CEO"), Chris Mengler was president of Impax's generics division, Margaret Snowden was Impax's vice president of intellectual property litigation and licensing, and Arthur Koch was Impax's CFO. Mr. Mengler was Impax's lead settlement negotiator until he was replaced as the lead negotiator by Mr. Koch and Ms. Snowden on June 4, 2010. (Koch, Tr. 217-18, 227-30, 310-11, 322-23; Snowden, Tr. 362).

114. At the time of the settlement negotiations (fall 2009 until settlement on June 8, 2010), Guy Donatiello was Endo's senior vice president of intellectual property and Alan Levin was Endo's CFO. Mr. Donatiello and Mr. Levin were the principal negotiators for Endo. (Snowden, Tr. 362, 373-74).

115. Impax was aware during settlement discussions with Endo in the fall of 2009 that Endo already had agreed to a July 15, 2011 entry date for

Actavis' generic oxymorphone ER dosages. (CX4003 (Snowden, IHT at 56-57); CX0309 at 001-02).

116. Settlement discussions between Endo and Impax in the fall of 2009 included potential generic entry dates. Specifically, Ms. Snowden proposed to Mr. Donatiello that Impax should be able to enter around July 2011 or possibly December 2011 or January 2012, to approximate the midpoint between the expiration of the 30-month stay in June 2010 (F. 63) and the expiration of the asserted patents in September 2013 (F. 53). Mr. Donatiello rejected Ms. Snowden's proposal, arguing that Impax's entry date should be around the midpoint between the conclusion of litigation through appeal and patent expiration. (CX4003 (Snowden, IHT at 56-57); Snowden, Tr. 418-20; Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶10).

117. Settlement discussions between Endo and Impax in the fall of 2009 included discussions of a potential product collaboration. (*See* II.C.3).

118. Settlement discussions between Endo and Impax that had commenced in the fall of 2009 ended after a conference call on December 7, 2009. (CX1301 at 112).

119. Impax and Endo resumed settlement discussions in mid-May 2010, approximately one month before the June 14, 2010 expiration of the 30-month stay of Impax's ANDA imposed by the Hatch-Waxman Act and approximately three weeks before the scheduled June 3, 2010 trial in the Endo-Impax patent litigation. (Snowden, Tr. 418; CX0310 at 004; CX1301 at 112; F. 63, 73).

120. On or about May 14, 2010, Endo became aware that Impax had received tentative FDA approval for generic Opana ER, based on a press release issued by Impax. Endo had a discussion with its outside counsel the same day regarding the status of settlement discussions with Impax. (CX1307 at 001; CX1301 at 112).

121. In an internal Impax email between Dr. Hsu and Mr. Mengler on May 14, 2010, Dr. Hsu hypothesized a settlement with Endo with a January 2011 launch and a no-AG provision,[9] to which Mr. Mengler replied that he would "love" a settlement. (CX0505 at 001).

122. On May 17, 2010, Mr. Donatiello of Endo contacted Ms. Snowden of Impax by voicemail and email to resume settlement discussions. That afternoon, Ms. Snowden and Mr. Donatiello discussed a potential settlement for the first time since December 2009. (CX0310 at 004; RX316 at 0001; CX4003 (Snowden, IHT at 83-84)).

123. The SLA and the DCA were negotiated together, with contract terms for both agreements discussed in the same documents exchanged between Endo and Impax. (Koch, Tr. 244; *see, e.g.*, CX0320; RX565; CX0406 at 001; CX0407 at 001-02; CX3183 at 001).

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[9] A no-AG provision, also referred to as a no-AG agreement, is a provision through which a brand-name drug company agrees not to launch an authorized generic in competition with the generic drug company's product during the 180-day exclusivity period. (Koch, Tr. 235; Snowden, Tr. 392).

2. The Settlement and License Agreement

a. Overview of relevant provisions

124. Under the SLA, Impax agreed not to launch its generic oxymorphone ER product until January 1, 2013. (RX364 at 0001-02, 0009 (executed SLA §§1.1, 4.1(a)) (granting license and defining the "Commencement Date")).

125. Under the SLA, Endo granted Impax a license both to the initial Opana ER patents (defined in the SLA as the '933, '456, and '250 patents and any reissuances thereof), and to "any patents and patent applications owned by Endo or Penwest ... that cover or could potentially cover the manufacture, use, sale, offer for sale, importation, marketing or distribution of products ... that are the subject of the Impax ANDA ... ." (RX364 at 0009 (SLA §4.1(a)); Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-009-10 ¶35).

126. Under the SLA, Endo provided Impax with a "covenant not to sue," which prohibited Endo and its affiliates from suing Impax for patent infringement on any of the patents licensed pursuant to section 4.1(a) (F. 125). (RX364 at 010 (SLA §4.1(b)); *see also* Figg, Tr. 1963-64; Hoxie, Tr. 2885).

127. Under the SLA, the license granted by Endo to Impax to sell generic Opana ER was exclusive during Impax's 180-day first-filer exclusivity period for the five dosage strengths for which Impax had filed an ANDA. This exclusive license grant meant that Endo could not sell an authorized generic product of these five dosages until Impax's 180-day exclusivity

period ended. (RX364 at 0010-11 (SLA §4.1(c)); CX3164 at 009- 10).

128. Under the SLA, Impax would be obligated to pay Endo a 28.5% royalty on Impax's generic Opana ER sales during Impax's 180-day exclusivity period in the event that sales of Opana ER grew by a specific percentage prior to Impax's entry. Specifically, the royalty was owed if Opana ER sales in the quarter before Impax's licensed entry "exceed[ed] $46,973,081 compounded quarterly at an annual rate of ten percent ... ." Otherwise, Impax had no obligation to pay a royalty. (RX364 at 0012 (SLA §4.3)).

129. Under the SLA, pursuant to a provision titled "Endo Credit," Endo would be obligated to make a cash payment to Impax in the event Endo's Opana ER dollar sales (as calculated by units multiplied by the wholesale acquisition cost ("WAC") fell by more than 50% from the "Quarterly Peak" (the highest sales quarter between Q3'2010 and Q3'2012) to the fourth quarter of 2012 (the quarter before Impax would be permitted to launch its generic oxymorphone ER product). (RX364 at 0003-06, 0012 (SLA §§1.1, 4.4, definitions of "Endo Credit," "Market Share Profit Factor," "Market Share Profit Value," "Pre-Impax Amount," "Prescription Sales," "Quarterly Peak," and "Trigger Threshold")).

130. In January 2013, Impax launched generic oxymorphone ER in the 5, 10, 20, 30, and 40 mg dosage strengths per the terms of the SLA. (Second Set of Joint Stipulations, JX003 ¶40).

b. Negotiations of the SLA

i. Initial term sheet

131. On May 26, 2010, Mr. Donatiello of Endo sent to Mr. Mengler and Ms. Snowden of Impax two term sheets.[10] Endo's initial term sheet for the SLA included a proposed license agreement with a no-AG provision. Specifically, the proposed license agreement provided that Impax would have an "Exclusivity Period" of 180 days for each of the dosages for which Impax held first-to-file exclusivity (5, 10, 20, 30, and 40 mg), during which Impax's license "would be exclusive as to all but (i) Opana ER®-branded products that are not sold as generic products and (ii) generic products covered by prior license agreements executed as of the effective date of the License Agreement with Impax." (CX0320 at 009-10).

132. Endo's May 26, 2010 initial term sheet for the SLA included a proposed license agreement that granted Impax a license to sell generic Opana ER with a commencement date of March 10, 2013 and provided that Impax would not enter the market prior to that commencement date. (CX0320 at 009).

133. Delaying Impax's entry was valuable to Endo. Endo calculated that "[e]ach month that generics are delayed beyond June 2010 is worth ~$20 million in net sales per month." Endo forecasted that if Impax launched its generic in July 2010, Endo would lose approximately $100 million in branded Opana ER sales during the first six months Impax was on the market. Endo forecasted that it would lose 85%

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[10] The May 26, 2010 term sheet relating to the DCA is discussed in F. 294.

of its branded Opana ER sales within three months of generic entry. (CX1106 at 005; CX3445 at 001, 002; CX1320 at 007).

134. The proposed license agreement included with Endo's May 26, 2010 initial term sheet for the SLA was limited to the then-issued Opana ER patents (defined as the '933, '456 and '250 patents), and any issued continuations thereof. (CX0320 at 006-07, 009-10).

135. The proposed license agreement included with Endo's May 26, 2010 initial term sheet for the SLA contained a provision requiring Impax to pay royalties to Endo at a rate of 35% on Impax's gross sales of generic Opana ER during Impax's 180-day exclusivity period, if Endo's gross sales of Opana ER during the three full calendar months before Impax's entry date exceeded a certain specified dollar amount. (CX0320 at 010).

ii. Impax's counteroffer

136. Impax responded to Endo's May 26, 2010 initial term sheets (F. 131) on May 27, 2010, with a counteroffer. (RX318).

137. Impax's May 27, 2010 counteroffer to Endo, transmitted by Mr. Mengler to Mr. Levin of Endo, provided for a generic launch date of January 1, 2013, "with no authorized generic and certain acceleration triggers, including market degradation to any alternate product." (RX318 at 0001; Koch, Tr. 237-38; Snowden, Tr. 432; Mengler, Tr. 532).

138. An acceleration provision or trigger for market degradation would allow Impax to launch its generic oxymorphone ER product earlier than

January 1, 2013 in the event that Opana ER brand sales fell by a certain amount or percentage. (CX4010 (Mengler, IHT at 33- 34)).

139. Impax wanted a market acceleration provision as "protection in case Endo had any intentions of moving the market to a next-generation product." Impax had included similar provisions in other patent settlements with brand companies. (CX4032 (Snowden, Dep. at 104); CX4003 (Snowden, IHT at 121-22)).

140. Although Impax did not have specific information about Endo's plans to reformulate Opana ER, Impax was concerned that Endo had "a secret plan to damage the market" with the introduction of a reformulated Opana ER product. (CX0217 at 001; *see* Snowden, Tr. 433-34; Mengler, Tr. 569-70; CX4017 (Levin, Dep. at 118)).

141. Impax had seen analyst reports suggesting that Endo was working on crush-resistant drugs generally. (CX2540 at 001; Mengler, Tr. 579-80).

142. In light of concern about opioid abuse, the FDA encouraged opioid manufacturers to "figure out a way to make them tamper-resistant [and] the primary manner in which companies were doing that was to make the tablet in such a manner that [it] couldn't be crushed." (Mengler, Tr. 569).

143. Impax was aware that Purdue Pharma, L.P., the manufacturer of OxyContin, had introduced a reformulated, crush-resistant version of its product and was withdrawing its original formulation. (Mengler, Tr. 569; CX4017 (Levin, Dep. at 118-19)).

144. Impax's May 27, 2010 counteroffer to Endo revised Endo's formula for calculating royalties to Endo in connection with the license to sell generic Opana ER by raising the amount of gross sales that would trigger a royalty payment, and revising the royalty calculation. (RX318 at 0001).

145. After receiving Impax's May 27, 2010 counteroffer, Mr. Levin of Endo responded by email that the parties were "[c]learly ... too far apart" and suggested a conference call among Mr. Mengler and Ms. Snowden for Impax, and Mr. Levin and Mr. Donatiello for Endo. (CX1305 at 001).

146. Negotiators for Endo and Impax conferred by telephone on May 27, 2010, and over the weekend of May 28 and 29, 2010. (CX1301 at 113; CX310 at 005).

iii. Rejection of acceleration trigger and development of the Endo Credit

147. Endo opposed the concept of accelerated entry and rejected Impax's request for a market acceleration trigger. Endo insisted to Impax "that they had no interest in" moving the market to a crush-resistant version of Opana ER and "they weren't planning to." (CX4032 (Snowden, Dep. at 104, 106-07); Snowden, Tr. 385; CX4014 (Hsu, IHT at 85- 87)).

148. Endo's rejection of an acceleration trigger increased Impax's concern that Endo was going to switch the market to a crush-resistant version of Opana ER. (Mengler, Tr. 568).

149. Because the proposed settlement provided for "a period of time between the date of [FDA] approval and the ... launch [in] January [2013].

[Impax was] worried about the control the brand had over their product during that time, and [Impax was] looking for a way to gain - take back some of that control away from the brand." (Koch, Tr. 240-41).

150. Mr. Mengler responded to Endo's insistence that Endo was not planning to move the market to a crush-resistant version of Opana ER that, "if you're telling me the truth and the product is really going to grow, well, you know, there will be something in it for you as well [and] if you're not telling me the truth, you're going to pay me what I would have made anyway." (CX4010 (Mengler, IHT at 35-36); *see also* CX4026 (Nguyen, Dep. at 164-66) (the "gist" of the Endo Credit was "Mr. Mengler basically telling Endo to put its money where its mouth was")).

151. At an in-person meeting among negotiators for Endo and Impax held on June 1, 2010, Endo proposed to Impax that "if the product declines by more than 50%, [Impax] would be entitled to a 'make good' payment such that [Impax's] potential profits would equal to 50%." (RX387 at 0001 (June 1, 2010 Mengler internal email recapping the "current proposal"); *see also* CX0310 at 005).

152. On June 1, 2010, Mr. Mengler of Impax, in an internal email to Dr. Hsu, Ms. Snowden and others, described the current proposal as including a generic launch date of February 1, 2013, with acceleration triggers. In addition, "[i]f the product grows beyond certain levels, we pay them [a percentage of profits] during the six month exclusivity ... [I]f the product declines by more than 50%, we would be entitled to a 'make good' payment such that our potential profits would equal to 50%." Mr. Mengler stated his opinion

that he "still like[s] January" for the agreed generic launch date and that "[t]he make-good trigger is too low. A similar arrangement with, say a 75% number might be quite attractive." (RX387).

153. Once Endo refused to agree to an acceleration trigger, and agreed instead to the concept of a make-whole payment, Impax stopped pursuing an acceleration trigger. (CX4018 (Koch Dep. at 71); Snowden, Tr. 385).

154. On the afternoon of June 3, 2010, negotiators for Endo and Impax reached an agreement in principle for settling the litigation. That same day, in an internal email from Mr. Mengler of Impax to Dr. Hsu, Ms. Snowden, Mr. Koch, and others, Mr. Mengler described the key provisions for the SLA. Generic launch would be January 1, 2013. The royalty provisions were further adjusted and "[i]f the units decline by more than 50% from peak at launch, make whole provisions kick in that protect the downside." (CX0407 at 001-02; CX3334 at 001 (Mr. Levin reporting that Endo had "reached a handshake agreement with Impax); CX4012 (Donatiello, IHT at 139) ("Endo and Impax reached an agreement in princip[le] around midday on June 3rd."); CX0114 at 001 (June 3, 2010, email from Mengler reporting that "[i]t seems all parties internally are good to go").

155. On June 4, 2010, Mr. Mengler was replaced as Impax's lead negotiator by Mr. Koch and Ms. Snowden. After an internal Impax management discussion that day, at the instruction of Impax management, Mr. Koch and Ms. Snowden had a conference call with Endo in which they proposed dropping the existing terms for the SLA and DCA, and

entering into a "simple settlement" with the same July 15, 2011 entry date that Endo provided to Actavis in their settlement. (CX4032 (Snowden, Dep. at 97-99); Snowden, Tr. 372-74; CX507 at 001).

156. In response to Impax's June 4, 2010 proposal for a simple settlement with a July 15, 2011 entry date (F. 155), Mr. Levin of Endo expressed anger that the terms of the deal he had negotiated with Mr. Mengler were not being honored, refused Impax's request, and insisted on reverting back to the deal he had negotiated with Mr. Mengler. (CX4032 (Snowden, Dep. at 99-102); Snowden, Tr. 374-75).

iv. Finalizing the SLA

(a) No-AG provision and Endo Credit

157. Between June 4 and June 7, 2010, Endo and Impax exchanged numerous drafts, and redlined revisions thereto, of the SLA. (*See, e.g.*, CX0323 (June 4, 2010 Endo first draft); CX0324 (June 5, 2010 Impax revisions); CX2771 (June 6, 2010 Endo revisions); CX1813 (June 7, 2010 Endo revisions); CX2767 (June 7, 2010 Impax revisions); RX336 (June 7 Impax revisions); RX322 (June 7 Endo revisions); RX364 (SLA)).

158. Each draft of the SLA exchanged by Endo and Impax, as well as the final executed SLA, provided for an entry date of January 1, 2013. (*See, e.g.*, CX0323 §1.1 (definition of "Commencement Date"), §4.1(a); CX0324 (same); CX2771 (same); CX1813 (same); CX2767 (same); RX336 (same); RX364 (SLA)).

159. Endo's initial term sheet to Impax, provided on May 26, 2010, as well as each settlement draft

exchanged by Endo and Impax, contained a no-AG provision. (*See, e.g.*, F. 131; CX0323 §4.1(c); CX0324; CX2771; CX1813; CX2767; RX336; RX364 (SLA)).

160. Endo drafted the first iteration of the make-whole provision, which was included in the first draft of the SLA Endo sent to Impax on Friday June 4, 2010 as section 4.4 of the SLA. Under Endo's proposal, Endo's obligation to pay Impax a cash amount would be triggered if the amount of oxymorphone active pharmaceutical ingredient ("API") shipped in the Opana ER strengths for which Impax was first to file fell below a set threshold from the peak consecutive three-month sales period between the SLA's effective date and the fourth quarter of 2012. The amount Endo would ultimately be obligated to pay depended on Impax's sales during its 180-day exclusivity period. Generally, the lower Impax's net profits during the exclusivity period, the lower the amount Endo was obligated to pay. (CX0323 at 001, 005-07, 012 (June 4, 2010 draft SLA §1.1 (definitions of "Impax's Net Profit," "Impax Product," "Exclusivity Period, "Pre-Impax Amount," "Three Month Shipment Amount," and "Trigger Threshold"), §4.4).

161. Roberto Cuca, Endo's vice president of financial planning and analysis, was tasked with developing a provision that became known as "the Endo Credit" (F. 95-96). Mr. Cuca's "goal was to make the provision be as beneficial to Endo as possible." Mr. Cuca looked for ways to "improve the economic effect of this provision to Endo." (CX4035 (Cuca, Dep. at 68-69, 96-97); Cuca, Tr. 612, 614-15).

162. On Saturday, June 5, 2010, counsel for Impax sent a revised draft of the SLA to Endo. Impax

renamed Endo's section 4.4 the "Endo Credit" and proposed two changes to Endo's proposal. First, Endo's obligation to pay the Endo Credit would be dependent on a decline of 50% or more in Opana ER unit sales rather than API. Second, if Endo's obligation to pay was triggered, the amount to be paid would not rely on Impax's actual sales of generic oxymorphone ER during its exclusivity period, but rather on the revenues Impax would have expected to make during the exclusivity period had Endo not switched the market. To approximate this expected amount, the formula incorporated the generic substitution rate (90%), the generic price (75% of the WAC brand price), and the length of the exclusivity period (50%, or half a year or 180 days). (CX0324 at 001, 045 (June 5, 2010 draft SLA §4.4, definitions of "Endo Credit," "Market Share Factor," "Market Share Value," "Pre-Impax Amount," "Trigger Threshold," and "Quarterly Peak.").

163. On Sunday, June 6, 2010, Endo responded to Impax's proposal for the Endo Credit with two additional changes. First, Endo proposed that its obligation to pay the Endo Credit would be dependent on a decline of 50% or more in Opana ER dollar sales, as calculated by multiplying unit sales by the wholesale acquisition cost (WAC), instead of unit sales. Second, Endo wanted the amount to reflect Impax's expected profits during the exclusivity period, rather than Impax's expected revenues, which would effectively reduce any amount to be paid to Impax under the Endo Credit. (CX2771 at 001, 005-07, 014 (June 6, 2010 draft SLA §1.1 (definitions of "Endo Credit," "Market Share Profit Factor," "Market Share Profit Value," "Pre-Impax Amount," "Prescription

Sales," and "Quarterly Peak"), §4.4; Cuca, Tr. 639). *See also* CX4035 (Cuca, Dep. at 105-06) ("[T]hat is one of the ways that the Endo team would have negotiated to make it more financially favorable to Endo.")).

164. Endo believed that incorporating Impax's net profit margin into the Endo Credit was consistent with the objective of "trying to make [Impax] whole at the bottom line, so at their profit line, whereas the prior provision would have made them whole at the revenue line and actually would have advantaged them as compared to what was trying to be achieved." (Cuca, Tr. 638-39).

165. Impax agreed to the two changes to the Endo Credit proposed by Endo in Endo's June 6, 2010 revised draft to Impax. (CX2767 at 004, 006-07, 013 (June 7, 2010 Impax draft SLA §4.4, definitions of "Endo Credit," "Market Share Profit Factor," "Market Share Profit Value," "Pre-Impax Amount," "Prescription Sales," and "Quarterly Peak"); RX364 at 0003-06, 0012 (SLA §1.1 (definitions of "Endo Credit," "Market Share Profit Factor," "Market Share Profit Value," "Pre-Impax Amount," "Prescription Sales," and "Quarterly Peak"), §4.4).

(b) Scope of patent license

166. Both Endo's May 26, 2010 initial term sheet for the SLA and Endo's June 4, 2010 first draft of the SLA limited Impax's license to the three patents then listed in the Orange Book for Opana ER (the '933, '456, and '250 patents). (CX0320 at 006-07, 009-10 (May 26, 2010 Endo term sheets); CX0323 at 006, 010 (June 4, 2010 draft SLA §§1.1, 4.1(a))).

167. At the time the negotiations were being conducted, Impax was aware that Endo had additional

pending patent applications relating to Opana ER and recognized that Endo could acquire still other patents. (RX398 at 001; RX568; Mengler, Tr. 571-72; Snowden, Tr. 440, 442-43; *see also* Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-010 ¶36).

168. Given the possible effects of Endo's additional patent applications relating to Opana ER, a reasonable litigant would have been concerned with Endo's future patents. (Figg, Tr. 1938).

169. On June 5, 2010, Impax proposed broadening the patent license in the SLA to "any patents and patent applications owned by or licensed to Endo ... that cover or could potentially cover" Impax's generic oxymorphone ER product. (CX0324 at 030 (June 5, 2010 Impax revised draft of SLA §4.1(a)); *see also* CX4026 (Nguyen, Dep. at 153-55) (testifying that the June 5 SLA draft expanded the scope of the patent license); CX4012 (Donatiello, IHT at 93)).

170. Endo accepted Impax's language, referenced in F. 169. (CX2771 (June 6 Endo revisions); CX1813 (June 7 Endo revisions); CX2767 (June 7 Impax revisions); RX336 (June 7 Impax revisions); RX322 (June 7 Endo revisions)).

c. Value transferred to Impax under the SLA

i. No-AG provision

171. First-filer exclusivity (F. 21) is very valuable to a generic drug manufacturer. First-filer exclusivity gives the first filer 180 days, or "six months of runway," before any potential entry by another

generic and helps the generic company make more money. (Koch, Tr. 232-33).

172. A first-filer generic manufacturer makes a substantial portion of its profits during the 180-day exclusivity period. The introduction of an authorized generic during that exclusivity period reduces the value of the exclusivity period by causing lower prices and fewer sales for the first filer. (Reasons, Tr. 1213-15; Koch, Tr. 232-33).

173. Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30, and 40 mg dosages of oxymorphone ER, which comprised all of the dosages of Opana ER except the 7.5 and 15 mg dosages. The five doses as to which Impax was the first to file constitute the five most popular dosages of Opana ER, comprising 95% of Endo's Opana ER sales. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶13; Mengler, Tr. 525; Koch, Tr. 231-32; Snowden, Tr. 354, 414).

174. As the first filer on the 5, 10, 20, 30 and 40 mg dosages of oxymorphone ER, Impax was entitled to 180 days of generic exclusivity. During that 180 days, no other ANDA filer could market a generic version of Opana ER because the applicable statute does not allow the FDA to give final approval to any other ANDA filer during that 180-day time period. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶14; Second Set of Joint Stipulations, JX003 ¶7; Snowden, Tr. 414; *see also* Mengler, Tr. 522-23).

175. The term "authorized generic" is a term of art used in the pharmaceutical industry to describe a

generic that is made available for sale using the brand company's New Drug Application approval. An authorized generic is generally launched by the brand company or another company licensed by the brand company. Launching an authorized generic helps a company partially recoup sales of the branded product that are lost to generic competition. (Mengler, Tr. 523; Koch, Tr. 233; Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶¶28-31; Reasons, Tr. 1211-12).

176. The 180-day exclusivity period does not prevent the brand company from launching an authorized generic. The brand company, if it chooses, can launch an authorized generic during the 180-day exclusivity period and compete with the first-filing generic during that period. (Mengler, Tr. 523-24; *see also* Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶28; Second Set of Joint Stipulations, JX003 ¶7).

177. Having an authorized generic competitor during the 180-day exclusivity period generally results in a decrease in the first filer's prices of approximately 30 to 35%. The first filer's share of the generic market will also be reduced as the first generic manufacturer will have to split the sales with the authorized generic manufacturer. (Reasons, Tr. 1213-14; Mengler Tr. 524).

178. Endo, as the holder of the approved NDA for Opana ER, could market its own authorized generic version of Opana ER during Impax's exclusivity period. (Second Set of Joint Stipulations, JX003 ¶7).

179. Impax was aware that an authorized generic would adversely impact Impax's market share and

profits. (CX0514 at 004 (5/16/2010 email from Chris Mengler attaching 5-year forecast 2010 showing Impax with less than 100% of the generic market share within the 180-day exclusivity period); CX2825 at 008 (2/11/2010 email from Ted Smolenski attaching 5-year forecast 2010 showing same)).

180. If there were no authorized generic, then Impax would be the only generic product on the market during its 180-day exclusivity period and could charge a higher price for generic Opana ER compared to a marketplace that had two companies selling generic products. (Reasons, Tr. 1215; Snowden, Tr. 392).

181. Impax executives estimated that if Endo launched an authorized generic when Impax entered the market, Endo's authorized generic would capture as much as half of sales of generic Opana ER and cause substantially lower generic prices during the exclusivity period than would be the case if Impax sold the only generic. (CX4037 (Smolenski, Dep. at 53-54); CX4002 (Smolenksi, IHT at 80-81); CX0202 at 001).

182. Impax would generally seek a no-AG provision as an element of negotiating a settlement agreement with a brand manufacturer. The absence of an authorized generic would mean more control for the generic company, and control can often lead to higher profits for the generic company. (Koch, Tr. 234).

183. Mr. Mengler, Impax's primary negotiator with Endo, believed that getting a no-AG provision would be beneficial to Impax. Along with obtaining the earliest possible entry date, a no-AG agreement is among the more important things that Impax would

seek in a negotiation in order to get the best possible deal for Impax. (Mengler, Tr. 526).

184. A six-month no-AG provision was one of the terms included as part of the Endo-Impax settlement throughout the settlement negotiations. (F. 159).

185. The no-AG provision in the SLA prohibited Endo from selling an authorized generic product for any of the five specified dosages as to which Impax was first to file until after Impax's 180-day exclusivity period ended. (F. 127; RX364 at 0010-11 (SLA §4.1(c)).

186. At time of the execution of the SLA, Impax did not know whether, absent the settlement, Endo would launch an authorized generic. (CX3164 at 019-20).

187. The no-AG provision in the SLA guaranteed to Impax that Impax, as the first to file on generic Opana ER, would be the only seller of generic Opana ER during its first 180 days on the market and would not face competition from an Endo authorized generic. (Snowden, Tr. 392; CX0320 at 009-10; CX4003 (Snowden, IHT at 111-13)).

188. The no-AG provision in the SLA was worth substantial value to Impax when the SLA was executed because the no-AG provision ensured that Impax would face no generic competition during the 180-day exclusivity period and would earn greater profits by not having to share generic sales with an Endo authorized generic. (CX5000 (Noll Expert Report at 153-55 ¶¶346-48); Noll, Tr. 1452-54).

189. In 2010, Impax forecasted the effect of an authorized generic by Endo on Impax's expected generic sales. In what Impax referred to as the

"upside" scenario, Impax assumed that Endo's authorized generic Opana ER would enter about two months after Impax's launch of generic Opana ER. Under the upside scenario, Impax's share of generic sales was estimated to fall to 60% and Impax's average price was estimated to fall by 36% (from 55% of brand WAC to 35%). Under what Impax referred to as its "base" scenario, Impax assumed that Endo's authorized generic Opana ER would enter simultaneously with Impax, would capture half of the market, and would cause prices to fall by the same 36%. (CX4037 (Smolenski, Dep. at 147-50, 166); CX0004 at 005-19; CX0222 at 004-11; CX2825 at 008-17; CX2830 at 004-09; CX2831 at 003-08; CX2853 at 007-15).

190. Complaint Counsel's economic expert, Professor Roger Noll, applying Impax's forecasts in 2010 (F. 189), calculated that under Impax's upside scenario, entry by an authorized generic during Impax's 180-day exclusivity period would cause Impax's revenues to fall by 61.6%, or approximately $23 million. Under Impax's "base" assumptions (F. 189), entry by an authorized generic during Impax's 180-day exclusivity period would cause Impax's revenues to fall by 68%, or approximately $33 million. (CX5000 (Noll Expert Report at 155 ¶350)).

191. In May 2010, Todd Engle, of Impax's sales and marketing team, prepared an analysis for Dr. Hsu and Mr. Mengler of the effect of an authorized generic on Impax's profits during Impax's 180-day exclusivity period, which projected lost profits in the amount of $24.5 million if an AG entered within two to four weeks after Impax's launch of generic oxymorphone

ER. (CX2753 at 004 (six month lost profits model for oxymorphone ER, predicting profits of $53 million with no AG, and $28.5 million with AG)).

192. On June 1, 2010, Endo approximated the revenues it would gain from launching an authorized generic of Opana ER, if Impax launched at risk and Endo launched its authorized generic on July 1, 2010, to be $25 million. (CX1314).

193. The no-AG provision in the SLA was worth between $23 and $33 million in projected sales revenue to Impax at the time Impax entered into the SLA. F. 189-191.

194. The no-AG provision had substantial value to Impax even if original Opana ER sales grew so much that Impax ended up having to pay a royalty to Endo, pursuant to the SLA. If Endo's sales of original Opana ER reached a sufficiently high level prior to Impax's generic entry, Impax would be obligated to pay a royalty to Endo in the amount of 28.5% of Impax's net sales of generic Opana ER. Because the royalty percentage is lower than the expected decline in Impax's revenue attributable to competition from an AG, Impax's revenues with the no-AG provision and a royalty are always higher than revenues with competition from an AG and no royalty. In all cases, Impax would benefit more from being the only seller of a generic oxymorphone ER product, than it would be required to pay Endo in royalties. (RX364 at 0012 (SLA §4.3); CX5001 (Bazerman Expert Report at 026 ¶51); CX5000 (Noll Expert Report at 155-56 ¶¶350-51); Mengler, Tr. 533).

ii. Endo Credit

195. Under section 4.4 of the SLA, titled "Endo Credit," Endo agreed to pay Impax an amount, determined by a mathematical formula, in the event that prescription sales of Opana ER declined by more than 50% from the quarterly peak sales during the time period from July 2010 to September 2012. (RX364 at 0003-06, 0012 (SLA §§1.1, 4.4) ("If the "Pre-Impax Amount is less than the Trigger Threshold, then Endo shall pay to Impax the Endo Credit"); CX3164 at 010-11).

196. The formula for calculating the Endo Credit incorporates a number of factors that relate to Impax's sales of generic Opana ER multiplied by the market opportunity for the generic product in the quarter of peak sales. The agreement defines Impax's "Market Share Profit Value" as the product of (1) an assumed generic substitution rate for original Opana ER (90%), (2) an assumed net realized generic price discounted from the brandname price (75%), (3) an assumed generic profit margin (87.5%), (4) 50% (expressing the 180-day exclusivity period as half of a year), and (5) the annualized sales of Opana ER during the quarter of peak sales for Opana ER during the period from the third quarter of 2010 to the third quarter of 2012 divided by 100. (RX364 at 0003 ("Endo Credit" definition), 0004 ("Market Share Profit Factor" definition & "Market Share Profit Value" definition), 0005 ("Pre-Impax Amount" definition), 0005-06 ("Quarterly Peak" definition), 0006 ("Trigger Threshold" definition), 0012 ("Endo Credit" provision)).

(a) Purpose of the Endo Credit

197. The Endo Credit was designed to "back-up" the value of the no-AG provision and provide value to Impax regardless of whether Endo launched a reformulated version of Opana ER. (F. 198-215).

198. When brand companies introduce a reformulated drug, they often cease marketing and selling the original product. They can also withdraw the original product's referencelisted drug designation, preventing generic products from having AB-rated status. (CX4003 (Snowden, IHT at 30-31); CX4014 (Hsu, IHT at 152)).

199. By introducing a reformulated drug, the brand company can greatly reduce the opportunity for generic versions of the original drug since those generic products are no longer bioequivalent to - and not subject to automatic substitution in place of - the reformulated product. (Snowden, Tr. 434; CX4030 (Hsu, Dep. at 108); Koch, Tr. 238 (reformulation can "switch patients away from the brand product" as to which Impax has the generic "in favor of a line extension" not covered by the ANDA)).

200. Impax's generic Opana ER would not be AB-rated to a reformulated Opana ER product. (Mengler, Tr. 528).

201. Protecting the market for Impax's entry date was a priority for Impax. (Snowden, Tr. 490).

202. Because "the generic would rely on the ... automatic substitution in the pharmacy," not having a reference brand product means that pharmacists

"can't substitute" the generic for the branded drug. (CX4014 (Hsu, IHT at 152)).

203. For a generic drug to be sold where there is no branded drug for which it is automatically substituted, doctors must actually write out a prescription for the generic product. (CX4014 (Hsu, IHT at 152); CX4004 (Engle, IHT at 221)).

204. If Endo were to move to a reformulated Opana ER, then Impax's market opportunity for its generic product would be significantly reduced or even zero, because Opana ER in its original form disappears or becomes insignificant. (Snowden, Tr. 434; Mengler, Tr. 527).

205. Mr. Mengler was concerned that reformulation was an effort by Endo to "subvert the value of the deal" he was trying to put together to get Impax's product on the market. (Mengler, Tr. 526-27).

206. If Endo did destroy the market for Impax's generic Opana ER, Mr. Mengler wanted Impax "to be made whole for the profits that [Impax] would have otherwise achieved." (Mengler, Tr. 533).

207. If "the market changed substantially before the date that the parties agreed that Impax could launch," the provision "would be a way of making Impax whole." (Cuca, Tr. 617; CX4035 (Cuca, Dep. at 69-70) ("If sales of Opana ER had decreased," the provision would "kind of fix that ... [b]y making a true-up payment to Impax. ... The true-up payment would correct for the loss in the value of the market that had occurred before the generic entry date.")).

208. Getting downside protection for Impax in the event Endo reformulated Opana ER was "super, super

important" to Impax's primary negotiator of the Endo-Impax Settlement. According to Mr. Mengler, "something that didn't protect us from the downside was ... a deal-breaker." (Mengler, Tr. 535-36; CX4010 (Mengler, IHT at 44)).

209. A sharp decline in the sales of branded Opana ER before Impax's generic launch would decrease the value of the no-AG provision that Impax agreed to with Endo, because the total market potential for generic Opana ER would be decreasing. The Endo Credit payment was designed to "correct for the loss in the value of the market that had occurred before the generic entry date." (Reasons, Tr. 1218; CX4035 (Cuca, Dep. at 69-70)).

210. If the market for Opana ER did not decline, the value of the no-AG provision would be higher, but if the market did decline, the Endo Credit provision was designed to provide Impax with a payment. (Reasons, Tr. 1218-19; CX4020 (Reasons, Dep. at 55-56)).

211. The Endo Credit was designed as insurance against the risk of Endo reformulating Opana ER. If the market for Opana ER did not decline, the value of the no-AG provision would be higher, but if Endo effected a "switchout" to reformulated Opana ER, then the Endo Credit provision was designed to provide Impax with a payment. (Koch, Tr. 265-66; Reasons, Tr. 1218-19; CX4020 (Reasons, Dep. at 55-56)).

212. If Endo's obligation to pay the Endo Credit were triggered, based on declining sales of Opana ER prior to Impax's generic entry, the calculations of the Endo Credit were designed to approximate the net profits Impax would have expected to make during its

six-month exclusivity period, with no AG. The provision achieved this by basing the calculation in part on the expected generic substitution rate (90%), the expected generic price (75% of the brand WAC price), Impax's net profit margin (87.5%), and the length of the no-AG exclusivity period (50%, or 180 days expressed as half a year). (RX364 at 0004 (SLA §4.4, definitions of "Market Share Profit Value"); *see also* Cuca, Tr. 635- 37). By including Impax's net profit margin rather than just looking to Impax's expected revenues, any amount Endo would be required to pay was reduced by 12.5%. (RX364 at 0004 (SLA §4.4, definitions of "Market Share Profit Value"); Cuca, Tr. 640-41).

213. The Endo Credit provision "was intended to insulate" Impax from the risk of substantial decrease in Opana ER sales prior to the agreed generic entry date. The goal was, "if the market changed substantially before the date that the parties agreed that Impax could launch, there would be a way of making Impax whole" by providing Impax with the profits that Impax otherwise would have achieved during its 180-day exclusivity period, had a change in the marketplace not occurred. (Cuca, Tr. 617; CX4035 (Cuca, Dep. at 81-82); Mengler, Tr. 533).

214. The Endo Credit provision was designed to provide an approximation of the profits that Impax would have earned from sales of generic Opana ER during Impax's six-month exclusivity period, based on pricing, share and other assumptions. (CX4010 (Mengler, IHT at 36-37); CX4035 (Cuca, Dep. at 69-70) ("If sales of Opana ER had decreased," the provision would "kind of fix that ... [b]y making a true-up

payment to Impax. ... The true-up payment would correct for the loss in the value of the market that had occurred before the generic entry date.")).

215. During a November 2011 earnings call, Impax's CFO, Mr. Koch, who also helped negotiate the SLA, discounted the impact of Endo switching Opana ER to a new formulation because of the terms of the Endo-Impax Settlement, stating: "Fortunately, though, we do have [downside] protection built into the agreement so we should have a reasonable outcome almost no matter what happens." (Koch, Tr. 264-65; CX2703 at 012-13).

(b) Dollar value of the Endo Credit at the time of settlement

216. The dollar value of the Endo Credit was uncertain at the time of settlement. The dollar value was contingent on unknown future events that were outside of Impax's control, such as the figure for quarterly peak sales for Opana ER prior to generic entry, which was the biggest "input" in the Endo Credit formula. (Cuca, Tr. 629; Snowden, Tr. 437-38).

217. The formula that determined any Endo Credit payment required (1) determining Endo's quarterly peak sales between July 2010 and September 2012; (2) determining the "Pre- Impax amount" of Opana ER sales, meaning the sales of Opana ER in the fourth quarter of 2012, immediately prior to Impax's January 2013 generic entry; (3) comparing the quarterly peak number to the pre-Impax amount, and determining if the pre-Impax amount is less than 50%, which triggered a payment obligation; and (4) multiplying the difference between

the quarterly peak number and the pre-Impax number by a specified amount to calculate the final sum due. Each of these formula inputs was unknown at the time of settlement. (Snowden, Tr. 437-38; *see* RX364 at 006; Engle, Tr. 1749-50).

218. Impax did not forecast a payment under the Endo Credit in Impax's business forecasts. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88)).

219. Financial projections by Endo and Impax at the time of the settlement anticipated continued growth in Opana ER sales. (CX0222 at 003-11 (Impax forecasts for Opana ER); CX2530 at 007-08 (Endo forecasts for Opana ER)).

220. Prior to the settlement, Mr. Cuca ran some calculations for the Endo Credit formula to "make sure that it was producing outputs that [he] thought it was supposed to be producing." Using the Excel program, Mr. Cuca spent approximately five minutes entering potential "peak sales" figures into the Endo Credit formula to make sure it produced a sensible result. These calculations produced a range of payouts, including a possible zero payment. For the "peak sales" input, Mr. Cuca relied on Endo sales forecasts. (Cuca, Tr. 628-31; CX4035 (Cuca, Dep. 79-84)).

221. Prior to the settlement, Impax's director of market planning, Ted Smolenski, told Mr. Mengler that there were certain circumstances under which the Endo Credit would not result in a payment to Impax, including a situation in which Endo would withdraw its NDA for original Opana ER and time the elimination of sales in such a way that the Endo Credit would result in zero payment. Mr. Mengler decided not to pursue the issue further because he did not

deem the potential to be likely enough to be "worth the energy" to try to "correct for it in the agreement." (Mengler, Tr. 589-90; CX4037 (Smolenski, Dep. at 253); *see also* CX0219 at 001 (Smolenski email to Hsu describing "downside scenario as probably unlikely" and stating that Mengler viewed the "potential downside scenario" as "so unlikely it wasn't worth worrying about")).

222. The amount of any payment under the Endo Credit could not be estimated before learning the quarterly peak sales of Opana ER between July 2010 and September 2012. (Cuca, Tr. 668-69).

223. Endo first reported a liability under the Endo Credit in May 2012. (RX494 at 0007 (Endo SEC Form 8-K from May 1, 2012); CX4017 (Levin, Dep. at 140-41)).

224. In or about May 2012, Endo took a pre-tax charge in the amount of $110 million "to reflect a one-time payment that the company now expects to make to Impax per the terms of Endo's 2010 settlement and license agreement with Impax." (RX117 at 0021 (Endo SEC Form 10-Q for 1Q12 showing $110 million "[a]ccrual for payment to Impax related to sales of Opana ER")).

(c) 2013 payment under the Endo Credit

225. Endo filed a supplemental New Drug Application (No. 201655) for a reformulated version of Opana ER ("reformulated Opana ER") in July 2010. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶48; CX3189).

226. The FDA approved Endo's supplemental NDA for a reformulated version of Opana ER in December 2011. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶48).

227. At the end of 2011, after discovering manufacturing deficiencies, the FDA shut down the plant where Novartis Consumer Health, Inc. ("Novartis"), another pharmaceutical company, manufactured original Opana ER for Endo. The shutdown of the Novartis plant caused a supply disruption for original Opana ER and required Endo to scale up its manufacturing of reformulated Opana ER. (CX4017 (Levin, Dep. at 136-39)).

228. The Novartis plant shutdown at the end of 2011 created a "supply chain crisis" for original Opana ER. (CX4017 (Levin, Dep. at 136-39); *see* RX094 at 0003-04; RX563 at 0001; RX139 at 0001).

229. In or about February 2012, the FDA ordered Endo to cease selling original Opana ER in order to avoid consumer confusion. Specifically, the FDA informed Endo that "once any tablets of CRF [crush-resistant formulation] were sold, [Endo] could no longer sell any tablets of the old formulation." (CX4017 (Levin, Dep. at 138-39, 155); RX100 at 0001; RX094 at 0004).

230. In March 2012, Endo stopped distributing original Opana ER and launched reformulated Opana ER. (Second Set of Joint Stipulations, JX003 ¶33; CX4017 (Levin, Dep. 139)).

231. It was not until after the Novartis supply disruption in late 2011, the FDA's order to stop selling original Opana ER in February 2012, and the launching of reformulated Opana ER in March 2012,

that Endo first concluded that it would have to make a payment under the Endo Credit provision. The first time Endo knew that its sales of Opana ER would be zero was in the last quarter of 2012, after the supply interruption caused by the Novartis plant shutdown. (Cuca, Tr. 665, 671, 677; Reasons, Tr. 1203, 1229; RX039; RX094 at 0003-06).

232. On May 31, 2012, Endo requested that the FDA move original Opana ER to the Orange Book Discontinued List. (Second Set of Joint Stipulations, JX003 ¶34).

233. In August 2012, Endo filed multiple citizen petitions with the FDA, in which Endo argued that the FDA should (1) determine that original Opana ER was discontinued for safety reasons and could no longer serve as a reference-listed drug for any ANDA; (2) refuse to approve any ANDA pending for original Opana ER; and (3) withdraw any already-granted approvals for original Opana ER ANDAs. (Snowden, Tr. 476-77, 479- 80; CX3203 (Endo's citizen petitions); Second Set of Joint Stipulations, JX003 ¶34).

234. Impax formally responded to the petition and offered scientific evidence that the discontinuation of Endo's original Opana ER was unrelated to safety or effectiveness. (Snowden, Tr. 480).

235. The FDA concluded that Endo did not withdraw original Opana ER for safety or efficacy reasons. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-012 ¶51).

236. On January 18, 2013, Ms. Snowden, Impax's vice president for intellectual property litigation and licensing, provided Endo with written documentation supporting payment under the Endo Credit provision

in the amount of $102,049,199.64. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶45; Snowden, Tr. 386-89; CX0332 at 007-08).

237. On April 18, 2013, pursuant to section 4.4 of the SLA, Impax received a payment from Endo in the amount of $102,049,199.64. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶46; Reasons, Tr. 1204; CX0333; CX1301 at 007).

iii. Complaint Counsel's expert's valuations

238. Complaint Counsel's economic expert, Professor Noll devised four examples of what the potential value of the no-AG and Endo Credit could be to Impax based on assumptions as to future events. Professor Noll did not attach any probabilities to the assumed events occurring. (Noll, Tr. 1613, 1650-51; CX5000 (Noll Expert Report at 240 Appendix F)).

239. Professor Noll's purported calculations of the value of the Endo Credit (F. 238) were based on discounting the amount of the actual payment under the Endo Credit in 2013. (CX5000 (Noll Expert Report at 169)).

240. Professor Noll did not calculate the expected value of the Endo Credit at the time of settlement. (Noll, Tr. 1591, 1613, 1651-52; Addanki, Tr. 2384).

241. Professor Noll acknowledged that he had not seen any documents predating June 2010 in which either Impax or Endo estimated the value for the Endo Credit. (Noll, Tr. 1611).

242. Professor Noll acknowledged that whether the Endo Credit would be paid, or the amount that would be paid, depended on contingent events and

that there was a possibility that Impax would not receive any payment under the Endo Credit. (Noll, Tr. 1611-12).

243. Although Professor Noll acknowledged that it is important to take agreements as a whole, Professor Noll did not consider the value of the patent license rights Impax received under the SLA. (Noll, Tr. 1648).

3. The Development and Co-Promotion Agreement

a. Overview of relevant provisions

244. On June 7, 2010, Endo and Impax executed a Development and Co-Promotion Agreement ("DCA") with respect to a Parkinson's disease treatment known internally at Impax as IPX-203. (Snowden, Tr. 397-99; Nestor, Tr. 2935; RX365 (executed DCA)).

245. The DCA was executed simultaneously with the SLA and is incorporated into the SLA. (RX312; CX0326; Second Set of Joint Stipulations, JX003 ¶69).

246. Under the DCA, Impax and Endo agreed to collaborate with respect to the development and marketing of a potential treatment for Parkinson's disease using an extended release, orally administered product containing a combination of levodopa and carbidopa. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-010 ¶37).

247. Endo agreed to pay Impax an "Upfront Payment" of $10 million within five days of the agreement's effective date. The $10 million payment was guaranteed and nonrefundable. (Joint

Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-010 ¶39; Snowden, Tr. 399-400).

248. The DCA contained the possibility that Endo would make up to $30 million in additional "Milestone Payments" for achieving specified milestone events in the development and commercialization of the product. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-010 ¶40; Snowden, Tr. 408).

249. Under the DCA, Impax and Endo agreed to share promotional responsibilities, with Impax promoting IPX-203 to its network of neurologists, and Endo promoting IPX-203 to its network of non-neurologists, including primary care physicians who prescribe Parkinson's disease medications. (RX365).

250. If the target product, IPX-203, was successfully commercialized, Endo would be entitled to a share of the profits. Specifically, Endo would receive a co-promotion fee equal to 100% of gross margins on sales resulting from prescriptions by non-neurologists. (RX365 ¶3.4).

251. On June 24, 2010, Endo wired a payment of $10 million to Impax in accordance with section 3.1 of the DCA. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶44).

252. Upon receipt of Endo's $10 million payment, Impax deferred the accounting of the money, attributing it as an investment related to research and development work that would be accomplished in the future. (Reasons, Tr. 1242-43).

253. Impax and Endo terminated the DCA by mutual agreement effective December 23, 2015. At the time of termination, the development had not met any

of the milestones that would have required additional payment from Endo and Endo made no additional payments to Impax. (Joint Stipulations of Jurisdiction, Law, and Fact, and Authenticity, JX001-011¶43; Snowden, Tr. 461).

b. Background to the DCA

i. Endo's reliance on collaboration agreements

254. Endo generally does not research or discover new drug molecules on its own. Instead, it acquires and licenses drugs from other pharmaceutical companies. This means that Endo enters many collaboration agreements with other pharmaceutical companies. (Cobuzzi, Tr. 2513-15).

255. Endo's collaboration agreements with other pharmaceutical companies can relate to drugs at every stage of the development lifecycle, including early-stage development agreements. Because Endo had "no discovery pipeline ... in place," Endo would enter "very early, very speculative agreements." (Cobuzzi, Tr. 2516).

256. In connection with a collaboration agreement, Endo identifies therapeutic areas of interest and companies that own promising drug molecules in those areas and enters into earlystage development deals. Endo also regularly licenses technology from and collaborates with other companies for more developed products. For Opana ER, Endo licensed the necessary technology to make both original and reformulated Opana ER. (Cobuzzi, Tr. 2516-17).

ii. Endo's interests in neurology products and Parkinson's disease treatments

257. In 2005, the areas of significant interest to Endo were pain, neurology, areas of movement disorders, including Parkinson's disease, and gastroenterology. (Cobuzzi, Tr. 2518).

258. By 2010, although Endo's focus had shifted away from pain and neurology to urology, endocrinology, and oncology, Endo's sales force still had a focus on pain and neurology and Endo was interested in products that were compatible with Endo's existing products and sales efforts. (Cobuzzi, Tr. 2518-19).

259. In 2010, Endo was selling Frova, which Endo marketed to neurologists and primary care physicians who treat migraine sufferers. (Cobuzzi, Tr. 2519-21).

260. For a number of years, Endo sold an immediate-release Parkinson's disease drug known as Sinemet, which was the original formulation of carbidopa and levodopa. (Cobuzzi, Tr. 2524; Nestor, Tr. 2938; CX1007 at 001).

261. In the 2010 timeframe, Endo evaluated collaborations with other companies related to treatments for Parkinson's disease. This included exploring potential Parkinson's disease collaboration opportunities with an Italian company called Newron, which had multiple Parkinson's disease products, and conducting due diligence on a Parkinson's disease product with a novel mechanism of action that was owned by a Finnish company. (Cobuzzi, Tr. 2520-22).

iii. Impax's efforts to develop Parkinson's disease treatments

262. Impax, formed in 1995, is a manufacturer of generic pharmaceutical drugs. Impax created a separate brand division to manufacture and sell its own branded drugs in 2006. (Koch, Tr. 219-20; Nestor, Tr. 2926, 2929; CX4014 (Hsu Dep. at 9)).

263. When Impax's brand division was founded in 2006, it focused its efforts on central nervous system and neurology products, with a specific focus on improved treatments for Parkinson's disease. As part of this focus, Impax's brand division also concentrated on developing a network of relationships with neurology physicians. (Nestor, Tr. 2929-31).

264. Impax promoted other companies' products to the neurology community, including Carbitol, an epilepsy product, and licensed Zoming, a migraine drug created by AstraZeneca. Impax did so because it "wanted to begin the process of developing those relationships with the neurology physicians." (Nestor, Tr. 2931-32).

265. The "gold standard" treatment for Parkinson's disease is a combination of carbidopa and levodopa molecules. (Nestor, Tr. 2929).

266. The majority of carbidopa-levodopa medications are available only in immediate-release formulations. (Nestor, Tr. 2929).

267. Immediate release carbidopa-levodopa requires frequent dosing and often results in patients losing control of their motor skills as they experience rapid increases and decreases in the concentration of

medicine in their bodies, especially as the disease progresses. (Nestor, Tr. 2929-30, 2939).

268. Impax's first attempt to develop an extended-release carbidopa-levodopa treatment for Parkinson's disease was known as Vadova. That product was intended to combine carbidopa-levodopa with controlled-release technology to give a much smoother effect to the amount of medication in Parkinson's patients' blood, providing for more control over motor symptoms. Vadova was never fully developed or marketed. (Nestor, Tr. 2926-27, 2929-30).

269. Impax's second attempt to develop an extended-release Parkinson's disease medication was IPX-066. (Nestor, Tr. 2930-31).

270. IPX-066 was a combination of carbidopa and levodopa that had been formulated to extend the release profile of Parkinson's disease drugs. (Cobuzzi, Tr. 2524; *see* Reasons, Tr. 1236).

271. As with Vadova, IPX-066 was intended to better treat Parkinson's patients by allowing for less frequent and more consistent dosing of up to six hours, as well as more consistent motor symptom control. (Nestor, Tr. 2930-31; *see* RX247).

272. By significantly extending the absorption of the drug, IPX-066 would provide "significant improvement of the patient's quality of life." (CX4014 (Hsu, IHT at 38-39)).

273. IPX-066 had reached Phase III clinical trials[11] in 2010 and was marketed under the name Rytary in 2015. (Snowden, Tr. 401; Nestor, Tr. 2930-31).

274. By 2010, Impax had begun efforts to develop a "next generation" of IPX-066. The goal of the next-generation product, which was first designated as IPX-066a and later became known as IPX-203, was to further improve treatment to Parkinson's patients by extending dosing time even longer than IPX-066. (Cobuzzi, Tr. 2599; Nestor, Tr. 2935-36; *see* RX247).

c. Negotiations of the DCA

i. Background to the negotiations

275. In early 2009, Impax approached Endo about a collaboration with respect to Endo's central nervous system drug Frova, which treats migraine headaches. (RX393 at 0014; *see* Nestor, Tr. 2932; Koch, Tr. 318-19; CX4036 (Fatholahi, Dep. at 51-52)).

276. Impax was interested in collaborating with Endo on Frova because the product fit with Impax's focus on central nervous system and neurology products. (Snowden, Tr. 453-54; Nestor, Tr. 2929).

277. Endo rejected Impax's proposal to collaborate on Frova in the early 2009 discussions (F. 275). (Nestor, Tr. 2932).

278. In late 2009, after Endo and Impax began discussions relating to the settlement of the Opana ER

[11] Phase III of clinical development is the last stage of development before submitting a drug application for approval to the FDA. (Nestor, Tr. 3003).

patent litigation (F. 112), Shawn Fatholahi, the head of sales and marketing for Impax's brand division, contacted Ms. Snowden to express his interest in a codevelopment arrangement with Endo on Frova. (Snowden, Tr. 346, 454-55).

279. In October 2009, Impax and Endo discussed a potential business collaboration on Frova and executed a non-disclosure agreement in connection with those discussions. (Snowden, Tr. 455-56; RX359; CX1816).

280. The discussions between Impax and Endo relating to Frova did not result in a collaboration agreement. (Snowden, Tr. 495).

281. In the fall of 2009, in the course of Endo's and Impax's discussions relating to the settlement of the Opana ER patent litigation, Endo became aware of Impax's efforts to develop drugs for Parkinson's disease and expressed an interest. (Koch, Tr. 323-24).

282. In December 2009, Endo and Impax ended their discussions on a potential settlement of the '456 and '933 patent infringement litigation. (Second Set of Joint Stipulations, JX003 ¶17).

ii. Negotiations resume in May 2010

283. On May 17, 2010, Endo and Impax resumed discussions on the potential settlement of the'456 and '933 patent infringement litigation. (Second Set of Joint Stipulations, JX003 ¶21).

284. After discussions relating to settlement of the Opana ER litigation resumed on May 17, 2010, Impax and Endo began discussing a potential joint development agreement and Endo expressed an

interest in marketing IPX-066. (CX0310 at 004; CX4003 (Snowden, IHT at 89-90); Koch, Tr. 320, 323-24).

285. On May 19, 2010, in conjunction with the discussion of a potential collaboration agreement, Mr. Donatiello of Endo confirmed to Ms. Snowden and Mr. Mengler of Impax that the confidential disclosure agreement Endo and Impax had entered as part of negotiations in October 2009 (F. 279) was still in effect. (CX2966 at 002; CX1816 at 001).

286. Between May 17 and 26, 2010, Impax and Endo held two conference calls and exchanged numerous emails and materials regarding IPX-066. (CX2966; RX272 at 0001-03, 0005-08; CX1301 at 112-13; CX0310 at 004-05).

287. At Endo, the senior vice president of corporate development, Dr. Robert Cobuzzi, and his team of employees were responsible for evaluating potential pharmaceutical business deals for further development. Dr. Cobuzzi first learned about a potential collaboration with Impax on IPX-066 from Endo's chief financial officer, Mr. Levin, who was not part of the corporate development group. Dr. Cobuzzi was not involved in the SLA negotiations, and was only vaguely aware of them. (Cobuzzi, Tr. 2513, 2567-68, 2584).

288. On May 19, 2010, David Paterson, Impax's vice president of business development, provided initial written materials on IPX-066 to Dr. Cobuzzi, including a presentation entitled "IPX066: Licensing Opportunity For Parkinson's Disease." The presentation touted the clinical benefits of IPX-066 over Sinemet, the leading carbidopa-levodopa brand

product, and projected a launch of IPX-066 in the United States in the second half of 2012. (CX2966 at 001, 003, 038, 040-45, 73).

289. On May 20, 2010, Dr. Cobuzzi directed his team of employees to work on an opportunity evaluation worksheet ("OEW") to assess a potential collaboration with Impax on IPX- 066. Dr. Cobuzzi noted that IPX-066 will be positioned with Frova, that it is a known molecule, that Endo has looked at the space before, and that it fits with Frova. (CX1006 at 001).

290. On May 21, 2010, Endo asked an outside consulting firm to provide guidance about the potential value of IPX-066, stating: "There is no time for market research on this as we need the forecast by Wed. of next week (that's right, it's not a typo!!) ... . No detailed proposal is needed at this point given the extremely tight timelines ... ." (RX072; Cobuzzi, Tr. 2587).

291. On May 22, 2010, Dr. Paterson of Impax provided Dr. Cobuzzi and a number of additional Endo employees access to a "data room" with "a large amount of IPX-066 related documents." The documents covered: (i) intellectual property/legal; (ii) chemistry, manufacturing, and controls; (iii) commercial; (iv) regulatory; (v) clinical; (vi) clinical pharmacology; and (vii) Impax's unredacted confidential presentation on IPX- 066. (RX272 at 0001).

292. On May 25, 2010, the outside consulting firm hired by Endo (F. 290), informed Dr. Cobuzzi that: its best estimate of peak U.S. revenue for IPX-066 was [redacted]; the data suggest that IPX-066 will be

superior to a comparator drug; and although the current market is heavily genericized, "we think that if the final data continue to show a [redacted], neurologists will push through payer barriers to the drug for at least some of their patients." (RX072, *in camera*).

293. On May 25, 2010, Dr. Cobuzzi directed his staff to help in the assessment of IPX-066, stating: "It is a controlled-release formulation of carbidopa-levodopa for Parkinson's disease that benefits by [redacted]. We have very little time for this evaluation ... . All of the information is available in an e-dataroom ... . As this is an area we know well as a company both in terms of past evaluations, and by virtue of the fact that we previously held the rights to IR Sinemet, this should not be a difficult evaluation." (CX1007 at 001, *in camera*).

294. On May 26, 2010, Mr. Donatiello of Endo sent to Mr. Mengler and Ms. Snowden of Impax two term sheets.[12] The initial term sheet for what evolved into the DCA proposed an option agreement concerning IPX-066 "and all improvements, modifications, derivatives, formulations and line extensions thereof." The term sheet gave Endo the option to receive either the right to co-promote the product to non-neurologists within the United States or to purchase an exclusive license to the product in the United States. Endo would pay Impax a $10 million "Option Fee" upon signing the agreement and a $5 million milestone fee upon the FDA's acceptance of the NDA

[12] The May 26, 2010 term sheet relating to the SLA is discussed in F. 131.

for the product. If Endo exercised the option to co-promote, Endo would receive a fee of 50% "on the net sales" from prescriptions by non-neurologists in the United States. If Endo exercised the option for a license, Endo would pay Impax a one-time license fee based on projected sales. (RX565 at 0002; CX320 at 002-05).

295. On May 27, 2010, Mr. Mengler responded to the May 26, 2010 term sheet (F. 294) that any collaboration would be "for a product I will designate as [IPX]-066a. This is our next generation of [IPX]-066. We have significant data and can name the product at signing." Impax set out milestone payments for the collaboration, beginning with a payment at signing of $3 million, and followed by up to six additional payments of increasing amounts based on reaching specified milestones, for a total of $60 million. (RX318 at 0001 (Impax's response to Endo's initial term sheet) (proposed milestones as follows: signing ($3 million); Phase II initiation ($4 million); Phase II completion ($6 million); Phase III initiation ($8 million); Phase III completion ($11 million); application filing ($13 million); FDA approval ($15 million)).

296. Following a June 1, 2010 in-person meeting between Endo and Impax, internal Impax emails referred to the deal structure for the co-development of IPX-066a. (RX387 at 0001; CX0406 at 001; CX1011).

297. In an internal Impax email dated June 1, 2010, Mr. Mengler described the "current proposal ... [w]ith regard to the R&D collaboration" for "project 066a: milestone funding totaling 40M" including $5 million at signing. Mr. Mengler stated his opinion that

he "like[s] the 40M. 5M guaranteed and the rest is success based. A lot of this depends on how successful we think this program will be - and how much the program will cost." (RX387 at 0001).

298. On June 2, 2010, Mr. Levin of Endo clarified to Impax that Endo's offer for IPX-066a was for an upfront payment of $10 million and a single additional milestone payment of $5 million upon successful completion of Phase II. If Endo elected to exclusively inlicense the compound, Endo would pay Impax five times the projected first four years of sales (rather than three years) as well as give Impax a co-promote on 10% of the total promotion effort. (CX1011).

299. In an internal Impax email dated June 3, 2010, Mr. Mengler stated that the current proposal for the R&D collaboration was a total of $20 million, with half ($10 million) upfront. (CX0114 at 001).

300. On June 3, 2010, Mr. Mengler of Impax and Mr. Levin of Endo reached an agreement in principle on the SLA and the DCA. (CX3334 at 001; CX0412 (Donatiello, IHT at 139)).

301. After Endo rejected Impax's June 4, 2010 proposal for a simple settlement with a July 15, 2011 entry date for Impax's generic version of Opana ER and no compensation terms (F. 155-156), Impax dropped its request for such a settlement and sought Endo's agreement to an increase in the milestone payments under the DCA. (F. 302, 306; Snowden, Tr. 378-80; CX4032 (Snowden, Dep. at 197-99)).

302. On June 4, 2010, Mr. Koch proposed to Endo new terms for the IPX-066a development agreement, with Endo paying Impax $10 million upfront, $20 million more in development milestones, and an

additional $10 million if annual sales were projected to exceed $150 million within the product's first ten years on the market. (CX0410 at 001- 02).

303. In a June 4, 2010 email, Impax informed Endo that IPX-203 was the product that had been designated as IPX-066a and provided Endo with additional information on IPX-203. (CX1311).

304. In an internal Endo email dated June 4, 2010, Mr. Levin stated that he received a call from Impax "looking to recut the economics on the R&D collaboration." (CX1311).

305. In an internal Impax email dated June 4, 2010, Mr. Koch expressed his belief that Mr. Mengler had "dropped" the milestones for the product collaboration too dramatically from the prior proposal of $40 million. Mr. Koch agreed with the proposal's including a $10 million upfront payment. (CX407 at 001).

306. On June 4, 2010, Impax and Endo exchanged first drafts of the SLA and the DCA. After exchanging the first drafts, Impax and Endo continued to negotiate the language of the documents, exchanging numerous drafts and holding at least ten teleconferences between June 4 and June 7, 2010. (CX4003 (Snowden, IHT at 137-38); RX406 at 0001; CX1301 at 114-18; CX0310 at 006-11).

307. On June 7, 2010, Dr. Cobuzzi provided the final opportunity evaluation worksheet on IPX-203 to Endo's executive team, stating: "I believe this OEW provides adequate and fair representation of what I would define as a good deal for Endo." (CX2748).

308. On June 7, 2010, an execution version of the DCA was circulated. (CX0326).

d. Relationship between IPX-066 and IPX-203

309. In 2010, Impax was not looking for a partner in the United States for IPX-066 because Impax planned to market the product domestically on its own, utilizing its established neurologist network. (Snowden, Tr. 456-57; Koch, Tr. 319-20; CX4036 (Fatholahi, Dep. at 77, 80) (Impax "could effectively market [IPX-]066 here in the U.S. ourselves and didn't need any assistance.")).

310. In 2010, Impax had already shouldered all development risks and development costs of IPX-066. Therefore, it made little sense to Impax to share potential profits from the drug with a partner. (Nestor, Tr. 2941-42).

311. Dr. Michael Nestor, the head of Impax's brand division,[13] was "absolutely not" willing to consider an agreement with Endo regarding IPX-066. (Nestor, Tr. 3054-55).

312. Impax ultimately engaged GlaxoSmithKline ("Glaxo") as a partner for marketing IPX- 066 outside the United States and Taiwan. Glaxo would assist with the regulatory and infrastructure hurdles associated with commercializing a product outside the United States and Taiwan and could ensure the

[13] As president of the brand division, Dr. Nestor had to approve any co-development and co-promotion agreement. (Nestor, Tr. 3054-55).

commercialization process proceeded in non- U.S. markets. (Nestor, Tr. 2942-43).

313. In response to Endo's May 26, 2010 proposal for an agreement concerning IPX-066 and all improvements, modifications, derivatives, and line extensions thereof (F. 294), Impax countered on May 27, 2010 that any collaboration would be for IPX-066a. (F. 295; *see also* Snowden, Tr. 405-06 (testifying that "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX-066 and the follow-on product, but Impax wasn't interested in doing the deal on IPX-066. So there wasn't actually ... a switch as much as Endo was trying to negotiate for both product rights and Impax was only interested in doing product rights on the one product.")).

314. IPX-066a, which later became known as IPX-203 (F. 303), was Impax's "next generation" version of IPX-066 and was a planned carbidopa-levodopa-based product that Impax hoped would improve the treatment of Parkinson's disease symptoms and also have favorable dosing over IPX-066. (Reasons, Tr. 1236; *see* Koch, Tr. 320; Nestor, Tr. 2935).

315. At the time of the DCA negotiations, IPX-203 was in the beginning of the formulation stage. Impax had not landed on a final formulation for the product, but, based on the opinion of Dr. Suneel Gupta, the chief scientific officer at Impax in 2010, Impax believed that the product concept for IPX-203 would be "doable." (Nestor, Tr. 2946, 3030-31; RX387 at 0001).

316. Dr. Gupta had expertise in reformulating existing chemical compounds to create commercial

and clinical improvements through reformulation and "is renowned for taking existing compounds and reformulating them and turning those products into very successful drugs in the marketplace that meet significant medical need[s]." When Dr. Gupta tells Impax management that a product concept is "doable," they believe him and rely on his judgment. (CX4033 (Nestor, Dep. at 80-83)).

317. Impax's expertise has long been the development of extended-release technologies, which gives it "the basis of knowledge to know what kinds of things to look for in a formulation that would give you" longer effective time for a Parkinson's disease medication. Such expertise is "a very important asset for" Impax and allows it to regularly "take advantage of that [controlled-release] technology" to compete successfully. (Nestor, Tr. 2955-56; *see* CX4014 (Hsu, IHT at 10, 30) (Impax is "a company specialized in the controlled release" of medications.)).

318. Impax was already planning to withdraw promotion and sampling of IPX-066 (Rytary) once IPX-203 reached the market, allowing patients to continue successful use of IPX- 066 while avoiding any division of Impax's sales force between multiple Parkinson's disease products. This was consistent with the commercial goal of extending the IPX- 066 franchise. (Nestor, Tr. 2935-37).

319. The ultimate goal of IPX-203 was to further extend the amount of time patients have control over their motor symptoms after taking the medication. (Nestor, Tr. 2935 ("the whole idea behind this product ... is to be able to even extend more the effective time that a patient is on IPX-203, meaning that they have

a longer period of time when their motor control symptoms are under control"); CX4014 (Hsu, IHT at 39)).

320. IPX-203 would also employ a "much more simplified" dosing regimen than IPX-066, making it more intuitive for neurologists to prescribe the product. (Nestor, Tr. 2994).

321. Impax projected that the total cost of development for IPX-203 would be between $80 and $100 million. The projected costs were a "natural extrapolation" of the development costs incurred in connection with IPX-066. (Nestor, Tr. 2944-45; Koch, Tr. 321; RX387 at 0001).

e. Due diligence efforts by Endo

i. Review of information regarding IPX-203

322. Impax provided Endo with information regarding Impax's research into the IPX-203 product concept and about how IPX-203 would improve upon existing Parkinson's disease therapies, including IPX-066. (RX377; Cobuzzi, Tr. 2525-26, 2602).

323. The information Impax provided on IPX-203 made clear that IPX-066 and IPX-203 were intended to be [redacted]. (Cobuzzi, Tr. 2530, *in camera*).

324. IPX-203 was intended to be a modification of carbidopa and levodopa, a well-known combination treatment for Parkinson's disease. (CX1209 at 003; Nestor, Tr. 3004; Cobuzzi, Tr. 2524).

325. Levodopa generally is not well absorbed in the colon. (Cobuzzi, Tr. 2535).

326. IPX-203 would have [redacted] (Nestor, Tr. 2950-51, 2957, *in camera*; Cobuzzi, Tr. 2529- 30, 2538, *in camera*).

327. The information Impax provided on IPX-203 [redacted]. (Cobuzzi, Tr. 2530, 2534-35, *in camera*; *see* RX377 at 0031, 0040-41, *in camera*).

ii. Review of information regarding IPX-066

328. Impax sent IPX-066 materials to Endo to "help [Endo] frame their evaluation of the market environment into which IPX-203 could be launched as a successor to IPX-066." (Cobuzzi, Tr. 2539; RX376 at 0001; *see* RX272 at 0001; RX080 at 0006 ("IPX-066 affords a reasonable surrogate for IPX-203 given the anticipated similarities in constituents and formulation.")).

329. Impax sent IPX-066 materials to Endo because (1) Impax had already established a data room regarding IPX-066 when it sought a partner to market the product outside the United States, and (2) IPX-203 was a follow-on product to IPX-066; therefore "the foundational aspects of what was in the data room about IPX-066 were relative to the kind of product we envisioned IPX-203 ultimately to be, which is an extended release carbidopa-levodopa formulation that would offer clinically meaningful benefit[s] over and above what the current standard of care was." (Nestor, Tr. 3055-56).

330. The materials Impax provided regarding IPX-066 aided Endo's assessment of IPX-203 "tremendously." Dr. Cobuzzi explained that IPX-066 was relevant to his assessment of IPX-203 because, among other reasons, both products would contain

carbidopa and levodopa, and the only difference was [redacted], "which we viewed as being relatively simple, although it does change the chemistry." (Cobuzzi, Tr. 2625, 2539-40, *in camera*).

331. Julie McHugh, Endo's chief operating officer at the time of settlement and the individual responsible for assessing the commercial opportunity of any product, deemed IPX-066 an appropriate commercial proxy for assessing IPX-203. (CX2772 at 001; Cobuzzi, Tr. 2541-42).

332. The IPX-066 materials, as well as Endo's experience with other Parkinson's disease treatments, suggested that the successful development of IPX-203 would more effectively treat Parkinson's disease symptoms. (Cobuzzi, Tr. 2634-35).

333. The materials Impax provided regarding IPX-066 showed that IPX-066 was forecasted to have [redacted] in sales by 2019. (RX376 at 0050, *in camera*).

334. Endo used those forecasts (F. 333) to calculate "conservative estimates" for IPX-203 sales. (CX2780 at 001; *see* RX080 at 0011-12; CX2533 at 001 ("I think we can hold to the original forecast assumptions with a shift out in the sales line to reflect the 2017 launch versus the 2013 launch with IMPAX-066.")).

335. Endo's reliance on information about a related drug when evaluating IPX-203 was not unusual. Endo relies on information about one pharmaceutical asset to assess another, related pharmaceutical asset "all the time." (Cobuzzi, Tr. 2624).

336. When information about related pharmaceutical assets is available, it is "much easier" to evaluate a proposed drug than it is to evaluate a new chemical entity on its own. (Cobuzzi, Tr. 2625).

iii. Sufficiency of time and information

337. Dr. Robert Cobuzzi was the head of Endo's corporate development group as well as the lead scientist on the team that evaluated the commercial and scientific merits of the DCA with Impax. (Cobuzzi, Tr. 2523).

338. Dr. Cobuzzi and his team conducted Endo's due diligence review of the DCA. (Cobuzzi, Tr. 2547-48).

339. Dr. Cobuzzi holds a Ph.D. in molecular and cellular biochemistry and wrote his dissertation on Parkinson's disease. (Cobuzzi, Tr. 2511-12).

340. Dr. Cobuzzi's team included at least one other scientist with a background in Parkinson's disease treatments. Dr. Kevin Pong, who was in charge of evaluating Endo's scientific licenses, had a "significant amount of experience" in the area of Parkinson's disease treatments. (Cobuzzi, Tr. 2512-13).

341. Endo also employed an outside consulting firm to provide guidance about the potential value of IPX-066. (RX072).

342. Dr. Cobuzzi believes that Endo had sufficient time to assess IPX-203 before entering into the DCA, particularly in light of Dr. Cobuzzi's and Endo's familiarity with Parkinson's disease treatments (F. 257-261, 293) and the detailed nature of the

information Impax provided on IPX-066 (F. 328-332). (Cobuzzi, Tr. 2543, 2563, 2625).

343. In his May 25, 2010 email to the Endo team performing due diligence on a potential Parkinson's disease treatment collaboration with Impax, Dr. Cobuzzi wrote: "this is an area we know well as a company both in terms of past evaluations, and by virtue of the fact that we previously held the rights to IR Sinemet [another Parkinson's disease treatment], this should not be a difficult evaluation." (CX1007 at 001; Cobuzzi, Tr. 2547-48).

344. Endo knew "the underlying molecules, the carbidopa and levodopa, and we looked at a number of Parkinson's opportunities in the past, so we knew the general landscape of the area in which we were looking at this as a commercial opportunity." (Cobuzzi, Tr. 2548- 49).

345. Taken together, Dr. Cobuzzi believed that Endo had adequate time and "the information [it] needed" to evaluate the DCA properly. (Cobuzzi, Tr. 2563).

f. Endo's valuation of IPX-203

346. Any time Endo considers a pharmaceutical collaboration, it completes an OEW (opportunity evaluation worksheet), which is Endo's standard method of assessing the science, medical information, commercial opportunity, and related financial considerations behind a potential collaboration project. (Cobuzzi, Tr. 2540-41, 2546-47).

347. In Endo's OEW on IPX-203, Dr. Cobuzzi and his team concluded that Endo should enter the DCA. Dr. Cobuzzi made that recommendation to Endo's

CEO, CFO, and board of directors. (Cobuzzi, Tr. 2544, 2561; CX2748 at 001).

i. Commercial aspects

348. Endo's OEW on IPX-203 stated that the DCA was "a good deal for Endo." (CX2748 at 001; *see* Cobuzzi, Tr. 2545-46, 2554; CX4017 (Levin, Dep. at 166-67)).

349. Dr. Cobuzzi recommended the DCA as "an exciting opportunity for Endo" because it "further builds our product pipeline for the future with a drug candidate that fits with our commercial footprint." (CX1209 at 001; Cobuzzi, Tr. 2549-50).

350. In 2010, Endo did not have many products in its commercial pipeline and did not have the capacity to develop new products in-house. (Cobuzzi, Tr. 2515, 2562).

351. Endo's OEW on IPX-203 stated: "[m]arket research provided by Impax is similar to work done several years ago by Endo in evaluating other [Parkinson's disease] related opportunities." (CX1209 at 011).

352. Endo also analyzed the net present value of its initial investment under the DCA. Endo generally requires a 10% rate of return on its investment before agreeing to a development and co-promotion deal. (Cobuzzi, Tr. 2561).

353. Endo determined that the DCA and IPX-203 had a "very reasonable rate of return" of [redacted]. (Cobuzzi, Tr. 2560, *in camera*; CX1209 at 018, *in camera* (estimating net present value of the DCA to be [redacted]); RX080 at 0017, *in camera*).

354. Endo thought it could realize the type of return referenced in F. 353, even though the market for Parkinson's disease treatments was heavily genericized, because IPX-203 would offer a superior product. (CX2748 at 0012; Cobuzzi, Tr. 2622-23).

355. Dr. Cobuzzi explained that "the better [a product] is for the patient or the end user, the more likely they are to want it, need it, or use it," and the more likely that doctors will prescribe the new compound. (Cobuzzi, Tr. 2536-37).

ii. Medical aspects

356. Endo's OEW on IPX-203 stated that market research "indicate[d] that most physicians who treat [Parkinson's] patients are generally satisfied by existing treatment options with two exceptions: 1) existing treatments do not modify the course of the disease, they only palliate symptoms; and, 2) existing drugs begin to lose effectiveness within 10-15 years after initiation of therapy due to the development of feedback inhibition and other biochemical mechanisms that can be classified loosely as 'resistance.' Other unmet needs include a need for better control of efficacy over time ... ." (CX1209 at 011).

357. IPX-203 was intended to address the second exception described in F. 356. Specifically, it would extend the period of time over which the drug is absorbed, which would allow doctors to lower the doses needed for effective treatment. Over time, lower doses would also prevent the drug from losing effectiveness in patients. (Cobuzzi, Tr. 2555; *see* Nestor, Tr. 2935 ("the whole idea behind this product ... is to be able to even extend more the effective time that a patient is

on IPX-203, meaning that they have a longer period of time when their motor control symptoms are under control")).

358. Endo's OEW on IPX-203 (F. 356) explained that "IPX066 has been developed by Impax to address physician[s'] desire for a superior long-acting carbidopa-levodopa product, and IPX-203 represents a still greater improvement in pharmaceutical profile with a value proposition that includes faster onset of action, superior management of motor fluctuations and convenient oral dosing in a simplified regimen that could require no more than twice-daily administration, and in some cases even once-daily administration." (CX1209 at 012).

359. Taking the drug less frequently would be particularly beneficial for Parkinson's patients, who can have trouble "even picking up the pill." (Cobuzzi, Tr. 2557).

360. Dr. Cobuzzi and his team concluded that the attributes ascribed in F. 357-359 (to lower doses and taking drugs less frequently) would make IPX-203 a "greater improvement in disease control and ease of use relative to" IPX-066. (RX080 at 0011).

361. Dr. Cobuzzi and his team concluded that IPX-203 "had the opportunity to move very quickly through development" and "was an exciting compound in that it was made up of... two compounds that have already been approved by the FDA ... ." (CX4017 (Levin, Dep. at 166-67)).

362. Dr. Cobuzzi and his team concluded that there was "a higher than average probability that we might be able to get this drug approved if they were

able to make the modification" envisioned in the IPX-203 product concept. (Cobuzzi, Tr. 2537-38).

363. Dr. Cobuzzi believed that IPX-203 had a path to approval that would successfully bring IPX-203 to the market. (Cobuzzi, Tr. 2552).

iii. Allocation of risk

364. Endo's OEW analysis on IPX-203 explained to Endo's board of directors that the DCA's "deal structure acceptably mitigates Endo's exposure despite the early development stage." (CX1209 at 003; Cobuzzi, Tr. 2543-44 (noting that most of the risk under the DCA was borne by Impax)).

365. One way in which the DCA mitigated risks to Endo is that Endo had to make a single contribution to Impax's development work and would make additional payments only if the "risk associated with proving the concept would have been retired" through successful completion of development milestones such as Phase II clinical trials. Thus, Endo knew its maximum development costs up front even though "[d]rug development is extremely expensive." (Cobuzzi, Tr. 2543-44, 2558; *see* CX1209 at 003).

366. A second way in which the DCA mitigated risks to Endo is that it did not require Endo to perform any development work or otherwise expend internal resources. (Cobuzzi, Tr. 2558-59, 2627-28).

367. A third way in which the DCA mitigated risks to Endo is that Endo retained the same profit-sharing rights no matter how much time or money Impax expended on IPX-203's development. (Cobuzzi, Tr. 2564, 2627-28).

368. These factors (F. 365-367) left Endo "comfortable" with the collaboration from the perspective of risk. (Cobuzzi, Tr. 2543-44).

369. Dr. Cobuzzi believed that the profit-sharing rights Endo received under the DCA justified Endo's payment obligations. (Cobuzzi, Tr. 2564).

370. Compared to other collaboration agreements, Endo's $10 million investment to buy into the IPX-203 opportunity was "not an uncharacteristically large amount of money." (Cobuzzi, Tr. 2559).

g. Impax's valuation of IPX-203 and the DCA

371. Dr. Michael Nestor, president of Impax's brand division, noted in 2010 that he "would hate to have to sell" IPX-203 since the product was envisioned as a better product than, and "a potential franchise extender for," IPX-066. (RX387 at 0001).

372. In negotiating the DCA, Impax initially wanted to retain any profits flowing from prescriptions written by high-prescribing non-neurologists - which were the profits Endo sought under the DCA - because of the "significant" amount of money those prescriptions represented. (RX405 at 0001; *see* CX4033 (Nestor, Dep. at 123); CX1009 at 008 (non-neurologists "manage about 40%" of Parkinson's patients)).

373. Impax knew that there were at least "a couple of thousand physicians who were primary care physicians that prescribed Parkinson's patients, somewhat like a neurologist. So that was the audience that we had envisioned promoting IPX-203 to." (Nestor, Tr. 2948).

374. With the DCA, Impax "got a partner who would fund some of the costs to get [IPX-203] approved." (Koch, Tr. 321).

375. In 2010, Impax did not have the money to begin working on the clinical research for IPX- 203. Impax could not fund the IPX-203 project internally because its shareholders did not "want to see large sums of money being spent over an extended time period on a single product. They were accustomed to R&D investments being made on many individual products that you bring to market as a generic." (Nestor, Tr. 3052-53).

376. Impax needed external funding to move the IPX-203 product forward in development and explored a number of possible funding approaches, including seeking money from venture capital firms. (Nestor, Tr. 2941, 3052-53).

377. When the idea was raised of obtaining funding for IPX-203 through a co-development program with Endo, Impax's brand drug development team was "very excited about that." (Nestor, Tr. 2941).

h. Impax's efforts to develop IPX-203

378. As early as November 2009, Impax had reviewed [redacted]. (Nestor, Tr. 2952-53, *in camera*; RX247, *in camera*).

379. Following execution of the DCA, Impax devoted substantial efforts to IPX-203's development. Impax personnel have spent over [redacted] working on IPX-203 since June 2010. (Nestor, Tr. 2970-71, *in camera*; RX241, *in camera*).

380. In 2010, Impax commissioned preclinical pharmacokinetic studies testing several relevant compounds and began laboratory research. (RX241; RX242).

381. In the course of its development efforts, Impax explored various IPX-203 formulations in an effort to achieve the desired clinical outcome. This involved multiple rounds of pharmacokinetic studies of various formulations to assess their pharmacokinetic profiles, a metric that spoke directly to the clinical improvement Impax was seeking to achieve with the program. (Nestor, Tr. 2961-62; CX0310 at 26-27; RX242; CX3166 at 039-42).

382. Impax completed pharmacokinetic studies of IPX-203 no later than 2012. Impax then conducted additional pharmacokinetic studies and completed Phase I clinical trials. (RX242 (Tab 2012); CX3166 at 039-42; Nestor, Tr. 2957; RX157 at 0020).

383. Impax manufactured a clinical supply of IPX-203, developed protocols for Phase II clinical trials, submitted those protocols to the FDA, and secured FDA approval for efficacy and safety studies in November 2014. (RX157 at 0020).

384. Further development work on IPX-203 was delayed after Impax experienced delays in the development of IPX-066, the brand drug IPX-203 was intended to extend and improve upon. (Reasons, Tr. 1237-38; CX4021 (Ben-Maimon, Dep. at 145) (IPX-066 development was delayed for a "[c]ouple years"); CX4033 (Nestor, Dep. at 135-36)).

385. Bryan Reasons, Impax's current chief financial officer, explained that when IPX-066 was delayed, "resources were put to focus on the approval

of Rytary [IPX-066] so that we could get that to market, grow that ... commercially, and it would also be beneficial to ... when we launched the next generation of [IPX]-203." (Reasons, Tr. 1237-38).

386. Further development work on IPX-203 was also delayed after Impax received an FDA Warning Letter in 2011 relating to Impax's manufacturing processes, which caused Impax to direct its scientific staff to spend their time helping the operations people correct the deficiencies that the FDA noted in its last inspection. (Nestor, Tr. 2968, 2985- 86).

387. Impax's research and development team "worked to help remediate" any issues identified by the FDA and to prepare for "the FDA to come in and do their re-inspection," which meant that "nothing was going to go forward until such time as we got over that hurdle." (Nestor, Tr. 2985-88).

388. Notwithstanding the delays (F. 387) and the DCA's termination (F. 389), Impax has continued development work on IPX-203. (Nestor, Tr. 2970).

389. IPX-203 is currently Impax's "lead compound on the brand side of [its] R&D programs. It's really our strategy to continue to grow and extend the duration of our Parkinson's franchise." (Reasons, Tr. 1238).

390. Impax has now completed Phase II clinical trials for IPX-203 and plans to begin Phase III clinical trials at the beginning of 2018. (Nestor, Tr. 2978; Reasons, Tr. 1238).

391. Phase II clinical trials of IPX-203 revealed a statistically significant improvement in treatment over IPX-066 and other existing treatments, reducing

the amount of time Parkinson's patients are without control over their motor symptoms. (Nestor, Tr. 2978).

392. The Phase II clinical trials of IPX-203 suggest that it will offer an improvement of over two hours in motor symptom control when compared to immediate-release carbidopalevodopa treatments and one hour of improvement over IPX-066. (Nestor, Tr. 2984-85; *see also* RX208 at 0015-16).

393. An improvement of over two hours in motor symptom control over existing medications is a "terrific result" that is "highly statistically significant" and "clinically meaningful." (Nestor, Tr. 2978-79, 2984-85).

394. The Phase II clinical results of IPX-203 suggest that Parkinson's patients will have "their symptoms ... under control for a longer time period," which is "a very important thing" for patients. (Nestor, Tr. 2937, 2966).

395. Impax also sought, and the FDA granted, a special protocol assessment for further clinical trials of IPX-203 in 2017. A special protocol assessment is an agreement between a pharmaceutical company and the FDA regarding the design of clinical trials. When a special protocol assessment is in place, the FDA will not question the trial designs in Phase III clinical trials, which "takes an element of risk out of a new drug application review." (Nestor, Tr. 3001-02).

i. Termination of the DCA

396. Impax's IPX-203 development efforts revealed that the formulation of IPX-203

contemplated by the DCA could not achieve the intended clinical benefits. (Snowden,

Tr. 459-60; *see* Nestor, Tr. 2960-61).

397. Between 2014 and 2015, Impax's research team determined it could not achieve the desired product profile with a [redacted] formulation. Impax consequently began pursuing alternative approaches to an extended-release formulation of carbidopa and levodopa. (Snowden, Tr. 459-60; Nestor, Tr. 2960-61).

398. After extensive research and testing, [redacted]. (Nestor, Tr. 2961-62, *in camera*).

399. In 2014, Impax filed an Investigational New Drug Application with the FDA regarding [redacted], which the FDA accepted. (Nestor, Tr. 2963, *in camera*).

400. Although the specific formulation of IPX-203 changed, Impax still viewed [redacted] it had been developing since 2009 "[b]ecause it was all towards the same end. It still involved carbidopa-levodopa. It was just a variation in formulation." (Nestor, Tr. 2962, *in camera*).

401. Under the terms of the DCA, Impax and Endo formed a joint development committee that was to meet four times a year. These meetings were intended to be "[e]ssentially a progress report on clinical development by Impax." (Nestor, Tr. 3036-37; RX365 at 0016-17 (DCA §§7.2, 7.3); CX3345 at 006).

402. As of 2014, the joint development committee had not met. Michael Nestor, the president of Impax's brand division, explained that Impax really had nothing to discuss with Endo until the formulation work was settled. Once Impax's formulation work had reached that point, Impax met with Endo in 2015 regarding the status of Impax's IPX-203 development

work. (CX3165; Nestor, Tr. 2963-64, 2967-69; CX4033 (Nestor, Dep. at 163-64)).

403. In April 2015, Impax approached Endo to update it on the status of Impax's IPX-203 development work, including the change in formulation strategy. Impax made a presentation describing Impax's formulation testing and results and [redacted]. (Nestor, Tr. 2963-64, *in camera*; RX208, *in camera*).

404. Impax viewed the presentation (F. 403) as a "precursor" to the joint development committee meetings called for by the DCA. (Nestor, Tr. 2967; CX4033 (Nestor, Dep. at 164)).

405. Endo and Impax "had not had a meeting of the joint development committee" before 2015 "because, quite frankly, we really had nothing to discuss with them" until the formulation work was settled. (Nestor, Tr. 2967-69; *see* CX4033 (Nestor, Dep. at 163- 64)).

406. Indeed, Impax "had to make sure we had a formulation first and that we were ready to go into the clinic" before meetings of the joint development committee "would be relevant." (CX4033 (Nestor, Dep. at 163-64); *see* Nestor, Tr. 2967-68).

407. By 2015, Impax had sufficient formulation research, as well as [redacted], to report to Endo. (Nestor, Tr. 2963, *in camera*).

408. During the parties' April 2015 discussion (F. 403), Impax offered to amend the DCA so that the DCA would cover the [redacted] to IPX-203. (Nestor, Tr. 3057, *in camera*; CX2928 at 013, *in camera*).

409. Impax was prepared to amend the DCA to include the new formulation of IPX-203 because it wanted to work with Endo in order to move the drug forward and Impax believed the new formulation would give it "an avenue through which we could continue the development of IPX-203." (Nestor, Tr. 3056-57).

410. Endo initially agreed to the proposed amendment (F. 408), noting that it "would like to maintain or even increase [its] involvement with the development program ... as [it] remain[ed] optimistic this will be a successfully differentiated product, which Endo looks forward to the opportunity to co-promote ... with Impax." (RX218 at 0001; *see* Snowden, Tr. 459-60).

411. Following Endo's initial agreement (F. 410), Impax consequently prepared an amendment to the DCA and expected the parties to continue collaborating on IPX-203. (Snowden, Tr. 458-59; *see* CX2747).

412. Endo subsequently informed Impax that Endo had "decided not to amend the existing agreement" and would no longer "participat[e] in [the] program," but did not provide any explanation. (CX2747).

413. Endo's decision surprised Impax because "fairly recently" Endo "had said the opposite, that they were interested in continuing forward with the program and amending the agreement." (Snowden, Tr. 460-61; RX221 at 0001 (Endo's decision not to amend DCA was "a surprise")).

414. Because Endo retracted its initial expression of interest in amending the DCA to cover the new

formulation for IPX-203, Impax and Endo terminated the DCA by mutual agreement effective December 23, 2015. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶43); Snowden, Tr. 407; RX219 at 0001-02; RX198 at 0005-07 (termination agreement)).

j. Complaint Counsel's experts' opinions

415. Complaint Counsel's expert in pharmaceutical business development agreements, Dr. John Geltosky, has worked on a handful of development deals in their early stages and has never negotiated a development and co-promotion agreement similar to the DCA. The majority of Dr. Geltosky's experience with pharmaceutical collaboration agreements relates to his employment with large pharmaceutical companies and Dr. Geltosky admitted that he could not speak to how the universe of small or mid-sized pharmaceutical companies approach partnerships for early-stage products. (Geltosky, Tr. 1141-45).

416. Dr. Geltosky acknowledged that Endo's senior vice president of corporate development (Dr. Cobuzzi) is better qualified to assess the strategic fit of the DCA for Endo than he is. (Geltosky, Tr. 1163).

i. Bona fide product collaboration

417. Dr. Geltosky did not offer an opinion regarding whether the DCA was a bona fide scientific collaboration or whether Endo exercised good business judgement in entering the DCA. (Geltosky, Tr. 1125-28).

418. Dr. Geltosky acknowledged that the DCA was a way for Impax and Endo to share both risks and costs associated with developing IPX-203. (Geltosky, Tr. 1135).

419. Dr. Geltosky did not offer an opinion regarding whether Endo or Impax bore more of the risk under the DCA and did not quantify any risk related to the DCA or opine what the appropriate payment would be to reflect that risk. (Geltosky, Tr. 1138, 1147).

420. Dr. Geltosky acknowledged that at the time of settlement, Impax estimated costs for the development of IPX-203 to be between $80 and $100 million, that Impax had to cover all development costs in excess of Endo's specified milestone contributions, no matter how much the development work cost, and that Endo's risks and costs associated with developing IPX-203 were limited to the milestone payments. (Geltosky, Tr. 1136-38).

421. Dr. Geltosky's opinion that IPX-203 did not fit within Endo's strategic area of focus was based on his review of certain Endo documents provided to him by Complaint Counsel, which did not list Parkinson's disease as an area of interest, and one of which stated that Endo was interested in near-term revenue generators. In reaching that opinion, Dr. Geltosky did not consider other deals contemplated or completed by Endo. Dr. Geltosky did not have contact with the individuals involved in evaluating the DCA. (Geltosky, Tr. 1159-61).

422. Dr. Geltosky acknowledged that Endo has entered into very-early, discovery-stage pharmaceutical partnership deals and that

pharmaceutical companies enter early-stage development deals "all the time." (Geltosky, Tr. 1145-46).

423. Dr. Geltosky offered no criticism of Impax's behavior with regard to the DCA. (Geltosky, Tr. 1183).

ii. Due diligence

424. Dr. Geltosky reached an opinion of Endo's due diligence efforts in evaluating the DCA based on one document provided to him by Complaint Counsel. (Geltosky, Tr. 1159).

425. Dr. Geltosky admits that Impax provided Endo with comprehensive information regarding IPX-066, including clinical information regarding safety and efficacy, intellectual property, technical due diligence, and financial analysis. (Geltosky, Tr. 1156-58; RX272 at 0005-08).

426. Dr. Geltosky admits that information about IPX-066 provides useful information for IPX- 203 because IPX-203 was a follow-on drug, because the two products could compete, and because, in modeling how IPX-203 might perform in the market, Impax and Endo needed to use IPX-066 as a benchmark. (Geltosky, Tr. 1153-56).

427. Dr. Geltosky did not offer an opinion on whether Endo exercised good business judgment in its due diligence of the DCA. (Geltosky, Tr. 1128).

iii. Valuation

428. Dr. Geltosky has never performed a financial valuation of a pharmaceutical collaboration. (Geltosky, Tr. 1179-80).

429. Dr. Geltosky did not conduct any valuation analysis of the DCA, did not calculate a net present value of the DCA at the time it was executed, and did not conduct any other form of empirical analysis regarding the DCA. (Geltosky, Tr. 1125, 1133).

430. Dr. Geltosky did not offer any opinion about the actual value of the DCA to Endo. (Geltosky, Tr. 1125).

431. Dr. Geltosky did not compare the payment terms in the DCA to the payment terms in other pharmaceutical collaboration agreements. (Geltosky, Tr. 1139-40).

432. Dr. Geltosky did not address the actual value of the profit-sharing rights acquired by Endo or whether Endo's profit-sharing rights justified its DCA payment obligations. (Geltosky, Tr. 1124-25).

433. Dr. Geltosky agreed that Endo's profit-sharing rights remained the same regardless of the development costs incurred by Impax. (Geltosky, Tr. 1137-38).

434. Dr. Geltosky did not offer an opinion regarding whether the profit-sharing provisions in the DCA favored Impax or Endo. (Geltosky, Tr. 1138).

435. Complaint Counsel's economic expert, Professor Noll, acknowledged that, if a payment from a brand company to a generic company is used to purchase a bundle of rights at a fair market price, the payment is justified. (Noll, Tr. 1620).

436. Professor Noll did not independently analyze the DCA to determine whether it was justified, had value to either party, or represented an overpayment. (Noll, Tr. 1456, 1581- 82).

437. Professor Noll relied on Dr. Geltosky's "analysis of the degree to which the $10 million payment and co-development deal represented the acquisition of an asset that was approximately valued at a $10 million price." (Noll, Tr. 1582).

438. Professor Noll agreed that if Dr. Geltosky did not offer an opinion regarding the actual value of the DCA to Endo at the time it was executed, then Professor Noll "would not include the $10 million as part of the large payment that was unjustified." (Noll, Tr. 1585-86).

439. Professor Noll agreed that if Dr. Geltosky did not provide a "sufficiently welldocumented rationale for the conclusion that the payment [under the DCA] was unjustified, then you would pull [the DCA] out of the case." (Noll, Tr. 1582-83).

D. Anticompetitive Effects

1. Harm to competition

440. A basic economic principle is that consumers benefit from increased competition in the form of lower prices and increased choice. (CX5000 (Noll Expert Report at 011 ¶24, *see also* at 109-10 ¶250)).

441. Harm to competition occurs when the conduct of firms on one side of a market (usually sellers) inflict harm on participants on the other side of the market (usually consumers). Harm to competition is not limited to the certain elimination of competition, but also includes eliminating the possibility that participants on the other side of the market will have the opportunity to experience the benefits of competition, such as lower prices. (CX5000 (Noll Expert Report at 011 ¶24)).

442. Normally when a generic drug launches, the competition between the brand-name firm and the generic firm causes the price of the drug to drop, which is a benefit to consumers. Reverse payment settlements can harm consumers, to the extent that the settlement extends the period in which the brand-name firm is the only seller of a drug, by requiring the generic firm to forego entering at an earlier date. (CX5000 (Noll Expert Report at 118, 132 ¶¶268, 300); Noll, Tr. 1425-27).

443. A reverse payment settlement replaces the possibility of successful generic entry with a certainty. To this extent, the brand-name firm is buying an insurance policy by which it pays the generic firm a premium in exchange for the generic firm guaranteeing it will not compete prior to the date specified in the settlement of the patent litigation. (CX5000 (Noll Expert Report at 118 ¶268); Noll, Tr. 1427-28).

444. Payment to an alleged patent infringer, in exchange for a certain entry date, converts the possibility of substantial loss of profits for the patent-holder, due to generic competition, into the certainty that it will continue to earn profits as the sole seller of the drug until the entry date agreed to in the settlement of the patent litigation. (CX5000 (Noll Expert Report at 104 ¶239)).

445. By eliminating the possibility of generic competition for a period of time, reverse payment settlements interfere with the competitive process and can harm consumers by depriving them of the possible benefits of increased competition in the period prior to the entry date provided under the settlement

agreement. (Noll, Tr. 1422-23; CX5000 (Noll Expert Report at 119 ¶269)).

446. A large reverse payment can imply that the market entry date in the settlement agreement is later than the date that the patent holder expected the alleged patent infringer would enter the market since it is unlikely that a patent holder would agree by a settlement to pay an alleged patent infringer anything more than saved litigation costs, only to obtain entry on the date the alleged patent infringer would have entered anyway. (CX5000 (Noll Expert Report at 103-04 ¶238); *see also* Bazerman, Tr. 873-74; CX5001 (Bazerman Expert Report at 006 ¶10) ("[L]itigation costs to the parties increase the viability of a negotiated agreement, as both parties save these costs if they can negotiate an agreement.")).

447. A brand-name pharmaceutical firm has an economic incentive to pay the generic firm as part of a settlement if the payment is less than the profits the brand firm would earn during the period before the agreed-upon entry date of the generic product. (CX5000 (Noll Expert Report at 124-26 ¶¶280, 284-85); CX5001 (Bazerman Expert Report at 023 ¶46) (stating that it is a "common pattern" in the pharmaceutical industry that the brand company's gains from not facing generic competition are greater than the costs to the generic for agreeing not to sell a generic product)).

448. A generic pharmaceutical firm has an economic incentive to enter into reverse payment settlements. By agreeing not to launch its generic product for some period of time, the generic firm loses profits it would earn on sales of its generic product.

However, if the brand-name firm compensates the generic firm with a sufficiently large payment, the generic firm will be willing to postpone its launch until a later date. (CX5000 (Noll Expert Report at 128-29 ¶¶290-92)).

449. The Hatch-Waxman regulatory framework creates additional incentives for pharmaceutical companies to enter into reverse payments. Because of the 180-day exclusivity period granted to first filers (*see* F. 21), by settling with the first filer, the brand company not only eliminates the possibility of entry by the first filer during the period before the generic firm's product's entry date in the agreement, but also eliminates the possibility of market entry for six months beyond this period by other potential generic drug competitors. (CX5000 (Noll Expert Report at 104 ¶239)).

2. At-risk launch

450. Impax would not have launched its generic Opana ER at risk. (F. 451-548).

a. At-risk launches generally

451. Launching a generic product before a non-appealable decision in patent litigation is commonly known as an "at-risk launch." (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-008 ¶23; *see* Koch, Tr. 246; Bingol, Tr. 1282; Hoxie, Tr. 2831).

452. An at-risk launch can occur any time after FDA final approval, including (1) before a district court decision, (2) after a district court decision but before an appellate decision by the Federal Circuit, or (3) after a Federal Circuit opinion if the case is

remanded or otherwise continues. (Hoxie, Tr. 2810-11; CX4021 (Ben-Maimon, Dep. at 133-34); CX4026 (Nguyen, Dep. at 47-48)).

453. If a generic company launches a product before a non-appealable court decision or patent expiration, brand companies can be awarded damages, as measured by the brand seller's own lost profits rather than by the generic seller's earned profits. Lost profits are measured by the profits the patent owner would have made on sales of its branded product but for the launch of the generic product. Damages can be trebled if the infringement is found to be willful, for instance, if the generic product was launched before a district court ruled on the patent dispute. (Koch, Tr. 286-87; Figg, Tr. 1921-23; Hoxie, Tr. 2782; CX4030 (Hsu, Dep. at 48-49)).

454. Generic companies often risk far more in infringement liability than they earn from each sale when launching at risk. (Koch, Tr. 286-87; CX4021 (Ben-Maimon, Dep. at 159) (atrisk launches could result in generic "pay[ing] more to the brand company than [generic] made"); *see also* CX4039 (Noll, Dep. at 74)).

455. The risk of damages for launching at risk represent "bet-the-company" stakes and can "take [away] the solvency of the company entirely." Damages can be in the billions of dollars if the sales of the branded drug are high enough. The profits that the brand company loses would almost always be greater than the total revenues that the generic company receives. (Koch, Tr. 287; Hoxie, Tr. 2782; Figg, Tr. 1922-23; *see* CX4030 (Hsu, Dep. at 43) ("the risk can

be huge depending on the size of the product and depending on whether we're first to file")).

456. A first filer's launch of a generic product triggers the beginning of the 180-day exclusivity period, which is "extremely valuable." If the generic launches at risk and is enjoined from making sales, the generic forfeits some of its 180-day exclusivity because the 180-day time period would continue to run during the period the generic is enjoined. Even if the injunction was eventually lifted or the infringer prevailed in the underlying patent litigation, the patent infringer could never recover the forfeited part of its 180-day exclusivity period. (Snowden, Tr. 503-04; Figg, Tr. 1923-24; Hoxie, Tr. 2754, 2778-80; CX4021 (Ben-Maimon, Dep. at 164-65)).

457. If the branded company wins its action against a generic company that has launched at risk and the generic's actions are deemed "exceptional," courts may award attorney's fees to the brand company. (Figg, Tr. 1924).

458. At-risk launches are fairly uncommon across the entire pharmaceutical industry. (Figg, Tr. 1924-26).

459. At-risk launches are most common when there are multiple ANDA filers who have received approval from the FDA, no ANDA filer has exclusivity, and there subsequently is a race to the market by generic firms. (Hoxie, Tr. 2704-05).

460. When at-risk launches do occur, they generally are undertaken by large pharmaceutical companies that can absorb significant financial risk in the event they are found to infringe. (Figg, Tr. 1925).

461. Complaint Counsel's expert, Professor Noll, identified 48 at-risk launches over a 15-year period (August 2001 thru April 2015). Twenty-one of those forty-eight at-risk launches were conducted by Teva, which Professor Noll explains, "is by far the most likely company to do at-risk launches." (Noll, Tr. 1607-09; CX5004 (Noll Rebuttal Expert Report at 92-99)).

462. Teva is a "very large pharmaceutical company" and, as a result, can undertake at-risk launches more regularly. (Figg, Tr. 1925; *see also* Hoxie, Tr. 2820 (Complaint Counsel's expert noting that Teva has "a high willingness to take risks" and "a greater appetite for risk than others.")).

463. Of the 48 at-risk launches identified by Professor Noll (F. 461), only 4 were conducted by companies with less than $1 billion in revenue. (Noll, Tr. 1609).

464. Mr. Hoxie agreed with industry analysts who empirically analyzed at-risk launches between 2003 and 2009 that, generally, "at-risk launches are fairly uncommon." (Hoxie, Tr. 2827-28).

b. Impax's history of at-risk launches

465. Impax is a small pharmaceutical company. In 2010, Impax's revenues were less than $1 billion. (Koch, Tr. 275, 287; *see* Figg, Tr. 1925; CX3278 at 45 (Impax 2010 Annual Report)).

466. Impax is "incredibly conservative" with respect to at-risk launches. (CX4021 (Ben- Maimon, Dep. at 34); *see* Koch, Tr. 287).

467. Mr. Koch, Impax's CFO at the time of the Endo-Impax Settlement, explained that "being a small

company," Impax "could not bet the company on any one product." (Koch, Tr. 275; *see* CX4018 (Koch, Dep. at 97) (describing risks as "huge")).

468. Impax only "infrequently" considers the possibility of an at-risk launch. (Koch, Tr. 246- 47).

469. Prior to the Endo-Impax patent litigation, Impax had launched a product at risk only once. That at-risk launch was for one dosage strength of a generic version of oxycodone. Impax limited its risk of damages by capping its potential sales at $25 million. Impax launched at risk only after it received a favorable district court decision holding the relevant patents unenforceable and after Teva, the first ANDA filer for the relevant dosage, had launched at risk six months earlier. (Koch, Tr. 274-75; Snowden, Tr. 425-26).

470. The risks to a second generic company launching at risk are lower than the risks associated with an initial at-risk launch because (1) the second generic company does not have first-filer exclusivity at stake, and (2) the patent holder may have a harder time arguing that damages are the result of any one particular generic company's sales. (Hoxie, Tr. 2817-18).

471. Since the Endo-Impax Settlement in 2010, Impax has considered possible at-risk launches. Only one of those launches occurred, and only in a limited manner. (Snowden, Tr. 466-67; CX2927 at 014-19).

472. Impax's one post-settlement at-risk launch involved a drug called azelastine, a nasal spray antihistamine. Impax and Perrigo, the ANDA holder and marketer of azelastine, entered a partnership agreement through which Impax would share

development costs and litigation expenses in return for a share of the drug's profits. In 2014, Perrigo notified Impax that it intended to launch azelastine at risk. Under the terms of the Impax- Perrigo partnership agreement, Impax could participate in the launch and earn a share of the profits or could not participate, in which case Perrigo would receive all azelastine profits. Impax participated in Perrigo's at-risk launch, but limited its exposure to potential damages by capping its participation at 150,000 units. (Snowden, Tr. 462-65; CX4021 (Ben-Maimon, Dep. at 37-39, 153); CX2689 (minutes of special meeting of Impax Board)).

c. Impax's process for approval of an at-risk launch

473. It is an absolute prerequisite for Impax's board of directors to formally approve any atrisk launch. (Koch, Tr. 276-77 ("every at-risk launch is a board-level decision"); Snowden, Tr. 426; CX4030 (Hsu, Dep. at 128); CX4021 (Ben-Maimon, Dep. at 160)).

474. Many steps take place before at an-risk launch is formally approved by Impax's board of directors. F. 474-483.

475. Impax's process for evaluating a possible at-risk launch starts with Impax's new product committee, which evaluates the science, marketing opportunity, and legal issues related to the drug under consideration for an at-risk launch. If Impax's new product committee recommends an at-risk launch, Impax's research and development team conducts further due diligence regarding the drug. (Koch, Tr. 276).

476. When evaluating whether to launch a product at risk, Impax's in-house legal team conducts an analysis regarding the specifics, including any pending patent litigation between Impax and the brand company, and the strength of the underlying patents. (Koch, Tr. 276; CX4021 (Ben-Maimon, Dep. at 166)).

477. When evaluating whether to launch a product at risk, Impax's division heads, including those from the legal, marketing, and operations departments, and from the generics division, meet with Impax's CFO to formulate a risk analysis profile. Impax's CFO must present a risk analysis profile to Impax's executive committee, which has to approve any at-risk launch. (Koch, Tr. 276-77).

478. Impax's CEO must approve any decision to launch at risk. (CX4030 (Hsu, Dep. at 127); CX4021 (Ben-Maimon, Dep. at 167-68)).

479. If Impax's CEO and executive committee approve a possible at-risk launch, a presentation is made to Impax's board of directors by Impax's CFO, legal department, president of the generics division, and the manufacturing department ("Board presentation"). (Koch, Tr. 277; *see* CX2689; CX3223).

480. The Board presentation includes background on the product, the basis for the executive committee's decision to propose an at-risk launch, and a resolution seeking the Board's vote on the matter. (Koch, Tr. 277).

481. Impax's board of directors must formally authorize any at-risk launch. (Koch, Tr. 276-77 ("every at-risk launch is a board-level decision"); Snowden, Tr. 426; CX4021 (Ben- Maimon, Dep. at 160)).

482. For an at-risk launch, Impax has "to have sign off from the Board, because we're such a small company, and a launch at risk would ... potentially cause our company problems if we were hit with damages, big damages." (CX4026 (Nguyen, Dep. at 55-56)).

483. If the Board formally authorizes an at-risk launch, the Board approval is recorded in the board of director's minute book. (Koch, Tr. 286).

484. In the case of azelastine, the nasal spray antihistamine that Impax did launch at risk (F. 472), Impax's senior management, including the president of Impax's generics business, Impax's general counsel, and Impax's in-house attorney responsible for intellectual property, made a presentation and recommendation regarding a limited at-risk launch at a special board of directors meeting. A resolution was then placed before the Board, and the Board voted to approve the resolution. (Snowden, Tr. 463-66; CX4021 (Ben-Maimon, Dep. at 153-54); CX2689 (minutes of special meeting of Impax Board regarding azelastine)).

485. Impax would not launch a product at risk if it did not have Board approval. (Snowden, Tr. 470).

d. Impax did not seek or receive Board approval for an at-risk launch of generic Opana ER

486. Impax did not seek or receive Board approval for an at-risk launch of Opana ER. (F. 487-502).

487. Impax's senior management never decided to pursue an at-risk launch of generic Opana ER.

(Mengler, Tr. 547-48, 584; Koch, Tr. 299, 324-25; Snowden, Tr. 470-71).

488. In 2010, senior management was looking at possible scenarios and modeled an at-risk launch to forecast how that might impact Impax's budget if the decision to launch at risk were made. (Koch, Tr. 299-300; *see* CX4014 (Hsu, IHT at 129-30) ("We could settle, we could launch at risk, we could do many other things, and as the job of CEO, I just have to, you know, lay out everything, get prepared so I don't get accused by the board and say, well, wait a minute, how come you didn't prepare for plan B?")).

489. On May 9, 2010, Impax's CEO, Dr. Hsu, informed Mr. Koch, Impax's CFO, that "[i]t's unlikely we will launch Opana ER this year (I actually prefer not to launch this year for obvious reason[s])." (RX297 at 0002).

490. In response to an internal Impax email reporting that on May 13, 2010, the FDA granted tentative approval to Impax's ANDA for generic Opana ER (F. 64), Dr. Hsu stated that Impax would most likely "make launch decision based on court decision on the PI." (CX2929 at 001; Koch, Tr. 310).

491. After the FDA granted tentative approval to Impax's ANDA for generic Opana ER (F. 64), when customers inquired about the status of Impax's Opana ER product, on May 17, 2010, Todd Engle, a senior member of Impax's sales and marketing team, told members of the Impax sales team that "[a] launch decision has not been made yet. There is nothing we can tell the customers yet." (Engle, Tr. 1778-79; RX323 at 0001).

492. Impax told the court presiding over the Endo-Impax patent litigation on May 20, 2010 that Impax would not launch at risk during trial. (Snowden, Tr. 471-72; RX251).

493. Mr. Mengler, president of Impax's generics division, created a presentation for the May 2010 board of directors meeting, in which he listed an at-risk launch of oxymorphone as a "current assumption" for the purpose of projecting sales of oxymorphone ER. Mr. Mengler's assumptions with respect to possible sales numbers did not "imply or mean that any legal decision ha[d] been made to clear the way for a launch." (CX2662 at 012; Koch, Tr. 337-38; Mengler, Tr. 552-53).

494. The minutes of the meeting of the board of directors meeting on May 25 and 26, 2010 note that Mr. Mengler "expressed the view that [o]xymorphone was a good candidate for an at-risk launch." (CX2663 at 001).

495. Mr. Mengler raised oxymorphone ER at the May 2010 Board meeting to put oxymorphone ER "on the radar" of the Board and to "alert the board as to the product being out there that might get to the point of an at-risk launch." Mr. Mengler discussed potential revenues from oxymorphone ER and told the Board that he thought oxymorphone ER "was a great market opportunity" because it was a "very rapidly growing product." (Mengler, Tr. 584-85; Koch, Tr. 294-95, 300-01).

496. Mr. Koch, who wrote the minutes of the meeting of the board of directors meeting on May 25 and 26, 2010, explained that Mr. Mengler was communicating his evaluation of the oxymorphone

market and sharing that information with the Board because senior management was unsure of what direction it would "ultimately take and ... [did not] want to come back to the board seeking an at-risk launch with them never having heard of it before." (Koch, Tr. 301).

497. Dr. Hsu explained that senior management "want[s] to alert the board that we are considering this [as] one of the scenario[s] so that if we do come up with a final recommendation to the board, there will be no surprise. ... [T]his is very typical." (CX4030 (Hsu, Dep. at 82)).

498. Impax's senior management did not make a recommendation to the Board for an at-risk launch, did not discuss the risk or benefits of an at-risk launch, and did not ask the Board to approve an at-risk launch at the May 25 and 26, 2010 Board meeting. (Koch, Tr. 295, 299; Mengler, Tr. 584-85; Snowden, Tr. 470-71; CX4030 (Hsu, Dep. at 85)).

499. There was no substantive discussion of an at-risk launch at the May 2010 board of directors meeting. (Koch, Tr. 295; Mengler, Tr. 584).

500. If a recommendation, discussion, or approval to launch at risk had been made to or by the board of directors, it would have been "very carefully" recorded in detailed Board meeting minutes, and would include the at-risk launch discussion, the resolution regarding the possible launch, a formal request for a vote, and the actual Board vote about the at-risk launch. No such meeting minutes exist. (Koch, Tr. 289-90, 297-98 ("I would have written the resolution, and there was no resolution for oxymorphone.")).

501. As of June 8, 2010, the Impax board of directors had not been asked to vote on whether or not to launch generic oxymorphone ER at risk. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-009 ¶29; Koch, Tr. 299; CX4030 (Hsu, Dep. at 85)).

502. The board of directors never voted on or approved an at-risk launch of generic oxymorphone ER. (CX4030 (Hsu, Dep. at 85); Koch, Tr. 298-99).

e. Impax's launch preparedness efforts

i. Impax's general preparedness practices

503. Impax generally strives to have its products that have been filed with Paragraph IV certifications ready to launch after the expiration of the Hatch-Waxman Act's 30-month stay. (Engle, Tr. 1768-69).

504. Impax's supply chain department is responsible for producing and packaging Impax's products. Joseph Camargo was Impax's vice president of the supply chain group from 2006 through 2011. (Camargo, Tr. 950-51).

505. Each month, the supply chain group receives from Impax's marketing department a product forecast for the next 18 months which the supply chain group uses to begin routine launch planning. (Camargo, Tr. 958; CX4023 (Hildenbrand, Dep. at 78-79)).

506. When a product is 18 months away from its earliest theoretical launch, the supply chain group begins prelaunch preparation activities. (Camargo, Tr. 958; CX4023 (Hildenbrand, Dep. at 9-12, 79)).

507. Impax uses a computer system called Enterprise Resource Planning ("ERP") and a product launch checklist to plan and track product production projects within the 18- month planning horizon. The ERP system tracks the purchasing of materials, shop floor activities, financials associated with paying suppliers, and other planning activities based on projected batch sizes, necessary materials, and how the product is produced. (Camargo, Tr. 959-61).

508. Once a product is uploaded into the ERP system, the supply chain group undertakes the following tasks: requests a quota from the U.S. Drug Enforcement Agency ("DEA") to purchase any active pharmaceutical ingredients ("API") that are controlled substances; purchases the API and other unique materials necessary to produce the finished product; conducts "process validation" (F. 510) to prove that Impax's manufacturing process is repeatable and makes the product in a satisfactory manner; and produces a "launch inventory build" to ensure that Impax has enough product to meet expected demand on the launchable date. (Camargo, Tr. 964-68).

509. The supply chain group holds monthly meetings called "launch coordination meetings" to assess the status of any products in the 18-month planning horizon, which are chaired by Impax's vice president of supply chain and attended by representatives of all departments who have responsibilities related to the planning of a product launch, including the marketing, purchasing, and regulatory departments. (Camargo, Tr. 962-63).

510. Process validation is an FDA requirement imposed on all pharmaceutical manufacturers to

prove that their manufacturing processes are satisfactory and repeatable. Every product must undergo successful process validation before it can be launched. (Camargo, Tr. 966-67; Koch, Tr. 270).

511. Impax's practice is to begin process validation six months before FDA approval of the relevant drug is expected, even if the product is the subject of active litigation. (Koch, Tr. 269-70; CX3278 at 101 (Impax's 2010 10-K report: "When the Company concludes FDA approval is expected within approximately six months, the Company will generally begin to schedule manufacturing process validation studies as required by the FDA to demonstrate the production process can be scaled up to manufacture commercial batches.").

512. Impax may build pre-launch quantities of the products in its planning pipeline before either FDA approval is granted or a formal launch decision is made. (CX3278 at 101 (Impax's 2010 10-K report: "the Company may build quantities of pre-launch inventories of certain products pending required final FDA approval and/or resolution of patent infringement litigation, when, in the Company's assessment, such action is appropriate to increase the commercial opportunity, FDA approval is expected in the near term, and/or the litigation will be resolved in the Company's favor.")).

513. Impax generally builds pre-launch quantities of products because it takes months to build up launch inventory. (CX4030 (Hsu, Dep. at 42); Koch, Tr. 270-71).

514. Impax considers its production of pre-launch quantities "routine" and consistent with industry practice. (Koch, Tr. 271; CX3278 at 100-01).

515. By having pre-launch quantities ready, Impax is able to "increase the commercial opportunity" for its drugs and have the option of launching if the decision to launch is made. (CX3278 at 100-01; CX4030 (Hsu, Dep. at 86)).

516. Because Impax's operations team prepares products for launch before FDA approval or a formal decision about launch timing, it is not unusual for Impax to discard and write off some of the products and raw materials in its inventory. (Camargo, Tr. 1020-21, 1033 (discarding of products or materials was "a matter of course pretty much every month"); Koch, Tr. 273 (writing off and destroying product is a routine and "small cost" of doing business in the generic industry)).

ii. Impax's launch preparedness efforts for generic Opana ER

517. Impax's operations team sought to be ready to launch its generic oxymorphone ER product at the expiration of the Hatch-Waxman Act's 30-month stay, June 14, 2010. (Mengler, Tr. 558; Engle, Tr. 1769).

518. To meet a June 2010 launch date, Impax began planning oxymorphone ER production in 2009. (Camargo, Tr. 969).

519. The supply chain group created master data for oxymorphone ER in its ERP system to manage production capacity and materials planning and put oxymorphone ER on its product launch checklist to

coordinate all launch-related activities. (Camargo, Tr. 1006).

520. In June 2009, the supply chain group acknowledged that the "odds of launching [oxymorphone in June 2010] when the 30-month stay expires may be low." Mr. Camargo explained that "it didn't seem likely to me that we would actually launch" in mid-2010 because the company "tended to shy away from" at-risk launches and oxymorphone ER would have been an at-risk launch given the ongoing litigation. (RX181; Camargo, Tr. 1009-10).

521. Impax undertook its normal launch preparations for oxymorphone ER to be prepared for a potentially "very lucrative" situation, even if the odds of an actual launch in June 2010 were low because the "upside [was] substantial and ... we may want to plan for" it. (RX181; *see* Camargo, Tr. 1008-10).

522. Because oxymorphone, the API for generic Opana ER, is a controlled substance, purchasing oxymorphone is regulated by the DEA. (Camargo, Tr. 965; CX4027 (Anthony, Dep. at 13-14, 150-51)).

523. Impax requested a procurement quota from the DEA for oxymorphone, a necessary step before it could purchase oxymorphone API for any reason, including to conduct process validation of its oxymorphone ER product. (Camargo, Tr. 974, 1013).

524. Impax was initially allotted 9.0 kg (of anhydrous base) of procurement quota for oxymorphone for 2010 by the DEA. The initial allotment of oxymorphone quota was for product development manufacturing. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX-001-008 ¶24; CX4027 (Anthony, Dep. at 145-48)).

525. On January 18, 2010, Impax submitted a request for additional oxymorphone procurement quota to the DEA, which was approved. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX-001-008 ¶¶25-26).

526. On April 15, 2010, Impax submitted another request for additional oxymorphone procurement quota to the DEA, which was approved. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX-001-008-009 ¶¶27, 30).

527. Impax conducted process validation for oxymorphone ER in 2010. (Camargo, Tr. 1011- 12).

528. Impax used a matrix approach for conducting process validation for its generic Opana ER product. A matrix approach to process validation takes less time, reduces the amount of product produced during the validation process, and ultimately reduces the costs incurred by Impax. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX-001- 009 ¶31; Camargo, Tr. 1012-13).

529. As of May 20, 2010, Impax had completed process validation for the 5 mg, 10 mg, 20 mg, and 40 mg dosages of generic oxymorphone ER. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX-001-008 ¶28).

530. The process validation batches that Impax had built were not sufficient to meet the market demand for a full launch. (Koch, Tr. 292-93).

531. As a general practice, after process validation is complete, the Impax operations team does not build launch inventory without management approval. (Camargo, Tr. 1015-16; RX186 at 0004).

532. In the case of oxymorphone ER, the Impax operations team never received instructions from senior management to begin a launch inventory build. (Camargo, Tr. 1016-17, 1020; CX2898-001 (internal Impax email from Mr. Camargo on May 12, 2010: "[W]e will not commence the launch inventory build until we receive direction to do so from senior mgmt."); RX186 at 0004 (we "await management decision to proceed with 8-lot launch inventory build."); Engle, Tr. 1778-79; RX323 at 0001 (internal Impax email from Mr. Engle on May 17, 2010: "There has been no decision yet to complete the launch build.")).

533. Impax never actually completed a launch inventory build in support of an oxymorphone ER launch. (Camargo, Tr. 1020).

534. By May 28, 2010, Impax's operations team had still not produced enough oxymorphone ER to support a product launch. (Engle, Tr. 1783; CX0006 at 001 (internal Impax email from Todd Engle, Impax's vice president of sales and marketing for the generics division, to Impax's operations team that Impax would need at least one additional lot of 20 mg and three additional lots of 40 mg oxymorphone ER to meet sales estimates for even one month of sales)).

535. Having less than one month's worth of product would have prohibited a product launch because Impax would "rapidly run out of product, and most likely ... would have started to incur penalties from [its] customers for not delivering on time." (Engle, Tr. 1784-85).

536. The time required to produce the necessary amount of oxymorphone ER would have made a

product launch soon after FDA approval in mid-June 2010 impossible. (Engle, Tr. 1780).

537. Impax had solicited letters of intent from four customers asking customers for their good faith estimate of how much product they likely would buy if generic oxymorphone ER came on the market, but Impax did not have any pricing contracts or agreements to purchase with those customers. (CX2868 at 001; CX2882; Engle, Tr. 1780-81, 1797-98).

538. Prior to the Endo-Impax Settlement, Impax's inventory included finished goods of generic oxymorphone ER, including three lots of 10 mg, as well as bright stock[14] of generic oxymorphone ER, including three lots of 5 mg, one lot of 20 mg, and two lots of 40 mg dosage strengths. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX-001-009 ¶32).

539. Based on the cost of materials and labor, the total value of Impax's manufactured oxymorphone ER at the time of Endo-Impax Settlement was $1,387,883. (Camargo, Tr. 994-95).

540. Following the Endo-Impax Settlement in June 2010, Impax accounted for the oxymorphone ER product as likely to be rejected because the product could not be used and the finished goods eventually were destroyed. (Camargo, Tr. 998; Koch, Tr. 273).

541. In June 2010, Impax also possessed oxymorphone API that had not been incorporated into any finished products which may have been used later

[14] Bright stock is product that has been manufactured and placed in bottles, but has not been labeled yet. (Koch, Tr. 253).

to manufacture other products. (Camargo, Tr. 1022; CX2928 at 015).

542. Because Impax seeks to be prepared for all possible outcomes, discarding product "falls under the category of cost of doing business in weighing all your options." (CX4004 (Engle, IHT at 181); *see also* Engle, Tr. 1785-86 ("Throwing away product or discarding product in about a 1.5 million range happens frequently and it - it's not unusual."); Camargo, Tr. 1020-21, 1033 (discarding products or materials was "a matter of course pretty much every month"); Koch, Tr. 273 (discarding and writing off product is a routine and "small cost" of doing business)).

543. Impax wrote off over $1 million worth of non-oxymorphone ER products in April 2010, and $560,000 worth of non-oxymorphone ER product in June 2010. Impax also discarded and wrote off roughly $25 million in finished product in 2017. (CX2905 at 003; CX2896 at 002-03; Camargo, Tr. 1023-24; Engle, Tr. 1786).

f. Economic disincentives

544. Had Impax launched a generic version of Opana ER at risk, Impax's potential liability for damages would have exceeded any profits Impax realized from the launch. (Addanki, Tr. 2379-80; F. 545-546).

545. Impax projected a total of $28 million in potential oxymorphone ER sales over six months in 2010 following an at-risk launch. (CX2662 at 015).

546. Based on Endo documents indicating that at the time of the Endo-Impax Settlement Endo's Opana ER net sales were $20 million per month and an

assumption that Endo had a 90% profit margin on those sales such that Endo's profits were $18 million per month, if Impax sold a month's worth of Opana ER at risk, and if Impax took 50% of Endo's sales, Impax could be risking as much as $9 million per month or $54 million for six months of sales. If Endo showed that Impax's infringement was willful and was awarded treble damages, Impax could be risking as much as $162 million for six months of sales. (CX1106 at 005; Hoxie, Tr. 2784-92).

547. The 180-day exclusivity period starts from the day of launch. If Impax launched at risk and then was subsequently enjoined, the 180-day exclusivity period would continue to run and Impax would forfeit that part of the 180-day exclusivity period. (Addanki, Tr. 2380-81).

548. Because of these economic disincentives for an at-risk launch by Impax (F. 544-547), it "was perfectly reasonable for Impax to view a launch at risk as a losing proposition." (Addanki, Tr. 2380).

g. Complaint Counsel's experts

549. Although Mr. Hoxie identified risks to Impax of an at-risk launch, he did not quantify the risk to Impax from an at-risk launch, conduct a risk-benefit analysis for an at-risk launch by Impax, or evaluate the magnitude of potential lost-profit damages that Impax would have faced if it launched at risk. (Hoxie, Tr. 2760, 2769-70, 2782-83, 2910).

550. Mr. Hoxie did not opine that an at-risk launch would have been a reasonable risk from Impax's perspective. (Hoxie, Tr. 2808).

551. Professor Noll, Complaint Counsel's economic expert, did not analyze Impax's economic incentives to determine whether it was economically rational for Impax to launch at risk. (Noll, Tr. 1601-02).

552. Professor Noll testified that an at-risk launch was a hypothetical possibility, but did not offer an opinion about whether Impax would have launched at risk or when it would have done so, and did not conduct any economic analysis to determine if a launch at risk would have been good, bad, or economically rational for Impax. (Noll, Tr. 1600-06).

3. Launch after litigation

553. At the time of the Endo-Impax Settlement, the outcome of the Endo-Impax patent litigation was uncertain. (RX548 (Figg Expert Report at 0030-31 ¶69)).

554. The outcome of the Endo-Impax patent litigation on appeal, if there was one, was also uncertain. (Figg, Tr. 2007-08, 2046; CX4045 (Figg, Dep. at 132); CX5007 (Hoxie Rebuttal Expert Report at 043 ¶79)).

555. If Impax and Endo had not entered into the Endo-Impax Settlement, the trial in the patent litigation would have continued. (Snowden, Tr. 400-01).

556. Following a trial in the Endo-Impax patent litigation, the parties would have had to wait for the district court to issue findings of fact, conclusions of law, and an order. Based on a review of Hatch-Waxman cases from the district court of New Jersey conducted by Impax's patent litigation expert, Mr.

Figg, a decision would have been issued approximately four to five months after completion of trial, in or around November 2010. (Figg, Tr. 1906-07, 2027-28).

557. Mr. Figg is an attorney specializing in intellectual property, primarily involving the chemical, pharmaceutical, healthcare and biotechnology industries. Mr. Figg has practiced patent law since 1978 and his principal emphasis is patent litigation. He has served as lead counsel in numerous complex patent litigation matters, including Hatch- Waxman litigation, in federal district court and the Federal Circuit Court of Appeals.. (Figg, Tr. 1810; RX548 (Figg Expert Report at 006-08 ¶¶6-10)).

558. Regardless of when the district court would have issued its decision in the Endo-Impax litigation, an appeal was likely, and would take 30 days to be docketed in the Federal Circuit Court of Appeals. (Figg, Tr. 1908).

559. Based on statistics maintained by the Federal Circuit and reviewed by Mr. Figg, the median time from docketing to final decision was approximately eleven months in 2010 and 2011. Applying these statistics, Mr. Figg estimated that an appellate decision in the Endo-Impax patent litigation would have been issued in November 2011. This estimate is "very conservative" because the median time from docketing to a final decision includes settlements and summary affirmances. (Figg, Tr. 1908-09).

560. The Federal Circuit is generous with briefing extensions, which increases the time it takes to receive a decision. (Figg, Tr. 1909-10).

561. If Impax had lost at the trial level, the "centerpiece" of the appeal would have been the trial court's claim construction ruling. Impax would have had "substantial arguments" regarding that ruling on appeal. (Figg, Tr. 1911-12; Hoxie, Tr. 2694).

562. If the appellate court agreed with Impax's arguments regarding the district court's claim construction, it is likely that the appellate court would remand to the trial court for further development of the evidentiary issues. This is because the parties would need to litigate infringement and validity under Impax's construction of the claims. Because the trial court's claim construction ruling was in favor of Endo, Endo never developed a record that Impax infringed its patents under Impax's construction of the claims. Absent a record on the issue of infringement and validity, the Federal Circuit would not decide these issues itself, but would instead direct such decision to the trial court via remand. (Figg, Tr. 1912-13).

563. If the appellate court ruled in favor of Impax and remanded the case to the trial court, the evidentiary proceedings on remand would likely have taken up to 18 months to complete, and therefore would not be concluded until a date close to January 2013. (Figg, Tr. 1914- 15, 1973).

564. If Impax had lost in the Federal Circuit, Impax would be enjoined and would not have been able to launch its oxymorphone ER product until the expiration of the patents in September 2013. (Figg, Tr. 1915, 1973).

E. Procompetitive Benefits

1. Broad license agreement

565. In settlement negotiations with brand companies, Impax would regularly seek a broad patent license whenever it intended to launch and continue to sell its generic product indefinitely, in order to provide Impax with as much flexibility as possible. In any negotiation where the brand company tried to narrow the scope to the patents being litigated, Impax was "very firm," explaining that "this is not about the patents being litigated. This is about a product, and we want the ability to operate." (CX4026 (Nguyen, Dep. at 155-58)).

566. For Impax, every "agreement has to cover all the patent[s], not just the patent [at issue] today, but cover all future patent[s] as well ... [O]therwise you end up with [a] launch [of] the product and still have to be under the [patent] risk, and that doesn't really help [Impax]." (CX4014 (Hsu, IHT at 116)).

567. The SLA contains a broad license agreement and a covenant not to sue that covered all patents "that would ever be owned by [Endo and Penwest] that would cover the Impax product, so the patents that existed at the time as well as future patents" were covered. (Snowden, Tr. 439; RX364 at 009).

568. Section 4.1(a) of the SLA grants Impax a license both to the "Opana ER Patents" (defined in the SLA as the '933, '456, and '250 patents and any reissuances thereof) and to "any patents and patent applications owned by Endo or Penwest ... that cover or could potentially cover the manufacture, use, sale, offer for sale, importation, marketing or distribution of products ... that are the subject of the Impax ANDA

... ." (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-009-10 ¶35).

569. The Settlement and License Agreement identified "the patent applications (and any patents issued thereunder)" as the "Pending Applications." (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-010 ¶36).

570. In section 4.1(b) of the SLA, Endo provided Impax with a covenant not to sue, which prohibited Endo and its affiliates from suing Impax for patent infringement on any of the patents licensed pursuant to section 4.1(a) (F. 568-569). This provision meant that Endo could not sue Impax for infringement of Endo's patents listed in the Orange Book at the time of settlement, as well as any continuations, continuations in part, or divisions of those patents, or patent applications owned or controlled by Endo that could cover the product described in Impax's ANDA for original Opana ER. (RX364 at 0010 (SLA); *see also* Figg, Tr. 1964; Hoxie, Tr. 2885).

2. Endo's additional patents and patent litigation

571. After entering into the SLA, Endo obtained additional patents and patent licenses that it has asserted cover both original and reformulated Opana ER (the "after-acquired patents"). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-012 ¶55).

572. At the time of the Endo-Impax Settlement, some of the after-acquired patents (F. 571) were pending and it was uncertain whether any new patents would issue. (Snowden, Tr. 440, 442-43; CX3455 at 022-23).

a. The Johnson Matthey Patent

573. Endo acquired its first post-settlement patent - U.S. Patent No. 7,851,482 - from Johnson Matthey in March 2012 (the "Johnson Matthey patent"). (Snowden, Tr. 442-43; RX127; Addanki, Tr. 2362; Figg, Tr. 1949).

574. The Johnson Matthey patent addressed a process for making a purified type of oxymorphone and was issued in December 2010. (Snowden, Tr. 443; CX4017 (Levin, Dep. at 150-51); CX3329 at 006).

b. The '060, '122, and '216 patents and New York litigation

575. The Patent and Trademark Office issued U.S. Patent Nos. 8,309,060 and 8,309,122 to Endo on November 13, 2012 ("the '060 and '122 patents"). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-012 ¶56).

576. The Patent and Trademark Office issued U.S. Patent No. 8,329,216 to Endo on December 11, 2012 ("the '216 patent"). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-012 ¶57).

577. In December 2012, Endo began asserting the '060, '122, and '216 patents against drug manufacturers seeking to market generic versions of both original and reformulated Opana ER. At that time, Endo did not assert these patents against Impax's generic version of original Opana ER. Endo did, however, assert these patents against Impax's generic version of reformulated Opana ER, as to which Impax had filed an ANDA. (Joint Stipulations of

Jurisdiction, Law, Fact, and Authenticity, JX001-012-13 ¶58; Snowden, Tr. 440-41, 444-45).

578. In August 2015, the district court for the southern district of New York held that the '122 and '216 patents were not invalid and were infringed by other companies' generic versions of original Opana ER and by generic versions of reformulated Opana ER, including Impax's version of reformulated Opana ER. The court issued an injunction barring all defendants except Impax from selling their generic versions of original Opana ER until 2023. That ruling is currently on appeal to the Federal Circuit. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-013 ¶62; Snowden, Tr. 444-45).

c. The '737 and '779 patents and Delaware litigation

579. The U.S. Patent and Trademark Office issued U.S. Patent No. 8,808,737 to Endo on August 19, 2014 ("the '737 patent"). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-013 ¶59).

580. The U.S. Patent and Trademark Office issued U.S. Patent No. 8,871,779 on October 28, 2014 ("the '779 patent"). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-013 ¶60).

581. Endo also acquired an exclusive field-of-use license to U.S. Patent No. 8,871,779 from Mallinckrodt. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-013 ¶61).

582. The '779 patent specifies the maximum levels of impurity that can be contained in the active

pharmaceutical ingredient for generic Opana ER. (Figg, Tr. 1965).

583. Endo asserted the '737 and '779 patents in litigation in the district court of Delaware against drug manufacturers seeking to market both original and reformulated Opana ER. (Snowden, Tr. 450-51).

584. Endo did not assert these patents (F. 583) against Impax's generic version of original Opana ER because of the SLA's broad license provision, but did assert them with respect to Impax's ANDA for a generic version of reformulated Opana ER. (Snowden, Tr. 450).

585. In November 2015, the federal district court in Delaware held that the '737 patent was invalid. The ruling is currently on appeal to the Federal Circuit. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-013 ¶63).

586. In October 2016, the federal district court in Delaware held that the '779 patent was not invalid and was infringed by a generic version of reformulated Opana ER. That ruling is currently on appeal to the Federal Circuit. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-013 ¶64; *see* Snowden, Tr. 441).

587. In August 2017, the district court in Delaware ruled that the '779 patent was not invalid following a bench trial against certain ANDA filers. In September 2017, Judge Andrews entered a final order, enjoining all defendants from selling generic Opana ER until the patents expire in 2029. (Second Set of Joint Stipulations, JX003 ¶¶56, 58; RX544; RX575).

588. The '779 patent expires in 2029. (Snowden, Tr. 451).

d. The Endo v. Impax New Jersey litigation

589. On May 4, 2016, Endo filed a lawsuit against Impax in federal district court in New Jersey, alleging that Impax was in breach of the SLA for failing to negotiate with Endo in good faith a royalty for three after acquired patents - the '122, '216 and '737 patents. Endo included claims for patent infringement in its complaint, predicated on the alleged breach and termination of the contract, which would have terminated Impax's license under the SLA. (CX2976; Figg, Tr. 2050-51).

590. On August 5, 2017, Endo and Impax resolved the New Jersey litigation (F. 589) regarding the breach of the SLA by entering into a Contract Settlement Agreement. (CX3275).

591. The August 5, 2017 Contract Settlement Agreement (F. 590) includes [redacted]. (CX3275 at 011-15, *in camera*).

3. Effect of the broad license agreement

592. The broad patent license and covenant not to sue provided in the SLA (collectively, the "broad patent license" or "broad license agreement") gave Impax freedom to operate "[u]nder both the litigated patents as well as future patents that Endo might obtain in this area." (Figg, Tr. 1936-37).

593. The broad license agreement in the SLA gave Impax protection against any future patents being asserted against Impax and potentially preventing

continued sales of Impax's generic version of original Opana ER. (Addanki, Tr. 2376).

594. The January 2013 entry date and the broad license agreement in the SLA allowed Impax to launch its product eight months before the original patents expired and sixteen years before the after-acquired patents expired, and to "continue with the sale of that product right up to the present day because ... Endo did not sue Impax for infringement of the second wave patents or the third wave patents for the original Opana ER product." (Figg, Tr. 1971-72; *see* Noll, Tr. 1674).

595. Although every other Opana ER ANDA filer settled patent claims asserted by Endo related to Opana ER, no other drug manufacturer negotiated rights to future Opana ER patents similar to the broad license agreement that Impax obtained in the SLA. (RX441; RX442; RX443; CX3192; *see* Snowden, Tr. 440; Figg, Tr. 1939-40, 1947; Hoxie, Tr. 2714, 2886).

596. Taken together, Endo's acquisition and litigation of additional patents (F. 575-588) has led to all generic manufacturers other than Impax being enjoined from selling a generic version of Opana ER until Endo's patents expire. Impax's product is the only generic Opana ER available to consumers. (Snowden, Tr. 440-42).

597. Impax has sold generic Opana ER without interruption since launching its product in January 2013. (Snowden, Tr. 476).

598. Impax's product is now the only oxymorphone ER product available to consumers. (Second Set of Joint Stipulations, JX003 ¶59; Figg, Tr. 1972).

599. Complaint Counsel's economic expert, Professor Noll, admits that consumers are better off today because Impax is selling oxymorphone ER. (Noll, Tr. 1669).

600. The "real-world effect" of the SLA 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." (Figg, Tr. 1975-76).

III. ANALYSIS

A. Overview of the Case

This is the FTC's first administrative enforcement action challenging an alleged reverse payment patent settlement agreement since the Supreme Court's decision in *FTC v. Actavis*, 133 S. Ct. 2223 (2013). A reverse payment settlement refers to when a patent holder sues another company for patent infringement and the patent litigation is settled with a payment from the patent holder to the claimed infringer and an agreement from the claimed infringer to stay out of the market until a certain date. *In re Lipitor Antitrust Litig.*, 2018 U.S. App. LEXIS 93, *5-6 (3rd Cir. Jan. 3, 2018). A distinguishing feature of a reverse payment settlement is that the period in which the patent challenger agrees to stay out of the market falls within the term of the patent at issue, when the patent holder would normally enjoy a government-conferred monopoly. *Id.* at *6. "[M]ost if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation, and specifically in the context of suits brought under statutory provisions allowing a generic drug manufacturer (seeking speedy marketing approval) to challenge the validity of a

patent owned by an already-approved brand-name[15] drug owner." *Actavis*, 133 S. Ct. at 2227.

Prior to 2013, the federal courts of appeal disagreed as to how to assess the legality of reverse payment settlement agreements. Some circuits followed the "scope-of-the-patent" test, which held that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012); *accord In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro*"), 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212-13 (2d Cir. 2006). The Third Circuit, in *In re K-Dur Antitrust Litigation*, held that reverse payment settlement agreements were presumed unlawful, although the presumption could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offered some procompetitive benefit. 686 F.3d 197, 218 (3d Cir. 2012), *vacated by, remanded by Merck & Co. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013), *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013). The Supreme Court, in *FTC v. Actavis*, resolved the split in the circuit courts, holding that reverse payment patent settlements are not immune from antitrust scrutiny, anticompetitive effects should not be presumed from the presence of a reverse payment alone, and that reverse payment settlements

[15] The terms "brand-name drugs," "branded drugs," or "brand drugs" are used interchangeably by the courts and the parties and in this Initial Decision.

are to be evaluated under the rule of reason, as more fully explained in Section III.B.2, below.

Antitrust inquiries "must always be attuned to the particular structure and circumstances of the industry at issue." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, LLP, 540 U.S. 398, 411 (2004). The distinctive features of the pharmaceutical industry provide the context for assessing the agreement challenged in this case.

1. The Hatch-Waxman Act

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 *et seq*., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§355(b)(2) and 355(j) and 35 U.S.C. §271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

A company seeking to market a new pharmaceutical product must file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"), demonstrating the safety and efficacy of the new product. 21 U.S.C. §355. Pursuant to the Hatch-Waxman Act, the FDA requires a company seeking to market a new pharmaceutical product to identify any patents that the company believes reasonably could be asserted against a generic company that makes, uses, or sells a generic version of the branded product. *See* 21 U.S.C. §§355(b)(1) and (c)(2); 21 C.F.R. §§314.53(b) and (c)(2). These patents are listed in an FDA publication titled,

"Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"). *See King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 395 (3d Cir. 2015).

A company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application ("ANDA") with the FDA. 21 U.S.C. §355(j); *Actavis*, 133 S. Ct. at 2228. The generic applicant must demonstrate that its generic drug is therapeutically equivalent to the brand-name drug that it references and for which it seeks to be a generic substitute. *Id.* When the brand-name drug is covered by one or more patents listed in the Orange Book, a company seeking to market a generic version before the patents expire must make a "Paragraph IV certification" in its ANDA certifying that the listed patents are invalid, unenforceable, and/or will not be infringed by the generic drug. *Id.* If a company makes a Paragraph IV certification, it must notify the patent holder of the filing of its ANDA. *King Drug*, 791 F.3d at 395 n.7.

If the brand-name drug company initiates a patent infringement suit within 45 days of an ANDA filing, the FDA must withhold approval of the generic drug for at least 30 months while the parties litigate the validity or infringement of the patent. *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 241 (3d Cir. 2017), *cert. denied,* 138 S. Ct. 983, 984 (2018) (citing *Actavis*, 133 S. Ct. at 2228; 21 U.S.C. §355(j)(5)(B)(iii)). If a court decides the infringement claim within this 30- month period, then the FDA will follow that determination. *Id.* However, if the litigation is still proceeding at the end of the 30-month period, the FDA may give its

approval to the generic drug manufacturer to begin marketing a generic version of the drug. *Id.* The generic manufacturer then has the option to launch "at risk," meaning that, if the ongoing court proceeding ultimately determines that the patent was valid and infringed, the generic manufacturer will be liable for the brand-name manufacturer's lost profits despite the FDA's approval. *Id.* (citing *King Drug*, 791 F.3d at 396 n.8).

The Hatch-Waxman framework grants the first company to file a Paragraph IV certification ("first filer") a 180-day period of market exclusivity, beginning on the first day of its commercial marketing. *Actavis*, 133 S. Ct. at 2229. The FDA may not grant final approval to any subsequent ANDA filer until the first filer's exclusivity period expires or is forfeited. *Id.* "If the first-to-file generic manufacturer can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars.'" *Id.* (citation omitted).

Although the 180-day exclusivity period enables the first filer to sell its product without competition from other generic companies, it does not prevent the brand-name drug manufacturer from selling its own "authorized generic." *King Drug*, 791 F.3d at 393. An authorized generic, or "AG," is a non-branded version of a brand-name drug that is produced by the brand-name company itself. *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 158 n.37 (3d Cir. 2017). Brand-name companies often introduce AGs to recoup some of the losses they face once a generic drug has entered the market. *See King Drug*, 791 F.3d at 405.

2. Generic drug competition

Generic drugs are unique sources of competition for their brand-name drug counterparts. *See New York v. Actavis PLC*, 787 F.3d 638, 655-56 (2nd Cir. 2015). Generic drugs that are "therapeutically equivalent" to their brand-name counterpart receive an "AB" rating from the FDA. An AB-rated generic drug is the same as a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. F. 14. A generic drug must also contain identical amounts of the same active ingredient(s) as the brandname drug, although its inactive ingredients may vary. F. 14.

An AB-rated generic drug may be automatically substituted for the brand-name drug at the pharmacy counter. F. 29. All 50 states and the District of Columbia have enacted laws that either permit or require a pharmacist to substitute an AB-rated generic drug for the brand-name drug, unless a physician directs or the patient requests otherwise. F. 29.

Generic manufacturers typically charge lower prices than branded drug sellers. F. 31 (The first one or two generic products are typically offered at a 10% to 25% discount to the branded product. Subsequent generic entry creates greater price competition, which typically leads to discounts between 50% to 80% off the brand price). Automatic substitution of the generic drug for the branded drug is the primary way that generic drug companies make their sales. F. 32. Because of the price advantages of generic drugs over branded drugs, many thirdparty payors of prescription drugs (e.g., health insurance plans and

Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. F. 30.

3. Endo-Impax patent litigation and settlement

The FTC's Complaint challenges the agreement entered into between Respondent Impax Laboratories, Inc. ("Impax" or "Respondent") and Endo Pharmaceuticals Inc. ("Endo") to settle patent litigation brought by Endo against Impax ("Endo-Impax patent litigation"). The Endo- Impax patent litigation arose in connection with Endo's branded product, Opana ER.

Opana ER is an extended release form of oxymorphone hydrochloride marketed for the relief of moderate to severe pain. F. 46. Endo's NDA for Opana ER was approved by the FDA in June 2006, and Endo launched the product the following month.[16] F. 46-47. In October 2007, Endo listed three additional patents in the Orange Book as covering Opana ER: U.S. Patent Nos. 7,276,250 ("the '250 patent"), 5,662,933 ("the '933 patent"), and 5,958,456 ("the '456 patent"). F. 51-53.

In November 2007, Impax filed an ANDA seeking to market a generic version of Opana ER and submitted a Paragraph IV certification certifying that Endo's patents were not valid and/or would not be infringed by Impax's generic drug. F. 58-59. Impax

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[16] When Endo launched Opana ER in 2006, it only listed a single patent in the Orange Book as covering Opana ER, U.S. Patent No. 5,128,143 ("the '143 patent"). F. 49. The '143 patent was set to expire in September 2008. F. 50.

was the first to file an ANDA for the 5, 10, 20, 30, and 40 milligram ("mg") dosage strengths of Opana ER. F. 173. Thus, Impax was entitled, upon obtaining FDA approval, to a 180-day period of exclusivity for those dosage strengths without competition from other ANDA filers. F. 174.

On January 25, 2008, Endo sued Impax, alleging that Impax's ANDA for generic oxymorphone ER infringed Endo's '456 and '933 patents. F. 61. This suit triggered the statutory 30-month stay, meaning that the FDA could not approve Impax's ANDA until the earlier of the expiration of 30 months or resolution of the patent dispute in Impax's favor. F. 62. The 30-month stay was set to expire on June 14, 2010. F. 63.

After Impax filed its ANDA, other generic companies, including Actavis South Atlantic LLC ("Actavis"), filed ANDAs seeking to market generic versions of Opana ER before the expiration of Endo's patents. F. 82, 84. Endo sued each ANDA filer for alleged patent infringement. F. 83, 85-86.

On May 13, 2010, a month before the 30-month stay was set to expire, the FDA granted tentative approval to Impax's ANDA. F. 63-64. Impax received final approval on the 5, 10, 20, and 40 mg dosage strengths of generic Opana ER on June 14, 2010, upon expiration of the statutory 30-month stay, and was granted final approval by the FDA for the 30 mg dosage strength on July 22, 2010. F. 66-67. Pursuant to the Hatch-Waxman framework, once Impax received final approval from the FDA, Impax had the option to launch its generic oxymorphone ER product "at risk." F. 66-67, 451-452.

On June 3, 2010, the trial in the patent litigation between Endo and Impax began. F. 73. The parties settled the patent litigation on June 8, 2010 by entering into two agreements: a Settlement and License Agreement ("SLA") and (2) a Development and Co-Promotion Agreement ("DCA") (collectively, the "Endo-Impax Settlement" or the "Challenged Agreement"). F. 74. The DCA was executed simultaneously with the SLA and is incorporated into the SLA. F. 75, 245.

In summary, pursuant to the SLA, Endo granted Impax a license to the '933, '456, and'250 patents, as well as any additional patents then pending or subsequently issued that could cover Impax's generic oxymorphone ER product ("licensed patents"), and Impax agreed not to launch its generic oxymorphone product before January 1, 2013. F. 124-125. Endo also agreed not to sue Impax for patent infringement with respect to any of the licensed patents. F. 126. In addition, Endo agreed in the SLA that Impax's license to sell generic Opana ER would be exclusive during Impax's 180-day first-filer exclusivity period, meaning that Endo agreed not to sell an authorized generic for Opana ER (in the five dosage strengths covered by Impax's ANDA) until Impax's 180-day exclusivity period ended (the "no-AG provision"). F. 127. Furthermore, pursuant to a provision titled "Endo Credit," Endo would be obligated to make a cash payment to Impax in the event Endo's Opana ER dollar sales fell by more than 50% of their quarterly peak, prior to Impax's entering the market with its generic drug. F. 129. In addition, the SLA obligated Impax to pay Endo a 28.5% royalty on Impax's generic Opana ER sales during Impax's 180-day exclusivity

period in the event that sales of Opana ER grew by a specific percentage. F. 128.

Under the DCA, Impax and Endo agreed to collaborate with respect to the development and marketing of a potential treatment for Parkinson's disease, IPX-203. F. 244, 246. Endo agreed to make an upfront payment to Impax of $10 million and to make additional "milestone payments" for achieving specified milestone events in the development and commercialization of the product. F. 247-248. If the product was successfully commercialized, Endo would be entitled to a share of the profits resulting from prescriptions by non-neurologists. F. 250. While Endo agreed to take on some of the costs for the development of IPX-203, with a cap on its contributions based on accomplished milestones, Impax was responsible for all IPX-203 development work. F. 248, 365-366.

B. Overview of Applicable Law

1. Introduction

The Complaint charges that the Endo-Impax Settlement constitutes an agreement to restrain competition and is an unfair trade practice in violation of Section 5(a) of the FTC Act. Complaint ¶¶101, 102.[17] The FTC Act's prohibition of unfair methods of

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[17] Section 5(a)(2) of the FTC Act gives the Commission jurisdiction "to prevent persons, partnerships, or corporations ... from using unfair methods of competition in or affecting commerce ...." 15 U.S.C. §45(a)(2); *Kaiser Aluminum & Chem. Corp. v. FTC*, 652 F.2d 1324, 1327 n.2 (7th Cir. 1981). Respondent develops, manufactures, and markets pharmaceutical drugs. F. 3. Respondent is a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. §44, and Respondent's

competition encompasses violations of Section 1 of the Sherman Act. *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 762 & n.3 (1999). "[T]he analysis under §5 of the FTC Act is the same ... as it would be under §1 of the Sherman Act." *Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 32 (D.C. Cir. 2005); *see also FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 451-52 (1986). Accordingly, Sherman Act jurisprudence is appropriately relied upon in determining whether challenged conduct violates Section 5 of the FTC Act. *Cal. Dental Ass'n*, 526 U.S. at 762 n.3; *Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 824 (6th Cir. 2011).

Section 1 of the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States ... ." 15 U.S.C. §1.[18] Despite its broad language, the ban on contracts in restraint of trade extends only to unreasonable restraints of trade, i.e., restraints that unreasonably

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challenged activities relating to the sale of pharmaceutical drugs are in or affect commerce in the United States, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. §44. F. 1-5. The parties have stipulated that the FTC has jurisdiction over the subject matter of this proceeding and over Respondent Impax. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-002 ¶7). Thus, the Commission has jurisdiction over Respondent and the subject matter of this proceeding, pursuant to Section 5 of the FTC Act.

[18] There is no dispute in this case that there was a contract, combination, or conspiracy. The patent litigation between Endo and Impax relating to Impax's generic Opana ER was settled by agreement of the parties on June 8, 2010. F. 74. "[C]oncerted action may be amply demonstrated by an express agreement." *United States v. Delta Dental*, 943 F. Supp. 172, 175 (D.R.I. 1996).

restrain competition. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997).

2. Antitrust scrutiny of reverse payment settlements: *Actavis*

In *Actavis*, the Supreme Court held that reverse payment patent settlements are not immune from antitrust scrutiny, can sometimes violate the antitrust laws, and are to be evaluated under the rule of reason. By way of background, the FTC's complaint in *Actavis* had alleged that the defendants violated Section 5 of the FTC Act "by unlawfully agreeing 'to share in [the brandname drug manufacturers'] monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with [the brand-name drug] for nine years.'" *Actavis*, 133 S. Ct. at 2230 (citation omitted). The district court held that the allegations did not set forth an antitrust law violation, and dismissed the complaint. *In re Androgel Antitrust Litig., (No. II)*, 687 F. Supp. 2d 1371, 1379 (N.D. Ga. 2010).

On appeal by the FTC, the Court of Appeals for the Eleventh Circuit affirmed. *Watson Pharms*., 677 F.3d 1298. The appellate court held that patent holders have a "lawful right to exclude others from the market," and that a patent "conveys the right to cripple competition." *Id.* at 1307, 1310 (internal quotation marks omitted). The appellate court further reasoned that the public policy in favor of settling litigation weighs against requiring parties to continue to litigate in order to avoid any antitrust liability. *Id.* at 1313-14. *See also e.g., Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072 (11th Cir. 2005) (stating that "[t]he general policy of the law is to favor the

settlement of litigation, and the policy extends to the settlement of patent infringement suits"); *Cipro*, 544 F.3d at 1333 (highlighting the "long-standing policy in the law in favor of settlements, ... [which] extends to patent infringement litigation").

The Supreme Court reversed the lower court's dismissal of the FTC's complaint, holding that "reverse payment settlements ... can sometimes violate the antitrust laws." *Actavis*, 133 S. Ct. at 2227. It rejected the appellate court's scope-of-the-patent test, reasoning that "to refer ... simply to what the holder of a valid patent could do does not by itself answer the antitrust question. The patent ... may or may not be valid, and may or may not be infringed." *Id.* at 2230-31. Thus, even though a patent, if valid and infringed, would confer a right to charge supracompetitive prices and exclude competitors, this fact does not "immunize the agreement from antitrust attack." *Id*. at 2230. Rather, "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly' - and consequently antitrust law immunity - that is conferred by a patent." *Id.* at 2231. The question of antitrust legality can be answered by "considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents." *Id.* at 2231. Furthermore, the Supreme Court held that the fear "that antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of

the settlement," should not be determinative. *Id.* at 2234.

The Court stated that "five sets of considerations lead [the Court] to conclude that the FTC should have been given the opportunity to prove its antitrust claim": (1) reverse payment settlements have the "potential for genuine adverse effects on competition"; (2) such anticompetitive consequences "will at least sometimes prove unjustified"; (3) patent holders often possess market power; (4) litigating patent validity may not be necessary in order to determine whether a settlement is legal under antitrust laws, as "large and unexplained" reverse payment settlements indicate that the patent holder has doubts about the patent's ability to withstand scrutiny; and (5) parties can still settle patent litigation, despite the risk of antitrust scrutiny, by avoiding reverse payment settlements. *Actavis*, 133 S. Ct. at 2234-37.

Regarding the "potential for genuine adverse effects on competition," the Court explained that a reverse payment settlement can amount to "a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." *Id.* at 2234. In such case, the patent holder loses any supracompetitive profits it would have obtained for the remaining life of the patent, which "then would flow in large part to consumers in the form of lower prices." *Id.*

However, a settlement that provides a "payment in return for staying out of the market -simply keeps prices at patentee-set levels, ... while dividing that

return between the challenged patentee and the patent challenger." *Id.* at 2234-35. In that instance, "[t]he patentee and the challenger gain; the consumer loses." *Id.* at 2235. The Court was clear that the relevant anticompetitive harm potentially posed by reverse payment settlements is that the payment is used by the patent holder to avoid the risk of patent invalidation and the resulting generic competition that such patent invalidation would enable. *Id.* at 2236. *See also id.* (stating that the relevant "anticompetitive consequence" is the patent holder's agreement to share supracompetitive profits with the patent challenger, "rather than face what might have been a competitive market ...").

In addition, the Court reasoned that a large and unexplained payment suggests that "the patentee has serious doubts about the patent's survival." *Id.* at 2236. The Court therefore rejected the notion that it would necessarily be required to litigate the validity of the patent in order to resolve the antitrust claim, stating that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id.* at 2236-37 (citing 12 Areeda ¶2046, at 350-52).

The Court summarized the considerations supporting antitrust scrutiny of reverse payment settlements as follows:

> In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to

> explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments. In our view, these considerations, taken together, outweigh the single strong consideration - the desirability of settlements - that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.

Id. at 2237.

Finally, the Court expressly rejected the FTC's argument that reverse payment settlement agreements "are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason.'" *Id.* at 2237. "That is because the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.*

3. Rule of reason framework generally

Actavis holds that the rule of reason applies to evaluating the legality of a reverse payment settlement agreement. 133 S. Ct. at 2237. The rule of reason inquiry asks "whether under all the

circumstances of the case the restrictive practice imposes an unreasonable restraint on competition." *Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332, 343 (1982). A full rule of reason analysis may include an analysis of "'the facts peculiar to the business, the history of the restraint, and the reasons why it was imposed.'" *Realcomp*, 635 F.3d at 825 (citations omitted).

"'[T]here is always something of a sliding scale in appraising reasonableness,' [and] 'the quality of proof required should vary with the circumstances.'" *Cal. Dental Ass'n*, 526 U.S. at 780 (quoting 7 Areeda ¶1507, at 402 (1986)); *Actavis*, 133 S. Ct. at 2237-38. *See also Cal. Dental Ass'n*, 526 U.S. at 781 (holding that rule of reason analysis looks to "the circumstances, details, and logic of a restraint"). As the Court indicated in *Actavis*, trial courts should "structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question - that of the presence of significant unjustified anticompetitive consequences." *Actavis*, 133 S. Ct. at 2238.

Under the traditional burden-shifting framework of the rule of reason, the plaintiff bears the initial burden of proving that the challenged agreement "produced adverse, anti-competitive effects within the relevant product and geographic markets." *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993). *See also Cipro*, 544 F.3d at 1331-32 (The first step in a rule of reason analysis is for the plaintiff to show that the challenged action has had an actual adverse effect

on competition in the relevant market.); *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 506-07 (2d Cir. 2004) (same).

The burden of proving anticompetitive effects in a traditional rule of reason case may be met by proving actual anticompetitive effects in the relevant market, or by "an indirect showing based on a demonstration of defendant's market power, which when combined with the anticompetitive nature of the restraints, provides the necessary confidence to predict the likelihood of anticompetitive effects." *In re Realcomp II, Ltd.*, 2009 FTC LEXIS 250, at *90 (Oct. 30, 2009) (citing *Tops Mkts., Inc. v. Quality Mkts., Inc.*, 142 F.3d 90, 96 (2d Cir. 1998) (plaintiff has "two independent means by which to satisfy the adverse-effect requirement" -direct proof of "actual adverse effect on competition" or "indirectly by establishing ... sufficient market power to cause an adverse effect on competition"); *Law v. NCAA*, 134 F.3d 1010, 1019 (10th Cir. 1998) ("[P]laintiff may establish anticompetitive effect indirectly by proving that the defendant possessed the requisite market power within a defined market or directly by showing actual anticompetitive effects.").

If the plaintiff meets its burden of demonstrating anticompetitive effects, the burden shifts to the defendant to prove procompetitive justifications for the challenged restraint. *Realcomp*, 635 F.3d at 825; *Polygram*, 416 F.3d at 36. "If the defendant is able to demonstrate procompetitive effects, the plaintiff then must prove that the challenged conduct is not reasonably necessary to achieve the legitimate objectives or that those objectives can be achieved in a

substantially less restrictive manner." *Law*, 134 F.3d at 1019. "Ultimately, if these steps are met, the harms and benefits must be weighed against each other in order to judge whether the challenged behavior is, on balance, reasonable." *Id.* The plaintiff bears the overall burden of establishing that the challenged restraints "engendered a net harm" to competition in the relevant market. *Cal. Dental Ass'n v. FTC*, 224 F.3d 942, 957-58 (9th Cir. 2000).

4. Reverse payment cases

A number of courts have addressed the structure for a rule of reason analysis in the reverse payment context, but with somewhat inconsistent results. *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 669 (D. Conn. 2016) (noting that "[v]arious district courts have struggled to fill the gaps that *Actavis* left open, and not always with consistent results.") Moreover, these courts have opined on a rule of reason framework in the context of motions to dismiss and motions for summary judgment, but have not been called upon to apply the rule of reason to a complete evidentiary record developed after trial.[19]

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[19] *In re Nexium (Esomeprazole) Antitrust Litigation*, which was a private cause of action, appears to be the first post-*Actavis* case to be submitted to a jury. *See Am. Sales Co., LLC v. AstraZeneca LP (In re Nexium (Esomeprazole) Antitrust Litig.)*, 842 F.3d 34, 39 (1st Cir. 2016). The appellate court's review of the special verdict form provided to the jury does not clearly address the elements of a rule of reason analysis, for purposes of the instant case. *Nexium*, 842 F.3d at 50, 60 (holding that jury's answers to special verdict form questions on market power, "large and unjustified" payment, and anticompetitive effects, indicated jury found an antitrust violation).

The Court of Appeals for the Third Circuit described a rule of reason framework in *King Drug*, stating:

> The *Actavis* Court provided initial guidance on how to structure rule-of-reason litigation in the reverse payment context. The Court explained that such antitrust questions must be answered "by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents." *Actavis,* 133 S. Ct. at 2231.
>
> First, to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition. "[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Actavis*, 133 S. Ct. at 2237.
>
> Second, the burden then shifts to the defendant to show "that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Id.* at 2235-36. The reverse payment, for example, may amount to no more than a rough approximation of the

> litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform - such as distributing the patented item or helping to develop a market for that item. There may be other justifications. *Id.* at 2236. The Court does not foreclose other justifications, and we need not decide today what those other justifications might be.
>
> Finally, the plaintiff will have the opportunity to rebut the defendant's explanation.

791 F.3d at 412. The court remanded to the district court "to proceed with the litigation under the traditional rule of reason, tailored, as necessary, to the circumstances of th[e] case." *Id.*

In *In re K-Dur Antitrust Litigation*, 2016 U.S. Dist. LEXIS 22982 (D.N.J. Feb. 25, 2016), after examining *Actavis* and subsequent cases, the court adopted the following burden-shifting framework:

> "To make out a prima facie case that a challenged agreement is an unlawful restraint of trade, a plaintiff must show the agreement contains both a limit on the generic challenger's entry into the market and compensation from the patentee to the challenger. The defendants bear the burden of ... coming forward with evidence of litigation costs or valuable collateral products or services that might explain the compensation; if the defendants do so, the plaintiff has the burden of demonstrating the

> compensation exceeds the reasonable value of these. If a prima facie case has been made out, the defendants may come forward with additional justifications to demonstrate the settlement agreement nevertheless is procompetitive. A plaintiff who can dispel these justifications has carried the burden of demonstrating the settlement agreement is an unreasonable restraint of trade ... ."

Id. at *46 (quoting *In re Cipro Cases I & II*, 348 P.3d 845, 871 (Cal. 2015)). *See also K-Dur*, 2016 U.S. Dist. LEXIS 22982, at *44 ("[T]he burden must be on Plaintiffs to show that the settlement delayed the generic company's entry onto the market, that the brand-name company paid the generic company consideration of some kind, and that the consideration exchanged in the settlement exceeded the estimated cost of litigation and the costs of other services and products, in order to establish a prima facie case.").

The approach in *In re Nexium*, 42 F. Supp. 3d 231, 262-63 (D. Mass 2014), is somewhat similar to that of *K-Dur*. The court in *Nexium,* evaluating a motion for summary judgment, held that, for the initial burden, the plaintiff must present evidence that the brand-name manufacturer "made a payment to a generic manufacturer that exceeded anticipated future litigation costs, exceeded the costs of other services, and lacked 'any other convincing justification.'" *Id.* at 262 (quoting *Actavis*, 133 S. Ct. at 2237). Once this showing is made, the burden then shifts to the defendant to show a justification for the payment, "such as avoided litigation costs or fair value for services ... ." *Id.* (quoting *Actavis*, 133 S. Ct. at 2236).

If the defendant justifies the payment, then "the burden shifts back to the [p]laintiff[] to establish, under the rule of reason, that the settlement is nevertheless anticompetitive on balance." *Id*. at 262-63.

Incorporating elements of both *King Drug* and *Nexium*, the district court in *In re Loestrin 24 Fe Antitrust Litigation*, 261 F. Supp. 3d 307 (D.R.I. Aug. 8, 2017), held that the rule of reason in a reverse payment case is applied in a three-step process:

> [A] plaintiff must first "prove anticompetitive effects," by demonstrating "a payment for delay, or, in other words, payment to prevent the risk of competition." *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 412 (3d Cir. 2015) ("*Lamictal*"), cert. denied, 137 S. Ct. 446, 196 L. Ed. 2d 328 (2016) (citing *Actavis*, 133 S. Ct. at 2235-36). "[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Actavis*, 133 S. Ct. at 2237. Second, if the plaintiffs satisfy the first step, "the burden then shifts to the [d]efendants to show that a challenged payment was justified by some precompetitive objective"; and third, "the burden shifts back to the [p]laintiffs to establish, under the rule of reason, that the settlement is nevertheless anticompetitive on

> balance." *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 262-63 (D. Mass. 2014) ("*Nexium II*").

Id. at 329.

The district court in *King Drug Company of Florence v. Cephalon, Inc.* ("*Cephalon*"), 88 F. Supp. 3d 402 (E.D. Pa. 2015), adopted a somewhat different approach. There, the court held that in order to meet the initial burden of proving anticompetitive effects, the plaintiff must demonstrate that the brand-name company made a "large" payment in the settlement agreement and that the brand-name company had market power. *Id.* at 414. The court held that, for purposes of avoiding summary judgment, a payment is sufficiently "large" if there is evidence that the payment exceeded saved litigation costs and a reasonable jury could find that the payment was significant enough to induce the generic company to stay off the market. *Id.* at 417. If the plaintiff meets this burden, the burden shifts to the defendant to demonstrate procompetitive justifications for the reverse payment. *Id.* at 416. The plaintiff "must then rebut those justifications and establish that the 'restraint is not reasonably necessary to achieve the stated objective.'" *Id.* "If the plaintiff provides evidence to rebut the defendant's justifications, the fact-finder will then weigh the anticompetitive and procompetitive effects, as in other rule of reason cases." *Id.*

5. Contentions of the parties as to structure for rule of reason analysis

Complaint Counsel acknowledges that it has the initial burden of proving anticompetitive effects. CCB

at 21. Complaint Counsel contends that it meets its initial burden by proving that Endo induced Impax to accept a share of Endo's monopoly profits in exchange for staying out of the market. Complaint Counsel urges that this is demonstrated by proof that: (1) Endo made a large reverse payment to Impax; and (2) Endo possessed market power. CCB at 23-24, citing *Cephalon*. According to Complaint Counsel, if it proves a large payment and market power, the burden then shifts to Respondent to prove a "legitimate, cognizable justification" for the payment. CCB at 28. Complaint Counsel contends next that if Respondent fails to justify the reverse payment, the antitrust inquiry ends and the agreement is condemned. If Respondent justifies the reverse payment, according to Complaint Counsel, Complaint Counsel may prevail by showing that the reverse payment was not reasonably necessary to achieve the stated objectives, and only if Complaint Counsel fails to make this showing is there any weighing of anticompetitive and procompetitive effects.

Complaint Counsel further asserts that it has no obligation to show that the Challenged Agreement resulted in increased prices for consumers or other payors, or caused an actual delay in the onset of generic competition. Complaint Counsel argues that under *Actavis*, the relevant anticompetitive harm is paying the generic challenger to drop its patent challenge and stay out of the market, thereby avoiding the risk of competition from a finding of patent invalidation or noninfringement. Complaint Counsel further contends that such an agreement harms the competitive process.

Respondent contends that for Complaint Counsel to prove that the Challenged Agreement constitutes an unreasonable restraint under the rule of reason, Complaint Counsel must prove: (1) that the alleged reverse payment was both "large" and "unjustified"; (2) that Endo had monopoly power in a properly defined relevant market; (3) that the Challenged Agreement caused actual anticompetitive effects; and (4) that any alleged less restrictive alternative to the Challenged Agreement was actually feasible. Respondent further contends that the assessment of procompetitive justifications is not limited to justifications for the payment itself, but that the rule of reason considers procompetitive benefits arising from the Challenged Agreement as a whole. Moreover, Respondent asserts, in order to prevail, Complaint Counsel must prove that the asserted anticompetitive effects outweigh the procompetitive benefits.

6. Relevant market

In a traditional rule-of-reason case, the relevant market must be defined to allow a court "to determine the effect that an allegedly illegal act has on competition." *Southeast Mo. Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608, 613 (8th Cir. 2011); *see also Reifert v. S. Cent. Wis. MLS Corp.*, 450 F.3d 312, 320 (7th Cir. 2006).[20] However, several post-*Actavis* cases have evaluated anticompetitive effects of reverse payment

[20] An antitrust market is comprised of a relevant geographic market and a relevant product market. *Brown Shoe Co. v. United States*, 370 U.S. 294, 324 (1962). The parties have stipulated that the relevant geographic market is the United States. Joint Stipulations of Jurisdiction, Law, and Fact, and Authenticity, JX001-002 ¶10.

agreements without a separate determination of the relevant market. *E.g., King Drug*, 791 F.3d at 410 (describing the "market the agreement is said to have protected"); *Wellbutrin*, 868 F.3d 132 at 165 (no mention of relevant market other than stating that the branded drug company's patent prevented market entry by the generic); *Lipitor*, 868 F.3d at 250, 258 (referring only to the "patentee's market"). As explained in *In re Cipro Cases I & II*, although "[p]roving that a restraint has anticompetitive effects often requires the plaintiff to '"delineate a relevant market and show that the defendant plays enough of a role in that market to impair competition significantly,"' i.e., has market power ... . [P]roof of a sufficiently large payment is a surrogate" in reverse payment settlement cases. 348 P.3d at 869 (citations omitted).

In *King Drug*, the Court of Appeals for the Third Circuit, after stating that *Actavis* explained that antitrust questions must be answered '"by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents,"' *Actavis*, 133 S. Ct. at 2231, laid out its own rule of reason framework to use in a reverse payment case. *King Drug*, 791 F.3d at 412. Nowhere in the *King Drug* framework for determining the likelihood of anticompetitive effects, summarized above, does the appellate court direct the district court to define the relevant market. *Id.* Instead, it invited the district court to "proceed with the litigation under the traditional rule of reason, tailored, as necessary, to the circumstances of this case." *Id.* at 412.

As stated by one district court in a reverse payment settlement case, evidence of market power will be available "even without an express articulation of the relevant market definition." *Aggrenox Antitrust Litig.*, 199 F. Supp. 3d at 665.[21] "[A]s a practical matter, the only 'relevant' market in this case, and in similar cases brought under *FTC v. Actavis*, will be the market in which the challenged settlement agreement allegedly acted as an anticompetitive restraint: that is, in this case, it will be implicitly defined by the scope of the disputed patent." *Id.* at 665-66. It is also noteworthy that while *Actavis* itself did not expressly identify the relevant market, it did refer to patent settlements as "allowing the generic manufacturer to enter *the patentee's market*." *Actavis*, 133 S. Ct. at 2237 (emphasis added).

Thus, in the context of a settlement of patent litigation arising under the peculiar framework of the Hatch-Waxman Act, which promotes generic competition and facilitates patent challenges, and where a valid patent gives the brand holder a legal monopoly, the appropriate market in which to assess the anticompetitive effects of a reverse payment settlement agreement is the market that is the subject of that agreement - the branded pharmaceutical product and its generic equivalents. Accordingly, in the instant case, the relevant market is the market for

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[21] The district court certified the ruling regarding the relevance of evidence pertaining to the substitutability of other drugs for the product at issue for interlocutory appeal. *Aggrenox*, 199 F. Supp. 3d at 670. The court of appeals declined to provide interlocutory review. *In re Aggrenox Antitrust Litig.*, Case 3.14-md-02516-SRU (2nd Cir. Jan. 9, 2017).

oxymorphone ER, branded and generic, which is the market that mattered to Impax and Endo, the parties to the Challenged Agreement.

7. Conclusion

Having fully considered *Actavis*, subsequent court decisions, and the parties' arguments, the rule of reason analysis to be applied in the instant case will proceed as set forth below.

First, in order to determine whether the evidence shows any anticompetitive effect in connection with the Challenged Agreement, the analysis will determine whether the Endo-Impax Settlement provided "payment for delay, or, in other words, payment to prevent the risk of competition." *King Drug,* 791 F.3d at 412. The analysis will consider direct evidence from the parties' settlement negotiations, as well as inferences reasonably drawn from the payment's "size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Actavis*, 133 S. Ct. at 2237; *King Drug*, 791 F.3d at 412. *See* Aaron Edlin, The *Actavis* Inference, 67 Rutgers U. L. Rev. 585, 587, 592 (2015) (stating that under *Actavis*, a "reasonable inference of harm to consumers from lessened competition ... can be established by identifying a large and otherwise unexplained payment of cash or something else of value made by the patent holder to the alleged infringer in exchange for that firm's agreement not to enter the market for some period of time. ... [An antitrust plaintiff may also] prove by direct evidence that "the patent holder paid the

alleged infringer to delay its entry into the market and thereby restrict competition ... e.g., if there is other contemporaneous evidence indicating that the purpose and effect of a reverse payment was to delay entry.").

The formulation of the initial burden set forth in *Cephalon*, upon which Complaint Counsel relies, to the extent it holds that anticompetitive effects can be demonstrated solely by proof of a large payment and market power, has not been adopted by any other court[22] and presents an unduly truncated burden of proof. *See Actavis*, 133 S. Ct. at 2238 (noting that trial courts should avoid "the use of antitrust theories too abbreviated to permit proper analysis"). *Realcomp* states that the rationale for substituting proof of market power for proof of actual anticompetitive effects is that proof of market power "when combined with the anticompetitive nature of the [challenged] restraints, provides the necessary confidence to predict the likelihood of anticompetitive effects." 2009 FTC LEXIS 250, at *90. However, *Actavis* does not hold that a "large" reverse payment is anticompetitive "by nature." Rather, it is a large *and unjustified* reverse payment that "can bring with it the risk of significant anticompetitive effects." *Actavis*, 133 S. Ct. at 2237 (emphasis added). Furthermore, in the context of a reverse payment patent settlement, proof of market power adds little in the way of burden because,

[22] Although the Third Circuit in *King Drug* cited the *Cephalon* case in a footnote, it is unclear for what proposition. Furthermore, *King Drug's* articulation of the initial burden of proving anticompetitive effects is clearly different than that set forth in *Cephalon*.

as explained further in Section III.D. below, a large payment is already a strong indicator of market power.[23] *Actavis,* 133 S. Ct. at 2236. Accordingly, the formulation of the initial burden set forth in *Cephalon* is rejected.

For the second step of the rule of reason inquiry, the analysis will consider evidence of procompetitive effects arising from the Endo-Impax Settlement. Consistent with the traditional rule of reason framework, the burden of proving such effects is properly placed on Respondent. *Realcomp*, 635 F.3d at 825; *Polygram*, 416 F.3d at 36 (holding that if the plaintiff meets its burden of demonstrating anticompetitive effects, the burden shifts to the defendant to prove procompetitive justifications for the challenged restraint).

Complaint Counsel's position that the only relevant procompetitive justifications are those that justify the reverse payment, thereby barring all other evidence of procompetitive benefits from the settlement and condemning the settlement on the basis of the reverse payment alone, is inconsistent with *Actavis* and the rule of reason generally. *Actavis* expressly identified "redeeming virtues" of a patent settlement as among the "traditional antitrust factors" that can be considered in evaluating antitrust legality. *Actavis*, 133 S. Ct. at 2231. *See also K-Dur*, 2016 U.S. Dist. LEXIS 22982, at *46 ("If a prima facie case has been made out, the defendants may come

[23] It is noteworthy that market power was not even at issue in *Cephalon*, as the defendants there had "not challenged [p]laintiffs' ability to demonstrate market power." *Cephalon*, 88 F. Supp. 3d at 419.

forward with additional justifications to demonstrate the settlement agreement nevertheless is procompetitive. A plaintiff who can dispel these justifications has carried the burden of demonstrating the settlement agreement is an unreasonable restraint of trade ..."); *see also In re Impax Labs, Inc.*, 2017 FTC LEXIS 130, at *29-32 (Oct. 27, 2017) (refusing to bar evidence and argument concerning post-settlement events). Focusing only on the reverse payment, without any consideration of offsetting procompetitive benefits arising from the settlement, conflates the initial burden of proving anticompetitive effects with the ultimate burden of proving that an agreement is, on the whole, an unreasonable restraint of trade. The "restraint" in a reverse payment settlement agreement is not the payment alone, but the use of the payment to restrain potential generic competition. Simply put, to condemn an agreement based on the reverse payment term alone is an approach that is "too abbreviated to permit proper analysis." *Actavis*, 133 S. Ct. at 2238.

Third, the analysis will consider whether the evidence proves that the demonstrated procompetitive benefits of the Endo-Impax Settlement could have been achieved with a less restrictive agreement.

Fourth, the analysis will weigh the demonstrated anticompetitive effects against the demonstrated procompetitive effects to determine whether the Challenged Agreement is anticompetitive on balance. Such balancing properly considers the extent to which the Endo- Impax Settlement delayed generic competition. *See Impax Labs*, 2017 FTC LEXIS 130, at *29. As recognized in *In re Cipro Cases I & II,* under

Actavis, "the relevant benchmark in evaluating reverse payment patent settlements should be no different from the benchmark in evaluating any other challenged agreement: What would the state of competition have been without the agreement?" 348 P.3d at 863.

The analysis now turns to the application of the foregoing principles to the record in this case.

C. Anticompetitive Harm

Actavis explains that a brand patent holder's use of a payment to induce a generic challenger to drop its patent challenge and agree to stay out of the market, rather than face the risk of patent invalidation and resulting generic competition, is an anticompetitive harm. *Actavis*, 133 S. Ct. at 2236 (for shorthand purposes, alternatively referred to as payment to "prevent" or to "eliminate" the risk of competition). *See also King Drug*, 791 F.3d at 403 (holding that, under *Actavis*, harm occurs when the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger, rather than face what might have been a competitive market). Complaint Counsel has the initial burden of proving anticompetitive harm which, as noted above, in the reverse-payment context, means the burden of proving that the Endo-Impax Settlement included payment to prevent the risk of competition. Complaint Counsel has met this initial burden, as explained below.

1. Economic theory of anticompetitive harm

A basic economic principle is that consumers benefit from increased competition in the form of lower prices and increased choice. F. 440. Harm to

competition is not limited to the certain elimination of competition, but also includes eliminating the possibility that participants on the other side of the market will have the opportunity to experience the benefits of competition, such as lower prices. F. 441.

Normally, when a generic drug manufacturer launches a generic version of a branded drug, the competition between the brand-name firm and the generic firm causes the price of the drug to drop, which is a benefit to consumers. F. 442. Reverse payment settlements can harm consumers, to the extent that, by requiring the generic company to forego the possibility of entering at an earlier date, the settlement extends the period in which the brand-name manufacturer is the only seller of a drug. F. 442.[24] Moreover, a large reverse payment can imply that the market entry date in the settlement agreement is later than the date that the patent holder expected the alleged patent infringer to enter the market. This is based on the theory that it is unlikely that a patent holder would agree by settlement to pay an alleged patent infringer anything more than saved litigation costs, only to obtain entry on the date the alleged patent infringer would have entered anyway. F. 446.

A reverse-payment settlement replaces the possibility of entry by the generic drug with the certainty that generic competition will not occur prior to an agreed date. F. 443. To this extent, the brand-name firm is buying an insurance policy, by which it

[24] This theory of economic harm assumes that issues of patent validity and/or infringement were pending and unresolved at the time of settlement.

pays the generic company a premium in exchange for the generic firm's guaranteeing it will not compete prior to the date specified in the settlement. F. 443. Payment to an alleged infringer, in exchange for a certain entry date, converts the possibility of substantial loss of profits for the patent-holder, due to generic competition, into the certainty that the brand manufacturer will continue to earn profits as the sole seller of the drug, until the agreed entry date set by the settlement. F. 444. By eliminating the possibility of generic competition for a period of time, reverse-payment settlements interfere with the competitive process and can harm consumers by depriving them of the possible benefits of increased competition in the period prior to the entry date provided under the settlement. F. 445.

A brand-name pharmaceutical firm has an economic incentive to pay the generic firm as part of a settlement, to the extent that the payment is less than the profits the brand firm would earn during the period before the agreed-upon generic entry date. F. 447. A generic pharmaceutical firm also has an economic incentive to enter into reverse-payment settlements. F. 448. While the generic firm stands to lose profits it would have earned by launching prior to the agreed-upon date, a sufficiently large payment can compensate for that loss and thereby induce the generic company to forego the opportunity to launch earlier than the agreed-upon date. F. 448.

2. Size of the payment

a. Applicable legal principles

Under *Actavis*, the size of the reverse payment is central to the antitrust inquiry, and therefore the

reviewing court or factfinder must measure the value of the payment. *Rochester Drug Co-Operative, Inc. v. Warner Chilcott Co. (In re Loestrin 24 Fe Antitrust Litig.)*, 814 F.3d 538, 551-52 (1st Cir. 2016). While *Actavis* refers to "large" and "unexplained," or "unjustified," payments as being material to the evaluation of a reverse payment settlement, the Court did not specify what makes a payment "large." *Cephalon*, 88 F. Supp. 3d at 416 ("*Actavis* did not identify any specific formula for determining whether a reverse payment is sufficiently large.").

The fact-finder must determine the value of the reverse payment in order to determine the payment's size. *Loestrin*, 814 F.3d at 551-52. Valuing the payment is particularly important in the case of non-cash payments, such as the no-AG provision challenged in the instant case. Although it is settled that *Actavis* applies to non-cash payments, *see, e.g.*, *King Drug*, 791 F.3d at 403; *Loestrin*, 814 F.3d at 549-50, there must be a reliable calculation of the payment's value. *Lipitor*, 868 F.3d at 255 (upholding complaint based on plausible allegations that non-monetary payment was worth "hundreds of millions of dollars," noting that "more detailed, advanced calculations related to those allegations" come later in the proceeding); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 244 (D. Conn. 2015) ("[C]ourts interpreting *Actavis*, while holding that reverse 'payments' are not limited to cash transfers, have observed the importance of the court's ability to calculate the value of any nonmonetary payments ..."). Furthermore, the value of the payment must be assessed at the time the parties entered into the settlement. *Loestrin 24 Fe Antitrust Litig.*, 261 F.

Supp. 3d at 337 ("The deal must be valued at the time the parties entered the deal ...").

In addition, the size of a reverse payment is properly determined by considering the total compensation provided under the settlement, as a whole, rather than examining each component of the settlement in a piecemeal fashion. *Loestrin*, 261 F. Supp. 3d at 331. *See also In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 718 (N.D. Ill. 2016) (refusing to assess components of the settlement in a "piecemeal fashion" to determine whether "each individual payment fails to rise to the level of a large and unjustified payment" in favor of "determin[ing] whether, when taken as a whole, the total payment ... was large and unjustified"). This is particularly true where, as here, the Challenged Agreement consists of both the SLA and the DCA, executed the same day. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) ("[D]efendants may not improperly 'dismember' [the complaint] by examining each of the three settlement agreements in isolation. Rather, the Licensing Agreement must be read in conjunction with the Co-Promotion and Manufacturing Agreements executed that same day.").

The fact that a payment exceeds saved litigation costs is a relevant benchmark in assessing whether a payment is "large," but it is not dispositive. Even if a payment exceeds saved litigation costs, "the *Actavis* factors - the size of the payments, their scale in relation to litigation costs, their independence from other services for which they might be fair

consideration, and any other convincing justification - still matter." *Aggrenox*, 94 F. Supp. 3d at 243.

Actavis noted that a large payment may provide "strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits ... ." 133 S. Ct. at 2235. Interpreting *Actavis*, a number of courts have considered whether the payment induced the patent challenger to drop its patent challenge and stay out of the market until the agreed date. *See King Drug*, 791 F. 3d at 411 (upholding allegations of anticompetitive harm, noting that the promise of no authorized-generic competition during the generic's 180-day exclusivity period was alleged to have induced the generic to drop the patent challenge and thereby enabled the brand to avoid the risk of patent invalidation); *Loestrin*, 814 F.3d at 550 (holding that *Actavis* applies to payments that "induce the generic to abandon a patent challenge"). *See also Cephalon*, 88 F. Supp. 3d at 417 (holding that, in addition to considering whether a payment exceeded saved litigation costs, determination of "large" payment must also consider whether the payment was sufficiently large to induce the generic to forfeit its claim and agree to stay off the market).

With the foregoing principles in mind, the analysis now assesses the value of the reverse payment provided under the Endo-Impax Settlement.

b. Valuation

The Endo-Impax Settlement provided a cash payment in the amount of $10 million, pursuant to the terms of the DCA. F. 247. In addition to the $10 million cash payment under the DCA, pursuant to the

terms of the SLA, as further explained below, the Endo-Impax Settlement included a non-cash payment, in the form of a no-AG provision, under which Endo agreed not to compete with Impax during Impax's 180-day exclusivity period by launching an authorized generic. In addition, the Endo-Impax Settlement provided Impax with security for the value conveyed by the no-AG provision in the form of the Endo Credit.

i. No-AG provision

Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30, and 40 mg dosage strengths of oxymorphone ER. F. 58. As the first filer on these dosages, Impax would be entitled to a 180-day exclusivity period as to the five most popular dosages of Opana ER, comprising 95% of Endo's Opana ER sales. F. 173-174. However, Impax's 180-day exclusivity period was not a bar to Endo's launching an authorized generic during that exclusivity period because the Hatch-Waxman Act does not prevent a brand-name drug company from launching an authorized generic. F. 21-22, 176. At the time Endo and Impax reached a settlement of their patent litigation, Impax did not know whether or not, absent the settlement, Endo would launch an authorized generic. F. 186. The no-AG provision guaranteed to Impax that Impax would be the only seller of generic Opana ER during its first 180 days on the market and would not face competition from an Endo authorized generic. F. 187.

The no-AG provision was valuable to Impax. Impax would generally seek a no-AG provision as part of a settlement agreement with a brand-name drug manufacturer. F. 182. Indeed, along with obtaining

the earliest possible entry date, a no-AG agreement is among the more important things that Impax would seek in a negotiation. F. 183. A first-filer generic manufacturer makes a substantial portion of its profits during the 180-day exclusivity period, and the introduction of an authorized generic during that exclusivity period reduces the value of the exclusivity period, by causing lower prices and fewer sales for the first filer. F. 172.

Impax witnesses acknowledged that the absence of an authorized generic means more control for the generic company, which can often lead to higher profits for the generic company. F. 182. Conversely, the introduction of an authorized generic during the exclusivity period reduces the value of the 180-day exclusivity period, by causing lower prices and fewer sales for the first filer. F. 172. Specifically, as Impax witnesses testified, an authorized generic competitor during the 180-day exclusivity period generally results in a price decrease of approximately 30 to 35%, and reduces the generic company's share of generic sales. F. 177. Impax executives estimated that if Endo launched an authorized generic when Impax entered the market, Endo's authorized generic would capture as much as half of the sales of generic Opana ER and cause substantially lower generic prices during the exclusivity period than would be the case if Impax was the only generic seller. F. 181.

In May 2010, Todd Engle, of Impax's sales and marketing team, prepared an analysis that projected lost profits in the amount of $24.5 million if an Endo AG entered within two to four weeks after Impax's launch of generic oxymorphone ER. F. 191. In

addition, in 2010, Impax forecasted the effect of an Endo AG on Impax's expected generic sales. F. 189. In what Impax referred to as the "upside" scenario, Impax assumed that Endo's authorized generic Opana ER would enter the market about two months after Impax's launch of generic Opana ER. F. 189. Under the upside scenario, Impax's share of generic sales was estimated to fall to 60% and Impax's average price was estimated to fall by 36%. F. 189. In what Impax referred to as its "base" scenario, Impax assumed that Endo's authorized generic Opana ER would enter the market simultaneously with Impax. Under the base scenario, it was estimated that Endo would capture half of the market and that prices would fall by the same 36%. F. 189.

Employing the figures from Impax's 2010 forecasts, Complaint Counsel's economic expert witness, Professor Roger Noll, calculated that: (1) under Impax's upside scenario, market entry by an authorized generic during Impax's 180-day exclusivity period would cause Impax's revenues to fall by approximately $23 million; and (2) under Impax's base assumptions, market entry by an authorized generic during Impax's 180-day exclusivity period would cause Impax's revenues to fall by approximately $33 million. F. 190.

Respondent contends that, notwithstanding the value to Impax, the no-AG provision had little value to Endo because Endo offered the no-AG agreement as part of its initial settlement offer to Impax. *See* F. 131. However, this fact does not compel the inference that the no-AG agreement was worthless to Endo. Moreover, evidence contemporaneous to the parties'

negotiations shows that Endo estimated that, if Impax launched at risk, Endo could recoup $25 million in lost revenues by launching an authorized generic to compete with Impax. F. 192; *see also* F. 175.

Respondent also contends that it was not guaranteed to receive the value of the no-AG agreement because Endo was planning to reformulate Opana ER and remove original Opana ER from the market, which could render the no-AG agreement illusory and potentially defeat Impax's generic market opportunity entirely. However, the evidence shows that Endo agreed to compensate Impax for this possibility, and to insure the value of the no-AG provision, by agreeing to the Endo Credit, as further explained in subsection 2.b.ii below.

Based on the foregoing, the no-AG provision in the SLA was worth between $23 and $33 million in projected sales revenue to Impax at the time Impax entered into the SLA. F. 193. By agreeing not to compete with Impax through launching an authorized generic, Endo was promising to provide Impax with a monopoly on generic sales of Opana ER during Impax's 180- day exclusivity period, which would enable Impax to charge a higher price for generic Opana ER compared to a market that had two companies selling generic products. F. 187-189, 191. *See also* F. 190 (expert opinion that the no-AG provision provided substantial value to Impax when the SLA was executed by ensuring that Impax would face no generic competition during its 180-day exclusivity period and would thereby earn greater profits on its generic sales).

ii. Endo Credit

Under section 4.4 of the SLA, titled "Endo Credit," Endo agreed to make a cash payment to Impax in the event that Endo's Opana ER sales fell by more than 50% from the "Quarterly Peak" (defined as the highest sales quarter between the third quarter of 2010 and the third quarter of 2012) to the fourth quarter of 2012 (the last quarter before the agreed generic entry date of January 2013). F. 195. The formula for calculating the Endo Credit incorporates a number of factors that relate to Impax's sales of generic Opana ER, multiplied by the market opportunity for the generic product in the quarter of peak sales. F. 196. Specifically, the agreement relies on Impax's "Market Share Profit Value," defined as the product of (1) an assumed generic substitution rate for original Opana ER (90%), (2) an assumed net realized generic price discounted from the brand-name price (75%), (3) an assumed generic profit margin (87.5%), (4) 50% (expressing the 180-day exclusivity period as half of a year), and (5) the annualized sales of Opana ER during the quarter of peak sales for Opana ER during the period from the third quarter of 2010 to the third quarter of 2012, divided by 100.[25] F. 196.

(a) Purpose of Endo Credit

As further explained below, the intent and the design of the Endo Credit were to provide Impax with a payment approximating the profits Impax would

[25] Although in 2013, the Endo Credit formula yielded a payment to Impax in the amount of $102 million, this is not the appropriate measure of the value of the Endo Credit, for the reasons explained in subsection b.ii.(c) below.

lose if, during the two and a half year time period between the June 2010 settlement and the agreed January 2013 Impax entry date, Endo launched a reformulated version of Opana ER in such a way as to substantially eliminate the market for original Opana ER. In this scenario, Impax stood to lose the value of its 180-day exclusivity period, including the generic monopoly during this period that Endo promised to Impax in the no-AG provision. The Endo Credit was designed to make Impax whole for this potential loss. To understand the role of the Endo Credit in the reverse payment conferred to Impax under the Endo-Impax Settlement, a review of the parties' negotiations is helpful.

Endo sent Impax an initial term sheet for the SLA on May 26, 2010. F. 131. The initial term sheet for the SLA included, among other things, a no-AG provision and a generic entry date of March 2013. F. 131-132. Impax accepted the no-AG offer, but counter-offered a generic entry date of January 1, 2013, plus "certain acceleration triggers, including market degradation to any alternate product." F. 136-137. An acceleration trigger for market degradation would have allowed Impax to launch its generic oxymorphone ER product earlier than January 1, 2013, in the event that Opana ER brand sales fell by a certain amount or percentage. F. 138.

Impax wanted a market acceleration trigger as "protection in case Endo had any intentions of moving the market to a next-generation product." F. 139. Impax had included similar provisions in other patent settlements with brand companies. F. 139. Although Impax did not have specific information about Endo's

plans to reformulate Opana ER, Impax had seen analyst reports suggesting that Endo was working on crush-resistant drugs generally.[26] F. 140- 141. Impax was aware that the FDA had been encouraging opioid manufacturers to make opioids tamper-resistant, which companies were accomplishing primarily by manufacturing tablets that could not be crushed. F. 142. Impax was also aware that Purdue Pharma, L.P., the manufacturer of the brand-name drug OxyContin, had introduced a reformulated, crush-resistant version of its product and was withdrawing its original formulation. F. 143.

Pharmacists are allowed or sometimes required to dispense an AB-rated generic version of a drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise. F. 29. Automatic substitution of the generic drug for the branded drug is the primary way that generics make their sales. F. 32. When brand companies introduce a reformulated drug, they often cease marketing and selling the original product. F. 198. They can also withdraw the original product's reference-listed drug designation, preventing generic products from having AB-rated status. F. 198. By introducing a reformulated drug, the brand company can greatly reduce the ability of generic companies to sell generic versions of the original drug because those generic products are no longer bioequivalent to - and not subject to automatic substitution in place of - the

[26] At the time of settlement, Endo had not filed any supplemental NDAs for a reformulated version of Opana ER. F. 226. Relevant facts regarding Endo's launching of a reformulated Opana ER are further addressed in subsection b.ii.(c) below.

reformulated product. F. 199. For a generic drug to be sold where there is no branded drug for which it is automatically substituted, doctors must actually write out a prescription for the generic product. F. 202-203.

If Endo reformulated Opana ER, Impax's generic Opana ER would not be AB-rated to the reformulated Opana ER product. F. 200. To the extent that original Opana ER disappeared or became insignificant, Impax's opportunity to sell a generic Opana ER would be significantly reduced or even eliminated. F. 204. Impax was concerned that Endo would be able to "subvert the value of the deal" being negotiated by introducing a reformulated version of Opana ER. F. 205.

Endo rejected the concept of accelerated entry for Impax and rejected Impax's demand for a market acceleration trigger. F. 147. This increased Impax's concern that Endo was going to switch the market to a crush-resistant version of Opana ER, notwithstanding Endo's denial of such a plan. F. 148. When Endo insisted to Impax that Endo was not planning to move the market to a crush-resistant version of Opana ER, Impax told Endo, "if you're not telling me the truth, you're going to pay me what I would have made anyway." F. 150. If Endo did destroy the market for Impax's generic Opana ER, Impax wanted "to be made whole for the profits that [it] would have otherwise achieved." F. 206. *See also e.g.*, F. 207, 213 (If "the market changed substantially before the date that the parties agreed that Impax could launch," the provision "would be a way of making Impax whole"); F. 151-152 (describing the then-current proposal as including a "make good"

payment). Once Endo refused to agree to an acceleration trigger, and agreed instead to the concept of a make-whole payment, Impax stopped pursuing an acceleration trigger. F. 153. Thereafter, Endo and Impax proceeded instead to finalize the terms of this "make-good" or "make-whole" provision, which eventually became the Endo Credit. F. 154, 160-165. In addition, Endo agreed to a January 2013 generic entry date for Impax. F. 154.

As Impax's then-CFO, Arthur Koch, explained, Impax was "worried about the control" Endo would have during the two and a half year time period before the agreed launch date of January 2013, and was "looking for a way to gain - take back some of that control away from the brand." F. 149. Impax's goal was, "if the market changed substantially before the date that the parties agreed that Impax could launch, there would be a way of making Impax whole" by providing Impax with the profits that Impax otherwise would have achieved during its 180-day exclusivity period. F. 213.

Impax described the make-whole provision as "protect[ing] the downside." F. 154; *see also* F. 208. If Endo's obligation to pay the Endo Credit were triggered, based on declining sales of Opana ER prior to Impax's generic entry, the calculations of the Endo Credit were designed to approximate the net profits Impax would have expected to make during its six-month exclusivity period, with no AG. F. 212; *see also* F. 214. Getting this downside protection for Impax in the event Endo reformulated Opana ER was "super, super important" to Impax's primary negotiator, Mr. Mengler, who testified that "something that didn't

protect us from the downside was ... a deal-breaker." F. 208.

If the market for Opana ER did not decline, the value of the no-AG provision would be higher. F. 210. A sharp decline in the sales of original Opana ER before Impax's generic launch, however, would decrease the value of the no-AG provision, because the total market potential for generic Opana ER would decrease. F. 209. The Endo Credit would then "correct for the loss in the value of the market that had occurred before the generic entry date." F. 209. In this way, the Endo Credit was designed as insurance against the risk of Endo reformulating Opana ER, and thereby degrading the market for Impax's generic drug. F. 211. *See also* F. 213 (The Endo Credit provision "was intended to insulate" Impax from the risk of a substantial decrease in Opana ER sales prior to the agreed generic entry date.).

In summary, the Endo Credit was designed to "back-up" the value of the no-AG provision and provide value to Impax regardless of whether Endo reformulated Opana ER. F. 197. *See also* F. 215 (Impax CFO Mr. Koch in 2011 characterizing the settlement as having "protection [against reformulation] built into the agreement so we should have a reasonable outcome almost no matter what happens").

(b) Monetary value of Endo Credit

The evidence shows that the monetary value of the Endo Credit was uncertain at the time of settlement and was contingent on unknown future events that were outside of Impax's control, such as

the figure for quarterly peak sales for Opana ER prior to generic entry, which was the biggest "input" in the Endo Credit formula. F. 216.

Complaint Counsel's economic expert witness, Professor Noll, devised four scenarios to approximate the value of the no-AG provision and the Endo Credit at the time of the settlement, and opined that the value ranged from $16.5 to $62 million, depending on his assumptions regarding the sales of Opana ER in the years after the settlement. *See* CX5000 at 240 (Noll Expert Report Appendix F). Professor Noll failed to adequately describe or explain the bases for his assumptions or his calculations, either in his expert report, or in his testimony. Without an understandable and verifiable basis for his estimates, the estimates are unsupported, are conclusory at best, and are, thus, rejected.

Respondent contends that the Endo Credit should be deemed to have added no value to the Endo-Impax Settlement because, by virtue of the contingent nature of the Endo Credit, the Endo Credit did not actually "guarantee" a payment to Impax. Respondent asserts that it was possible that Endo could time the introduction of reformulated Opana ER so as to avoid any payment obligation under the Endo Credit, while still diluting Impax's sales of generic original Opana ER (referred to by Respondent as a "late switch" strategy). Respondent relies on evidence that, prior to the settlement, Impax's director of market planning, Ted Smolenski, told Chris Mengler, Impax's principal negotiator, that there were certain circumstances under which the Endo Credit would not result in a payment to Impax, including a situation in which

Endo would withdraw its NDA for original Opana ER and time the elimination of sales in such a way that the Endo Credit would result in zero payment. F. 221. *See also* F. 220 (preliminary calculations by Mr. Cuca of Endo included potential for zero payment under Endo Credit). However, Mr. Smolenski considered this "downside" scenario unlikely to occur. Moreover, Mr. Mengler decided not to pursue the issue further because he did not deem the potential to be likely enough to try to correct for it. F. 221.

Even if there was a theoretical possibility of a zero payment under the Endo Credit, the notion that Impax bargained to obtain a zero payment under the Endo Credit is implausible. It is also against the weight of the evidence, including evidence that the Endo Credit formula was designed to provide an approximation of the net profits Impax would have expected to make during its six-month exclusivity period, with no AG; Impax viewed the Endo Credit provision as "super, super important" and a "deal-breaker"; Impax viewed the Endo Credit as insurance; and Impax expected a "reasonable outcome almost no matter what happens." F. 208, 212, 214-215. Moreover, Impax gave up its request for an acceleration trigger in exchange for the Endo Credit. F. 150-154. In summary, the facts belie the assertion that Impax bargained to obtain nothing.

In addition, the evidence does not support Respondent's assertion that Endo was in fact planning the above-mentioned "late switch" strategy for introducing reformulated Opana ER in order to avoid payment under the Endo Credit. Respondent points to evidence that Endo's 2012 budget contemplated a

launch date for reformulated Opana ER of August 2012, with a full conversion of the market from original Opana ER to reformulated Opana ER within two to three months, while continuing sales of original Opana ER into the last quarter of 2012. RX094 at 0003. However, the Endo document cited by Respondent clearly states that "significant uncertainties existed around manufacturing capabilities, market acceptance and our ability to transition to the new formulation." *Id.* The document notes that Endo was "particularly concerned with [transition time], as [Endo] knew that Purdue's OxyContin transition took 6 months." *Id.* In fact, an orderly transition from original Opana ER to reformulated Opana ER was expected to take about six to nine months. F. 106.

Moreover, even if sales of original Opana ER continued into the fourth quarter of 2012, it does not follow that this would enable Endo to avoid any payment under the Endo Credit. A cash payment under the Endo Credit was to be triggered if Endo's original Opana ER dollar sales in the fourth quarter of 2012 fell by more than 50% from the "Quarterly Peak" (the highest sales quarter between the third quarter of 2010 and the third quarter of 2012). F. 129, 195. Having some sales of original Opana ER in the fourth quarter of 2012 would not necessarily be sufficient to avoid triggering an Endo Credit payment. Rather, to avoid triggering an Endo Credit payment, the total dollar sales of original Opana ER in the fourth quarter of 2012 would need to be at least 50% of the Quarterly Peak sales.

The weight of the evidence is that, at the time of the settlement, Endo's principal interest in the timing of the launch of reformulated Opana ER was to launch as soon as possible, and sufficiently ahead of entry of a generic for original Opana ER to maximize the value of its reformulated product. F. 99-104. The assertion that Endo's priority was instead to avoid payment under the Endo Credit is unsupported and unconvincing, and is, therefore, rejected.

(c) 2013 payment under Endo Credit

On April 18, 2013, Impax received a payment pursuant to the Endo Credit in the amount of $102 million. F. 237. This amount is not, however, the proper measure of the value of the Endo Credit, which must be measured as of the date of settlement. *Loestrin*, 261 F. Supp. 3d at 337. To the extent that any of Professor Noll's estimates of the value of the Endo Credit at the time of settlement are based upon discounting the value of the Endo Credit payment made in 2013 (F. 239) such valuation would be improper and provides an additional reason to reject those estimates.

Furthermore, the evidence shows that the amount of money that Endo eventually paid under the Endo Credit was a function of a number of unforeseen factors that were outside of Impax's control. F. 216, 227-235. At the end of 2011, after discovering manufacturing deficiencies, the FDA shut down the plant where Novartis Consumer Health, Inc. ("Novartis"), another pharmaceutical company, manufactured original Opana ER for Endo. F. 227. The shutdown of the Novartis plant caused a supply

chain crisis for Opana ER. F. 228. Thereafter, in or about February 2012, the FDA ordered Endo to cease selling original Opana ER in order to avoid consumer confusion with Endo's reformulated Opana ER, which had just been approved by the FDA in December 2011. F. 225-226, 229. Accordingly, Endo stopped distributing original Opana ER and launched reformulated Opana ER in March 2012. F. 230.[27] It was not until after the Novartis supply disruption in late 2011, the FDA's order to stop selling original Opana ER in February 2012, and the launching of reformulated (crush-resistant) Opana ER in March 2012, that Endo first concluded that it would have to make a payment under the Endo Credit provision. In fact, the first time Endo knew that its sales of Opana ER would be zero was in the last quarter of 2012, after the supply interruption caused by the Novartis plant shutdown. F. 231. There is no basis in the record for concluding that anyone at the time of settlement did foresee, or reasonably could have foreseen, the occurrence of all these events.

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[27] Endo also took steps to have original Opana ER removed from the market. In August 2012, Endo filed multiple citizen petitions with the FDA, in which Endo argued that the FDA should (1) determine that original Opana ER was discontinued for safety reasons and could no longer serve as a reference-listed drug for any ANDA; (2) refuse to approve any ANDA pending for original Opana ER; and (3) withdraw any already-granted approvals for original Opana ER ANDAs. F. 233. Impax formally responded to the petition and offered scientific evidence that the discontinuation of Endo's original Opana ER was unrelated to safety or effectiveness. F. 234. The FDA concluded that Endo did not withdraw original Opana ER for safety or efficacy reasons. F. 235.

Although $102 million is not the appropriate measure of the value of the Endo Credit at the time of settlement, the fact that a payment was made confirms the purpose of the Endo Credit. As noted above in Section III.C.2.b.ii.(b), the purpose of the Endo Credit was to provide Impax the profits it would have received as the sole seller of generic Opana ER during its 180- day exclusivity period, with no AG, in the event of a sharp decline in the market. To the extent that the 2013 Endo Credit payment includes the value of such profits, the Endo Credit payment fulfilled its purpose.

c. Conclusion as to valuation of reverse payment

Based on the foregoing, the evidence proves that, at the time of settlement, the value of the no-AG provision, as secured by the Endo Credit, was between $23 and $33 million in projected sales, and the actual value of the cash payment under the DCA was $10 million, for a total reverse payment under the SLA and DCA of between $33 and $43 million.

3. Scale in relation to litigation costs

Although litigation costs vary substantially among cases, a survey by the American Intellectual Property Lawyers Association estimated that the median litigation cost for all patent cases with more than $25 million at stake averages about $5.5 million for each party. F. 77. When such a case is handled by a large firm (with more than 76 attorneys), the median litigation cost average is somewhat higher, at approximately $7 million for each party. F. 77.

The top end of the range that Impax uses in its budgeting process to estimate costs for generic patent

litigation is about $3 to $4 million per case. This $3 to $4 million estimate represents total expenses from the start of litigation to completion and is based primarily on expenses for outside counsel, such as hourly attorneys' fees. F. 79. In November 2011, Impax represented in a public earnings conference call that it was saving $3 million in litigation expenses because of recent settlements, including the Endo settlement. F. 80. At the time of the Endo-Impax Settlement, which occurred during the patent trial, Endo had spent between $6 and $7 million and Impax had spent about $4.7 million on litigation in the infringement case. F. 78.

Based on the foregoing, a reasonable estimate of the combined saved litigation costs for both Endo and Impax for settling the patent litigation in June 2010 is approximately $5 million. F. 81. As set forth above, the value of the no-AG provision, secured by the Endo Credit, was between $23 and $33 million, based on projected sales revenue to Impax, and the actual value of the cash payment under the DCA was $10 million, for a total reverse payment under the SLA and DCA of between $33 and $43 million. Therefore, the value of the reverse payment substantially exceeded the estimated saved litigation costs.

4. Justifications for reverse payment

a. Legal principles

Actavis holds that a reverse payment can be justified as "compensation for other services that the generic has promised to perform - such as distributing the patented item or helping to develop a market for that item. There may be other justifications." *Actavis*, 133 S. Ct. at 2236. *See also id* at 2237 (holding that

likelihood of anticompetitive effects in connection with reverse payment settlement depends on, among other things, "independence from other services for which it might represent payment, *and the lack of any other convincing justification*") (emphasis added). Clearly, *Actavis* did not limit the types of justifications for a reverse payment that can be asserted. *See also King Drug*, 791 F.3d at 412 ("The Court does not foreclose other justifications.").

The parties dispute who has the burden of proof on the issue of justification, with each party placing the burden of proof on the other party. Complaint Counsel points to language in *Actavis* stating that "[a]n antitrust defendant may show ... that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason," 133 S. Ct. at 2236, and argues this shows that the defendant bears the burden of proving that a payment was justified. However, *Actavis* also cites "the lack of any … convincing justification" as an element of proving anticompetitive effects, 133 S. Ct. at 2237, which indicates that the burden of proving that a payment was unjustified should fall on the plaintiff.

Post-*Actavis* cases have held that the plaintiff challenging a reverse patent settlement must allege plausible facts to support a conclusion that an alleged reverse payment was large and unjustified. *Loestrin*, 814 F.3d at 552. In addition, it has been held that when a defendant comes forward with evidence of justifications for the payment, the burden is on the plaintiff to prove that the asserted justifications are unsupported. *Cipro Cases I & II*, 348 P.3d at 871

(citing *Polygram*, 416 F.3d at 37-38). *See also K-Dur*, 2016 U.S. Dist. LEXIS 22982, at *46 (holding that plaintiff must "dispel" justifications offered by defendant). As the court in *In re Cipro Cases I & II* explained, if a plaintiff dispels all justifications explaining the reverse payment, "the conclusion follows that the settlement payment must include, in part, consideration for additional delay in entering the market." 348 P.3d at 871. *See also In re Aggrenox Antitrust Litig.*, 2015 U.S. Dist. LEXIS 94516, at *37 (D. Conn. July 21, 2015) (holding that an antitrust violation requires proof, among other things, "that the settlement included a large and unjustified reverse payment giving rise to an inference of payment in order to avoid the risk of competition"). Other post-*Actavis* cases have held that the burden is on the defendant to prove the justifications for the payment. *See, e.g., King Drug*, 791 F.3d at 412; *Cephalon*, 88 F. Supp. 3d at 416. *See also Lipitor*, 868 F.3d at 256-57 (rejecting the argument that the complaint's allegations of lack of justification were insufficient, stating that *Actavis* "clearly placed the onus of explaining or justifying a large reverse payment on antitrust defendants").

In the instant case, the parties have vigorously litigated the question of justification for the reverse payment and have developed a complete record on the issue. Notwithstanding Complaint Counsel's assertion that the burden of proving justification is on Respondent, Complaint Counsel nevertheless asserts that the reverse payment was unjustified, and offers evidence and argument in an effort to support that claim (*see, e.g.*, CCB at 27-31, CCFF Section XII). Regardless of which party has the ultimate burden of

proof on the issue of justification for the payment, as discussed in detail below, the evidence proves that, of the total payment provided to Impax under the Endo-Impax Settlement: (1) the payment conferred to Impax by the no-AG and Endo Credit provisions of the SLA was unjustified; and (2) the $10 million payment to Impax pursuant to the DCA was justified.

b. Payment under the SLA

i. Contentions of the parties

Respondent argues that, even if the no-AG and Endo Credit provisions of the SLA conferred a large reverse payment to Impax, the payment was not unjustified because the payment was not provided "in return for staying out of the market." RB at 60.[28] Respondent points to evidence that the no-AG provision was included in Endo's initial offer and that during negotiations, the entry date moved back from Endo's initial proposed entry date of March 2013, to the agreed entry date in the settlement of January 2013. Respondent further argues that the Endo Credit was not tied to the negotiation of the entry date, but rather was coupled with a royalty provision in the SLA designed to (1) encourage Endo to support sales of Opana ER in the time period between the date of the settlement and the date set for entry of Impax's generic product, and (2) discourage Endo from transitioning to a reformulated Opana ER product.

[28] Respondent does not assert that the reverse payment conferred to Impax by the no-AG and Endo Credit provisions of the SLA reflects compensation for services provided to Endo by Impax.

Respondent refers to this as a "carrot and stick." RB at 61.

Complaint Counsel contends that the no-AG and Endo Credit provisions are unjustified. Complaint Counsel argues that these provisions were directly linked to the January 2013 entry date provided under the Endo-Impax Settlement, and the fact that the entry date in the settlement was slightly earlier than the March 2013 entry date initially proposed by Endo does not justify these provisions. Further, Complaint Counsel argues, Respondent's assertion that the Endo Credit was part of a "carrot and stick" designed to discourage Endo from transitioning to a reformulated product is legally non-cognizable and factually unsupported.

ii. Analysis

Evidence from the parties' negotiations readily supports the conclusion that the reverse payment conferred to Impax by the no-AG provision, secured by the Endo Credit, was directly linked to negotiation of the generic entry date as compensation to Impax for giving up its patent challenge and committing not to launch a generic Opana ER until January 2013. Endo's initial offer included a no-AG provision, but this initial offer was not sufficient to induce Impax to settle the patent litigation and agree to the March 2013 entry date proposed by Endo. F. 131-132. Impax accepted the no-AG provision, but counter-proposed a January 2013 entry date, plus an acceleration trigger that would allow for entry prior to January 2013 in the event of a degradation of the market for Opana ER prior to Impax's entry. F. 136-139. Endo would not agree to an acceleration trigger, but agreed instead to

pay Impax a "make-good" payment, the Endo-Credit, and further agreed to the January 2013 entry date requested by Impax. F. 147, 151, 154. Once Endo and Impax agreed on the concept of a make-good payment, the parties reached an agreement in principle on the SLA. F. 147-154.

When weighed against the foregoing evidence, the facts that the no-AG provision was included in Endo's initial offer, and that the January 2013 entry date ultimately agreed to was two months earlier than the March 2013 date Endo initially offered, are not significant. Moreover, the issue is not whether the January 2013 entry date in the settlement was earlier than the date Endo initially offered, but whether the no-AG provision, as secured by the Endo Credit, was effectively payment by Endo to Impax for agreeing to drop its patent challenge and commit to staying out of the market *prior to* January 2013. *See Actavis*, 133 S. Ct. at 2237 (noting that parties may settle with an agreed entry date "without the patentee paying the challenger to stay out prior to that point"). *See also King Drug*, 791 F.3d at 408 (holding that the question is whether entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered). Viewed as a whole, the evidence supports the conclusion that the reverse payment conferred to Impax by the no-AG provision, secured by the Endo Credit, was unjustified.

Respondent's contention that the Endo Credit is not unjustified because it was part of a "carrot and stick" strategy is without merit for several reasons. First, the evidence does not support Respondent's assertion that the Endo Credit and the royalty

provision were "coupled." The evidence shows that a royalty proposal was made by Endo, as part of its initial term sheet for the SLA on May 26, 2010. F. 135. The proposal for a "make-good" payment did not occur until on or about June 1, 2010, and was not reduced to writing until June 4, 2010. F. 151, 160. Second, the assertion that the Endo Credit was part of a "carrot and stick" design is against the weight of the evidence, which shows that the Endo Credit was intended as a "make-whole" provision, to provide Impax with the profits Impax would have earned during its 180-day exclusivity period, with no AG, if Endo switched the market to a reformulated Opana ER. *See* Section III.C.2.b.ii.(a) above. While Respondent points to deposition and trial testimony to support the characterization of the Endo Credit as part of a "carrot and stick," *see* RFF 195-198, the phrase does not appear in contemporaneous documents from the parties' negotiations. Third, the assertion that the royalty provision was a "carrot" is unconvincing because the royalty imposed costs on Endo in the form of lost sales from its agreement not to launch an authorized generic. Under the SLA, Impax would be obligated to pay Endo a 28.5% royalty on Impax's generic Opana ER sales during Impax's 180-day exclusivity period only in the event that sales of Opana ER in the calendar quarter prior to Impax's entry grew by a specific percentage. F. 128, 194. However, if sales grew enough to require a royalty payment to Endo, the no-AG provision operated to prevent Endo from selling an AG into this increased market. *See* F. 127. Thus, while pursuant to the royalty provision, Endo would receive 28.5% of profits from Impax's generic sales, pursuant to the no-AG provision, Endo still would lose

100% of profits it could have earned from sales of an Endo AG. Moreover, even if Opana ER sales reached a sufficiently high level prior to Impax's generic entry to trigger royalty payments, Impax would be the only seller of a generic oxymorphone ER product, pursuant to the no-AG provision. F. 127-128, 194. Impax stood to gain more in sales of generic oxymorphone ER than Impax would lose in royalty payments. F. 194. For all these reasons, Respondent's contention that the Endo Credit is not unjustified because it was part of a "carrot and stick" strategy is rejected.[29]

iii. Conclusion

As explained above, the evidence supports the conclusion that the reverse payment conferred to Impax under the SLA by the no-AG provision, secured by the Endo Credit, was unjustified. The analysis now examines justification for the payment made to Impax under the DCA.

c. Payment under the DCA

i. Overview

On June 7, 2010, Endo and Impax executed a Development and Co-Promotion Agreement with respect to a Parkinson's disease treatment known internally at Impax as IPX- 203. F. 244. The DCA was executed simultaneously with the SLA and is incorporated into the SLA. F. 245. Under the DCA, Impax and Endo agreed to collaborate with respect to the development and marketing of a potential

[29] Because Respondent's "carrot and stick" justification is contrary to the weight of the evidence, it is not necessary to address Complaint Counsel's argument that such justification is not legally cognizable.

treatment for Parkinson's disease using an extended release, orally administered product containing a combination of levodopa and carbidopa. F. 246.

The DCA provided for an upfront payment of $10 million by Endo to Impax, and the possibility of payment of up to $30 million more, based on achieving specified milestone events in the development and commercialization of the product. F. 247-248. Impax and Endo agreed to share promotional responsibilities, with Impax promoting IPX-203 to its network of neurologists, and Endo promoting IPX-203 to its network of non-neurologists, including primary care physicians who prescribe Parkinson's disease medications. F. 249. If the target product was successfully commercialized, Endo would be entitled to a share of the profits. F. 250. Specifically, Endo would receive a co-promotion fee equal to 100% of gross margins on sales resulting from prescriptions by non-neurologists. F. 250. Endo paid Impax the $10 million upfront payment on June 24, 2010. F. 250.

Respondent contends that the $10 million payment by Endo to Impax under the DCA was justified as fair value for profit-sharing rights Endo received under the DCA.[30] Respondent asserts that

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[30] Respondent makes a single assertion in its brief that the $10 million paid under the DCA reflected fair value compensation for services by Impax. RB at 42. However, Respondent does not expand on the assertion, articulate what services it was to provide to Endo in exchange for the $10 million payment, or point to any evidence supporting the assertion. Accordingly, the assertion has not been sufficiently raised to warrant consideration. *See United States. v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990) ("[I]ssues adverted to in a perfunctory manner,

the evidence shows that Endo was interested in Parkinson's disease treatments; Endo's team was familiar with Parkinson's disease treatments; Endo analyzed the merits of the product collaboration; and Endo concluded that the DCA had financial and commercial merit for Endo. In addition, Respondent asserts that, among other things, the DCA entitled Endo to a share of profits without obligating Endo to perform any resource-intensive formulation or development work, the DCA capped Endo's total financial obligations, and, beyond the $10 million investment, Endo's obligations were contingent on Impax achieving specific milestones, regardless of how much it cost Impax to achieve those milestones.

Complaint Counsel contends that the $10 million payment from Endo to Impax under the DCA was not justified by Endo's profit-sharing rights. According to Complaint Counsel, the evidence demonstrates that the payment was not part of a bona fide product collaboration, but was instead payment for Impax's agreement under the SLA not to enter the market with its generic Opana ER until January 2013. In support of this argument, Complaint Counsel relies on expert opinion to contend that the DCA and the SLA were not independent agreements, because they were negotiated and executed together, and because, as adversaries, Endo and Impax would be unlikely to collaborate, but for the settlement discussions. In addition, Complaint Counsel asserts that the evidence shows that Endo did not have a genuine interest in

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unaccompanied by some effort at developed argumentation, are deemed waived.").

developing the drug that was the subject of the collaboration.

Furthermore, relying on expert opinion, Complaint Counsel argues that the negotiation process was unusual in comparison to industry standards, particularly with regard to Endo's due diligence. Complaint Counsel asserts that the evidence shows that Endo offered the same $10 million upfront payment at the beginning of negotiations of the DCA, despite a change in the product under discussion. Complaint Counsel further asserts that $10 million was an unusually large payment to make upfront, in light of the drug's early stage of development at the time the DCA was signed.

ii. Summary of facts

The detailed facts concerning the DCA are set forth in Section II.C.3 and are summarized below.

(a) Background facts

Endo has entered into many collaboration agreements with other pharmaceutical companies. F. 254. These include early-stage development deals, and potentially speculative deals. F. 255. This is because Endo generally does not research or discover new drug molecules on its own and instead acquires and licenses drugs from other pharmaceutical companies. F. 254. In connection with a collaboration agreement, Endo identifies therapeutic areas of interest and companies that own promising drug molecules in those areas and enters into earlystage development deals. F. 256. Endo also regularly licenses technology from and collaborates with other companies for more developed products. F. 256. For example, for Opana ER, Endo licensed the necessary technology to make both

original and reformulated Opana ER. F. 256. Endo's collaboration agreements with other pharmaceutical companies could relate to drugs at every stage of the development lifecycle, including early-stage development agreements. F. 255. Because Endo had no pipeline in place to discover new drugs on its own, Endo would enter into "very early, very speculative agreements." F. 255.

Beginning in 2005, Endo's significant areas of interest included pain, neurology, and movement disorders, including Parkinson's disease treatments. F. 257. In the 2010 timeframe, Endo evaluated collaborations with other companies related to treatments for Parkinson's disease. These included exploring potential Parkinson's disease collaboration opportunities with an Italian company called Newron, which had multiple Parkinson's disease products, and conducting due diligence on a Parkinson's disease product with a novel mechanism of action that was owned by a Finnish company. F. 261. For a number of years, Endo sold an immediaterelease Parkinson's disease drug known as Sinemet, which was the original formulation of carbidopa and levodopa.[31] F. 260. Thus, the evidence demonstrates that Endo had both an interest in Parkinson's disease treatments and knowledge about such treatments through its experience with Sinemet.

Impax also had a long-standing interest in Parkinson's disease treatments. When Impax's brand division was founded in 2006, it focused its efforts on

[31] A combination of carbidopa and levodopa molecules is the "gold standard" treatment for Parkinson's disease. F. 265.

central nervous system and neurology products, with a specific focus on improved treatments for Parkinson's disease. F. 263. As part of its focus on central nervous system and neurology products, Impax's brand division also concentrated on developing a network of relationships with neurology physicians. F. 263. In addition, in furtherance of its interest in Parkinson's disease treatment, Impax had undertaken attempts to develop an extended release drug for treatment of Parkinson's disease. F. 268-276. The majority of carbidopa-levodopa medications are available only in immediate-release formulations, which requires frequent dosing and often results in patients' losing control of their motor skills as they experience rapid increases and decreases in the concentration of medicine in their bodies, especially as the disease progresses. F. 266-267.

Impax's first attempt to develop an extended-release carbidopa-levodopa treatment for Parkinson's disease was known as Vadova. F. 268. That product was intended to combine carbidopa-levodopa with controlled-release technology to give a much smoother effect to the amount of medication in Parkinson's disease patients' blood, providing for more control over motor symptoms. F. 268. Vadova was never fully developed or marketed. F. 268.

Impax's second attempt to develop an extended-release Parkinson's disease medication was known as IPX-066, which was a combination of carbidopa and levodopa that had been formulated to extend the release profile of Parkinson's disease drugs. F. 269-270. As with Vadova, IPX-066 was intended to better treat Parkinson's disease patients by allowing for less

frequent and more consistent dosing of up to six hours, as well as more consistent motor symptom control. F. 271. By significantly extending the absorption of the drug, IPX-066 would provide "significant improvement of the patient's quality of life." F. 272. IPX-066 had reached Phase III clinical trials in 2010 and was marketed under the name Rytary in 2015. F. 273.

By 2010, Impax had also begun efforts to develop a "next generation" of IPX-066. F. 274. The goal of the next-generation product, which was originally designated by Impax as IPX-066a and later designated as IPX-203, was to further improve treatment for Parkinson's disease patients by extending dosing time even longer than IPX-066. F. 274.

(b) Negotiations

In early 2009, Impax approached Endo about a collaboration with respect to Endo's central nervous system drug Frova, which treats migraine headaches. F. 275-276. Endo declined. F. 277. Although Endo and Impax again discussed a potential product collaboration on Frova in late 2009, in connection with discussions about settlement of the Endo-Impax patent litigation, these discussions did not result in a collaboration agreement. F. 278-280. However, in the course of these discussions, Endo became aware of Impax's efforts to develop drugs for Parkinson's disease and expressed an interest. F. 281. Subsequently, in May 2010, after discussions regarding settlement of the Endo-Impax patent litigation resumed, Impax and Endo began discussing a potential joint development agreement and Endo

expressed an interest in marketing IPX-066. F. 283-284.

At Endo, the senior vice president of corporate development, Dr. Robert Cobuzzi, and his team of employees were responsible for evaluating potential pharmaceutical business deals for further development. F. 287. Between May 17 and 26, 2010, the date of Endo's initial term sheet for the DCA (F. 294), Impax and Endo held two conference calls and exchanged numerous emails and materials regarding IPX-066, including a presentation on the clinical benefits of IPX- 066 over Sinemet, which at that time was the leading carbidopa-levodopa brand product. F. 286, 288.

On May 20, 2010, Dr. Cobuzzi directed his team to work on an opportunity evaluation worksheet ("OEW") to assess a potential collaboration with Impax on IPX-066. F. 289. An OEW is Endo's standard method of assessing the science, medical information, commercial opportunity, and related financial considerations behind a potential collaboration project. F. 346. Any time Endo considers a pharmaceutical collaboration, it completes an OEW. F. 346.

On May 21, 2010, Endo asked an outside consulting firm to provide guidance about the potential value of IPX-066. F. 290. In addition, on May 22, 2010, Dr. Paterson, Impax's vice president of business development, provided Dr. Cobuzzi and a number of additional Endo employees access to a "data room" with a large amount of IPX-066 related documents, covering: (i) intellectual property/legal; (ii) chemistry, manufacturing, and controls; (iii)

commercial; (iv) regulatory; (v) clinical; (vi) clinical pharmacology; and (vii) Impax's unredacted confidential presentation on IPX-066. F. 291.

On May 26, 2010, Endo sent Impax an initial term sheet for an option agreement concerning IPX-066 "and all improvements, modifications, derivatives, formulations and line extensions thereof." F. 294. Under this proposal, Endo would have the option to receive either the right to co-promote the product to non-neurologists within the United States or to purchase an exclusive license to the product in the United States. F. 294. Endo would pay Impax a $10 million option fee upon signing the agreement and a $5 million milestone fee upon the FDA's acceptance of the NDA for the product. F. 294. If Endo exercised the option to co-promote the product, Endo would receive a fee of "50% on the net sales" from prescriptions by nonneurologists in the United States. F. 294. If Endo exercised the option for a license, Endo would pay Impax a fee based on projected sales. F. 294.

Endo's May 26 proposal was not acceptable to Impax. As Impax's vice president of intellectual property litigation and licensing, Margaret Snowden, explained: "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX- 066 and the follow-on product, but Impax wasn't interested in doing the deal on IPX-066." F. 313. Dr. Michael Nestor, the head of Impax's brand division, was "absolutely not" willing to consider an agreement with Endo regarding IPX-066. F. 311. In 2010, Impax had already shouldered all development risks and development costs for IPX-066 and it made little sense to Impax to share potential profits from the

drug with a partner. F. 310. Furthermore, in 2010, Impax was not looking for a partner in the United States for IPX-066 because Impax planned to market the product domestically on its own, utilizing its established neurologist network. F. 309.

Accordingly, Impax made a counter-offer to Endo on May 27, 2010 for a research and development collaboration for what Impax referred to as IPX-066a, its "next generation" of IPX- 066. F. 295, 313-314. Impax advised Endo that Impax would name this product "at signing." F. 295. IPX-066a, which later became known as IPX-203, was a planned carbidopa-levodopabased product that Impax hoped would improve the treatment of symptoms and also have more favorable dosing as compared to IPX-066. F. 314.

Contrary to the inferences urged by Complaint Counsel, designation of IPX-066a was not a "late switch" by Impax from IPX-066, but a rejection by Impax of Endo's proposal for a deal for both IPX-066 and IPX-066a, and a counterproposal by Impax for a collaboration for IPX- 066a only. Impax had initially sent IPX-066 materials to Endo to review in order to "help [Endo] frame their evaluation of the market environment into which IPX-203 could be launched as a successor to IPX-066." F. 328. When Impax sought a partner to market the product outside the United States, it had already established a data room regarding IPX-066. F. 329. Because IPX-203 was a follow-on product to IPX-066, the foundational information in the data room regarding IPX-066 was relevant to show Impax's plans for IPX-203. F. 329.

Impax's May 27, 2010 counter-offer for a collaboration for IPX-066a included an upfront

payment at signing of $3 million, and six additional milestone payments, tied to the initiation and completion of Phases II and III development and final FDA approval, for a total of $60 million. F. 295. Over the next ten days, Endo and Impax traded proposals regarding the timing and total amount of the payments under the DCA, which culminated in the final DCA terms, summarized above. F. 296-308. On June 4, 2010, Impax named IPX-203 as the product previously designated as IPX-066a. F. 303. Impax also provided additional information to Endo regarding Impax's research into the IPX-203 product concept, and about how IPX-203 would improve upon existing Parkinson's disease therapies, including IPX-066. F. 322.

(c) Relationship between IPX-066 and IPX-203

IPX-203 was intended to be a modification of carbidopa and levodopa, a well-known combination treatment for Parkinson's disease. F. 324. Levodopa generally is not well absorbed in the colon. F. 325. The information Impax provided on IPX-203 made clear that IPX-066 and IPX-203 were intended to be [redacted]. F. 323. IPX-203 would have [redacted]. F. 326. The information Impax provided Endo on IPA-203 [redacted]. F. 327.

Although IPX-203 was in the beginning of the formulation stage, Impax reasonably relied on Dr. Suneel Gupta, the chief scientific officer at Impax in 2010, who believed that the product concept for IPX-203 was "doable." F. 315-316. As early as November 2009, Impax had reviewed [redacted]. F. 378. Dr. Gupta had expertise in reformulating existing

chemical compounds to create commercial and clinical improvements through reformulation and "is renowned for taking existing compounds and reformulating them and turning those products into very successful drugs in the marketplace that meet significant medical need[s]." F. 316. When Dr. Gupta tells Impax management that a product concept is "doable," Impax's senior management believes him and relies on his judgment. F. 316. Moreover, Impax's expertise has long been the development of extended-release technologies. F. 317.

The ultimate goal of IPX-203 was to further extend the amount of time patients have control over their motor symptoms after taking the medication. F. 319. IPX-203 would also employ a "much more simplified" dosing regimen than IPX-066, making it more intuitive for doctors to prescribe the product. F. 320. Impax projected that the total cost of development for IPX-203 would be between $80 and $100 million by 2017, based on a "natural extrapolation" of the development costs incurred by IPX-066. F. 321.

Impax was planning to withdraw promotion and sampling of IPX-066 (Rytary) once IPX- 203 reached the market. F. 318. This would allow patients to continue successful use of IPX- 066 while avoiding any division of Impax's sales force between multiple Parkinson's disease products, which was consistent with the commercial goal of extending the IPX-066 franchise. F. 318.

(d) Endo's evaluation of product collaboration for IPX-203

Endo carefully evaluated the commercial, medical, and risk allocation aspects of the DCA. On June 7, 2010, Dr. Cobuzzi provided the final OEW on IPX-203 to Endo's executive team. F. 307. In terms of the commercial aspects of the DCA, Endo's OEW on IPX-203 stated that the DCA was "a good deal for Endo." F. 307. Endo analyzed the net present value of its initial investment under the DCA and determined that the DCA and IPX-203 had a "very reasonable rate of return" of [redacted] under base case assumptions, and a net present value of [redacted]. F. 352-353. Such a return would exceed Endo's general requirement of a 10% rate of return on a development and co-promotion deal. F. 352. Endo thought it could realize this return, notwithstanding that Parkinson's disease treatments were heavily genericized, because IPX-203 would offer a superior product to other generics. F. 354. In addition, Dr. Cobuzzi recommended the DCA as "an exciting opportunity for Endo" because it "further builds [Endo's] product pipeline for the future with a drug candidate that fits with [Endo's] commercial footprint." F. 349. Endo did not have many products in its commercial pipeline in 2010, and did not have the capacity to develop new products in-house. F. 350.

Endo's evaluation of the medical aspects of IPX-203 concluded that IPX-203 would extend the period of time over which the drug is absorbed, which would allow doctors to lower the doses needed for effective treatment. F. 357. This would provide an opportunity to address doctor dissatisfaction with existing drugs that tend to begin to lose effectiveness within 10 to 15 years after initiation of therapy, and would meet a need for better control of efficacy over time. F. 356.

Endo's OEW for IPX-203 also noted that IPX-203 represented a further improvement over IPX-066, including "faster onset of action, superior management of motor fluctuations and convenient oral dosing in a simplified regimen that could require no more than twice-daily administration, and in some cases even once-daily administration." F. 358. Taking the drug less frequently would be particularly beneficial for Parkinson's disease patients, who can have trouble "even picking up the pill." F. 359. Endo's evaluation team concluded that IPX-203 could move very quickly through development and "was an exciting compound in that it was made up of ... two compounds that have already been approved by the FDA." F. 361. Endo reasonably believed that there was a path to obtaining FDA approval and bringing IPX-203 to market. F. 361-363.

Endo also evaluated how risk was allocated under the DCA. Endo's analysis in the OEW on IPX-203 explained to Endo's board of directors that the DCA's "deal structure acceptably mitigates Endo's exposure despite the early development stage." F. 364. Endo was entitled to share in the profits from IPX-203 without performing any development work or otherwise expending internal resources. F. 365-366. Moreover, Endo retained the same profit-sharing rights no matter how much Impax spent on IPX-203's development, which Impax had projected could amount to $100 million by 2017. F. 321, 367. In addition, Endo was obligated to make only a single contribution ($10 million) to Impax's development work. Endo would be required to make any additional milestone payments only to the extent that there was successful completion of development milestones, such

as Phase II clinical trials. F. 365. Furthermore, the $10 million single investment to buy into the IPX-203 opportunity was "not an uncharacteristically large amount of money" to Endo, compared to other collaboration agreements. F. 370. Accordingly, Endo was "comfortable" with the collaboration from the perspective of risk. F. 368.

Dr. Cobuzzi believed that the profit-sharing rights Endo received under the DCA justified Endo's payment obligations. F. 369. Dr. Cobuzzi and his team concluded that Endo should enter into the DCA and Dr. Cobuzzi made that recommendation to Endo's CEO, CFO, and board of directors. F. 347.

(e) Value to Impax of collaboration for IPX-203

In 2010, Impax did not have the money to begin working on the clinical research for IPX- 203. F. 375. Impax could not fund the project internally because its shareholders did not "want to see large sums of money being spent over an extended time period on a single product. They were accustomed to [research and development] investments being made on many individual products that you bring to market as a generic." F. 375. Thus, Impax needed external funding to move the development of IPX-203 forward, and explored a number of options, including seeking money from venture capital firms. F. 376. Impax's brand drug development team was "very excited" about the idea of funding IPX-203 through a co-development program with Endo. F. 377.

In negotiating the DCA, Impax initially wanted to retain any profits flowing from prescriptions written by high-prescribing non-neurologists - which were the

profits Endo sought and eventually obtained under the DCA - because of the "significant" amount of money those prescriptions represented. F. 372. Impax envisioned promoting IPX-203 to at least "a couple of thousand physicians who were primary care physicians that prescribed [medications to] Parkinson's patients ... ." F. 373. Nevertheless, in order to get funding through a codevelopment program with Endo, Impax agreed to give up a share of the profits for IPX-203.

(f) Impax's continued efforts to develop IPX-203

Since executing the DCA in June 2010, Impax has devoted substantial efforts to IPX- 203's development, including over [redacted] in employee hours spent working on IPX- 203. F. 379. In 2010, Impax commissioned preclinical pharmacokinetic studies testing several relevant compounds and began laboratory research. F. 380. Impax undertook multiple rounds of pharmacokinetic studies to test various IPX-203 formulations in an effort to assess clinical improvements, which were completed as of 2012. F. 381. Since then, Impax conducted additional pharmacokinetic studies and completed Phase I clinical trials. F. 382. Impax manufactured a clinical supply of IPX-203, developed protocols for Phase II clinical trials, submitted those protocols to the FDA, and secured FDA approval for efficacy and safety studies in November 2014. F. 383.

Further development work on IPX-203 was delayed for approximately two years after Impax experienced delays in the development of IPX-066, the

drug IPX-203 was intended to extend and improve upon. F. 384. When IPX-066 was delayed, resources were shifted to getting IPX-066 approved and to market. F. 385. Growing the market for IPX-066 would benefit IPX- 203. F. 385. Further development work on IPX-203 was also delayed after Impax received an FDA Warning Letter in 2011 relating to Impax's manufacturing processes, which caused Impax to direct its scientific staff to spend their time helping the operations people correct the deficiencies that the FDA noted in its last inspection. F. 386. IPX-203 development was not going to go forward until Impax "got over that hurdle." F. 387.

Notwithstanding the delays and the DCA's termination (discussed below), Impax has continued development work on IPX-203. F. 388. IPX-203 is currently the leading compound in research and development in Impax's brand division. F. 389. Impax has completed Phase II clinical trials for IPX-203, which showed a statistically significant improvement in treatment over IPX-066 and other existing treatments, reducing the amount of time Parkinson's disease patients are without control over their motor symptoms, as compared to both immediate-release carbidopa-levodopa treatments and IPX-066. F. 390-391. Phase II trials suggest that IPX-203 will offer an improvement of over two hours in motor symptom control when compared to immediate-release carbidopa-levodopa treatments and one hour of improvement over IPX-066. F. 392. An improvement of over two hours in motor symptom control over existing medications is a "terrific result" that is "highly statistically significant" and "clinically meaningful." F. 393. Having symptoms under control

for a longer time period is "a very important thing" for patients. F. 394. Impax plans to begin Phase III clinical trials in 2018. F. 390.

Impax's IPX-203 development efforts revealed that the formulation of IPX-203 contemplated by the DCA could not achieve the intended clinical benefits. F. 396. Between 2014 and 2015, Impax's research team determined that it could not achieve the desired product profile with a [redacted] formulation. F. 397. Impax consequently began pursuing alternative approaches to an extended-release formulation of carbidopa and levodopa. F. 397.

After extensive research and testing, [redacted]. F. 398. In April 2015, Impax approached Endo to update it on the status of Impax's IPX-203 development work, including the change in formulation strategy, and made a presentation describing Impax's formulation testing and results and [redacted]. F. 403.[32]

(g) Termination of the DCA

Although the specific formulation of IPX-203 changed, Impax still viewed [redacted] it had been developing since 2009 "[b]ecause it was all towards the same end. It still involved carbidopa-levodopa. It was just a variation in formulation." F. 400. During the April 2015 meeting between Impax and Endo at which Impax updated Endo on the change in formulation strategy, Impax offered to amend the DCA so that the DCA would cover the [redacted]. F. 403, 408.

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[32] In 2014, Impax filed an Investigational New Drug Application with the FDA regarding [redacted], which the FDA accepted. F. 399.

Impax was prepared to amend the DCA to include the new formulation of IPX-203 in the DCA because it wanted to work with Endo in order to move the drug forward and believed the new formulation would give it "an avenue through which we could continue the development of IPX-203." F. 409. Endo initially agreed to the proposed amendment, noting that it "would like to maintain or even increase [its] involvement with the development program ... as [it] remain[ed] optimistic this will be a successfully differentiated product, which Endo looks forward to the opportunity to co-promote ... with Impax." F. 410. However, Endo subsequently informed Impax that Endo had decided not to amend the existing agreement and would no longer participate in co-development program, which surprised Impax. F. 412. Endo did not provide an explanation. F. 412.

Because Endo retracted its initial expression of interest in amending the DCA to cover the new formulation for IPX-203, Impax and Endo terminated the DCA by mutual agreement, effective December 23, 2015. F. 414.

iii. Conclusion

The evidence, summarized above and detailed in Section II.C.3, proves that the DCA was a bona fide product development collaboration, and that the $10 million payment was justified by the profit-sharing rights given to Endo under the DCA. The product collaboration for IPX- 203 was consistent with Endo's and Impax's business interests. Both Endo and Impax had a history of interest in Parkinson's disease treatments, and Endo had entered into many collaboration agreements with other pharmaceutical

companies, including risky early stage development collaborations. Impax required outside funding to advance the development of IPX-203, which Impax projected could cost between $80 and $100 million by 2017. Moreover, Impax continued its development efforts regarding IPX-203 for years after executing the DCA, which further indicates that the DCA was a bona fide agreement.

In addition, substantial weight is properly given to the fact that Endo analyzed the commercial and medical merits of co-promoting IPX-203, as well as the risk allocation under the DCA, and concluded that the DCA was a "good deal" for Endo. The record supports Endo's conclusion, including the facts that Endo would receive its share of the profits without performing any development work; Endo did not consider the upfront payment of $10 million to be uncharacteristically large; and the projected rate of return [redacted] was nearly [redacted] Endo's minimum requirements for a co-development deal.

iv. Complaint Counsel's arguments as to lack of justification

All of Complaint Counsel's arguments in support of a conclusion that the $10 million payment was unjustified have been fully reviewed, and have been rejected as either contrary to the weight of the evidence or insufficiently supported.[33] Only a few of

[33] For example, Complaint Counsel contends that Endo and Impax "understood" the DCA to be a payment for the Opana settlement, relying on two documents. Neither document warrants the inference urged by Complaint Counsel. The first document, an internal Endo document drafted by Dr. Cobuzzi,

Complaint Counsel's arguments require further elaboration, and are discussed below.

(a) Asserted "switch" from IPX-066 to IPX-203

Complaint Counsel asserts that the evidence shows that the $10 million upfront payment in the DCA was the same as the amount of the payment in Endo's initial offer, despite a "switch" from IPX-066 to IPX-203, which, according to Complaint Counsel, reduced the value of the deal to Endo. Thus, Complaint Counsel argues, the $10 million upfront payment was not in fact an exchange for value received by Endo under the DCA. However, the evidence shows that, while Endo's initial term sheet included a $10 million upfront payment for a proposed deal on IPX- 066, it also contained more limited profit-sharing terms than those agreed upon in the DCA. Under Endo's May 26, 2010 initial term sheet co-

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listed the "license deal completed with Impax" as adding "topline revenue for Opana." CX1701 at 005. However, although given the opportunity, Complaint Counsel did not elicit any testimony from Dr. Cobuzzi on the meaning of this document. The second document, an internal Impax document, listed $10 million as cash flow from the "Endo Settlement." However, when this document was shown to Impax's former CFO, Mr. Koch, he testified that he did not recognize the document, that it did not appear to be an accounting document, that other aspects of the document were inconsistent with Impax's common budgeting practices, and that it could have been referring to the research and development collaboration. CX2701 at 004; CX4018 (Koch, Dep. at 147-48). Furthermore, Complaint Counsel's assertion that the parties "understood" the DCA to be a payment for delay is not only unsupported, but is also against the weight of the evidence, which, as set forth above, demonstrates that the DCA was a bona fide product collaboration.

promote proposal, Endo would receive 50% of the profits from sales generated by non-neurologists. F. 294. Under the final DCA, Endo received a right to 100% of those profits. F. 250. Moreover, as explained in Section III.C.4.c.ii.(b) above, designation of IPX-066a (IPX-203) was not a "switch" by Impax from IPX-066, but a rejection by Impax of Endo's proposal for a deal regarding both IPX-066 and IPX-203, and a counterproposal by Impax for a collaboration on IPX-203 only. The evidence shows that Impax was never interested in partnering on IPX-066. Thus, Complaint Counsel's assertion that this "switch" shows the payment was unjustified is rejected.

(b) Due diligence

Complaint Counsel contends that Endo did not perform appropriate due diligence as to the merits of IPX-203 or the DCA. However, the evidence shows that Impax provided Endo with information regarding Impax's research into the IPX-203 product concept and about how IPX-203 would improve upon existing Parkinson's disease therapies, including IPX-066. F. 322. Impax had provided information to Endo about IPX-066, and the information Impax provided on IPX-203 made clear that IPX-066 and IPX-203 were intended to be [redacted]. F. 323.

In addition, the materials Impax sent to Endo to review regarding IPX-066 were, as stated by Dr. Cobuzzi, "tremendously" helpful to Endo in assessing IPX-203. F. 330. As Dr. Cobuzzi explained, both IPX-066 and IPX-203 were based on carbidopa and levodopa. The only difference in IPX-203 [redacted], which Endo viewed as "relatively simple," notwithstanding that this was a change in the

chemistry. F. 330. Endo's chief operating officer at the time of settlement and the individual responsible for assessing the commercial opportunity of any product, also deemed IPX-066 an appropriate commercial proxy for assessing IPX-203. F. 331. The IPX-066 materials, as well as Endo's experience with other Parkinson's disease treatments, including Sinemet, suggested to Endo that the successful development of IPX-203 would more effectively treat Parkinson's disease symptoms. F. 260, 332, 343. Endo's reliance on information about a related drug when evaluating IPX-203 was not unusual. F. 335. Rather, the evidence shows that Endo routinely relied on information about one pharmaceutical asset to assess another, related pharmaceutical asset. F. 335. Indeed, when information about related pharmaceutical assets is available, it is "much easier" to evaluate a proposed drug than it is to evaluate a new chemical entity on its own. F. 336.

Finally, as noted above, Dr. Cobuzzi was the lead scientist on the team that evaluated the commercial and scientific merits of the DCA for Endo. F. 337. Dr. Cobuzzi holds a Ph.D. in molecular and cellular biochemistry and wrote his dissertation on Parkinson's disease. F. 339. In addition, Dr. Cobuzzi's team included at least one other scientist with a background in Parkinson's disease treatments, Dr. Kevin Pong. F. 340. Dr. Pong, who was in charge of evaluating Endo's scientific licenses, had a "significant amount of experience" in the area of Parkinson's disease treatments. F. 340. Endo knew the underlying molecules, the carbidopa and levodopa, had looked at a number of Parkinson's disease opportunities in the past, and knew the general

commercial landscape. F. 344. Dr. Cobuzzi's belief that Endo had sufficient time to assess IPX-203 before entering into the DCA is entitled to substantial weight, given his qualifications, his and Endo's familiarity with Parkinson's disease treatments, and the detailed nature of the information Impax provided on IPX-066. F. 342-345. Accordingly, Complaint Counsel's assertion that Endo did not perform proper due diligence with regard to the DCA is rejected.

(c) Expert opinions

Complaint Counsel's argument that the $10 million payment under the DCA was unjustified because it was negotiated as part of the patent litigation settlement discussions, not as a standalone agreement, is based largely on the opinion of its proffered expert in negotiations, Professor Max Bazerman. Professor Bazerman opined that the adversarial relationship between Impax and Endo would have made independently negotiating the DCA highly unlikely, unless the business transaction was linked to settlement discussions. CX5001 (Bazerman Expert Report at 021-22 ¶43). This opinion ignores the significant facts that Impax and Endo had discussed a potential collaboration on Frova (another central nervous system drug) in early 2009, months before settlement discussions began (F. 275), that Endo had been looking for an opportunity in the Parkinson's disease area for a number of years (F. 257-261), and that Impax had been exploring a number of approaches to get external funding to move the IPX-203 product forward in development (F. 376). Even though the evidence shows that the DCA was negotiated and executed contemporaneously with the

SLA and is incorporated into the SLA (F. 123, 245), this neither compels the conclusion that the $10 million payment under the DCA was unjustified, nor precludes the conclusion that the $10 million payment under the DCA was justified as fair value for the profit-sharing rights Endo received under the DCA.

Complaint Counsel's argument that the $10 million payment under the DCA should be deemed unjustified because the DCA was not consistent with Endo's, or the industry's, usual business development practice, is based largely on the opinion of its proffered expert in pharmaceutical business development, Dr. John Geltosky.[34] Although he opined that Endo did not perform a comprehensive and integrated due diligence analysis of IPX-203 before agreeing to the terms of the DCA (CX5003 (Geltosky Expert Report at 023-24 ¶37)), Dr. Geltosky did not offer an opinion regarding whether Endo exercised good business judgement in its due diligence. F. 427. Furthermore, Dr. Geltosky admitted that information about IPX-066 provided useful information for IPX-203 and that Impax provided Endo with comprehensive information regarding IPX-066, including clinical information regarding safety and efficacy, intellectual property, technical due diligence, and financial

[34] Dr. Geltosky has worked on a handful of development deals in their early stages and has never negotiated a development and co-promotion agreement similar to the DCA. The majority of Dr. Geltosky's experience with pharmaceutical collaboration agreements relates to his employment with large pharmaceutical companies and Dr. Geltosky admitted that he could not speak to how the universe of small or mid-sized pharmaceutical companies approach partnerships for early-stage products. F. 415.

analysis. F. 425-426. The opinion offered by Dr. Geltosky is outweighed by documentary evidence and fact witness testimony summarized above showing the sufficiency of the due diligence steps taken by Endo.

In addition, although Dr. Geltosky testified that the DCA was not consistent with the normal practice in the pharmaceutical industry, he did not offer an opinion regarding whether the DCA was a bona fide scientific collaboration or whether Endo exercised good business judgement in entering the DCA. F. 417. Indeed, Dr. Geltosky acknowledged that Endo's senior vice president of corporate development (Dr. Cobuzzi) is better qualified to assess the strategic fit of the DCA for Endo than he is. F. 416.

Expert opinion that a process was unusual for the industry, even if accepted, does not warrant the inference that the DCA was a pretext, and not a bona fide side deal for value, because such inference would be contrary to the weight of the evidence showing that the DCA was justified as fair value for profit-sharing rights. *See Schering*, 402 F.3d at 1069-71; *In re Schering-Plough Corp.*, 2002 FTC LEXIS 40 at **254-55 (June 27, 2002), *rev'd by In re Schering-Plough Corp.*, 2003 FTC LEXIS 187 (2003), *rev'd by Schering-Plough*, 402 F.3d 1056. In *Schering*, the FTC argued that a $60 million payment from a branded drug manufacturer to a generic drug manufacturer, pursuant to a patent litigation settlement agreement through which the branded drug company obtained licenses for the generic company's products, was not a bona fide royalty payment, but instead was an inducement for the agreement by the generic to delay generic entry. 402 F.3d at 1068. Complaint Counsel in

the administrative litigation had relied on expert opinion that the parties' diligence was "strikingly superficial," *Schering*, 2002 FTC LEXIS 40, at **254-55, and "fell astonishingly short of industry standards." *Schering*, 402 F.3d at 1069. The Court of Appeals in *Schering* rejected these arguments, and held that "substantial and overwhelming evidence" weighed against the conclusion that the licenses were not worth the payment made and were exchanged for delay. *Id.* at 1070-71.

The evidence presented in *Schering* is analogous to the evidence in the instant case. Similar to the brand drug manufacturer in *Schering*, Endo had a demonstrated, ongoing interest in the type of product that was the subject of the collaboration, F. 257-261; *see Schering*, 402 F.3d at 1069, and was well-familiar with the relevant commercial environment. F. 337-345; *see Schering*, 2002 FTC LEXIS 40, at **251-52. And, as in *Schering*, Complaint Counsel's experts' criticisms of the diligence process in the instant case did "nothing to refute that [the brand's] payments [for the licensed products were] a fair price." F. 428-436; *see Schering*, 402 F.3d at 1071.

Dr. Geltosky also opined that the payment structure of the DCA was unusual because, in his opinion, the DCA payment structure was "frontloaded" with a large upfront payment with decreasing milestone payments, while early-stage development deals are typically "backloaded." However, Dr. Geltosky did not compare the payment terms in the DCA to the payment terms in other pharmaceutical collaboration agreement agreements. F. 431. Moreover, expert opinion that the payment

was "unusual" does not warrant an inference that the payment was unjustified. For purposes of justification, the issue is whether the payment was fair value for what was received. Dr. Geltosky did not opine on that value. F. 430, 432.

Indeed, Dr. Geltosky did not conduct any valuation analysis of the DCA, did not calculate a net present value of the DCA at the time it was executed, and did not conduct any other form of empirical analysis regarding the DCA. F. 429. Dr. Geltosky did not offer any opinion about the actual value of the DCA to Endo and did not address the actual value of the profit-sharing rights acquired by Endo or whether Endo's profit-sharing rights justified its DCA payment obligations. F. 430, 432. *See also* F. 417, 419, 421, 427, 434. These shortcomings incurably undermine Dr. Geltosky's opinions. *See Schering*, 402 F.3d at 1069 (stating that the court was "troubled" by expert opinion that a payment was "grossly excessive" and that Schering's due diligence fell short of industry standards, where the expert had "arrived at his conclusions without preforming a quantitative analysis" of the licensed products).

Moreover, Complaint Counsel's economic expert, Professor Noll, who relied on Dr. Geltosky's "analysis of the degree to which the $10 million payment and co-development deal represented the acquisition of an asset that was approximately valued at a $10 million price," agreed that if Dr. Geltosky did not offer an opinion regarding the actual value of the DCA to Endo at the time it was executed, then Professor Noll "would not include the $10 million as part of the large payment that was unjustified." F. 437-438. Professor

Noll also acknowledged that, if a payment from a brand company to a generic company is used to purchase a bundle of rights at a fair market price, the payment is justified. F. 435. Indeed, Professor Noll testified that if Dr. Geltosky did not provide a "sufficiently well-documented rationale for the conclusion that the payment was unjustified, then you would pull [the DCA] out of the case." F. 439.

(d) Conclusion

As explained above, the evidence proves that the $10 million payment made by Endo to Impax under the DCA was justified as fair value for profit-sharing rights Endo received under the DCA.

5. Conclusion on initial burden of proof

Of the total reverse payment conferred under the Endo-Impax Settlement, the $10 million payment under the DCA was justified. However, the value conferred to Impax by the no-AG provision of the SLA, secured by the Endo Credit, totaling $23 to $33 million in projected sales revenue for Impax, was an unjustified reverse payment. The value of this unjustified reverse payment substantially exceeded the estimated saved litigation costs. In addition, the evidence supports the inference that Endo and Impax agreed to this reverse payment as an inducement to Impax, to compensate Impax for giving up its patent challenge and committing not to launch a generic Opana ER until January 2013. Therefore, based on the totality of the record, viewed as a whole, the evidence supports the inference that the SLA included a payment to prevent the risk of competition.

Accordingly, Complaint Counsel has met its initial burden of proving an anticompetitive harm.

D. Market Power

Market power is "the power to control prices or exclude competition." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). It is unclear whether proof of market power is a necessary element of a reverse payment settlement challenge. Although *Actavis* referred to market power as one of several traditional antitrust considerations, market power is not expressly included among the factors listed in *Actavis* as determining the likelihood of anticompetitive effects. *Actavis*, 133 S. Ct. at 2237 (stating that "likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification"); *see also King Drug*, 791 F.3d at 412 (same). Regardless of whether proof of market power is mandatory, in the instant case the evidence supports the conclusion that Endo had market power in the relevant oxymorphone ER market at the time of the Endo-Impax Settlement, as explained below.

By their nature, pharmaceutical patents often carry with them market power. *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 755 (E.D. Pa. 2015), *aff'd* 868 F.3d 132 (3d Cir. 2017). As the court explained in *Aggrenox*, a patent "grant[s] the legal right to exclude generic competition and the practical ability to profitably charge higher prices than generic competitors would charge." 199 F. Supp. 3d at 668.

Accord Lipitor, 2018 U.S. App. LEXIS 93, at *6 ("A distinguishing feature of a reverse settlement is that the bargained-for abstention period falls within the term of the patent at issue, when the patent holder would normally enjoy a government-conferred monopoly.").

Actavis recognizes that market power is often associated with a pharmaceutical patent, and further holds that proof of that power, derived from the patent, can be found in the reverse payment settlement itself:

> [W]here a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice. At least, the "size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power" - namely, the power to charge prices higher than the competitive level. An important patent itself helps to assure such power. Neither is a firm without that power likely to pay "large sums" to induce "others to stay out of its market."

Id. at 2236 (citations omitted). *Accord Loestrin*, 814 F.3d at 552 n.12 ("*Actavis* explains how to evaluate the market power question: 'the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power.'"). The court in *In re Cipro Cases I & II* further explained:

> Logically, a patentee would not pay others to stay out of the market unless it had sufficient market power to recoup its payments through supracompetitive pricing. Consequently,

> proof of a reverse payment in excess of litigation costs and collateral products and services raises a presumption that the settling patentee has market power sufficient for the settlement to generate significant anticompetitive effects.

348 P.3d at 869. *See also Aggrenox*, 199 F. Supp. 3d. at 662 (stating that, while it is conceivable that a patent might be worthless, "[i]t is vanishingly unlikely ... that a large reverse payment would be made in such a case, which is why a large reverse payment is such a strong indicator of market power").

In the instant case, as held in Section III.C.2.c above, the evidence proves that Endo made an unjustified reverse payment to Impax that was sufficiently large to induce Impax to drop its patent challenge and agree not to enter the relevant oxymorphone ER market until January 2013. Under *Actavis*, this is strong proof of Endo's market power in the relevant market.

Other evidence also supports the conclusion that Endo had market power in the relevant oxymorphone ER market. The evidence shows that in 2010, Endo had a 100% share of the market for oxymorphone ER. F. 90. In addition to the intellectual property barriers to entry associated with Endo's patents, there are regulatory barriers created by the Hatch-Waxman Act. F. 92. For instance, the Hatch-Waxman Act imposes a 30-month stay on FDA approval of an ANDA, if a branded drug company files a patent infringement suit against a Paragraph IV ANDA filer. F. 93. Moreover, the first filer's 180-day exclusivity period provided by the Hatch- Waxman Act serves as

a barrier to entry by barring later ANDA filers from entering until the period expires. F. 93. These barriers gave Endo the power to exclude competitors even if its patents eventually were found not to be valid or infringed. F. 95.

Based on the foregoing, the evidence demonstrates that Endo had market power in the relevant market for oxymorphone ER. The analysis next turns to the procompetitive benefits of the SLA.

E. Procompetitive Benefits

1. Overview

Respondent argues that the SLA granted Impax a broad patent license, which enabled Impax to sell its generic Opana ER uninterrupted since Impax entered the market in January 2013, while all other generic manufacturers have been enjoined as a result of patent infringement litigation by Endo. Respondent argues that, therefore, the SLA provided substantial procompetitive benefits.

Complaint Counsel's opposing argument - that Respondent's asserted procompetitive benefits cannot be considered because the only legally cognizable procompetitive effects are those that arise from the reverse payment - is without merit, as explained in Section III.B.7 above. The "restraint" at issue in a reverse payment settlement case is not the payment itself, but the use of the payment in such a way as to restrain the onset of generic competition. Thus, procompetitive benefits arising in connection with the settlement agreement as a whole are properly considered as part of a well-structured rule of reason analysis. *See K-Dur*, 2016 U.S. Dist. LEXIS 22982, at *46 ("If a prima facie case has been made out, the

defendants may come forward with additional justifications to demonstrate the settlement agreement nevertheless is procompetitive."); *Cipro Cases I & II*, 348 P.3d at 871 (same); *see also In re Impax*, 2017 FTC LEXIS 130, at *27-33 (Commission rejecting Complaint Counsel's request to preclude consideration of entry prior to termination of patent and effect of post-settlement events as potential procompetitive justifications).

2. Relevant provisions

The SLA granted Impax a broad patent license and a covenant not to sue that covered not just the Opana ER patents owned by Endo at the time of the Endo-Impax patent litigation, but all patents "that would ever be owned by [Endo] that would cover the Impax product." F. 567. Specifically, pursuant to section 4.1(a) of the SLA, Impax obtained a license to the '933, '456, and '250 patents, and to any pending patents "that cover or could potentially cover the manufacture, use, sale, offer for sale, importation, marketing or distribution of" Impax's generic Opana ER product (collectively, the "licensed patents"). F. 568-569.

Furthermore, section 4.1(b) of the SLA included a "covenant not to sue," which prohibited Endo and its affiliates from suing Impax for patent infringement on any of the licensed patents. F. 570. This provision meant that Endo could not sue Impax for infringement based on Endo's Opana ER patents listed in the Orange Book at the time of settlement, as well as any continuations, continuations in part, or divisions of those patents or patent applications owned or controlled by Endo, that could cover Impax's generic

Opana ER. F. 570. (The broad patent license and covenant not to sue provided in the SLA are at times referred to collectively herein as the "broad license agreement" or "broad patent license.")

Impax would regularly seek a broad patent license in its settlement negotiations with brand-name drug companies whenever it intended to launch and continue to sell its generic product indefinitely, in order to provide Impax with as much flexibility as possible. F. 565. In any negotiation where the brand company tried to narrow the scope to the patents being litigated, Impax was "very firm," explaining that "this is not about the patents being litigated. This is about a product, and we want the ability to operate." F. 565. For Impax, every settlement agreement must cover all the patents that could affect the generic product, existing and future, "otherwise you end up with [a] launch [of] the product and still have to be under the [patent] risk, and that doesn't really help [Impax]." F. 566.

Given the possible effects of Endo's additional patent applications relating to Opana ER, a reasonable litigant would have been concerned with Endo's future patents. F. 168. Consistent with Impax's regular practice, in the Endo-Impax negotiations, Impax proposed broadening the patent license that Endo had offered in the SLA to include "any patents and patent applications owned by or licensed to Endo ... that cover or could potentially cover" Impax's generic oxymorphone ER product. F. 169. Endo accepted Impax's proposed language. F. 170.

3. Post-settlement patents and patent litigation

After entering into the SLA, Endo obtained additional patents and patent licenses that it has asserted cover both original and reformulated Opana ER (the "after-acquired patents"). F. 571. Endo acquired its first post-settlement patent - U.S. Patent No. 7,851,482 - from Johnson Matthey in March 2012 (the "Johnson Matthey patent"). F. 573. In addition, between November 2012 and October 2014, the Patent and Trademark Office issued the following patents to Endo: Patent Nos. 8,309,060 ("the '060 patent"); 8,309,122 ("the '122 patent"); Patent No. 8,329,216 ("the '216 patent"); Patent No. 8,808,737 ("the '737 patent"); and Patent No. 8,871,779 ("the '779 patent"). F. 575-576, 579-581.

In December 2012, Endo began asserting the '060, '122, and '216 patents in litigation against drug manufacturers seeking to market generic versions of both original and reformulated Opana ER. F. 577. At that time, Endo did not assert these patents against Impax's generic version of original Opana ER. F. 577. Endo did, however, assert these patents against a generic version of reformulated (crush-resistant) Opana ER, which was covered by an ANDA filed by Impax. F. 577. In August 2015, the district court for the southern district of New York held that the '122 and '216 patents were not invalid and were infringed by other companies' generic versions of original Opana ER and by all companies', including Impax's, generic versions of reformulated Opana ER. F. 578. That court issued an injunction barring all defendants, except Impax, from selling their generic versions of original Opana ER until 2023. That ruling is currently on appeal to the Federal Circuit. F. 578.

In addition, Endo asserted the '737 and '779 patents in litigation in the district court of Delaware against drug manufacturers seeking to market generic versions of both original and reformulated Opana ER. F. 583. Endo did not assert these patents against Impax's generic version of original Opana ER because of the SLA's broad patent license; however, Endo did assert the patents against Impax's ANDA for a generic version of reformulated (crush-resistant) Opana ER. F. 584. In October 2016, the Delaware court held that the '779 patent was not invalid and was infringed by a generic version of reformulated Opana ER. F. 586. That ruling is currently on appeal to the Federal Circuit. F. 586. In August 2017, the Delaware court again ruled that the '779 patent was not invalid, following a bench trial against other ANDA filers. F. 587. In September 2017, the Delaware court entered its final order, enjoining all defendants from selling generic Opana ER until the last of Endo's patents expires in 2029. F. 587-588.

4. Effect of broad license agreement

The broad license agreement gave Impax protection against any of Endo's future patents being asserted against Impax for its generic version of original Opana ER. F. 593. Thus, these provisions gave Impax freedom to sell its generic Opana ER under both the litigated patents and any future patents that Endo might obtain in this product area. F. 592. The January 2013 entry date provided in the SLA, together with the broad license agreement, enabled a generic Opana ER to enter the market eight months before the original patents expired, and sixteen years before Endo's after-acquired patents

expired, and to continue with the sale of that product up to the present day, without threat of patent infringement litigation relating to original Opana ER. F. 594.

Impax's product is the only generic Opana ER available to consumers. F. 596. Although every other Opana ER ANDA filer settled patent claims asserted by Endo related to Opana ER, no other drug manufacturer negotiated rights to future Opana ER patents similar to the broad license agreement that Impax obtained in the SLA. F. 595. Endo's acquisition and successful litigation of additional patents has led to all generic manufacturers, other than Impax, being enjoined from selling a generic version of Opana ER until the last of Endo's patents expires in 2029. F. 588, 596. Impax, in contrast, has sold generic Opana ER without interruption since launching its product in January 2013. F. 597.

5. Analysis

a. Procompetitive benefits

The Supreme Court has held that "enabl[ing] a product to be marketed which might otherwise be unavailable ... widen[s] consumer choice ... and hence can be viewed as procompetitive." *NCAA v. Board of Regents*, 468 U.S. 85, 102 (1984); *accord Brown Univ.*, 5 F.3d at 675 ("Enhancement of consumer choice is a traditional objective of the antitrust laws and has also been acknowledged as a procompetitive benefit.").

The evidence shows that Endo's acquisition of additional patents, and successful assertion of those additional patents in litigation, has led to all generic manufacturers, other than Impax, being enjoined from selling a generic version of Opana ER until the last of

Endo's patents expires in 2029. F. 592-598. This is clear evidence of the strength of the after-acquired patents, and supports the inference that, absent the SLA, such after-acquired patents also would have been successfully asserted to enjoin Impax from selling generic Opana ER - even if Impax had gone to trial and won its challenge to the patents at issue in the Endo-Impax patent litigation. Instead, as a result of the broad license agreement in the SLA, Impax has sold generic Opana ER without interruption since launching the product in January 2013. F. 598. This is despite Endo's efforts, through filing FDA citizen petitions with the FDA, to have original Opana ER removed from the market for alleged safety reasons. F. 233-235.

The case of *In re Wellbutrin XL Antitrust Litigation* is additional authority supporting the conclusion that the broad patent license in the SLA is procompetitive. In *Wellbutrin*, as part of a reverse payment patent settlement, the brand drug manufacturer, GlaxoSmithKline ("GSK"), granted to the generic manufacturers a sublicense to certain patents (the "Andrx patents") acquired by GSK in connection with the settlement of a separate patent lawsuit among GSK, Andrx, and the generic manufacturers. 133 F. Supp. 3d at 737, 747. The Andrx patents were not due to expire for 15 more years. *Id.* at 759. The court held that the sublicense provided under the settlement agreement was a cognizable procompetitive justification for the agreement because the sublicense "eliminat[ed] an independent and substantial hurdle to generic entry" and removed "the possibility that Andrx could prevent generic Wellbutrin XL from being marketed for the 15

years remaining on its patent." *Id.* at 758-59. The court further held that the plaintiffs had failed to present a genuine factual dispute as to this procompetitive justification. *Id.*

In the instant case, as in *Wellbutrin*, Impax negotiated for a broad license agreement in order to ensure that it had the freedom to sell generic Opana ER without concern of patent infringement liability going forward. F. 167, 169, 565-566. In addition, as in *Wellbutrin*, the SLA eliminated a separate, and substantial, hurdle that Endo could have imposed on Impax's sale of generic Opana ER by asserting after-acquired patents against Impax - patents that Endo successfully did assert against other generic manufacturers. F. 575-587.

In summary, the evidence proves that consumers have benefitted from the SLA by having uninterrupted and continuous access to generic Opana ER since January 2013. The real-world effect of the SLA 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. F. 600. This is procompetitive. *See NCAA*, 468 U.S. at 102; *Brown Univ.*, 5 F.3d at 675.

Furthermore, the Challenged Agreement settled litigation, which is favored in the law. *American Sec. Vanlines, Inc. v. Gallagher*, 782 F.2d 1056, 1060 (D.C. Cir. 1986) ("Few public policies are as well established as the principle that courts should favor voluntary settlements of litigation by the parties to a dispute."); *TBK Partners, Ltd. v. Western Union Corp.*, 675 F.2d 456, 461 (2d Cir. 1982) (noting "the paramount policy of encouraging settlements"). Although *Actavis* held

that the policy in favor of settlement was not a sufficient reason to bar antitrust review, *see* Section III.B.2 above, nothing in the language of *Actavis* holds that this factor is precluded from consideration. In addition, the fact that the SLA enabled Impax to enter the market prior to the expiration of Endo's Opana ER patents, while not dispositive, can be considered in assessing the competitive consequences of the Challenged Agreement. *See In re Impax*, 2017 FTC LEXIS 130, at *29. In the instant case, the SLA enabled Impax to enter the market in January 2013, nine months before expiration of the initial Opana ER patents in September 2013, and sixteen years before the expiration of Endo's after-acquired patents in 2029.

For all the foregoing reasons, Respondent has met its burden of proving that the SLA had procompetitive benefits.

b. Less restrictive alternative

Because Respondent has met its burden of proving that the SLA had procompetitive benefits, the burden shifts to Complaint Counsel to demonstrate that these benefits could have been achieved with a less restrictive settlement agreement. *See Law*, 134 F.3d at 1019. Complaint Counsel contends that Endo and Impax could have entered into a settlement that did not include any payment to stay off the market. However, Complaint Counsel fails to demonstrate that such hypothetical settlement could have, or would have, included the broad patent license.[35]

[35] With respect to the likelihood of a hypothetical alternative settlement with no reverse payment and an entry date earlier than January 2013, it is noteworthy that Impax twice proposed a

Accordingly, Complaint Counsel has failed to meet its burden of proving that the demonstrated procompetitive benefits of the SLA in this case could have been achieved through a less restrictive settlement agreement.

The final step of the rule of reason analysis, set forth below, weighs the anticompetitive and procompetitive effects of the SLA, to determine whether, on balance, the agreement is anticompetitive.

F. Balancing of Anticompetitive and Procompetitive Effects

Where the evidence proves that an agreement poses both anticompetitive harm and procompetitive benefits, "the harms and benefits must be weighed against each other in order to judge whether the challenged behavior is, on balance, reasonable." *Law*, 134 F.3d at 1019. Plaintiffs have the burden of establishing that "the settlement is nevertheless anticompetitive on balance." *Nexium*, 42 F. Supp. 3d at 262-63; *Loestrin*, 261 F. Supp. 3d at 329.

As the court recognized in *In re Cipro Cases I & II*, "the relevant benchmark in evaluating reverse payment patent settlements should be no different from the benchmark in evaluating any other challenged agreement: What would the state of competition have been without the agreement?" 348 P.3d at 863. Regardless of whether Complaint Counsel must prove actual delay in the onset of generic competition to meet its initial burden as to

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simple settlement with a 2011 entry date and no reverse payment, which Endo rejected. F. 116, 155.

anticompetitive effect, it is appropriate to assess the magnitude and/or extent of delayed generic competition in order to balance anticompetitive harm against demonstrated procompetitive benefits. *See Impax Labs*, 2017 FTC LEXIS 130, at *29-30 (holding that a settlement providing for entry prior to patent expiration might be found to enable generic competition on or prior to the entry date that would have resulted, on average, from litigating the patent suit to conclusion, which "[a]t a minimum ... affects the magnitude of any anticompetitive effect"). Complaint Counsel bears the overall burden of establishing that the Challenged Agreement "engendered a net harm." *Cal. Dental Ass'n*, 224 F.3d at 957-58.

Respondent argues that the Endo-Impax Settlement expedited generic competition, as compared to litigating the Endo-Impax patent dispute, regardless of the eventual outcome of that litigation. Respondent asserts that even if Impax had prevailed, the Endo-Impax patent litigation would have delayed generic competition until as late as January 2013.

Complaint Counsel urges rejection of Respondent's evidence as to the expected duration of the patent litigation. Complaint Counsel further argues that, regardless of when the underlying litigation might have ended, the evidence proves that, absent the Endo-Impax Settlement, Impax might have launched its generic Opana ER "at risk" to compete with Endo as early as June 2010, after Impax received

final FDA approval of its generic Opana ER. These arguments are analyzed below.[36]

1. Entry by at-risk launch

a. Background

As explained in Section III.A.3 above, Endo's patent infringement suit against Impax, filed on January 25, 2008, triggered the Hatch-Waxman 30-month stay on approval of Impax's ANDA for generic oxymorphone ER, meaning that the FDA could not approve Impax's ANDA until the earlier of the expiration of 30 months or resolution of the patent dispute in Impax's favor. F. 61-62. If litigation is still pending at the end of the 30-month period, the FDA may give its approval to the generic drug manufacturer to begin marketing a generic version of the drug. *Lipitor*, 868 F.3d at 241; 21 U.S.C. §355(j)(5)(B)(iii). Pursuant to the Hatch-Waxman framework, once Impax received final approval from the FDA in June 2010, Impax had the option to launch its generic oxymorphone ER product "at risk." F. 66-67, 451-452.

Launching at risk refers to the risk of liability for the brand-name manufacturer's lost profits, if the generic challenger launches its product prior to a non-

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[36] It is undisputed that the outcome of the Endo-Impax patent litigation was uncertain at the time of settlement. F. 553. The duration of continued litigation, as the alternative to the Endo-Impax Settlement, is relevant to the magnitude and/or extent of the anticompetitive effects of the Endo-Impax Settlement. Such analysis does not require, and does not include, an assessment of the merits of the underlying patent dispute. *See Actavis*, 133 S. Ct. at 2236 (stating that "it is normally not necessary to litigate patent validity to answer the antitrust question").

appealable decision in the underlying patent litigation and ultimately loses its patent challenge. F. 452-453; *Lipitor*, 868 F.3d at 241; *King Drug*, 791 F.3d at 396 n.8. Lost profits are measured by the profits the patent owner would have made on sales of its branded product, but for the launch of the generic product. F. 453. Damages can be trebled if the infringement is found to be willful, for instance, if the generic product is launched before the district court rules on the patent dispute. F. 453. In addition, if the brand company wins its action against a generic company that has launched at risk and the generic company's actions are deemed "exceptional," courts may award attorney's fees to the brand company. F. 457.

Generic companies often risk far more in infringement liability than they earn from each sale when launching at risk. F. 454. Damages are not measured by the generic's sales revenue, but by the profits the brand company would have earned on such sales. F. 454. Thus, potential damages for launching at risk can represent "bet-the-company" stakes and can "take [away] the solvency of the company entirely." F. 455. Damages can be in the billions of dollars, if the sales of the branded drug are high enough, and "would almost always be greater than the total revenues that the generic company receives" from launching at risk. F. 455.

Moreover, launching at risk jeopardizes a first filer's 180-day exclusivity period, which is "extremely valuable." F. 456. If the generic company launches at risk and is enjoined from making sales, the generic company forfeits some of its 180-day exclusivity because the 180-day time period continues to run

during the period the generic is enjoined. F. 456. Even if the injunction is eventually lifted or the infringer prevails in the underlying patent litigation, the patent infringer can never recover the forfeited part of its 180-day exclusivity period. F. 456.

At-risk launches are fairly uncommon across the entire pharmaceutical industry. F. 458. At-risk launches are most common when there are multiple ANDA filers who have received approval from the FDA, no ANDA filer has exclusivity, and there subsequently is a race to the market by generic firms. F. 459. When at-risk launches do occur, they generally are undertaken by large pharmaceutical companies that can absorb significant financial risk in the event they are found to infringe. F. 460. Complaint Counsel's expert witness, Professor Noll, identified 48 at-risk launches over a 15-year period (August 2001 thru April 2015). Twenty-one of those fortyeight at-risk launches were conducted by Teva, which, Professor Noll explains, "is by far the most likely company to do at-risk launches." F. 461. Teva is a "very large pharmaceutical company" and, as a result, can undertake at-risk launches more regularly. F. 462. Of the 48 atrisk launches identified by Professor Noll, only 4 were conducted by companies with less than $1 billion in revenue. F. 463. Impax's revenues in 2010 were less than $1 billion. F. 465.

b. Analysis

The evidence supports the conclusion that Impax would not have launched its generic Opana ER at risk, as further explained below. F. 451-548.

First, the evidence supports the conclusion that it would have been economically disadvantageous for

Impax to launch its generic Opana ER at risk. Unlike the overwhelming majority of companies that Professor Noll identified as undertaking at-risk launches, Impax is a small pharmaceutical company, with revenues in 2010 of less than $1 billion. F. 463, 465. Mr. Koch, Impax's CFO at the time of the Endo-Impax Settlement, explained that "being a small company," Impax "could not bet the company on any one product." F. 467. The potential liability for damages from launching a generic version of Opana ER at risk would have exceeded any profits Impax realized from the launch. F. 544. Impax's potential liability for Endo's lost profits could total as much as $54 million for six months of sales. F. 546. If it was ultimately determined that Impax's infringement was willful and Endo was awarded treble damages, Impax could be liable for as much as $162 million for six months of sales. F. 546. In contrast to this potential liability, potential sales of oxymorphone ER over six months in 2010, based on an atrisk launch, as projected by Impax, would total only $28 million. F. 545. In addition, if Impax launched at risk and was then enjoined, Impax would forfeit part of its 180-day exclusivity period. F. 547. Under these circumstances, it "was perfectly reasonable for Impax to view a launch at risk as a losing proposition." F. 548.

Second, Impax had no relevant history of at-risk launches. Impax is "incredibly conservative" with respect to at-risk launches and only "infrequently" considers the possibility. F. 466-468. Prior to the Endo-Impax patent litigation, Impax had launched a product at risk only once. F. 469. That at-risk launch was for one dosage strength of a generic version of oxycodone. F. 469. Impax limited its risk of damages

by capping its potential sales at $25 million, which, in turn, limited the lost profits it would have had to pay to the branded drug company. F. 469. In fact, Impax launched at risk only after it received a favorable district court decision holding the relevant patents unenforceable and after Teva, the first ANDA filer for the relevant dosage, had launched at risk six months earlier. F. 469. Since the Endo-Impax Settlement in 2010, Impax has undertaken only one at-risk launch, and did so in a limited manner. F. 471. Specifically, Impax and Perrigo, the ANDA holder and marketer of a nasal spray antihistamine named azelastine, entered a partnership agreement through which Impax would share development costs and litigation expenses in return for a share of the drug's profits. F. 472. In 2014, Perrigo notified Impax that it intended to launch azelastine at risk. F. 472. Under the terms of the Impax-Perrigo partnership agreement, Impax could participate in the launch and earn a share of the profits or could not participate, in which case Perrigo would receive all azelastine profits. F. 472. Impax participated in Perrigo's at-risk launch, but limited its exposure to potential damages by capping its participation at 150,000 units. F. 472.

Third, Impax did not seek, or obtain, approval for an at-risk launch from Impax's board of directors, which was an absolute prerequisite. F. 473, 481, 486. *See, e.g.*, F. 482 (Impax has "to have sign off from the Board, because [Impax is] such a small company, and a launch at risk would ... potentially cause [the] company problems" if found liable for substantial damages). Indeed, Impax has an extensive internal process for evaluating an at-risk launch, including a detailed review of the potential product launch by

Impax's new product committee, legal team, marketing team, operations department, and division heads. F. 474-477. Thereafter, Impax's CFO must present a risk analysis profile to Impax's executive committee, which has to approve any at-risk launch. F. 477. Impax's CEO also must approve any decision to launch at risk. F. 478. If Impax's CEO and executive committee approve a possible at-risk launch, a presentation is made to Impax's board of directors by Impax's CFO, legal department, president of the generics division, and the manufacturing department. F. 479-480. Thus, in the case of azelastine, discussed above, Impax senior management, including the president of Impax's generics business, Impax's general counsel, and Impax's in-house attorney responsible for intellectual property, made a presentation and a recommendation regarding the at-risk launch at a special board of directors meeting. F. 484. A resolution was then placed before the Board, and the Board voted to approve the resolution. F. 484. With respect to generic Opana ER, in contrast, Impax's senior management never decided to pursue an at-risk launch, and the question was never submitted to the board for approval. F. 486-487.

c. Complaint Counsel's arguments

The evidence fails to prove Complaint Counsel's assertion that, absent a settlement of the Endo-Impax patent litigation, Impax would have launched its generic Opana ER at risk, as explained below.

i. Consideration of at-risk launch

Complaint Counsel argues that Impax was "considering" an at-risk launch in 2010. CCB at 45-46.

Even if true, however, this fact does not warrant an inference that Impax planned to launch at risk, or was likely to launch at risk. Such an inference is against the weight of the contrary evidence, summarized above, that supports the conclusion that Impax was not going to launch its generic Opana ER at risk.

Moreover, the evidence upon which Complaint Counsel relies to support is argument lacks probative weight. Complaint Counsel points to evidence that Mr. Mengler, president of Impax's generics division, created a presentation for the May 2010 board of directors meeting, in which he listed an at-risk launch of oxymorphone as a "current assumption" for projecting sales of oxymorphone ER, and that according to the minutes of the meeting, Mr. Mengler "expressed the view that [o]xymorphone was a good candidate for an at-risk launch." F. 493-494. However, Mr. Mengler's assumptions with respect to possible sales numbers did not "imply or mean that any legal decision ha[d] been made to clear the way for a launch." F. 493. There was no substantive discussion of an at-risk launch at the May 2010 board of directors meeting; and Impax's senior management did not make a recommendation to the board for an at-risk launch, did not discuss the risk or benefits of an at-risk launch, and did not ask the board to approve an at-risk launch at the May 2010 board meeting. F. 498-499. In 2010, senior management was looking at various possible scenarios and modeled an at-risk launch to forecast how that might impact Impax's budget if the decision to launch at risk were made. F. 488. Mr. Mengler raised oxymorphone ER at the May 2010 Board meeting to put oxymorphone ER "on the radar" of the Board and to "alert the board as to the

product being out there that might get to the point of an atrisk launch." F. 495. As Impax's CEO, Dr. Hsu, explained, senior management "want[s] to alert the board that we are considering this [as] one of the scenario[s] so that if we do come up with a final recommendation to the board, there will be no surprise. ... [T]his is very typical." F. 497. Impax's then CFO, Mr. Koch, who wrote the minutes of the meeting of the May 2010 board of directors meeting, explained that Mr. Mengler was communicating his evaluation of the oxymorphone market and sharing that information with the Board because senior management was unsure of what direction it would "ultimately take and ... [did not] want to come back to the board seeking an at-risk launch with them never having heard of it before." F. 496.

ii. Launch preparedness

Complaint Counsel also argues that Impax prepared a "launch inventory build" in 2010, and argues that such evidence shows that Impax was planning to launch at risk. This argument is not supported by the evidence.

The evidence shows that it was Impax's general practice to have its products that have been filed with Paragraph IV certifications ready to launch after the expiration of the Hatch- Waxman Act's 30-month stay. F. 503. When a product is 18 months away from its earliest theoretical launch, Impax's supply chain group begins prelaunch preparation activities. F. 506. This includes requesting a quota from the U.S. Drug Enforcement Agency ("DEA") to purchase any active pharmaceutical ingredients ("API") that are controlled substances; purchasing the API and other unique

materials necessary to produce the finished product; conducting "process validation" to prove that Impax's manufacturing process is repeatable and makes the product in a satisfactory manner; and producing a "launch inventory build," to ensure that Impax has enough product to meet expected demand on the launchable date. F. 508.

The evidence further shows that Impax's practice is to begin process validation six months before FDA approval of the relevant drug is expected, even if the product is the subject of active litigation. F. 511. Impax may build pre-launch quantities of products in its planning pipeline before either FDA approval is granted or a formal launch decision is made. F. 512. Impax considers its production of pre-launch quantities "routine" and consistent with industry practice. F. 514. Moreover, because Impax's operations team prepares products for launch before FDA approval or a formal decision about launch timing, it is not unusual for Impax to discard and write off some of the products and raw materials in its inventory. F. 516, 542-543.

Consistent with Impax's general practice, Impax's operations team sought to be ready to launch its generic oxymorphone ER product at the expiration of the Hatch-Waxman Act's 30- month stay on June 14, 2010. F. 503, 517. Impax requested a procurement quota from the DEA for oxymorphone, which was a necessary step before it could purchase oxymorphone API for any reason, including to conduct process validation of its oxymorphone ER product. F. 523. The initial allotment of oxymorphone quota was for product development manufacturing. F. 524. In

January 2010 and in April 2010, Impax submitted additional requests for oxymorphone procurement quota, which were approved. F. 525-526. By May 20, 2010, Impax had completed process validation for the 5 mg, 10 mg, 20 mg, and 40 mg dosages of generic oxymorphone ER. F. 529. These process validation batches that Impax had built were not sufficient, however, to meet the market demand for a full launch ("launch inventory"). F. 530. The time required to produce the necessary amount of oxymorphone ER would have made a product launch soon after FDA approval in mid-June 2010 impossible. F. 536.

Moreover, Impax never completed a launch inventory build for its oxymorphone ER product. F. 533. Impax's operations team does not build launch inventory without management approval. F. 531. In the case of oxymorphone ER, the Impax operations team never even received instructions from senior management to begin a launch inventory build. F. 532. Although Impax had solicited letters of intent from four customers asking customers for their good faith estimate of how much product they likely would buy if generic oxymorphone ER came on the market, Impax did not have any pricing contracts or agreements to purchase with those customers. F. 537.

d. Conclusion regarding at-risk launch

The evidence supports the conclusion that, absent a settlement, Impax would not have launched its generic Opana ER at risk, and fails to prove Complaint Counsel's assertion that, absent a settlement of the Endo-Impax patent litigation, Impax might have launched its generic Opana ER at risk.

2. Entry after litigation

If Impax and Endo had not settled, their patent litigation would have continued. F. 555. Respondent's contention as to when the patent litigation would likely have concluded relies on the opinions of its intellectual property expert, E. Anthony Figg. Mr. Figg's extensive experience in litigating patent matters in the federal courts makes him well qualified to opine on this issue. Mr. Figg is an attorney specializing in intellectual property, primarily involving the chemical, pharmaceutical, healthcare and biotechnology industries. His principal emphasis is patent litigation. He has served as lead counsel in numerous complex patent litigation matters, including Hatch-Waxman litigation, in federal district court and the Federal Circuit Court of Appeals, among other venues. Mr. Figg has practiced patent law since 1978. F. 557. Accordingly, Mr. Figg's opinions on the likely duration of the Endo-Impax patent litigation are entitled to, and are given, substantial weight. Complaint Counsel's arguments that Mr. Figg's opinions on this issue should be rejected as unreliable and/or against the weight of the evidence (*see, e.g.*, CCRB 73-74; CCRRFF 1075-1091) have been considered and have been determined to be without merit.

The evidence shows that, following a trial in the Endo-Impax patent litigation, the parties would have had to wait for the district court to issue findings of fact, conclusions of law, and an order. Based on Mr. Figg's review of Hatch-Waxman cases from the district court in New Jersey, a decision would have been issued approximately four to five months after

completion of trial, in or around November 2010. F. 556. Regardless of when the district court would have issued its decision in the Endo-Impax patent litigation, however, an appeal was likely, and would take 30 days to be docketed in the Federal Circuit Court of Appeals. F. 588. Based on Mr. Figg's review of statistics maintained by the Federal Circuit, the median time from docketing an appeal to issuance of a final decision was approximately 11 months in 2010 and 2011. F. 559. Applying these statistics, Mr. Figg estimated that an appellate decision in the Endo-Impax litigation would have been issued in November 2011. F. 559. Mr. Figg's estimate of a November 2011 issuance of an appellate decision is "very conservative," however, because the median time from docketing to a final decision, reported in the Federal Circuit statistics, includes settlements and summary affirmances. F. 559. In addition, the Federal Circuit is generous with briefing extensions, which increases the time it takes to receive a decision. F. 560.

Moreover, if Impax had lost at the trial level, the "centerpiece" of the appeal would have been the trial court's claim construction ruling, issued on April 5, 2010, which adopted Endo's proposed constructions for "hydrophobic material" and "sustained release." F. 71, 561. Impax would have had substantial arguments regarding this ruling on appeal. F. 561. If the appellate court agreed with Impax's arguments, it is likely that the appellate court would remand to the trial court for further development of the evidentiary issues. F. 562. This is because the parties would need to litigate infringement and validity under Impax's construction of the claims. F. 562. Because the trial court's claim construction ruling was in favor of Endo,

Endo never developed a record that Impax infringed its patents under Impax's construction of the claims. F. 562. Thus, lacking a record on the issue of infringement and validity, the Federal Circuit would not decide these issues itself, but would instead direct such decision to the trial court via remand. F. 562. If the appellate court ruled in favor of Impax and remanded the case to the trial court, the evidentiary proceedings on remand would likely have taken up to 18 months to complete, and therefore would not be concluded until a date close to January 2013. F. 563. If Impax lost the appeal in the Federal Circuit, Impax would have been enjoined and would not have been able to launch its oxymorphone ER product until Endo's patents expired in September 2013. F. 564.

In conclusion, as explained above, the evidence proves that, absent the settlement, ongoing litigation would have prevented Impax's entry until November 2011 at the earliest, and more likely until a date close to January 2013, assuming Impax ultimately prevailed. If Impax ultimately lost its patent challenge against Endo, Impax would not have been able to launch its oxymorphone ER product until the litigated patents expired in September 2013.

3. Weighing of anticompetitive effects against procompetitive benefits

As explained in detail in Section III.C., the evidence proves that the Endo-Impax Settlement included payment to prevent the risk of competition, which, under *Actavis*, is an anticompetitive harm. Under the facts of the instant case, however, the magnitude or extent of such harm is largely theoretical, based on an inference that Impax's entry

date, and therefore generic competition, would have been earlier than January 2013, had the reverse payment not induced the settlement. *See, e.g.*, CCB at 47 (asserting that Challenged Agreement "eliminated risk" of generic competition "for over two years"). Although the Endo-Impax Settlement foreclosed the hypothetical possibility of Impax launching its generic Opana ER earlier than the date set forth in the SLA - either at risk or after litigation - the fact is that such earlier entry was unlikely. Moreover, pursuing litigation, which was the alternative to the Endo-Impax Settlement, would not have guaranteed the continued availability of Impax's generic Opana ER, even if Impax had prevailed on its patent claim, because, as explained in Section III.E., it is likely that Endo would have successfully asserted after-acquired patents to enjoin Impax, as it had against all other sellers of generic Opana ER.

In contrast to the largely theoretical anticompetitive harm asserted by Complaint Counsel, the real world procompetitive benefits of the Endo-Impax Settlement are substantial. As detailed in Section III.E, the January 2013 entry date provided in the SLA, together with the broad patent license provisions, enabled a generic Opana ER to enter the market eight months before Endo's original Opana ER patents expired, and sixteen years before Endo's after-acquired patents expired, and to continue selling generic Opana ER up to the present day, without threat of patent infringement litigation relating to original Opana ER. F. 592-596. Impax has sold generic Opana ER without interruption for more than five years, since launching its product in January 2013. F. 597. Furthermore, Impax's product is not only the sole

generic oxymorphone product available to consumers, F. 596, but the only available oxymorphone ER product.[37] F. 598. These actual consumer benefits outweigh the theoretical anticompetitive harm demonstrated in this case. Indeed, Complaint Counsel's economic expert witness, Professor Noll, admits that consumers are better off today because Impax is selling oxymorphone ER. F. 599. These actual consumer benefits are even more pronounced if it is accepted, as Complaint Counsel urges, that patients cannot readily switch to an alternative long acting opioid. *See*, *e.g.*, CCFF Section VIII.E., F.

Even if it is assumed that Impax would have entered the market as early as June 2010, and that the settlement therefore delayed generic entry (and extended Endo's patent monopoly) for two and a half years, the demonstrated consumer benefits of the settlement still outweigh the anticompetitive harm because the settlement enabled and allowed uninterrupted and continuous access to generic Opana ER for more than five years. Similarly, to the extent that Complaint Counsel argues that the no-AG provision of the SLA deprived consumers of the benefit of competition from an Endo authorized generic drug, such harm would be limited to the duration of the 180-day exclusivity period to which the no-AG provision applied, and is far outweighed by the more than five

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[37] In March 2012, after a supply disruption affecting production of original Opana ER, Endo launched reformulated Opana ER and, at the direction of FDA, stopped distributing original Opana ER. F. 227-230. On September 1, 2017, at the request of FDA, Endo also ceased sales of reformulated Opana ER. F. 111.

years of uninterrupted and continuous access to generic Opana ER.

Accordingly, having weighed and balanced the anticompetitive effects and the procompetitive benefits of the Endo-Impax Settlement, the evidence fails to prove the "presence of significant unjustified anticompetitive consequences," *Actavis*, 133 S. Ct. at 2238, or that the agreement "engendered a net harm." *Cal. Dental Ass'n*, 224 F.3d at 957-58. Rather, the evidence proves that the Endo-Impax Settlement was, on balance, procompetitive. Thus, the evidence fails to demonstrate that Endo-Impax Settlement constituted an unreasonable restraint of trade.

G. Conclusion

Having fully considered the applicable law, the arguments of the parties, and the entire record in this case, and for all the foregoing reasons, the evidence fails to prove a violation of Section 5 of the FTC Act.

Therefore, the Complaint must be DISMISSED.

IV. SUMMARY OF CONCLUSIONS OF LAW

1. Complaint Counsel bears the burden of proving jurisdiction and liability by a preponderance of evidence.

2. Respondent is a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. §44.

3. Respondent's challenged activities relating to the sale of pharmaceutical drugs are in or affect commerce in the United States, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. §44.

4. The Commission has jurisdiction over Respondent and the subject matter of this proceeding, pursuant to Section 5 of the FTC Act.

5. The FTC Act's prohibition of unfair methods of competition under Section 5 of the FTC Act encompasses violations of Section 1 of the Sherman Act.

6. Section 1 of the Sherman Act prohibits every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States. 15 U.S.C. §1.

7. Despite its broad language, the ban on contracts in restraint of trade extends only to unreasonable restraints of trade, i.e., restraints that impair competition.

8. The Supreme Court, in *FTC v. Actavis*, 133 S. Ct. 2223 (2013), held that reverse payment patent settlements are not immune from antitrust scrutiny, anticompetitive effects should not be presumed from the presence of a reverse payment alone, and that reverse payment settlements are to be evaluated under the rule of reason.

9. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 *et seq*., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§355(b)(2) and 355(j) and 35 U.S.C. §271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

10. In a traditional rule-of-reason case, the relevant market must be defined to allow a court to determine the effect that an allegedly illegal act has on competition. However, where a settlement of patent litigation arises in the context of the peculiar framework of the Hatch-Waxman Act, and where a valid patent gives the brand holder a legal monopoly, the appropriate market in which to assess the anticompetitive effects of a reverse payment settlement agreement is the market that is the subject of that agreement - the branded pharmaceutical product and its generic equivalents.

11. The relevant market in which to analyze the effects of the Challenged Agreement in the instant case is the market for oxymorphone ER, branded and generic, which is the market that mattered to Impax and Endo, the parties to the Challenged Agreement.

12. In a rule of reason analysis, Complaint Counsel has the initial burden of proving anticompetitive effects.

13. A brand patent holder's use of a payment to induce a generic challenger to drop its patent challenge and agree to stay out of the market, rather than face the risk of patent invalidation and resulting generic competition, is an anticompetitive harm under *Actavis*.

14. To meet the initial burden of proving anticompetitive effects in a reverse payment case, Complaint Counsel must prove payment for delay, or, in other words, payment to prevent the risk of competition. The likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated

future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.

15. Under *Actavis*, a reasonable inference of harm to consumers from lessened competition can be established by identifying a large and otherwise unexplained payment of cash or something else of value made by the patent holder to the alleged infringer in exchange for that firm's agreement not to enter the market for some period of time, or by direct evidence that the patent holder paid the alleged infringer to delay its entry into the market and thereby restrict competition, e.g., evidence indicating that the purpose and effect of a reverse payment was to delay entry.

16. The formulation of the initial burden of proving anticompetitive effects in a reverse payment case set forth in *King Drug Company of Florence v. Cephalon*, *Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015), upon which Complaint Counsel relies, is rejected, to the extent it holds that anticompetitive effects can be demonstrated solely by proof of a large payment and market power. This formulation has not been adopted by any other court and presents an unduly truncated burden of proof.

17. *Actavis* did not state that a "large" reverse payment is by nature anticompetitive. Under *Actavis*, it is a large *and unjustified* payment that can bring the risk of anticompetitive effects.

18. By their nature, pharmaceutical patents often carry with them market power. A valid patent grants the legal right to exclude generic competition and the

practical ability to profitably charge higher prices than generic competitors would charge.

19. If the initial burden of proving anticompetitive effects is met, the Respondent in a reverse payment case may demonstrate that the Challenged Agreement had offsetting procompetitive benefits.

20. Complaint Counsel's position that the only relevant procompetitive justifications are those that justify the reverse payment, thereby barring all other evidence of procompetitive benefits from the settlement and condemning the settlement on the basis of the reverse payment alone, is inconsistent with *Actavis* and the rule of reason generally.

21. Procompetitive benefits arising in connection with a reverse payment settlement agreement as a whole are properly considered as part of a well-structured rule of reason analysis.

22. Enabling a product to be marketed that might otherwise be unavailable widens consumer choice and is therefore procompetitive.

23. The fact that a reverse payment settlement agreement allows generic entry prior to patent expiration, while not dispositive, can be considered in assessing the competitive consequences of the agreement.

24. Where the evidence proves that an agreement poses both anticompetitive harm and procompetitive benefits, the harms and benefits must be weighed against each other in order to judge whether the challenged behavior is, on balance, reasonable.

25. Where the evidence proves that an agreement poses both anticompetitive harm and procompetitive

benefits, Complaint Counsel has the burden of establishing that the settlement is nevertheless anticompetitive on balance.

26. The relevant benchmark in evaluating reverse payment patent settlements should be no different from the benchmark in evaluating any other challenged agreement: What would the state of competition have been without the agreement?

27. It is appropriate to assess the magnitude and/or extent of delayed generic competition attributable to a reverse payment settlement agreement in order to balance anticompetitive harm against demonstrated procompetitive benefits.

28. A settlement providing for entry prior to patent expiration might enable generic competition on or prior to the entry date that would have resulted, on average, from litigating the patent suit to conclusion, which at a minimum affects the magnitude of any anticompetitive effect.

29. Based on weighing and balancing the anticompetitive effects and the procompetitive benefits of the Challenged Agreement, the evidence fails to prove the presence of significant unjustified anticompetitive consequences, or that the agreement engendered a net harm.

30. The evidence fails to demonstrate that the Challenged Agreement constituted an unreasonable restraint of trade.

31. The evidence fails to prove a violation of Section 5 of the FTC Act.

32. This Initial Decision makes no findings concerning alleged competitive effects of the 2017

settlement agreement between Endo and Impax, and Endo' s arguments as intervenor opposing any remedy that would order the nullification or otherwise affect Endo's rights under that agreement are moot.

ORDER

For the reasons stated above, IT IS ORDERED that the Complaint be, and hereby is, DISMISSED.

ORDERED:

[handwritten:signature]
D. Michael Chappell
Chief Administrative Law Judge

Date: May 18, 2018

Appendix D

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

15 U.S.C. §1

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

21 U.S.C. §355

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b) Filing application; contents

(1)

(A) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection

(a). Such persons shall submit to the Secretary as part of the application--

(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use;

(ii) a full list of the articles used as components of such drug;

(iii) a full statement of the composition of such drug;

(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;

(vi) specimens of the labeling proposed to be used for such drug;

(vii) any assessments required under section 355c of this title; and

(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that--

(I) claims the drug for which the applicant submitted the application and is a drug substance (active

ingredient) patent or a drug product (formulation or composition) patent; or

(II) claims a method of using such drug for which approval is sought or has been granted in the application.

(B) If an application is filed under this subsection for a drug, and a patent of the type described in subparagraph (A)(viii) is issued after the filing date but before approval of the application, the applicant shall amend the application to include the patent number and expiration date.

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include--

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)--

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) Notice of opinion that patent is invalid or will not be infringed

(A) Agreement to give notice

An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) Timing of notice

An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph--

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) Recipients of notice

An applicant required under this paragraph to give notice shall give notice to--

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) Contents of notice

A notice required under this paragraph shall-

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)

(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)

(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 262 of Title 42, which shall relate to promptness in conducting the

review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 262 of Title 42 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size--

(i)

(I) of clinical trials intended to form the primary basis of an effectiveness claim; or

(II) in the case where human efficacy studies are not ethical or feasible, of animal and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim; or

(ii) with respect to an application for approval of a biological product under section 262(k) of Title 42, of any necessary clinical study or studies.

The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by

the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except--

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division

personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 262 of Title 42 (including all scientific and medical matters, chemistry, manufacturing, and controls).

(6) An application submitted under this subsection shall be accompanied by the certification required under section 282(j)(5)(B) of Title 42. Such certification shall not be considered an element of such application.

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either--

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) Not later than 30 days after the date of approval of an application submitted under subsection (b), the holder of the approved application shall file with the Secretary the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii), except that a patent that is identified as claiming a method of using such drug shall be filed only if the patent claims a method of use approved in the application. If a patent described in subsection (b)(1)(A)(viii) is issued after the date of approval of an application submitted under subsection (b), the holder of the approved application shall, not later than 30 days after the date of issuance of the patent, file the patent number and the expiration date of the patent, except that a patent that claims a method of using such drug shall be filed only if approval for such use has been granted in the application. If the patent information

described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii). If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information under subsection (b) because no patent of the type for which information is required to be submitted in subsection (b)(1)(A)(viii) had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it. Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date

determined by applying the following to each certification made under subsection (b)(2)(A):

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably

cooperate in expediting the action, except that--

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on--

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed--

(I) if the judgment of the district court is appealed, the approval shall be made effective on-

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the

approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28 by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless--

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under

paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of

business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those

restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent

information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either--

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E)

(i) Repealed. Pub.L. 117-9, § 1(b)(1)(A), Apr. 23, 2019, 135 Stat. 258

(ii) If an application submitted under subsection (b) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under subsection (b), is approved after September 24, 1984,

no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of

approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application approved under subsection (b), is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection

(b) is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailabilty[1] studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this

subsection and for which the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from September 24, 1984.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(5)

(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

(B) A supplemental application is eligible for review as described in subparagraph (A) only if--

(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

(ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

(C) The Secretary shall post on the Internet website of the Food and Drug Administration and update annually--

(i) the number of applications reviewed solely under subparagraph (A) or section 262(a)(2)(E) of Title 42;

(ii) the average time for completion of review under subparagraph (A) or section 262(a)(2)(E) of Title 42;

(iii) the average time for review of supplemental applications where the Secretary did not use review flexibility under subparagraph (A) or section 262(a)(2)(E) of Title 42; and

(iv) the number of applications reviewed under subparagraph (A) or section 262(a)(2)(E) of Title 42 for which the Secretary made use of full data sets in addition to the qualified data summary.

(D) In this paragraph--

(i) the term "qualified indication" means an indication for a drug that the Secretary determines to be appropriate

for summary level review under this paragraph; and

(ii) the term "qualified data summary" means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the

application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to

facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for marketing approval of a drug.

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under

the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 360(k)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate

to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based. The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 355-1(g)(2)(D) of this title.

(f) Revocation of order refusing, withdrawing or suspending approval of application

Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Service of orders

Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2)

by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) Appeal from order

An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of Title 28. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable

grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of Title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary

(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon--

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b); and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer

or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including--

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)

(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that--

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any

human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 282 of Title 42.

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)

(A) An abbreviated application for a new drug shall contain--

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have

been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)

(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other

information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (ii) through (vi) of subsection (b)(1)(A);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)--

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) Notice of opinion that patent is invalid or will not be infringed

(i) Agreement to give notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) Timing of notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph--

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) Recipients of notice

An applicant required under this subparagraph to give notice shall give notice to--

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) Contents of notice

A notice required under this subparagraph shall--

(I) state that an application that contains data from bioavailability or bioequivalence

studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds--

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)

(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)

(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and

which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except--

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of

the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds--

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)

(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show--

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)

(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary

respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for

use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)

(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the

Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later

determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on--

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed--

(aa) if the judgment of the district court is appealed, the approval shall be made effective on--

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of

the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-day exclusivity period

(I) Effectiveness of application

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date

that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions

In this paragraph:

(aa) 180-day exclusivity period

The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant

As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application

As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(v) 180-day exclusivity period for competitive generic therapies

(I) Effectiveness of application

Subject to subparagraph (D)(iv), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

(II) Limitation

The exclusivity period under subclause (I) shall not apply with respect to a competitive generic

therapy that has previously received an exclusivity period under subclause (I).

(III) Definitions

In this clause and subparagraph (D)(iv):

(aa) The term "competitive generic therapy" means a drug--

(AA) that is designated as a competitive generic therapy under section 356h of this title; and

(BB) for which there are no unexpired patents or exclusivities on the list of products described in section 355(j)(7)(A) of this title at the time of submission.

(bb) The term "first approved applicant" means any applicant that has submitted an application that--

(AA) is for a competitive generic therapy that is approved on the first day on which any application for such competitive generic therapy is approved;

(BB) is not eligible for a 180-day exclusivity period

under clause (iv) for the drug that is the subject of the application for the competitive generic therapy; and

(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D).

(C) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless--

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent

brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition

described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the

restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent

brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either--

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term "forfeiture event", with respect to an

application under this subsection, means the occurrence of any of the following:

(I) Failure to market

The first applicant fails to market the drug by the later of--

(aa) the earlier of the date that is--

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action

brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) Withdrawal of application

The first applicant withdraws the application or the Secretary

considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification

The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval

The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner

The first applicant enters into an agreement with another

applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents

All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture

The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a

forfeiture event occurs with respect to that first applicant.

(iii) Subsequent applicant

If all first applicants forfeit the 180-day exclusivity period under clause (ii)--

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(iv) Special forfeiture rule for competitive generic therapy

The 180-day exclusivity period described in subparagraph (B)(v) shall be forfeited by a first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall

commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)

(i) Repealed. Pub.L. 117-9, § 1(b)(1)(B), Apr. 23, 2021, 135 Stat. 258

(ii) If an application submitted under subsection (b) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under subsection (b), is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an

application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application approved under subsection (b), is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of

the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was

submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended--

(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)

(A)

(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public--

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved

for safety and effectiveness under subsection (c) before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(iv) For each drug included on the list, the Secretary shall specify any exclusivity period that is applicable, for which the Secretary has determined the

expiration date, and for which such period has not yet expired, under--

(I) clause (ii), (iii), or (iv) of subsection (c)(3)(E);

(II) clause (iv) or (v) of paragraph (5)(B);

(III) clause (ii), (iii), or (iv) of paragraph (5)(F);

(IV) section 355a of this title;

(V) section 355f of this title;

(VI) section 360cc(a) of this title; or

(VII) subsection (u).

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list--

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(D) In the case of a listed drug for which the list under subparagraph (A)(i) includes a patent for such drug, and any claim of the patent has been cancelled or invalidated pursuant to a final decision issued by the Patent Trial and Appeal Board of the United States Patent and Trademark Office or by a court, from which no appeal has been, or can be, taken, if the holder of the applicable application approved under subsection (c) determines that a patent for such drug, or any patent information for such drug, no longer meets the listing requirements under this section--

(i) the holder of such approved application shall notify the Secretary, in writing, within 14 days of such decision of such cancellation or invalidation and request that such patent or patent information, as applicable, be amended or withdrawn in accordance with the

decision issued by the Patent Trial and Appeal Board or a court;

(ii) the holder of such approved application shall include in any notification under clause (i) information related to such patent cancellation or invalidation decision and submit such information, including a copy of such decision, to the Secretary; and

(iii) the Secretary shall, in response to a notification under clause (i), amend or remove patent or patent information in accordance with the relevant decision from the Patent Trial and Appeals Board or court, as applicable, except that the Secretary shall not remove from the list any patent or patent information before the expiration of any 180-day exclusivity period under paragraph (5)(B)(iv) that relies on a certification described in paragraph (2)(A)(vii)(IV).

(8) For purposes of this subsection:

(A)

(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements

intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if--

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the

alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of--

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)

(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this chapter, be eligible for

approval and shall not be considered misbranded under section 352 of this title if--

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

(11)

(A) Subject to subparagraph (B), the Secretary shall prioritize the review of, and act within 8 months of the date of the submission of, an original abbreviated new drug application submitted for review under this subsection that is for a drug--

(i) for which there are not more than 3 approved drug products listed under paragraph (7) and for which there are no blocking patents and exclusivities; or

(ii) that has been included on the list under section 356e of this title.

(B) To qualify for priority review under this paragraph, not later than 60 days prior to the submission of an application described in subparagraph (A) or that the Secretary may prioritize pursuant to subparagraph (D), the applicant shall provide complete, accurate information regarding facilities involved in manufacturing processes and testing of the drug that is the subject of the application, including facilities in corresponding Type II active pharmaceutical ingredients drug master files referenced in an application and sites or organizations involved in bioequivalence and clinical studies used to support the application, to enable the Secretary to make a determination regarding whether an inspection of a facility is necessary. Such information shall include the relevant (as determined by the Secretary) sections of such application, which shall be

unchanged relative to the date of the submission of such application, except to the extent that a change is made to such information to exclude a facility that was not used to generate data to meet any application requirements for such submission and that is not the only facility intended to conduct one or more unit operations in commercial production. Information provided by an applicant under this subparagraph shall not be considered the submission of an application under this subsection.

(C) The Secretary may expedite an inspection or reinspection under section 374 of this title of an establishment that proposes to manufacture a drug described in subparagraph (A).

(D) Nothing in this paragraph shall prevent the Secretary from prioritizing the review of other applications as the Secretary determines appropriate.

(12) The Secretary shall publish on the internet website of the Food and Drug Administration, and update at least once every 6 months, a list of all drugs approved under subsection (c) for which all patents and periods of exclusivity under this chapter have expired and for which no application has been approved under this subsection.

(13) Upon the request of an applicant regarding one or more specified pending applications under this subsection, the Secretary shall, as appropriate, provide review status

updates indicating the categorical status of the applications by each relevant review discipline.

(k) Records and reports; required information; regulations and orders; access to records

(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e). Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit

such officer or employee at all reasonable times to have access to and copy and verify such records.

(3) Active postmarket risk identification

(A) Definition

In this paragraph, the term "data" refers to information with respect to a drug approved under this section or under section 262 of Title 42, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

(B) Development of postmarket risk identification and analysis methods

The Secretary shall, not later than 2 years after September 27, 2007, in collaboration with public, academic, and private entities--

(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate--

(I) at least 25,000,000 patients by July 1, 2010; and

(II) at least 100,000,000 patients by July 1, 2012; and

(iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the development of effective research methods for the study of drug safety questions.

(C) Establishment of the postmarket risk identification and analysis system

(i) In general

The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures--

(I) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and in a manner that does not disclose individually identifiable health information in violation of paragraph (4)(B);

(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 355-1(b) of this title) submitted to the Secretary under paragraph (1), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;

(III) to provide for active adverse event surveillance using the following data sources, as available:

(aa) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

(bb) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

(cc) other data as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(IV) to identify certain trends and patterns with respect to data accessed by the system;

(V) to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative national adverse event trends; and

(VI) to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

(ii) Timeliness of reporting

The procedures established under clause (i) shall ensure that such data are accessed, analyzed, and reported in a timely, routine, and systematic manner, taking into consideration the need for data completeness, coding, cleansing, and standardized analysis and transmission.

(iii) Private sector resources

To ensure the establishment of the active postmarket risk identification and analysis system under this subsection not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), as required under clause (i), the Secretary may, on a temporary or permanent basis,

implement systems or products developed by private entities.

(iv) Complementary approaches

To the extent the active postmarket risk identification and analysis system under this subsection is not sufficient to gather data and information relevant to a priority drug safety question, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze such data and information, including--

> **(I)** approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and
>
> **(II)** existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

(v) Authority for contracts

The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

(4) Advanced analysis of drug safety data

(A) Purpose

The Secretary shall establish collaborations with public, academic, and private entities, which may include the Centers for Education and Research on Therapeutics under section 299b-1 of Title 42, to provide for advanced analysis of drug safety data described in paragraph (3)(C) and other information that is publicly available or is provided by the Secretary, in order to--

(i) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

(ii) provide the Secretary with routine access to outside expertise to study advanced drug safety questions; and

(iii) enhance the ability of the Secretary to make timely assessments based on drug safety data.

(B) Privacy

Such analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

(C) Public process for priority questions

At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or any successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on-

(i) priority drug safety questions; and

(ii) mechanisms for answering such questions, including through--

(I) active risk identification under paragraph (3); and

(II) when such risk identification is not sufficient, postapproval studies and clinical trials under subsection (o)(3).

(D) Procedures for the development of drug safety collaborations

(i) In general

Not later than 180 days after the date of the establishment of the active postmarket risk identification and analysis system under this subsection, the Secretary shall establish and implement procedures under which the Secretary may routinely contract with one or more qualified entities to--

(I) classify, analyze, or aggregate data described in

paragraph (3)(C) and information that is publicly available or is provided by the Secretary;

(II) allow for prompt investigation of priority drug safety questions, including--

(aa) unresolved safety questions for drugs or classes of drugs; and

(bb) for a newly-approved drugs,[2] safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);

(III) perform advanced research and analysis on identified drug safety risks;

(IV) focus postapproval studies and clinical trials under subsection (o)(3) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

(V) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

(ii) Request for specific methodology

The procedures described in clause (i) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

(E) Use of analyses

The Secretary shall provide the analyses described in this paragraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

(F) Qualified entities

(i) In general

The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

(ii) Qualification

The Secretary shall enter into a contract with an entity under clause (i) only if the Secretary determines that the entity has a significant presence in the

United States and has one or more of the following qualifications:

(I) The research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this paragraph, including the capability and expertise to provide the Secretary de-identified data consistent with the requirements of this subsection.

(II) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data.

(III) Experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data.

(IV) An understanding of drug development or risk/benefit balancing in a clinical setting.

(V) Other expertise which the Secretary deems necessary to fulfill the activities under this paragraph.

(G) Contract requirements

Each contract with a qualified entity under subparagraph (F)(i) shall contain the following requirements:

(i) Ensuring privacy

The qualified entity shall ensure that the entity will not use data under this subsection in a manner that--

(I) violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

(II) violates sections 552 or 552a of Title 5 with regard to the privacy of individually-identifiable beneficiary health information; or

(III) discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.

Nothing in this clause prohibits lawful disclosure for other purposes.

(ii) Component of another organization

If a qualified entity is a component of another organization--

(I) the qualified entity shall establish appropriate security measures to maintain the confidentiality and privacy of such data; and

(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

(iii) Termination or nonrenewal

If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

(I) Confidentiality and privacy protections

The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

(II) Disposition of data

The entity shall return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

(H) Competitive procedures

The Secretary shall use competitive procedures (as defined in section 132 of Title 41) to enter into contracts under subparagraph (G).

(I) Review of contract in the event of a merger or acquisition

The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this paragraph will continue to be met.

(J) Coordination

In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and to the extent practicable shall coordinate with the activities of private entities, professional associations, or other entities that may have sources of drug safety data.

(5) The Secretary shall--

(A) conduct regular screenings of the Adverse Event Reporting System database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse[3] Event Reporting System within the last quarter; and[4]

(B) on an annual basis, review the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, report to the Congress on these determinations, and assign

start dates and estimated completion dates for such commitments; and

(C) make available on the Internet website of the Food and Drug Administration-

(i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and

(ii) criteria for public posting of adverse event signals.

(l) Public disclosure of safety and effectiveness data and action package

(1) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown--

(A) if no work is being or will be undertaken to have the application approved,

(B) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(C) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(D) if the Secretary has determined that such drug is not a new drug, or

(E) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

(2) Action package for approval

(A) Action package

The Secretary shall publish the action package for approval of an application under subsection (b) or section 262 of Title 42 on the Internet Web site of the Food and Drug Administration--

(i) not later than 30 days after the date of approval of such applications--

(I) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

(II) for a biological product, no active ingredient of which has been approved in any other application under section 262 of Title 42; and

(ii) not later than 30 days after the third request for such action package for approval received under section 552 of

Title 5 for any other drug or biological product.

(B) Immediate publication of summary review

Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet Web site of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.

(C) Contents

An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

(i) Documents generated by the Food and Drug Administration related to review of the application.

(ii) Documents pertaining to the format and content of the application generated during drug development.

(iii) Labeling submitted by the applicant.

(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconcurrence with review conclusions.

(v) The Division Director and Office Director's decision document which includes--

(I) a brief statement of concurrence with the summary review;

(II) a separate review or addendum to the review if disagreeing with the summary review; and

(III) a separate review or addendum to the review to add further analysis.

(vi) Identification by name of each officer or employee of the Food and Drug Administration who--

(I) participated in the decision to approve the application; and

(II) consents to have his or her name included in the package.

(D) Review

A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.

(E) Confidential information

This paragraph does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of Title 5.

(m) "Patent" defined

For purposes of this section, the term "patent" means a patent issued by the United States Patent and Trademark Office.

(n) Scientific advisory panels

(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under this section or section 262 of Title 42, the Secretary shall establish panels of experts or use panels of experts established before November 21, 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 394 of this title to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of--

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology,

pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this chapter and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(5) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to

receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of Title 5, for persons in the Government service employed intermittently.

(6) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(7) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

(o) Postmarket studies and clinical trials; labeling

(1) In general

A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.

(2) Definitions

For purposes of this subsection:

(A) Responsible person

The term "responsible person" means a person who--

(i) has submitted to the Secretary a covered application that is pending; or

(ii) is the holder of an approved covered application.

(B) Covered application

The term "covered application" means--

(i) an application under subsection (b) for a drug that is subject to section 353(b) of this title; and

(ii) an application under section 262 of Title 42.

(C) New safety information; serious risk

The terms "new safety information", "serious risk", and "signal of a serious risk" have the meanings given such terms in section 355-1(b) of this title.

(3) Studies and clinical trials

(A) In general

For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.

(B) Purposes of study or clinical trial

The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:

(i) To assess a known serious risk related to the use of the drug involved.

(ii) To assess signals of serious risk related to the use of the drug.

(iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk.

(C) Establishment of requirement after approval of covered application

The Secretary may require a postapproval study or studies or postapproval clinical trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to

establish such requirement only if the Secretary becomes aware of new safety information.

(D) Determination by Secretary

(i) Postapproval studies

The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the active postmarket risk identification and analysis system as available under subsection (k)(3) will not be sufficient to meet the purposes set forth in subparagraph (B).

(ii) Postapproval clinical trials

The Secretary may not require the responsible person to conduct a clinical trial under this paragraph, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in subparagraph (B).

(E) Notification; timetables; periodic reports

(i) Notification

The Secretary shall notify the responsible person regarding a requirement under this paragraph to conduct a postapproval study or clinical trial by the target dates for communication of feedback from the

review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(ii) Timetable; periodic reports

For each study or clinical trial required to be conducted under this paragraph, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial. With respect to each study required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such study including whether any difficulties in completing the study have been encountered. With respect to each clinical trial required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such clinical trial including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any

difficulties completing the clinical trial have been encountered, and registration information with respect to the requirements under section 282(j) of Title 42. If the responsible person fails to comply with such timetable or violates any other requirement of this subparagraph, the responsible person shall be considered in violation of this subsection, unless the responsible person demonstrates good cause for such noncompliance or such other violation. The Secretary shall determine what constitutes good cause under the preceding sentence.

(F) Dispute resolution

The responsible person may appeal a requirement to conduct a study or clinical trial under this paragraph using dispute resolution procedures established by the Secretary in regulation and guidance.

(4) Safety labeling changes requested by Secretary

(A) New safety or new effectiveness information

If the Secretary becomes aware of new information, including any new safety information or information related to reduced effectiveness, that the Secretary determines should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under subsection (b) is not

currently marketed, the holder of an approved application under subsection (j).

(B) Response to notification

Following notification pursuant to subparagraph (A), the responsible person or the holder of the approved application under subsection (j) shall within 30 days--

(i) submit a supplement proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions, or new effectiveness information; or

(ii) notify the Secretary that the responsible person or the holder of the approved application under subsection (j) does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.

(C) Review

Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new

safety or new effectiveness information, and if so, the contents of such labeling changes.

(D) Discussions

Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.

(E) Order

Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue an order directing the responsible person or the holder of the approved application under subsection (j) to make such a labeling change as the Secretary deems appropriate to address the new safety or new effectiveness information. Within 15 days of such an order, the responsible person or the holder of the approved application under subsection (j) shall submit a supplement containing the labeling change.

(F) Dispute resolution

Within 5 days of receiving an order under subparagraph (E), the responsible person or the holder of the approved application under subsection (j) may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.

(G) Violation

If the responsible person or the holder of the approved application under subsection (j) has not submitted a supplement within 15

days of the date of such order under subparagraph (E), and there is no appeal or dispute resolution proceeding pending, the responsible person or holder shall be considered to be in violation of this subsection. If at the conclusion of any dispute resolution procedures the Secretary determines that a supplement must be submitted and such a supplement is not submitted within 15 days of the date of that determination, the responsible person or holder shall be in violation of this subsection.

(H) Public health threat

Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that such a labeling change is necessary to protect the public health, the Secretary may accelerate the timelines in such subparagraphs.

(I) Rule of construction

This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under subsection (j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).

(5) Non-delegation

Determinations by the Secretary under this subsection for a drug shall be made by individuals

at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(p) Risk evaluation and mitigation strategy

(1) In general

A person may not introduce or deliver for introduction into interstate commerce a new drug if--

(A)

(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 353(b) of this title; or

(ii) the application for such drug is approved under section 262 of Title 42; and

(B) a risk evaluation and mitigation strategy is required under section 355-1 of this title with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 355-1 of this title, including requirements regarding assessments of approved strategies.

(2) Certain postmarket studies

The failure to conduct a postmarket study under section 356 of this title, subpart H of part 314, or subpart E of part 601 of title 21, Code of Federal Regulations (or any successor regulations), is deemed to be a violation of paragraph (1).

(q) Petitions and civil actions regarding approval of certain applications

(1) In general

(A) Determination

The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) of this section or section 262(k) of Title 42 because of any request to take any form of action relating to the application, either before or during consideration of the request, unless--

(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.

Consideration of the petition shall be separate and apart from review and approval of any application.

(B) Notification

If the Secretary determines under subparagraph (A) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making such determination, the following information:

(i) Notification of the fact that a determination under subparagraph (A) has been made.

(ii) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

(iii) A brief summary of the specific substantive issues raised in the petition which form the basis of the determination.

(C) Format

The information described in subparagraph (B) shall be conveyed via either, at the discretion of the Secretary--

(i) a document; or

(ii) a meeting with the applicant involved.

(D) Public disclosure

Any information conveyed by the Secretary under subparagraph (C) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in such application.

(E) Denial based on intent to delay

If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid

scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe the factors that will be used to determine under this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

(F) Final agency action

The Secretary shall take final agency action on a petition not later than 150 days after the date on which the petition is submitted. The Secretary shall not extend such period for any reason, including--

(i) any determination made under subparagraph (A);

(ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or

(iii) the consent of the petitioner.

(G) Extension of 30-month period

If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the

Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

(H) Certification

The Secretary shall not consider a petition for review unless the party submitting such petition does so in written form and the subject document is signed and contains the following certification: "I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to such party and the names of such persons or

organizations inserted in the first and second blank space, respectively.

(I) Verification

The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and the subject document is signed and contains the following verification: "I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to the party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(2) Exhaustion of administrative remedies

(A) Final agency action within 150 days

The Secretary shall be considered to have taken final agency action on a petition if--

(i) during the 150-day period referred to in paragraph (1)(F), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

(ii) such period expires without the Secretary having made such a final decision.

(B) Dismissal of certain civil actions

If a civil action is filed against the Secretary with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

(C) Administrative record

For purposes of judicial review related to the approval of an application for which a petition under paragraph (1) was submitted, the administrative record regarding any issue raised by the petition shall include--

(i) the petition filed under paragraph (1) and any supplements and comments thereto;

(ii) the Secretary's response to such petition, if issued; and

(iii) other information, as designated by the Secretary, related to the Secretary's determinations regarding the issues raised in such petition, as long as the information was considered by the agency no later than the date of final agency action as defined under subparagraph (2)(A), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

(3) Annual report on delays in approvals per petitions

The Secretary shall annually submit to the Congress a report that specifies--

(A) the number of applications that were approved during the preceding 12-month period;

(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;

(C) the number of days by which such applications were so delayed; and

(D) the number of such petitions that were submitted during such period.

(4) Exceptions

(A) This subsection does not apply to--

(i) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

(ii) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

(B) Paragraph (2) does not apply to a petition addressing issues concerning an application submitted pursuant to section 262(k) of Title 42.

(5) Definitions

(A) Application

For purposes of this subsection, the term "application" means an application submitted under subsection (b)(2) or (j) of this section or section 262(k) of Title 42.

(B) Petition

For purposes of this subsection, other than paragraph (1)(A)(i), the term "petition" means a request described in paragraph (1)(A)(i).

(r) Postmarket drug safety information for patients and providers

(1) Establishment

Not later than 1 year after September 27, 2007, the Secretary shall improve the

transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that--

(A) provides links to drug safety information listed in paragraph (2) for prescription drugs that are approved under this section or licensed under section 262 of Title 42; and

(B) improves communication of drug safety information to patients and providers.

(2) Internet Web site

The Secretary shall carry out paragraph (1) by--

(A) developing and maintaining an accessible, consolidated Internet Web site with easily searchable drug safety information, including the information found on United States Government Internet Web sites, such as the United States National Library of Medicine's Daily Med and Medline Plus Web sites, in addition to other such Web sites maintained by the Secretary;

(B) ensuring that the information provided on the Internet Web site is comprehensive and includes, when available and appropriate--

(i) patient labeling and patient packaging inserts;

(ii) a link to a list of each drug, whether approved under this section or licensed under such section 262, for

which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

(iii) a link to the registry and results data bank provided for under subsections (i) and (j) of section 282 of Title 42;

(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

(vi) guidance documents and regulations related to drug safety; and

(vii) other material determined appropriate by the Secretary;

(C) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved under this section or licensed under such section 262;

(D) preparing and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs

approved under this section or section 262 of Title 42;

(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet Web site;

(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet Web site.

(3) Posting of drug labeling

The Secretary shall post on the Internet Web site established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 262 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

(4) Private sector resources

To ensure development of the Internet Web site by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(5) Authority for contracts

The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subsection.

(6) Review

The Advisory Committee on Risk Communication under section 360bbb-6 of this title shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet Web site established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.

(s) Referral to advisory committee

The Secretary shall--

(1) refer a drug or biological product to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee prior to the approval of such drug or biological if it is--

> **(A)** a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or
>
> **(B)** a biological product, no active ingredient of which has been approved in any other application under section 262 of Title 42; or

(2) if the Secretary does not refer a drug or biological product described in paragraph (1) to a Food and Drug Administration advisory committee prior to such approval, provide in the action letter on the application for the drug or biological product a summary of the reasons why the Secretary did not refer the drug or biological product to an advisory committee prior to approval.

(t) Database for authorized generic drugs

(1) In general

(A) Publication

The Commissioner shall--

(i) not later than 9 months after September 27, 2007, publish a complete list on the Internet Web site of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

(B) Notification

The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the

Federal Trade Commission, when the Commissioner first publishes the information described in subparagraph (A) that the information has been published and that the information will be updated quarterly.

(2) Inclusion

The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

(3) Authorized generic drug

In this section, the term "authorized generic drug" means a listed drug (as that term is used in subsection (j)) that--

(A) has been approved under subsection (c); and

(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.

(u) Certain drugs containing single enantiomers

(1) In general

For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing

as an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active moiety as that contained in the approved racemic drug, if--

(A)

(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

(ii) the application submitted under subsection (b) for such non-racemic drug--

(I) includes full reports of new clinical investigations (other than bioavailability studies)--

(aa) necessary for the approval of the application under subsections (c) and (d); and

(bb) conducted or sponsored by the applicant; and

(II) does not rely on any clinical investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use--

(i) in a therapeutic category in which the approved racemic drug has been approved; or

(ii) for which any other enantiomer of the racemic drug has been approved.

(2) Limitation

(A) No approval in certain therapeutic categories

Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

(B) Labeling

If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

(3) Definition

(A) In general

For purposes of this subsection, the term "therapeutic category" means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1395w-104(b)(3)(C)(ii) of Title 42 and as in effect on September 27, 2007.

(B) Publication by Secretary

The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

(4) Availability

The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after September 27, 2007, and before October 1, 2022.

(v) Antibiotic drugs submitted before November 21, 1997

(1) Antibiotic drugs approved before November 21, 1997

(A) In general

Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii)

and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

(B) Application; antibiotic drug described

(i) Application

An application described in this clause is an application for marketing submitted under this section after October 8, 2008, in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) Antibiotic drug

An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 357 of this title (as in effect before November 21, 1997).

(2) Antibiotic drugs submitted before November 21, 1997, but not approved

(A) In general

Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug--

(i)

(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under

clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

(ii) a patent term extension under section 156 of Title 35, subject to the requirements of such section.

(B) Application; antibiotic drug described

(i) Application

An application described in this clause is an application for marketing submitted under this section after October 8, 2008, in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) Antibiotic drug

An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 357 of this title (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

(3) Limitations

(A) Exclusivities and extensions

Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs[5] (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

(B) Conditions of use

Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before October 8, 2008.

(4) Application of certain provisions

Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).

(w) Deadline for determination on certain petitions

The Secretary shall issue a final, substantive determination on a petition submitted pursuant to subsection (b) of section 314.161 of title 21, Code of

Federal Regulations (or any successor regulations), no later than 270 days after the date the petition is submitted.

(x) Date of approval in the case of recommended controls under the CSA

(1) In general

In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

(2) Date of approval

For purposes of this section, with respect to an application described in paragraph (1), the term "date of approval" shall mean the later of--

(A) the date an application under subsection (b) is approved under subsection (c); or

(B) the date of issuance of the interim final rule controlling the drug.

(y) Contrast agents intended for use with applicable medical imaging devices

(1) In general

The sponsor of a contrast agent for which an application has been approved under this section may submit a supplement to the application

seeking approval for a new use following the authorization of a premarket submission for an applicable medical imaging device for that use with the contrast agent pursuant to section 360j(p)(1) of this title.

(2) Review of supplement

In reviewing a supplement submitted under this subsection, the agency center charged with the premarket review of drugs may--

(A) consult with the center charged with the premarket review of devices; and

(B) review information and data submitted to the Secretary by the sponsor of an applicable medical imaging device pursuant to section 360e, 360(k), or 360c(f)(2) of this title so long as the sponsor of such applicable medical imaging device has provided to the sponsor of the contrast agent a right of reference.

(3) Definitions

For purposes of this subsection--

(A) the term "new use" means a use of a contrast agent that is described in the approved labeling of an applicable medical imaging device described in section 360j(p) of this title, but that is not described in the approved labeling of the contrast agent; and

(B) the terms "applicable medical imaging device" and "contrast agent" have the meanings given such terms in section 360j(p) of this title.

35 U.S.C. §271

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory

infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)

(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit--

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)

(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)--

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not

earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section

2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)

(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent--

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product--

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the

action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

(f)

(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that

would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after--

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.