United States Court of Appeals for the Fifth Circuit

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Fifth Circuit
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Lyle W. Cayce
Clerk

No. 19-60394

IMPAX LABORATORIES, INCORPORATED, A CORPORATION,

Petitioner,

versus

FEDERAL TRADE COMMISSION,

Respondent.

On Petition for Review of an Order of the
Federal Trade Commission
FTC Docket No. 9373

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

GREGG 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 first-to-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 brand-name 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 just three days after the FDA's tentative approval of the generic. The parties settled the patent litigation in June 2010,

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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 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, 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.*

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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."

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").

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[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.

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

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

(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 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.

[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.

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 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

[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).

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

[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.

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." (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 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

[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.

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, 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

[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.

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.