Nos. 19-60394

IN THE

United States Court of Appeals

FOR THE FIFTH CIRCUIT

IMPAX LABORATORIES, INCORPORATED,

Petitioner,

v.

FEDERAL TRADE COMMISSION,

Respondent.

On Petition for Review from
The Federal Trade Commission, No. 9373

Brief of *Amicus Curiae* Open Markets Institute in Support of Respondent

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that *amicus curiae* Open Markets Institute is a non-profit corporation and, as such, no entity has any ownership interest in it. The Open Markets Institute has no financial interest in the outcome of this litigation.

/s/ Christopher L. Coffin
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INTEREST OF *AMICUS CURIAE*[1]

The Open Markets Institute (OMI) is a non-profit organization dedicated to promoting fair and competitive markets. It does not accept any funding or donations from for-profit corporations. Its mission is to safeguard our political economy from concentrations of private power that undermine fair competition and threaten liberty, democracy, and prosperity. OMI regularly provides expertise on antitrust law and competition policy to Congress, federal agencies, courts, journalists, and members of the public.

SUMMARY OF ARGUMENT

The Federal Trade Commission (FTC) has devoted substantial time and effort to fighting the illegal collusive and exclusionary conduct of prescription drug manufacturers. By raising the price of essential medicines, these unfair practices transfer billions of dollars annually from the public to the coffers of pharmaceutical corporations and jeopardize patient health and wellbeing. In this case, the FTC unanimously found Impax Laboratories, Inc. (Impax), a generic drug maker, liable under the FTC Act for accepting assorted consideration ultimately worth more than $100 million from Endo Pharmaceuticals, Inc. (Endo), a branded

[1] No party objects to the filing of this brief, and *amicus curiae* has moved for leave to file this brief. No counsel for any party authored this brief in whole or part. Apart from *amicus curiae*, no person contributed money intended to fund the brief's preparation and submission.

drug maker, in exchange for postponing entry into the market for an extended-release opioid by more than two years. Through this pay-for-delay agreement, Impax and Endo colluded and prospered at the expense of patients and the public. The FTC applied a structured antitrust analysis that is fully consistent with Supreme Court precedent and promotes the deterrence of pernicious pay-for-delay schemes among prescription drug makers. Accordingly, Impax's petition for review should be denied.

Pay-for-delay agreements are a form of market allocation. A branded drug company with valid patents has the right to exclude infringing rivals and obtain +damages for any infringement. Patents are "a limited exception to the general federal policy favoring free competition." *Lear, Inc. v. Adkins*, 395 U.S. 653, 663 (1969). A pay-for-delay scheme, however, is radically different from permissible patent-based exclusion. As the Supreme Court noted, "[A]n *invalidated* patent carries with it no such right [to exclude]. And even a valid patent confers no right to exclude products or processes that do not actually infringe." *FTC v. Actavis, Inc.*, 570 U.S. 136, 147 (2013) (emphasis in original).

In a pay-for-delay agreement, a branded drug company gives consideration (cash and non-cash items of value) to a generic rival in exchange for postponed generic market entry and rivalry. In effect, the branded drug company extends its monopoly by sharing a portion of the profits with the generic competitor. The

branded and generic drug manufacturers use a patent litigation settlement "as the pretext for an agreement between horizontal competitors not to compete, the *bête noir* of antitrust law." 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). The Supreme Court succinctly made this point: "The patentee and the challenger gain; the consumer loses." *Actavis*, 570 U.S. at 154.

Under longstanding Sherman Act precedent, horizontal market allocation, in general, is per se illegal. Nearly eighty years ago, the Supreme Court held, "Under the Sherman Act a combination formed for the purpose and with the effect of raising, depressing, fixing, pegging, or stabilizing the price of a commodity in interstate or foreign commerce is illegal per se." *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 223 (1940). *See also In re Cipro Cases I & II*, 348 P.3d 845, 870 (Cal. 2015) ("Antitrust law condemns the purchase of freedom from competition[.]"). Horizontal market allocation is even more sweeping than horizontal price fixing and eliminates *all* forms of direct competition between rivals, not just head-to-head price competition. *Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d 1406, 1415 (7th Cir. 1995) (Posner, J.).

Pay-for-delay agreements are an especially pernicious form of market allocation. The Hatch-Waxman Act sets up a system of temporary duopoly, meaning that a branded drug company, at first, faces only one potential generic

entrant. The Food and Drug Administration cannot permit a second generic rival's entry "when any first [generic entrant] is eligible for 180-day exclusivity or during the 180-day exclusivity period of a first [generic entrant]." 21 C.F.R. § 314.107(c)(1). In other words, until the first generic company's exclusivity period has ended, no other generic firm can enter. By buying off this generic rival, a branded drug maker can block all competitors. Ordinary market allocation agreements cannot offer this level of protection against competition.

By postponing generic entry and competition, pay-for-delay agreements inflict significant harm on the public. Pay-for-delay agreements raise the costs of prescription drugs to patients and health care payors by billions annually. Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 8 (2010); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 650 (2009). These higher costs can translate into patients forgoing vital medications and jeopardizing their health. In contrast, the benefits from these agreements are limited or highly speculative. Michael A. Carrier, *Payment After* Actavis, 100 Iowa L. Rev. 7, 19–25 (2014).

In its decision, the FTC applied a structured rule of reason that is fully consistent with Supreme Court guidance in *Actavis*. The Court encouraged the lower courts to develop a structured rule of reason to govern the practice. *Actavis*,

570 U.S. at 159–60. The Court offered several analytical criteria for the lower courts to use in evaluating pay-for-delay schemes. Under the FTC's structured rule of reason, plaintiffs, to establish a *prima facie* case, are required to show that the branded drug company made a large and unjustified payment to the generic rival in exchange for delayed entry and that the branded company possessed market power. This structuring is entirely faithful to Supreme Court guidance and indeed, in requiring a separate showing of market power, created a higher bar than the Court mandated in *Actavis*.

The FTC's test sensibly allocates the legal burdens and represents sound competition policy. Under the FTC's structured rule of reason, antitrust enforcers can, efficiently and effectively, identify and challenge harmful pay-for-delay schemes.

In contrast to the FTC's structured test, applying the full-blown rule of reason would result in severe under-deterrence of a harmful practice. Relying on the full rule of reason would, in practice, make pay-for-delay agreements legal. *See* Richard A. Posner, *The Rule of Reason and the Economic Approach: Reflections on the* Sylvania *Decision*, 45 U. Chi. L. Rev. 1, 14 (1977) ("[The rule of reason] is little more than a euphemism for nonliability."). The public would be forced to endure unjustified prescription drug monopolies in exchange for little or nothing in return.

ARGUMENT

I. Pay-for-Delay Agreements Are an Especially Pernicious Type of Market Allocation

Branded drug companies that pay generic rivals to stay out of the market engage in an especially harmful form of market allocation. Just as in a conventional horizontal market allocation scheme, a firm agrees not to compete with an actual or potential rival in a certain product line, geographic area, or period. Unlike typical market allocation arrangements, the branded drug company, under the regulatory framework governing generic drug competition, can buy off its *only* prospective competitor and cement its monopoly for an extended time. Market allocation agreements in most markets cannot offer this level of insulation against competition and typically can protect against only a subset of potential rivals.

A. Pay-for-Delay Agreements Are a Form of Market Allocation

Pay-for-delay agreements are a type of market allocation. A branded drug company with valid patents has the right to exclude infringing rivals and obtain damages for any infringement. In contrast, in a pay-for-delay agreement, a branded drug company—instead of exercising its patent rights—provides cash or non-cash consideration in exchange for a rival delaying market entry. This conduct is a form of horizontal market allocation, long per se illegal under the Sherman Act.

A branded drug company has the right to exclude rivals *only on the condition* it has valid patents. If a generic rival enters a branded drug market with a product that infringes the branded company's patent, the branded drug company has the right to exclude the infringing product and obtain damages for lost profits from the infringement. Patents are "a limited exception to the general federal policy favoring free competition." *Lear, Inc. v. Adkins*, 395 U.S. 653, 663 (1969). *See also* U.S. Const. Art. 1, § 8, cl. 8 ("Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries[.]").

A pay-for-delay scheme is very different from permissible patent-based exclusion. It does not fall into the "limited exception to the general federal policy favoring free competition." *Lear*, 395 U.S. at 663. As the Supreme Court noted, "[A]n *invalidated* patent carries with it no such right [to exclude]. And even a valid patent confers no right to exclude products or processes that do not actually infringe." *FTC v. Actavis, Inc.*, 570 U.S. 136, 147 (2013) (emphasis in original). In a pay-for-delay agreement, a branded drug company is *not* exercising a federally granted right to market exclusivity. Instead, it provides consideration to a generic rival in exchange for refraining from market entry and rivalry.[2] The branded drug

[2] In many instances, the branded drug company likely believes that its patents are invalid or not infringed and thereby cannot be the basis for excluding generic rivals. An FTC study examining settled or otherwise resolved patent litigation

maker can provide cash, licenses to other patents, or other consideration to the would-be generic rival. In return, the generic rival agrees to suspend its challenge to the branded drug company's patent(s) (on either invalidity or non-infringement grounds) and postpone its market entry. The branded drug company extends its monopoly by sharing a portion of the profits with the generic entrant.

This conduct is a form of market allocation. The branded and generic drug manufacturers "in effect use patent rights, however weak, as the pretext for an agreement between horizontal competitors not to compete, the *bête noir* of antitrust law." 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). In the most familiar forms of market allocation, two rivals agree to not to compete in the same product line or geographic area or for the same set of customers. The mutual forbearance is the consideration: firm 1 is protected from firm 2 in Market A and firm 2 is protected from firm 1 in Market B. *See, e.g.*, *Palmer v. BRG of Ga. Inc.*, 498 U.S. 46, 47 (1990) (per curiam) ("The parties agreed that HBJ would not compete with BRG in Georgia and that BRG would not compete with HBJ outside of Georgia."); *Affiliated Capital Corp. v. City of*

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between branded and generic drug manufacturers from 1992 to 2002 found that the generic firm won in 73 percent of these cases on the grounds of noninfringement, patent invalidity, or abandonment of suit by the branded company. Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study 19–20 (July 2002).

Houston, 700 F.2d 226, 233 (5th Cir. 1983) ("It is abundantly clear from the record of this case that a group of Houston businessmen decided to ensure the receipt of cable television franchises by agreeing to seek separate parts of the city.").

Pay-for-delay agreements allocate markets over time. The branded drug company pays off a generic competitor and prolongs its monopoly. By sharing a portion of its monopoly profits, the branded drug company secures a time-defined non-compete pledge from the generic rival. Consider a hypothetical pay-for-delay agreement: even though it could enter a market in 2020 without infringing relevant patents, a generic drug company promises to stay out of the branded drug's market until 2025 in return for a portion of the branded company's profits until then. *See* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 72 (2009) ("[I]nstead of allocating geographic space, in which the parties reserve for themselves particular territories, [the brand and generic companies] allocate time. The brand and generic, in other words, agree that the brand will not be subject to competition for a period of time, thereby dividing the market and preventing competition."); Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 29 (2005) (same).

Under longstanding Sherman Act precedent, horizontal market allocation, in general, is per se illegal. Nearly eighty years ago, the Supreme Court ruled, "Under the Sherman Act a combination formed for the purpose and with the effect of raising, depressing, fixing, pegging, or stabilizing the price of a commodity in interstate or foreign commerce is illegal per se." *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 223 (1940). *See also In re Cipro Cases I & II*, 348 P.3d 845, 870 (Cal. 2015) ("Antitrust law condemns the purchase of freedom from competition[.]"). Horizontal market allocation is even more sweeping than horizontal price fixing and eliminates *all* forms of head-to-head competition between rivals, not just head-to-head price competition. *Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d 1406, 1415 (7th Cir. 1995) (Posner, J.).

The courts have repeatedly affirmed the per se ban on horizontal market allocation. The Supreme Court has consistently held that the per se ban applies to horizontal market allocation. *Palmer*, 498 U.S. at 49–50; *United States v. Topco Associates, Inc.*, 405 U.S. 596, 608 (1972); *Timken Roller Bearing Co. v. United States*, 341 U.S. 593, 597–98 (1951). Like the Supreme Court, this Court has categorically condemned horizontal market allocation as per se illegal. *Affiliated Capital*, 700 F.2d at 237; *North Texas Specialty Physicians v. FTC*, 528 F.3d 346, 360 (5th Cir. 2008). *See also Hobart Bros. Co. v. Malcolm T. Gilliland, Inc.*, 471

F.2d 894, 899 (5th Cir. 1973) ("It is a per se violation of § 1 for competitors at the same level of the market structure to allocate territories in order to minimize competition.").

The per se rule applies to horizontal market allocation regardless of ultimate effects. The courts consider these agreements as generally inflicting harm on the public and, as a result, apply a per se rule, despite the potential for social benefits on rare occasion. The logic of per se rules "in part is to avoid the necessity for an incredibly complicated and prolonged economic investigation into the entire history of the industry involved, as well as related industries, in an effort to determine at large whether a particular restraint has been unreasonable—an inquiry so often wholly fruitless when undertaken." *Arizona v. Maricopa County Medical Society*, 457 U.S. 332, 351 (1982) (citation omitted). *See also Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*, 441 U.S. 1, 19-20 (1979) (stating per se rules are applied to conduct that "facially appears to be one that would always or almost always tend to restrict competition").

A horizontal market allocation scheme's failure to achieve its intended aim is no defense and offers no refuge from the per se rule. The conduct remains categorically unlawful. *See Catalano, Inc. v. Target Sales, Inc.*, 446 U.S. 643, 649 (1980) ("[W]hen a particular concerted activity entails an obvious risk of anticompetitive impact with no apparent potentially redeeming value, the fact that

a practice may turn out to be harmless in a particular set of circumstances will not prevent its being declared unlawful per se.") (italics removed); *In re High Fructose Corn Syrup Antitrust Litigation*, 295 F.3d 651, 656 (7th Cir. 2002) (Posner, J.) ("An agreement to fix list prices is . . . a per se violation of the Sherman Act even if most or for that matter all transactions occur at lower prices."). The Supreme Court recognized that some collusive arrangements may not always work their intended harm—and yet nonetheless affirmed their status as per se illegal. *See Maricopa County Medical Society*, 457 U.S. at 344 ("[T]he match between the presumed and the actual is imperfect. For the sake of business certainty and litigation efficiency, we have tolerated the invalidation of some agreements that a full[-]blown inquiry might have proved to be reasonable.").

B. Pay-for-Delay Schemes Neutralize the Only Potential Source of Rivalry for Branded Drug Companies

Pay-for-delay agreements are an especially pernicious form of market allocation. The Hatch-Waxman Act sets up a system of temporary duopoly under which a branded drug company, at first, faces only one potential generic entrant. Through pay-for-delay agreements, the branded drug company can buy off the only competitive threat to its monopoly. Ordinary market allocation agreements cannot offer this level of protection against competition.

To promote prescription drug competition, the Hatch-Waxman Act gives the first generic entrant, which obtains regulatory approval, a 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv). Critically, this exclusivity period does not begin to run until the first generic entrant begins marketing its product. The Food and Drug Administration cannot permit a second generic rival's entry "when any first [generic entrant] is eligible for 180-day exclusivity or during the 180-day exclusivity period of a first [entrant]." 21 C.F.R. § 314.107(c)(1). In other words, until the first generic company's exclusivity period has ended, no other generic firm can enter.

The logic of the Hatch-Waxman Act is that, without short-term exclusivity, all generic firms could free ride on the efforts of the first entrant to challenge the branded drug maker's patents. By setting up a time-limited duopoly, this exclusivity gives generic firms an incentive to challenge invalid branded drug patents or make bioequivalent versions without infringing these patents. The generic rival can enter the market after identifying and overcoming potential patent obstacles and earn profits on incurring the costs to clear the field for all generic entrants. Since its enactment in 1984, the Hatch-Waxman Act has been a major success and helped develop a vibrant generic drug industry. Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need A Re-Designed*

Approach for the Modern Era?, 15 Yale J. Health Pol'y, L. & Ethics, 293, 309–14 (2015).

In its effort to stimulate generic entry, however, the Hatch-Waxman Act creates a powerful incentive for branded drug companies to pursue collusive pay-for-delay agreements. Through a pay-for-delay agreement with *one* generic firm, the branded drug company blocks *all* generic competitors and extends its existing monopoly. Under a pay-for-delay scheme, the protection against competition is robust.

Pay-for-delay functions as a form of "super" market allocation. Consider the similarities—and differences—between a market allocation scheme between two would-be competing gas stations and a pay-for-delay agreement between two potential pharmaceutical competitors. A gas station with a local monopoly could induce a would-be rival to stay of the market for a decade by sharing a portion of its profits during this ten-year period. In buying off one prospective competitor, however, the gas station obtains only limited relief. Other would-be entrants are not bound by the agreement. They could still set up a rival gas station and threaten to end the incumbent's monopoly and compete away the associated profits.

The gas station cannot acquire certain protection against new entry. To obtain guaranteed protection from competition, the incumbent monopolist would have to strike a series of similar deals with a potentially large number of aspiring

entrants. As a practical matter, the pool of potential entrants may be unknown. In contrast, in a pay-for-delay agreement, the branded drug company, in paying the first generic filer to stay out, obtains protection from all would-be competitors.

Pay-for-delay agreements prolong monopoly and inflict substantial costs on the public. According to an analysis by the U.S. Food and Drug Administration, the first generic entrant discounts its drug per dose by 6 percent, on average, relative to the branded drug. U.S. Food & Drug Admin., Generic Competition and Drug Prices, https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm. Subsequent entry leads to more substantial price reductions. After the second and third generic competitors enter, generic makers reduce their price by 48 percent and 56 percent, respectively, relative to the branded version. *Id.*

Pay-for-delay agreements postpone this beneficial generic entry and competition at great cost to the public. In a 2010 study, the Federal Trade Commission concluded that pay-for-delay raises the costs of prescription drugs to health care payors and patients by approximately $3.5 billion annually. Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 8 (2010). An earlier analysis, which reviewed 20 settlements between branded and generic drug companies possessing the hallmarks of a pay-for-delay agreement,

concluded that these settlements transferred approximately $12 billion from the public to drug companies every year. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 650 (2009). By raising prescription drug prices, pay-for-delay agreements can force patients to forgo vital medicines and put their health and wellbeing in serious risk.

Whereas they extract billions from patients and payors, pay-for-delay agreements, in general, offer, at most, very limited offsetting benefits. Michael A. Carrier, *Payment After* Actavis, 100 Iowa L. Rev. 7, 19–25 (2014) ("Carrier, *After* Actavis"). As a basic matter, the side deals struck between branded and generic companies in pay-for-delay settlements are suspicious. As former FTC Chairman Jon Leibowitz testified, these deals were "observed in settlements that restrained generic entry, but virtually never in settlements that did not." Jon Leibowitz, Comm'r, Fed. Trade' Comm'n, Prepared Statement of the Federal Trade Commission Before the Committee on the Judiciary of the United States Senate on Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution 17 (Jan. 17, 2007).[3] Moreover, avoided litigation costs from

[3] The types of deals struck in these settlements are questionable given the respective strengths of branded and generic drug manufacturers. As one antitrust scholar has written:

a settlement are unlikely to exceed $10 million. Carrier, *After* Actavis, *supra*, at 20-21. That casts further doubt on the legitimacy of large reverse payments.

II. The FTC's Structured Rule of Reason is Fully Consistent with *Actavis* and Promotes Deterrence of Pay-for-Delay Agreements

The FTC applied a structured rule of reason that is both fully consistent with *Actavis* and good competition policy given the substantial harms from pay-for-delay agreements. While the Supreme Court rejected a presumptive illegality standard for agreements involving any reverse payment in exchange for delayed entry, it encouraged the lower courts to develop a structured rule of reason for the practice. The FTC's test is consistent with Supreme Court guidance and indeed goes beyond what *Actavis* demands. Importantly, given the close resemblance between pay-for-delay agreements and market allocation and the substantial harms from pay-for-delay, the FTC's test sensibly allocates the legal burdens. In contrast to the FTC's structured test, applying the full-blown rule of reason would result in severe under-deterrence of a harmful practice.

Do brands really need promotion by generics? As evidenced by armies of pharmaceutical sales representatives and commercials with wind-swept actors walking along the beach, brands tend not to be at a loss in marketing their drugs. And while brands sometimes rely on other brands for promotion, they do not use generics for this task outside the context of settlement. Carrier, *After* Actavis, *supra*, at 22–23.

The Supreme Court in *Actavis* invited the lower courts to develop a structured rule of reason for pay-for-delay cases. It wrote:

> As in other areas of law, trial courts can 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. We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation. *Actavis*, 570 U.S. at 159–60 (citation omitted).

The *Actavis* decision identified specific shortcuts that courts could use to structure the rule of reason. The Court wrote that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects." *Id.* at 158. Articulating this point, it added "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.* at 159.

Actavis offered two criteria for structuring the rule of reason. First, courts can allow plaintiffs to make their *prima facie* case by demonstrating the existence of an "unexplained large reverse payment" in exchange for delayed generic entry

because that "itself would normally suggest that the patentee has serious doubts about the patent's survival." *Id.* at 157. That inference, the Court noted, "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. *See* Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *The* Actavis *Inference: Theory and Practice*, 67 Rutgers U. L. Rev. 585, 587 (2015) (Under the *Actavis* inference, unlawfulness "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.").

Second, the Court restricted what qualifies as a legitimate procompetitive justification. It rejected the risk of patent invalidation as a defense under the rule of reason. *Id. See also* Davis & McEwan, *supra*, at 565 ("[A] trial court need not entertain the argument that the large payment is designed to avoid even a small risk of invalidity.") (citation omitted). Instead, the defendant can show that the reverse payment was large to "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." *Actavis*, 570 U.S. at 156.

The Court identified two legitimate justifications: compensation for services by the generic rival and avoided litigation costs. *Id.* at 156. If not compensation for these services though, the payment "likely seeks to prevent the risk of competition . . . that consequence constitutes the relevant anticompetitive harm." *Id.* at 157.

The FTC's test is a structured rule of reason that applies the factors the Supreme Court identified in *Actavis*. The FTC held that, to make a *prima facie* case, Complaint Counsel had to make the following showings: Endo made a large and unjustified payment to Impax in exchange for Impax postponing market entry and Endo possessed market power. Such a requirement is consistent with *Actavis* which established that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects[.]" *Id.* at 158. Once the Complaint Counsel made these showings, Impax had the opportunity to establish a legitimate justification, such as avoided litigation costs or compensation for services, to rebut the *prima facie* case.

In structuring and applying its rule of reason, the FTC *went further* than what *Actavis* requires. The FTC mandated a showing of market power in addition to establishing a large reverse payment for delay. *Actavis* does not dictate this requirement. As the Supreme Court acknowledged, a large, reverse payment in exchange for delayed generic entry into a medication's market can itself be sufficient for plaintiffs to show market power. *See id.* at 157 ("[T]he 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.") (citation omitted). In its structured rule of reason, the Third Circuit held that plaintiffs could establish a *prima facie* case by showing a reverse payment for delayed entry. *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 412 (3d Cir. 2015) ("First, to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition."). *See also* Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating* Actavis, 28 Antitrust 16, 17 (2013) ("[T]he [*Actavis*] Court also made clear that a 'long form' rule of reason was not necessary, and in particular that *both anticompetitive effect and market power could be inferred from large reverse payments themselves*.") (emphasis added).

The California Supreme Court recognized the connection between a large reverse payment and the branded drug maker's market power. It observed that "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." *Cipro*, 348 P.3d at 869. Under the test it adopted, "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." *Id.*

The FTC's structured rule of reason helps deter pay-for-delay agreements. It permits enforcers, in relatively efficient and effective fashion, to identify and challenge harmful pay-for-delay agreements. Plaintiffs can establish a *prima facie* case by showing that the branded company made a large and unjustified payment to the generic rival in exchange for delayed entry and that the branded company possessed market power. Under this test, plaintiffs do not have the burden of showing actual anticompetitive harm in the form of higher prices, persistently high prices, or reduced output. This test represents a soundly structured rule of reason because of the costs and benefits of pay-for-delay agreements. These schemes are a form of horizontal market allocation agreements and inflict real harms on the public while offering only limited or theoretical offsetting benefits. *See supra* Part I.

Evaluating pay-for-delay schemes under the full rule of reason, instead of the FTC's structured rule of reason, would lead to severe under-deterrence of these pernicious arrangements. The full rule of reason confers enormous advantages on defendants in litigation. Maurice E. Stucke, *Does the Rule of Reason Violate the Rule of Law?,* 42 U.C. Davis L. Rev. 1375, 1466–67 (2009). *See also* Michael A. Carrier, *The Real Rule of Reason: Bridging the Disconnect,* 1999 B.Y.U. L. Rev. 1265, 1293 (2006) (finding that 84 percent of all rule of reason cases from 1977 to 1999 did not even satisfy the standard's initial requirement of showing

anticompetitive effects). In practice, the full rule of reason is, in the words of Judge Posner, "little more than a euphemism for nonliability." Richard A. Posner, *The Rule of Reason and the Economic Approach: Reflections on the* Sylvania *Decision*, 45 U. Chi. L. Rev. 1, 14 (1977). Applying the full rule of reason to pay-for-delay agreements would confer on them *de facto* legality and would mean forcing the public to bear the burden of extended prescription drug monopolies in return for highly dubious benefits.

CONCLUSION

The Court should deny the petition for review.

DATED: DECEMBER 16, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

I am an attorney for amicus curiae Open Markets Institute (OMI). Pursuant to Fed. R. App. P. 32(a), I certify that the foregoing brief of WLF is in 14-point, proportionately spaced Times New Roman font. According to the word processing application use to draft this brief (Microsoft Word 365), the brief contains 5,217 words, not including the certificate of interested parties, table of contents, table of authorities, and this certificate of compliance.

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Dated: December 16, 2019

CERTIFICATE OF SERVICE

I hereby certify that on this date, I caused a true and correct copy of the foregoing to be served on counsel of record for all parties via ECF.

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Dated: December 16, 2019