No. 21-406

IN THE
Supreme Court of the United States

IMPAX LABORATORIES, INC.,
Petitioner,

v.

FEDERAL TRADE COMMISSION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* SUPPORTING PETITIONER

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INTEREST OF THE AMICUS CURIAE[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute more than 90% of all prescriptions dispensed in the United States, yet generics account for only 18% of total drug spending. AAM regularly participates in litigation as *amicus curiae*.

AAM and its members have a significant interest in the questions presented by the petition for certiorari. In the course of developing and bringing to market competitively priced generics and biosimilars, AAM's members must often engage in patent litigation with brand-name manufacturers. These cases "are among the longest, most time-consuming types of civil actions." *Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, 629 F.3d 1374, 1376 (Fed. Cir. 2011) (Moore, J., concurring). They are also exorbitantly expensive, with the average case costing millions for each patent in controversy.

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[1] AAM provided timely notice of intent to file this brief, and all parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the brief's preparation or submission.

And the litigation burden has continued to accelerate over the past decade, as brand manufacturers have obtained more and more patents covering their products, thus requiring a manufacturer of generic or biosimilar medicines to overcome numerous patents on a single product in order to come to market.

Given the high costs and uncertainty associated with patent litigation, settlement is a critical tool for advancing generic and biosimilar competition. This Court's decision in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), recognized that a certain type of settlement—a "large, unjustified reverse payment" from the brand company to the generic manufacturer—is subject to antitrust review. *Id.* at 158. But the Court also stated that its holding should not "prevent litigating parties from settling their lawsuit," and it squarely rejected the Federal Trade Commission's argument in favor of "a quick look" mode of review that would treat these settlements as "presumptively unlawful." *Id.* at 158-159.

In the years since, however, the FTC has tried to retract the safeguards in *Actavis*, reimposing a "quick look" standard of presumptive illegality in all but name. This case is a high-water mark of that improper approach. The FTC cast aside the real-world evidence that the settlement in this case plainly was procompetitive—the settlement allowed Petitioner Impax Laboratories, Inc. to enter the market years before the expiry of patents that were later found to be *valid* in separate litigation—by refusing to consider the strength of the patents at issue and adopting what amounts to a categorical presumption that the competitive benefits of patent settlements can always be achieved without an exchange of value from the brand to the generic. By blessing the FTC's misguided approach, the Fifth Cir-

cuit decision below stretches *Actavis* past its breaking point, jeopardizing the ability of AAM's members to enter procompetitive patent settlements that provide patients with access to lower-cost generic and biosimilars. This Court's review is urgently needed.

INTRODUCTION

Access to affordable and safe medication is critical to the national economy and the health of every American. AAM's membership is committed to ensuring that competitively priced and effective medicines remain available in the market. The numbers prove the importance of this mission: over roughly the past decade, generics have saved customers nearly $2.4 trillion.[2] And FDA-approved biosimilars—highly similar or interchangeable versions of brand-name biologic medicines—could save customers tens of billions of dollars more in the coming years.[3]

In order to bring lower-cost generic and biosimilar medicines to the public, AAM members must first run the gauntlet of notoriously expensive and lengthy patent litigation. When those multi-million-dollar cases are litigated to judgment, generic manufacturers prevail less than half of the time, in which case the generic

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[2] AAM, The U.S. Generic & Biosimilar Medicines Savings Report 6 (Oct. 2021), https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf ("Savings Report").

[3] Savings Report, *supra*, at 17; *see also* Statement of Chester "Chip" Davis, Jr. to the House Energy and Commerce Subcommittee on Health Hearing on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Competition" 1-2 (Mar. 13, 2019), www.congress.gov/116/meeting/house/109107/witnesses/HHRG-116-IF14-Wstate-DavisC-20190313.pdf ("Davis Statement").

medicine cannot enter the market until patent expiry. RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* 4 (Jan. 15, 2010), https://amlawdaily.typepad.com/pharmareport.pdf. The ability of AAM members to enter settlements to resolve those disputes is thus a critical tool for generic and biosimilar entry, allowing AAM members to begin marketing their medicines before patents covering the brand medicine expire—patents that the law treats as presumptively valid, *see* 35 U.S.C. § 282(a).

This Court in *Actavis* "recognize[d] the value of settlements and the patent litigation problem," and it "concede[d] that settlement on terms permitting the patent challenger to enter the market before the patent expires … bring[s] about competition, … to the consumer's benefit." 570 U.S. at 153-154. The Court nonetheless held that a narrow category of patent settlements—those that included a "large, unjustified reverse payment"—could be subjected to antitrust review. *Id.* at 158. But in doing so, the Court cautioned that its holding should not be understood to "prevent litigating parties from settling their lawsuit." *Id.* Significantly, the Court rejected the FTC's proposal to treat "reverse payment settlement agreements as presumptively unlawful," holding that the FTC must proceed under the standard "rule of reason" that governs antitrust review of most agreements, rather than relying on a "quick look" to confirm illegality. *Id.* at 159.

But while purporting to act within this Court's framework, the FTC has steadily pushed the law back in its own preferred direction by unduly narrowing the rule-of-reason inquiry and imposing categorical restrictions that are no different in practice from a presumption of illegality. This case makes that plain. It is

undisputed that the challenged settlement allowed Impax to sell its generic version of Opana ER *at least a decade* before the expiration of the last of the brand manufacturer's patents on the product—patents that were *upheld as valid* in litigation against other generic drug companies, which are enjoined from selling their versions until 2023. *See* Pet. 1, 11-12. Yet the FTC failed to meaningfully engage with the settlement's actual effects on competition, and relied instead on two categorical presumptions that together decisively stack the deck in favor of liability. First, the FTC treated an exchange of value that exceeded litigation costs and the fair value of services as inherently suspect. Indeed, it refused to look at case-specific justifications for the settlement, including significant evidence that the brand's patents were strong and would have blocked generic entry for years if the case had been litigated to judgment. Second, the FTC discounted the procompetitive benefits of the settlement by relying on sweeping generalizations about "industry practice" and "economics" to conclude that a settlement without a payment is always possible—despite real-world evidence from this case that the parties would not have bridged their differences without a transfer of value because the brand manufacturer, Endo Pharmaceuticals, Inc., refused to budge on an earlier entry date.

Considered as a whole, the FTC's approach dilutes the rule-of-reason framework beyond recognition, resulting in an effective presumption that any patent settlement with an alleged payment exceeding litigation costs is illegal—precisely the FTC position that the Court rejected in *Actavis*. 570 U.S. at 158-159. And by effectively endorsing the FTC's "quick look" redux, the Fifth Circuit's decision here means that manufacturers of generic medicines risk liability anytime an early-

entry settlement can be characterized as including a "payment," no matter how procompetitive the settlement is as a whole.

The implications of resuscitating "quick look" review in this context are far-reaching. Indeed, developments since *Actavis* only magnify the negative impacts from an overbroad rule that treats many pharmaceutical patent settlements as presumptively anticompetitive. On the one hand, the risk of incurring antitrust liability when settling a patent case has grown considerably, as lower courts—urged on by the FTC as both litigant and adjudicator—have adopted increasingly expansive definitions of what counts as a "payment" that might trigger *Actavis* scrutiny. On the other, the need for generic manufacturers to find a path to settlement is greater than ever, as generic companies increasingly must overcome dozens of patents on each brand medicine before they can bring a product to market.

The upshot is that, absent this Court's review, the costs and risks AAM's members must bear to offer generic and biosimilar competition will rise dramatically, and patients across the country will pay the price. That is precisely the *opposite* result that *Actavis* and the antitrust laws mean to encourage. The Court should grant certiorari and reverse, and, in doing so, should clarify the scope and application of *Actavis*.

ARGUMENT

I. The Fifth Circuit's Endorsement of the FTC's Quick-Look-Style Presumptions Contradicts *Actavis*.

Actavis established baseline principles for antitrust scrutiny of patent settlements that otherwise fall within a patent's exclusionary scope. For such settlements to give rise to potential antitrust liability at all, they must include an apparently "large and unjustified" payment. *Actavis*, 570 U.S. at 158. Even then, such settlements are *not* "presumptively unlawful," because their "complexities" make any bright-line antitrust rule inappropriate. *Id.* at 158-159.

For that reason, the Court in *Actavis* expressly rejected the FTC's preferred quick-look approach and refused to otherwise shift the initial burden of proof to the defendant. Instead, the FTC "must prove its case as in other rule-of-reason cases." *Id.* at 159. And in applying the rule-of-reason framework, lower courts must consider the full factual circumstances surrounding the payment—including "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"—to determine whether the payment truly is both "large *and* unjustified." *Id.* at 158-159 (emphasis added).

The Fifth Circuit's decision, affirming the order of the FTC, turns those principles on their head. In place of the rule of reason, the Fifth Circuit and the FTC have substituted a thinly-disguised version of the quick-look approach that the Court rejected in *Actavis*.

A. The Fifth Circuit and FTC Wrongly Presume That a "Payment' Is Unjustified and Ignore Overwhelming Evidence of Patent Strength.

The decision below breaks from *Actavis* by reviving in all but name the quick-look approach that the FTC sought and this Court explicitly rejected. The Fifth Circuit held that the FTC met its burden at the first step of the rule of reason simply by showing that there was a net transfer of value from the brand to the generic that exceeded "avoided litigation costs." Pet. App. 16-17. *Actavis*, however, requires plaintiffs to show the exchange of value is *both* "large *and* unjustified." *Actavis*, 570 U.S. at 158 (emphasis added). Simply showing that the payment is "large" because it exceeds "avoided litigation costs," Pet. App. 16, is not enough. Rather, as the Court recognized, "[t]here may be other justifications" for the inclusion of a payment in a settlement that eliminate any antitrust concern. 570 U.S. at 156; *see also In re Loestrin 24 Fe Antitrust Litig.,* 814 F.3d 538, 552 (1st Cir. 2016) ("[T]he plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large *and* unjustified reverse payment[.]" (emphasis added)).

The strength of the patent (or patents) at issue can be one such "other justification" that takes away "the risk of significant anticompetitive effects" from a reverse-payment settlement. *Actavis*, 570 U.S. at 158. After all, the only reason pharmaceutical patent settlements *sometimes* raise antitrust concerns is that the patents at issue "may or may not be valid, and may or may not be infringed"—if the patents *are* valid and infringed, then any alleged exchange of value falls within the scope of the lawful patent monopoly conferred by

Congress. *Id.* at 147; *see id.* at 163 (Roberts, C.J., dissenting) (recognizing that the Court declined to endorse antitrust immunity for all actions within the exclusionary scope of a patent because of the "uncertainty" about whether a patent is valid and infringed). To nonetheless ignore patent strength, as the FTC and the Fifth Circuit did here, would both "defeat[] the point of the patent, which is to confer a *lawful* monopoly on its holder," *id.* at 171, and also depart from rule-of-reason analysis. The rule of reason focuses on the "challenged restraint's *actual effect* on competition." *Nat'l Collegiate Athletic Ass'n v. Alston*, 141 S. Ct. 2141, 2151 (2021) (emphasis added) (citation and internal quotation marks omitted). Accordingly, in a case where there is strong reason to believe that litigation would have produced a finding of patent infringement and validity, a settlement that allows a generic to launch well before expiration of the brand patents is not anticompetitive, because its *actual effect* is to increase competition by allowing generic entry earlier than would otherwise have been possible.

This case illustrates the point. The settlement at issue permitted Impax to launch its generic version of Opana ER on January 1, 2013—*ten years* before any other generic will be able to enter the market, because the other generics chose not to settle, lost on their invalidity defenses against Endo's infringement claims, and have been enjoined from entering the market before 2023. Pet. 1, 11-12; pp. 4-5, *supra*. For the Fifth Circuit to nonetheless endorse the FTC's conclusion that the Endo-Impax settlement was "unjustified" within the meaning of *Actavis*, on the theory that the settlement "prevent[ed] the risk of competition," Pet. App. 16, ignores reality. Indeed, the imposition of liability under the facts of this case—where the patents subject to the

suit were "ultimately declared valid"—is an "absurd result[]." *Actavis*, 570 U.S. at 172-173 (Roberts, C.J., dissenting). "Under th[at] approach, a patent holder may be found liable under antitrust law for doing what its perfectly valid patent allowed it to do in the first place[.]" *Id.* at 173. And a generic manufacturer may be found liable for achieving a settlement that benefits competition and patients merely because it accepted compensation to secure an early entry date rather than press forward to a likely defeat.

The Fifth Circuit suggested that this result flows from *Actavis* itself, which the Fifth Circuit interpreted to reject any requirement that the FTC ever need consider "the likely outcome of the patent case in order to find anticompetitive effects." Pet. App. 18. But such reasoning sweeps far more broadly than what this Court endorsed. On any fair reading, *Actavis* offers no support for a categorical refusal to consider patent strength. To be sure, the Court reasoned that it is "*normally* not necessary to litigate patent validity to answer the antitrust question," and the Court recognized that, in some cases, "the size of the unexplained reverse payment *can* provide a workable surrogate for a patent's weakness." *Actavis*, 570 U.S. at 157-158 (emphasis added); *see also id.* at 158 ("[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[.]" (emphasis added)). But those carefully qualified statements do not suggest, as the Fifth Circuit held, that patent strength is *never* relevant to the rule-of-reason analysis. And it is simply illogical to treat the mere existence of an exchange of value as irrebuttable proof that a patent was weak when there is an *actual*

decision by an Article III judge determining that the same patent is indeed valid.[4]

B. The FTC's Approach Wrongly Presumes that Patent Cases Can Always Settle Without Any Exchange of Value.

The Fifth Circuit, by adopting the FTC's approach, did not just undermine *Actavis* at the first step of the rule of reason. The court effectively short-circuited the last two steps of the analysis, too, by blessing the FTC's view that any exchange of value never really benefits competition, because parties can always settle their patent dispute without that exchange. The adoption of this effectively irrebuttable presumption once again contradicts the rule-of-reason analysis that this Court prescribed, and it is divorced from real-world settlement practice.

Under the rule of reason, if the plaintiff satisfies its "initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market," then "the burden shifts to the defendant to show a procompetitive rationale for the restraint." *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018). Once the defendant does so, "the burden shifts back to the plaintiff to demonstrate

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[4] For the reasons provided, this Court should not read *Actavis* to impose an illogical rule that forbids any consideration of patent strength when evaluating the effect of a patent litigation settlement on competition. But if the Court believes that *Actavis* actually dictates the absurd outcome reached below—in which a generic manufacturer is being penalized for striking a deal to get on the market before *valid* patents are set to expire—then it should consider whether to limit or change that holding.

that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means." *Id.* This third step "does not require businesses to use anything like the least restrictive means of achieving legitimate business purposes," as courts (and agencies) "should not second-guess degrees of reasonable necessity." *NCAA*, 141 S. Ct. at 2161 (quotation marks omitted).

The Fifth Circuit here did not dispute that Impax had shown its settlement benefited competition by facilitating early generic entry, but it accepted the FTC's conclusion at the third step that this benefit could have been achieved without any alleged payment. Pet. App. 21-22. Although the Fifth Circuit styled its analysis as "case-specific" and driven by deference to agency fact-finding, *id.* at 28-30 & n.10—notwithstanding that the ALJ who actually heard the evidence came out the other way, *id.* at 9-10—its reasoning extends to pharmaceutical patent settlements across the board. As Impax explains (at 28-30), the Fifth Circuit relied on generalities about "industry practice" and "economics" to endorse the FTC's surmise that because it is *sometimes* possible to settle a patent dispute by agreeing to an early entry date without a payment, it must *always* be possible. Pet. App. 28-29. But as this case shows, the FTC's simplistic assumption that a brand and generic can always agree to a compromise on the generic entry date without adding other terms ignores that real-world negotiation dynamics are often more complicated than generalizations allow.

In fact, as both courts and commentators have recognized, "[a] negotiation is more likely to be successful when there are several issues to be resolved ('integrative bargaining') rather than just one, because it is eas-

ier in the former case to strike a deal that will make both parties feel they are getting more from peace than from war." *Duffy Tool & Stamping, L.L.C. v. NLRB*, 233 F.3d 995, 998 (7th Cir. 2000).[5] Here, for example, the record evidence shows that the parties had reached an impasse in bargaining over the entry date. In particular, Endo refused to consider dates before January 2013 because it was focused on securing lead time to transition the market to a new version of Opana before the onset of generic competition.[6] The terms providing Impax with an exclusive license to market a generic version of Opana and a credit for sales lost that might result from Endo's commercial strategy—the exchanges of value challenged by the FTC here—were thus essential to the parties' ability to bridge the gap between them and settle their dispute.

The FTC "refused to credit" evidence that Endo was unwilling to agree to an earlier entry date, Pet. App. 27, but not on the basis of anything affirmative. Rather, the FTC (and the Fifth Circuit) relied on the fact that Endo had not communicated an express red line. Pet. App. 28. As Impax explains, this holding is not plausibly "case-specific," because it creates an unrealistic clear-statement rule for settlement negotiations that makes it effectively impossible to show that a payment was needed to facilitate an early-entry settlement. Pet. 29. The result is to transform the third step of the rule of reason into an insurmountable least-restrictive-

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[5] *See also* Roger Fischer, William Ury & Bruce Patton, *Getting to Yes* 58-81 (3d ed. 2011); Howard Raiffa et al., *Negotiation Analysis: The Science and Art of Collaborative Decision Making* 17-19, 402 (2002); Michael L. Moffit, *Pleadings in the Age of Settlement*, 80 Ind. L. J. 727, 744-745 & nn. 67-69 (2005).

[6] *See* Pet. 9-11; Pet. App. 165 ¶116, 172 ¶147, 175 ¶156.

means test—a "recipe for disaster" this Court has rejected. *NCAA*, 141 S. Ct. at 2161.

At a minimum, the FTC's reasoning (which the Fifth Circuit endorsed) improperly inverts the burden of proof. The FTC presumes that a settlement for an earlier entry date would have been possible without a payment, leaving the defendant in the position of trying to disprove a counterfactual. Once again, this approach reinstates a "quick look" review in substance, directly contradicting the Court's holding in *Actavis*.

II. Because the Fifth Circuit and FTC's Presumption of Illegality Will Discourage Procompetitive Settlements and Harm Consumers, Immediate Review Is Warranted.

The sharp conflict between the decision below and *Actavis* is reason enough for this Court's intervention. But the problems with the Fifth Circuit and FTC's approach are compounded, and the need for review is heightened, by developments since *Actavis* was decided.

At the FTC's urging, lower courts have steadily expanded *Actavis*'s reach, to the point that some courts treat *any* consideration that generic manufacturers secure in settlement other than a non-exclusive license as an illicit payment that risks antitrust liability. With so many settlement forms now subject to second-guessing under the antitrust laws, it is all-the-more important for this Court to prevent the FTC-led evisceration of *Actavis*'s rule-of-reason standard. By contrast, if the Court leaves the Fifth Circuit's decision in place, manufacturers of generic medicines will be deterred from entering settlements with early generic entry dates, despite their benefits to consumers, because they will reasonably fear exposure to liability under the FTC's

quick-look-style test. And generic manufacturers, faced with fewer opportunities to settle and ever-increasing litigation costs, will invariably bring fewer patent challenges in the first place, ultimately resulting in fewer generic medicines on the market.

A. Lower Courts Have Expanded the Types of Patent Settlements Subject to Antitrust Scrutiny.

In *Actavis*, the alleged "payment" at issue was a straightforward cash transfer from the brand company to the generic. 570 U.S. at 145; *see also id.* at 152 (describing the challenged settlements as providing "money" to the generic challenger to drop its patent challenge). But as the Chief Justice predicted, this line has not held, with courts reasoning that "if antitrust scrutiny is invited for … cash payments, it may also be required for 'other consideration' and 'alternative arrangements.'" *Id.* at 173 (Roberts, C.J., dissenting).

Indeed, in the wake of *Actavis*, the FTC quickly pushed for a maximalist view of what qualifies as a payment,[7] and several lower courts have obliged, holding that a payment exists whenever there is a purported "unexplained large *transfer of value* from the patent holder to the alleged infringer." *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015) (emphasis added).[8] This logic has no

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[7] *E.g.*, Brief of FTC as *Amicus Curiae* at 19-23, *In re Lipitor Antitrust Litig.*, No. 14-2071 (1st Cir. filed June 25, 2015); Brief of FTC as *Amicus Curiae* in Support of Plaintiffs-Appellants at 22-28, *King Drug Co. of Florence v. SmithKline Beecham Corp.*, No. 14-1243 (3d Cir. filed Apr. 28, 2014).

[8] The Third Circuit's reasoning about what counts as a "payment" under *Actavis* is distinct from the aspect of the decision cited by

obvious stopping point. Under it, "*any* settlement agreement can be characterized as involving 'compensation' to the defendant," since a defendant typically "would not settle unless [it] had something to show for the settlement." *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J.). It is thus unsurprising that lower courts have subjected a wide variety of settlement terms to antitrust review, disregarding arguments that such terms do not present the same risk to competition as the cash payments in *Actavis*. Examples include:

- Exclusive-license agreements that let generic companies enter the market early in an exclusive arrangement;[9]
- Non-exclusive license agreements with variable royalty rates, which supposedly incentivize exclusivity;[10]
- Supply agreements for unrelated drug products;[11]
- Releases of damage claims from separate litigations between the same parties;[12]
- "Most favored entry" clauses that promote competition by allowing a generic manufacturer to

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Impax, which endorses consideration of patent strength in the rule-of-reason analysis. *See* Pet. 3, 24.

[9] *King Drug Co.*, 791 F.3d at 407.

[10] *In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639, 660-662 (D. Mass. 2020).

[11] *FTC v. AbbVie Inc.*, 976 F.3d 327, 356-357 (3d Cir. 2020).

[12] *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 253 (3d Cir. 2017).

> accelerate its market entry if another generic company gains approval and launches itself.[13]

Combining this unbounded definition of an *Actavis* "payment" with the FTC's *de facto* presumptions of illegality will impose a significant barrier to patent settlements, inhibiting companies from striking deals that get generic medicines to patients before the brand patents expire.

B. Settlements Are a Crucial Tool for Generic Manufacturers to Clear Through the Patent Estates Brands Have Erected.

If not reversed by this Court, the FTC's quick-look style of review will chill patent settlements at a time when they are more important and necessary than ever. In recent years, brand manufacturers have aggressively erected large patent estates that threaten timely generic and biosimilar market entry. Biosimilars Council, *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients*, 5 (June 2019), https://biosimilarscouncil.org/wp-content/uploads/2019/10/Failure-to-Launch-Part-1.pdf ("Failure to Launch"). Patent estates are an accumulation by a brand manufacturer of many, often dozens of, patents for the same drug, sometimes at the end of the drug's product lifecycle, shortly before the original patent covering the drug would expire. These additional patents can extend the

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[13] *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, No. 20-MD-02966-LHK, 2021 WL 3612497, at *23-25 (N.D. Cal. Aug. 13, 2021).

brand's monopoly on the drug far beyond that granted by the original patent. Failure to Launch, *supra*, at 5.[14]

These large patent estates are becoming increasingly common. In recent years, at least 78% of patents in the Orange Book cover existing drugs, not new ones; and more than 70% of the top 100 best-selling drugs are guarded by monopolies extending beyond the original patent's protection. Davis Statement, *supra*, at 5. Consider, for example, Humira, a blockbuster biologic medicine that has been on the market for decades. As of 2019, the brand manufacturer of Humira held *136* patents on the product—including 75 new patents that it applied for and obtained in the three years before the original compound patent for the product expired.[15] Although the Humira example is extreme, the general phenomenon is common. One study found that the brand manufacturers for the 12 top-grossing drugs in 2017 had accumulated 848 patents (71 per drug) blocking competition for an average of 38 years.[16]

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[14] *See also, e.g.*, FDA, Press Release, *Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilars Action Plan* (July 18, 2018), www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas (expressing concern that "patent thickets that are purely designed to deter the entry of approved biosimilars are spoiling … competition").

[15] Sy Mukherjee, *Protect at all costs: How the maker of the world's bestselling drug keeps prices sky-high*, FORTUNE (July 18, 2019).

[16] I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving up Drug Prices* 6 (2018), www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.

These types of patent estates can make the price of market entry prohibitive. Even if the brand's patent estate turns out to be meritless, manufacturers of generics and biosimilars still face years of cripplingly expensive litigation to prove invalidity in court. These lawsuits are infamously long and hard. *Ohio Willow Wood Co.*, 629 F.3d at 1376-1377 (Moore, J., concurring). One study estimates the cost of litigation to be $3 million per patent.[17] Costs are imposed on patients and consumers, too. As of September 2021, a full 11 of the 30 biosimilars approved by the FDA remain off the market,[18] and AAM's Biosimilars Council found that, as of June 2019, "delayed entry of biosimilars due to patenting has cost the U.S. health care system an astounding $7.6 billion in lost savings since 2015," Failure to Launch, *supra*, at 4.

Given the escalating complexity and cost of litigating these dense patent estates, it is essential for manufacturers of generic and biosimilar medicines to have the flexibility to bargain effectively for comprehensive deals that guarantee an early launch—providing licenses that cover future patents and agreeing to terms waiving parallel regulatory exclusivities. These are concessions that a generic manufacturer could not win by litigating its patent case to judgment. Davis Statement, *supra*, at 8. And because such terms are extremely valuable to a generic company, the FTC and some lower courts could theoretically try to characterize

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[17] Anne S. Layne-Farrar, *The Cost of Doubling Up: An Economic Assessment of Duplication in PTAB Proceedings and Patent Infringement Litigation*, 10 LANDSLIDE 1 (2018).

[18] *See Big Molecule Watch: FDA Approvals*, Goodwin Procter (last updated Sept. 26, 2021), https://www.bigmoleculewatch.com/fda-approved-ablas/.

them as "payments." *See* Part II.A, *supra*. But such settlements are a critical tool for bringing generic and biosimilar medicines to market, given the overwhelming difficulty and expense of litigating endless patents on a single product.

The FTC's resurrection of "quick look" review makes these deals harder to achieve by looking past the procompetitive value of comprehensive settlements and punishing generic manufacturers for finding creative solutions to patent disputes that guarantee early consumer access to generic and biosimilar medicines. Once again, this case is the perfect example. The settlement under review netted Impax a license protecting it from claims of infringement against *all* of Endo's relevant patents, including future patents—patents that were successfully asserted against other generic companies to keep them off the market for another decade. Pet. 26. But the FTC and the Fifth Circuit discounted this undisputed boon to patients by ignoring evidence of patent strength and presuming, contrary to all available evidence, that the parties could have settled without a brand-to-generic transfer of value. *See* Part I, *supra*. Absent a course correction by this Court, the FTC's approach will deter generic and biosimilar companies from entering these procompetitive settlements in the future, and in turn deter them from brining patent challenges in the first place. The public will bear the ultimate cost in the form of higher prices and reduced access to critical medicines.

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The FTC has reinstated a presumption of illegality that this Court rejected in *Actavis*, and the Fifth Circuit blessed that decision. Because the FTC's ongoing departure from this Court's precedent will substantially

chill procompetitive settlements that enable early access to lower-cost generic and biosimilar medicines, this Court should grant review.

CONCLUSION

The petition for certiorari should be granted.

Respectfully submitted.

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