No. 20-1293

IN THE

Supreme Court of the United States

ABBVIE INC., *et al.*,

Petitioners,

v.

FEDERAL TRADE COMMISSION,

Respondent.

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

BRIEF OF *AMICI CURIAE* LAW PROFESSORS IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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INTEREST OF THE *AMICI CURIAE*

Amici curiae are law professors who teach and write on patent law and policy, and are thus concerned when judicial decisions put at risk the protections that our legal system provides to innovators and to the companies that commercialize innovations in the marketplace (the "*Amici*").[1] This Court should grant the petition for a writ of certiorari and reject the Third Circuit's novel and truncated test for whether a patent owner had a subjective belief that his patent infringement suit lacked merit or was indifferent to the outcome of the suit. The Third Circuit's decision diminishes patentees' property rights and threatens innovation. *Amici* have no stake in the parties or in the outcome of the case.

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[1] Pursuant to Supreme Court Rule 37.6, Amici state that this brief was prepared in its entirety by *amici curiae* and their counsel. No monetary contribution toward the preparation or submission of this brief was made by any person other than *amici curiae* and their counsel. The Amici are listed in the Appendix to this brief. This brief is filed with the consent of both parties.

SUMMARY OF THE ARGUMENT

This Court should grant the petition for a writ of certiorari and reverse the Third Circuit's decision because it conflicts with this Court's sham-litigation test articulated in *PRE* by effectively eliminating the second step of the sham litigation test: the inquiry into whether a patent owner had a subjective belief that his patent infringement suit lacked merit or was indifferent to the outcome of the suit. The Third Circuit's novel approach—inferring subjective bad faith from a finding of objective baselessness—is at odds with *PRE* itself and sham-litigation jurisprudence in the other circuit courts. The petitioners address the relevant facts of this case, as well as this Court's applicable jurisprudence. Therefore, *Amici* offer additional insights concerning how the Third Circuit's decision threatens innovators' property rights, as well as the Congressionally created incentives in the Hatch-Waxman Act, and poses a real and serious threat to pharmaceutical innovation, a key pillar of the U.S. innovation economy.

The FTC's urging of the Third Circuit to adopt a truncated approach to the sham-litigation test is simply another attempt by the FTC to dictate that so-called "reverse-payment" settlement agreements in the pharmaceutical industry are necessarily anticompetitive. After failing to convince this Court in *Actavis* to adopt a "quick-look" approach to evaluating reverse-payment settlement agreements, the FTC is now seeking to avoid having to develop actual proof of subjective bad faith on the part of a patent owner. Instead of marshalling any such evidence, the FTC

seeks to rely on an inference that a finding that a patent suit was objectively baseless given a complicated patent validity issue necessarily means that the patent owner harbored a subjective belief that the suit was without merit or was indifferent to whether the suit succeeded.

This truncated inquiry into subjective intent undoes the safeguard that the bad-faith inquiry serves—namely, ensuring that litigants whose suits are ultimately found to be meritless but who sincerely sought a favorable outcome are immune from antitrust liability under the *Noerr-Pennington* doctrine. Moreover, the Third Circuit's novel approach to the subjective prong of the *PRE* test is particularly ill suited in the context of the Hatch-Waxman Act. The Third Circuit's subjective-motivation analysis conflicts with the incentives inherent in the Hatch-Waxman regime by subjecting an innovator to antitrust liability—and accompanying treble damages—when an innovator files a patent infringement suit against an alleged infringer and automatically activates the thirty-month-stay provision designed by Congress to encourage quick resolution of patent challenges.

If this Court allows the Third Circuit's new interpretation of the subjective-motivation prong of the sham-litigation test to stand, it will have detrimental chilling effects on Hatch-Waxman lawsuits and settlements, both of which are encouraged by Hatch-Waxman. In turn, the Third Circuit's truncated version of the sham-litigation test will discourage pharmaceutical innovation and harm our innovation economy—an acutely undesirable result in an era where the need for rapid pharmaceutical innovation is paramount.

This Court should reverse the Third Circuit's erroneous decision.

ARGUMENT

I. THE FTC IS SEEKING TO STRATEGICALLY MISUSE SHAM-LITIGATION JURISPRUDENCE TO CIRCUMVENT THIS COURT'S RULING IN *FTC v. ACTAVIS*

In *FTC v. Actavis, Inc.*, 570 U.S. 136, 158-60 (2013), this Court held that the rule-of-reason framework applies to "reverse-payment" settlement agreements. In so holding, the Court rejected the FTC's argument that reverse-payment settlement agreements should be evaluated using a "quick-look" analysis, *see id.* at 158-59, under which reverse payments would be treated as "presumptively anticompetitive," and the defendant would "bear 'the burden of procompetitive justification.'" Pet'r Br. 33-34, *FTC v. Actavis*, 570 U.S. 136 (2013) (No. 12-416), 2013 U.S. S. Ct. Briefs LEXIS 440, at *61-62 (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 771 (1999)). "Absent such a rebuttal" by the antitrust defendant, argued the FTC, "a reverse-payment agreement should be held unlawful." *Id.* at 17; *see also id.* at 34-36 (contending that reverse payments should be subject to a "quick-look" analysis because they "closely resemble" other agreements condemned as unlawful per se).

The Court "decline[d]" to adopt the FTC's proposed "quick-look" approach to evaluating reverse-payment settlement agreements. *Actavis*, 570 U.S. at

158-59.[2] It noted that the "quick-look" approach "is appropriate only where 'an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets,'" and found that reverse payments do not "meet this criterion." *Id.* at 159 (quoting *Cal. Dental*, 526 U.S. at 770). Rather, "complexities," such as the fact that "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" led the Court to hold that "the FTC must prove its case as in other rule-of-reason cases." *Id.*

Following this Court's decision in *Actavis*, it has become more difficult for plaintiffs to "prove [their] case" in reverse-payment suits. *See, e.g.*, *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017) (affirming judgment in favor of defendants on reverse-payment antitrust claims); *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34 (1st Cir. 2016) (same); *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811 (N.D. Ill. 2020) (dismissing reverse-payment claims under *Actavis* framework); *In*

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[2] As the law stands today, the quick-look test has nearly no applicability. Indeed, before rejecting the quick-look test in *California Dental*, 526 U.S. at 781, the Court had applied it in only three cases, each of which involved alleged restraints by professional associations. *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 458-59 (1986); *NCAA v. Bd. of Regents*, 468 U.S. 85, 100-01 (1984); *Nat'l Soc'y of Pro. Eng'rs v. United States*, 435 U.S. 679, 692-93 (1978).

re Effexor XR Antitrust Litig., No. 11-5479, 2014 U.S. Dist. LEXIS 142206 (D.N.J. Oct. 6, 2014) (same). Thus, in response to the Court's rejection in *Actavis* of the FTC's preferred quick-look approach to evaluating reverse-payment settlement agreements, the FTC now presses for a truncated analysis into whether the patent owner harbors a subjective anticompetitive intent. *See* FTC Third-Step (Reply/Resp.) Br. 60, *FTC v. AbbVie Inc.*, No. 18-2621 (3d Cir. July 19, 2019) (arguing that "[t]he filing of an objectively baseless Hatch-Waxman lawsuit . . . by itself supports a strong inference that the suit was intended 'primarily for the benefit of collateral injuries inflicted through the use of the legal process'" (quoting *Pro. Real Est. Invs. v. Columbia Pictures Indus.*, 508 U.S. 49, 65 (1993) ("*PRE*"))); *id.* at 63-64 ("[G]iven the unique structure of the Hatch-Waxman Act, which allows a plaintiff to thwart competition merely by filing suit, an objectively baseless Hatch-Waxman lawsuit gives rise to a strong inference that the suit was filed with the intent to interfere with competition.").

The FTC's approach in this case echoes their advocacy for applying the quick-look test in *Actavis*. In both cases, the FTC's test shortcuts a proper analysis of the agreement, and its impact on competition, to reach a preferred conclusion. In sum, the FTC is short-circuiting the subjective-motivation prong of the sham-litigation test to reach the same outcome it failed to convince this Court to adopt in *Actavis*: a rule that treats reverse-settlement agreements as inherently suspect.

The number of sham-litigation cases has increased in recent years, as plaintiffs have sought to

convert a "narrow" exception to *Noerr-Pennington* immunity into a routine cause of action. *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 556 (2014) ("We crafted the *Noerr-Pennington* doctrine—and carved out only a narrow exception for 'sham' litigation—to avoid chilling the exercise of the First Amendment right to petition the government for the redress of grievances."); *see, e.g.*, *United Food & Com. Workers Unions & Emps. Midwest Health Benefits Fund v. Novartis Pharms. Corp.*, 902 F.3d 1, 13-16 (1st Cir. 2018); *In re Wellbutrin*, 868 F.3d at 147-53; *In re Humira*, 465 F. Supp. 3d at 833; *UFCW v. Novartis Pharms. Corp.*, No. 15-cv-12732, 2017 U.S. Dist. LEXIS 102389, at *30-39 (D. Mass. June 30, 2017). Given this rise of sham-litigation suits, allowing the Third Circuit's decision to stand would severely discourage pharmaceutical patent owners from enforcing their intellectual property rights under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), 21 U.S.C. § 355 and 35 U.S.C. § 271. When confronted with potential infringement of its patent by a generic drug manufacturer, the patent owner would have to decide between allowing such infringement to continue or quickly bringing suit against the infringer—as intended under the Hatch-Waxman Act—and possibly facing ruinous damages if a court later deemed its suit objectively baseless and inferred from that a subjective intent to directly harm competition through the litigation process by activating the automatic thirty-month stay.

The Court should not permit the FTC to erode *Noerr-Pennington* immunity and patent protections in this manner. It should grant the petition for a writ

of certiorari and, once again, require the FTC to prove its case without the aid of a truncated competitive analysis.

II. THE THIRD CIRCUIT'S DECISION WILL CHILL LEGITIMATE PATENT ENFORCEMENT, AS WELL AS PATENT SETTLEMENTS

The Founders viewed patent rights as essential to the establishment of our nation's innovation economy. *See Grant v. Raymond*, 31 U.S. 218, 241 (1832) (Marshall, C.J.) ("To promote the progress of useful arts, is in the interest and policy of every enlightened government[,] [and] entered into the views of the framers of our constitution."); *see also* Stephen Haber, *Patents and the Wealth of Nations*, 23 Geo. Mason L. Rev. 811, 815 (2016) (positing that "there are no wealthy countries with weak patent rights, and there are no poor countries with strong patent rights"). Indeed, "[t]he stated objective of the Constitution in granting the power to Congress to legislate in the area of intellectual property is to 'promote the Progress of Science and useful Arts.'" *Kewanee v. Bicron*, 416 U.S. 470, 480 (1974). Thus, "[t]he patent laws encourage innovation by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development." *Id.*; *see Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."); *see also DOJ/FTC Antitrust Guidelines for the Licensing of Intellectual Property* § 1.0 (2017) (observing patent law's "purpose of

promoting innovation and enhancing consumer welfare"); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1369 (Fed. Cir. 1998) (providing that "a principal purpose of the patent system is to provide innovators with a property right upon which investment and other commercial commitments can be made," and thus, innovators "must have the right of enforcement of a duly granted patent, unencumbered by punitive consequences should the patent's validity or infringement not survive litigation"). As a result, especially in the context of patent litigation, the appropriate application of the narrow sham-litigation exception to *Noerr-Pennington* immunity is exceedingly important to innovation. *See Octane Fitness*, 572 U.S. at 556 ("We crafted the *Noerr-Pennington* doctrine—and carved out only a narrow exception for 'sham' litigation—to avoid chilling the exercise of the First Amendment right to petition the government for the redress of grievances."). Interpreting the sham-litigation doctrine too broadly would diminish innovators' property rights in the fruits of their productive labor and thus harm the U.S. innovation economy.

While the Third Circuit gave lip service to the narrow reach of the sham-litigation exception, noting that "a plaintiff seeking to show the sham litigation exception faces 'an uphill battle'" and that "the hill is steeper 'in the context of an ANDA case,'" the court's application of the exception ignored those principles and dramatically expanded this "narrow" exception precisely in the context of Hatch-Waxman litigation. *FTC v. AbbVie Inc.*, 976 F.3d 327, 361 (3d Cir. 2020). By conflating the subjective and objective prongs of the sham-litigation exception, the Third Circuit's decision essentially eliminates this Court's requirement

under *PRE* that an innovator subjectively intended to directly interfere with a competitor's business interests through the process of litigation. *See PRE*, 508 U.S. at 60-61; *AbbVie*, 976 F.3d at 370-71 (finding that the objective-baselessness and subjective-motivation prongs "are interrelated" and that subjective bad faith can be inferred from a finding of objective baselessness). Thus, the Third Circuit's decision subjects innovators to the very real threat of antitrust liability based on their filing of good-faith patent infringement suits. Such an outcome conflicts with this Court's decision in *PRE* and finds no support in other circuits' application of *PRE*. *See, e.g.*, *C.R. Bard*, 157 F.3d at 1369 (holding that plaintiffs bringing sham-litigation claims must present "affirmative evidence of bad faith" in order to overcome the "presumption that the assertion of a duly granted patent is made in good faith"); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009) (permitting sham-litigation claim where the defendants allegedly "knew their misconduct before the PTO had rendered the patent invalid").

Moreover, the Third Circuit's decision directly conflicts with the statutory purpose of the Hatch-Waxman regime—to encourage the prompt filing of patent infringement suits by innovators and the quick settlement of such claims. *See AbbVie*, 976 F.3d at 361 (acknowledging that courts "must not 'penalize a brand-name manufacturer whose litigiousness was a product of Hatch-Waxman'" because "[d]oing so would punish behavior that Congress sought to encourage" (quoting *Wellbutrin*, 868 F.3d at 158)); *see also Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399,

407-08 (2012). Under the Hatch-Waxman Act, innovators that file suit within forty-five days are rewarded with an automatic thirty-month stay of the generic manufacturer's FDA approval, thereby encouraging innovators to file patent infringement suits promptly. 21 U.S.C. § 355(j)(5)(B)(iii); *see Actavis*, 570 U.S. at 143 ("If the brand-name patentee brings an infringement suit within 45 days, the FDA then must withhold approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court."); *Wellbutrin*, 868 F.3d at 144 (providing that this provision of the Hatch-Waxman Act "encourages brand-name manufacturers to file patent infringement suits quickly"); *see also* H.R. Rep. No. 98-857, pt. 1, at 15 (1984) (reflecting the goal "to create a new incentive for increased expenditures for research and development" in the pharmaceutical industry). The rewarded thirty-month stay is an *outcome* of patent litigation provided for by statute, rather than a misuse of the governmental *process* of litigation, such as causing an opponent collateral expense or delay through the litigation itself. *See PRE*, 508 U.S. at 68-70 (Stevens, J., concurring) (explaining that a "sham" case is where "the plaintiff is indifferent to the outcome of the litigation itself, but has nevertheless sought to impose a *collateral harm* on the defendant by, for example, impairing his credit, abusing the discovery process, or interfering with his access to governmental agencies"); *City of Columbia* v. *Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380 (1991) ("A classic example is the filing of frivolous objections to the license application of a competitor, with no expectation of achieving denial of the license but simply in order to impose expense and delay."). By citing the availability of the thirty-month stay as evidence of

subjective bad faith, the Third Circuit penalizes innovators for behaving as Congress intended and turns every Hatch-Waxman lawsuit later deemed objectively baseless into a sham. *See PRE*, 508 U.S. at 69 (Stevens, J., concurring) ("We may presume that every litigant intends harm to his adversary. . . . Access to the courts is far too precious a right for us to infer wrongdoing from nothing more than using the judicial process to seek a competitive advantage in a doubtful case."). Litigation brought under the Hatch-Waxman Act should be *less* likely to be considered a sham, not more likely.

Also, because the Hatch-Waxman Act encourages expeditious resolution of patent-infringement suits and these suits involve complex issues of patent validity and high stakes, most parties opt for the certainty of settlement. *See* Lex Machina, *Hatch-Waxman ANDA Litigation Report 2017* at 14 (Apr. 2017) (finding that 56.5% of Hatch-Waxman cases filed 2009 to 2017 settled); RBC Capital Markets, *Pharmaceuticals: Analyzing Litigation Success Rates* (Jan. 15, 2010) (noting that over half of Hatch-Waxman suits filed 2000 to 2009 were settled or dropped); *see also* Bureau of Competition, *Overview of Agreements Filed in FY 2011* (Jan. 2012) (summarizing key information on the 156 final patent settlement agreements filed with the FTC during fiscal year 2011). Such settlements should be encouraged, not penalized. *See Actavis*, 570 U.S. at 154 (acknowledging "a general legal policy favoring the settlement of disputes," including in the context of Hatch-Waxman litigation); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003) (Posner, J.) ("The general policy of the law is to favor the settlement of litigation,

and the policy extends to the settlement of patent infringement suits."). Under the Third Circuit's decision, however, innovators would be dissuaded from settling Hatch-Waxman suits because if later faced with sham-litigation allegations, a settling innovator would be unable to defend the objective reasonableness of its suit by pointing to a win on the merits *and* unable to rely on its proper subjective motivation for filing suit. *See PRE*, 508 U.S. at 60 n.5 ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham.").

This Catch-22 would stymie pharmaceutical innovation. Developing new drugs is expensive, time-consuming, and risky. *See Actavis*, 570 U.S. at 142 (providing that the FDA NDA approval process is "long, comprehensive, and costly"); Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs*, 2016 JACC: Basic to Translational Sci. 170, 171 (finding that the average time between drug discovery and FDA approval is ten to fifteen years); Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 23, 25-26 (2016) (estimating that the average cost of developing a new drug and obtaining FDA approval was approximately $2.6 billion in 2013, and that only around 12% of drugs that enter Phase 1 clinical trials end up receiving final FDA approval). Given the high costs and significant risks involved in pharmaceutical research and development, branded pharmaceutical companies must be able to rely on patent protection—including the right to sue for possible infringement and settle such suits—to recoup past R&D efforts and to fund further R&D in the future. Pharmaceutical

companies would have no incentive to invest billions of dollars in the development of life-saving and life-enhancing technologies if upon entry of a generic competitor they must choose between allowing infringement of their patents, which were the product of significant time and resources, or filing suit and possibly facing bet-the-company damages in the form of treble damages paid to multiple classes of plaintiffs.

The Third Circuit's decision places innovators in just such a conundrum. In turn, if the Third Circuit's decision is permitted to stand, innovators will be less likely to invest the substantial time and resources necessary to invent new life-saving products in the first place. *See* Maureen K. Ohlhausen, *Patent Rights in a Climate of Intellectual Property Rights Skepticism*, 30 Harv. J. L. & Tech. 103, 117 (2016) ("[I]nnovation in the life sciences industry would suffer catastrophic decline without patent protection."); Henry G. Grabowski et al., *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34(2) Health Affairs 302, 303 (2015) ("Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market.").

Beyond Hatch-Waxman litigation, the Third Circuit's decision will negatively affect patent litigation and settlement agreements more generally. This Court's requirement of subjective bad faith is a crucial safeguard in the context of ubiquitous patent validity issues raised in all patent lawsuits, as these legal standards are complex and constantly changing. *See Asahi Glass*, 289 F. Supp. 2d at 993 ("No one can be *certain* that he will prevail in a patent suit."); Ted L.

Field, *"Judicial Hyperactivity" in the Federal Circuit: An Empirical Study*, 46 U.S.F. L. Rev. 721, 722-23, 776 (2012) (concluding that "the overall reversal rate of the Federal Circuit—both unadjusted and adjusted for summary affirmances—was statistically significantly greater than the overall reversal rate of the representative regional circuits taken as an aggregate," and "the Federal Circuit is more judicially hyperactive in patent cases than in non-patent cases"); Ted Sichelman, *Myths of (Un)Certainty at the Federal Circuit*, 43 Loy. L.A. L. Rev. 1161, 1164-71 (2010) (outlining categories of uncertainty in the patent system and the resulting high claim-construction reversal rates); David L. Schwartz, *Pre-Markman Reversal Rates*, 43 Loy. L.A. L. Rev. 1073, 1075 (2010) (providing that "[t]he Federal Circuit's reversal rate . . . has hovered between 20 and 45 percent"). Indeed, the fact that the Third Circuit in this case reversed the district court in part, finding that AbbVie's infringement suit against Teva was not objectively baseless, demonstrates that reasonable minds may differ on the merits of Hatch-Waxman cases. *See AbbVie*, 976 F.3d at 351. Because patent litigation is—to some extent—unpredictable, innovators must be able to bring a good-faith patent suit without the risk of treble damages if a court later, with the benefit of hindsight, finds their suit to be meritless.

Moreover, the particularly complex and fact-intensive nature of this case—in which the innovators claimed patent infringement based on the doctrine of equivalents, the generic company argued that prosecution-history estoppel applied, and the innovators contended that the "tangentiality" exception to prosecution-history estoppel applied—makes it even more

difficult to determine whether a litigant would have reasonably expected to succeed on the merits. The Third Circuit's inference of subjective bad faith is especially inappropriate under these circumstances, where the law is highly technical, case-specific, and constantly evolving.

In short, this Court should reverse the Third Circuit's new and unfounded approach to the subjective-motivation prong of the sham-litigation test, which will discourage patent owners from exercising their property rights in the face of potential treble damages and thus discourage innovation.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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