IN THE

Supreme Court of the United States

ABBVIE INC., ABBOTT LABORATORIES, UNIMED PHARMACEUTICALS LLC, AND BESINS HEALTHCARE, INC., Petitioners,

2)

FEDERAL TRADE COMMISSION.

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

WILLIAM F. LEE
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109

JEFFREY I. WEINBERGER
STUART N. SENATOR
ADAM R. LAWTON
MUNGER, TOLLES & OLSON LLP
MUNGER, TOLLES & OLSON LLP
350 South Grand Avenue
Los Angeles, CA 90071
MEDHA GARGEYA
WILMER CUTLER PICKERING
HALE AND DORR LLP
Washington, DC 20006
(202) 663-6000

ELAINE J. GOLDENBERG MUNGER, TOLLES & OLSON LLP 601 Massachusetts Ave., NW Suite 500 East Washington, DC 20001

SETH P. WAXMAN

Counsel of Record

LEON B. GREENFIELD

CATHERINE M.A. CARROLL

BRITTANY BLUEITT AMADI

CLAIRE H. CHUNG

MEDHA GARGEYA

WILMER CUTLER PICKERING

HALE AND DORR LLP

1875 Pennsylvania Ave., NW

Washington, DC 20006

(202) 663-6000

seth.waxman@wilmerhale.com

Counsel for AbbVie Inc., Abbott Laboratories, and Unimed Pharmaceuticals LLC

MELINDA F. LEVITT GREGORY E. NEPPL FOLEY & LARDNER, LLP 3000 K Street, NW Washington, DC 20007

Counsel for Besins Healthcare, Inc.

QUESTION PRESENTED

Whether the subjective element of the "sham litigation" exception to *Noerr-Pennington* immunity may be met by an inference from a finding that a challenged lawsuit was objectively baseless, even without evidence that the antitrust defendant actually believed the suit lacked merit or was indifferent to the outcome.

PARTIES TO THE PROCEEDING

Petitioners are AbbVie Inc., Abbott Laboratories, Unimed Pharmaceuticals LLC, and Besins Healthcare, Inc., which were defendants in the district court and appellees and cross-appellants in the court of appeals.

Teva Pharmaceuticals USA, Inc. was a defendant in the district court but was dismissed as a party by the court of appeals.

Respondent is the Federal Trade Commission, which was the plaintiff in the district court and appellant and cross-appellee in the court of appeals.

CORPORATE DISCLOSURE STATEMENT

AbbVie Inc. has no parent corporation, and no publicly held company owns 10% or more of its stock.

Abbott Laboratories has no parent corporation, and no publicly held company owns 10% or more of its stock.

Unimed Pharmaceuticals LLC is an indirect, wholly owned subsidiary of AbbVie Inc., a publicly traded company.

Besins Healthcare, Inc., is a wholly owned U.S. corporate subsidiary of Belgian company Besins Healthcare, S.A. Neither Besins Healthcare, S.A. nor its parent entity Besins Healthcare Holding LTD are publicly traded companies.

RELATED PROCEEDINGS

Federal Trade Commission v. AbbVie Inc., et al., Nos. 18-2621, -2748, -2758 (3d Cir.) (opinion and judgment issued September 30, 2020; opinion amended December 4, 2020; rehearing denied December 4, 2020).

Federal Trade Commission v. AbbVie Inc., et al., No. 2:14-cv-05151-HB (E.D. Pa.) (judgment issued July 18, 2018).

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PETITION FOR A WRIT OF CERTIORARI

AbbVie Inc., Abbott Laboratories, Unimed Pharmaceuticals LLC, and Besins Healthcare, Inc. (collectively, "AbbVie") respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Third Circuit in this case.¹

INTRODUCTION

This petition concerns a crucial and recurring issue at the intersection of patent law, antitrust law, and the First Amendment: When may a patent owner be held

¹ "AbbVie" refers here to all petitioners, except where Besins Healthcare, Inc. ("Besins") is separately mentioned.

liable under the antitrust laws for suing a competitor to enforce a valid patent? The Noerr-Pennington doctrine allows litigants to exercise their First Amendment right to petition the government for redress of grievances, including by litigating against a competitor, without fear of antitrust liability and attendant treble damages. Although this Court has recognized an exception to that immunity for "sham" litigation, the Court has insisted on a stringent test for identifying sham suits, to ensure adequate "breathing space" for First Amendment rights. BE&K Constr. Co. v. NLRB, 536 U.S. 516, 531 (2002). Thus, a plaintiff who claims that a lawsuit violated the antitrust laws must prove both (1) that the challenged suit was objectively baseless, and (2) that the antitrust defendant was subjectively motivated by an improper purpose in bringing the challenged suit. Professional Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60-61 (1993) ("PRE").

Under the subjective prong, the plaintiff must establish that the defendant's "subjective motivation" for suing was "to interfere directly with the business relationships of a competitor" by using "the [litigation] process—as opposed to the outcome of that process—as an anticompetitive weapon." PRE, 508 U.S. at 60-61 (quotation marks omitted). A "classic example" is litigation undertaken "with no expectation of achieving" success, "but simply in order to impose expense and delay." City of Columbia v. Omni Outdoor Advert., Inc., 499 U.S. 365, 380 (1991). In contrast, a litigant's mere intent to undermine a competitor—i.e., "an intent to restrain trade as a result of the government action sought"—"does not foreclose protection" under the First Amendment. Id. at 380-381.

The decision below vitiates the subjective element of the sham exception. In this antitrust action brought by the Federal Trade Commission, the court of appeals held that a patent-infringement suit AbbVie brought against Perrigo Company under the Hatch-Waxman Act was a sham and that AbbVie violated the antitrust laws by seeking to enforce its valid patent. The court first concluded that the infringement suit was objectively baseless. But then, rather than requiring the FTC independently to prove subjective bad faith, the court held that the subjective element could be inferred from the finding of objective baselessness. App. 68a-69a. In the court's view, a mere "intent to thwart competition" suffices to establish improper subjective motivation, App. 67a (quotation marks omitted); see App. 49a, and such an intent can be inferred through a logical "syllogism" whenever a litigant brings an objectively baseless lawsuit, App. 68a. Although the FTC had offered no probative evidence that AbbVie actually was indifferent to the outcome of the infringement suit or believed that the suit lacked any prospect of success, the court held that "evidence of [the] defendant's belief about the merits of its claims ... is not required." Id. Instead, the court treated circumstances that are present in virtually all Hatch-Waxman Act litigation—that AbbVie's patent-infringement suit was directed by experienced lawyers who understood the law and the financial stakes of the cases and who knew that a lawsuit under the Hatch-Waxman Act would automatically stay FDA approval of Perrigo's product—as supporting the inference of bad faith. App. 69a-70a.

That analysis conflicts with this Court's precedent and stands in significant tension with decisions of other courts. Whereas this Court has held that a lawsuit can violate the antitrust laws only if a plaintiff proves the suit is a sham "both objectively and subjectively," BE&K, 536 U.S. at 526; see PRE, 508 U.S. at 61, the court of appeals relieved the FTC of its burden to prove the latter component, allowing subjective motivation to be inferred from the finding of objective baselessness (at least where AbbVie had not waived attorney-client privilege to introduce its own direct evidence overcoming the inference), App. 68a-70a. Whereas this Court has emphatically held that an intent to thwart competition alone "does not render [petitioning] activity a 'sham," Omni, 499 U.S. at 381, the court of appeals agreed with the FTC that "what matters is the intent to thwart competition," App. 67a (quotation marks omitted); see App. 49a. And whereas this Court has held that a litigant's "indifferen[ce] to the outcome on the merits" is the hallmark of sham litigation, PRE, 508 U.S. at 65; see Omni, 499 U.S. at 380—and other courts have treated such evidence as dispositive—the court of appeals here held that evidence of AbbVie's belief about the merits was "not required," App. 68a.

The decision below thus eviscerates the Court's two-pronged sham-litigation exception, to the detriment of First Amendment rights and the innovation that patents protect. The court of appeals' analysis imputes a subjective intent to sue in bad faith to any law-suit that seeks a competitive advantage if the suit is later found objectively baseless, without distinguishing between litigants who hoped to achieve their objectives through a successful outcome and those who sought only to abuse the litigation process itself. As a result, litigants who seek to enforce their rights against a rival must face the substantial chilling effects of antitrust liability and treble damages whenever the objective merit of a suit is in question.

Those consequences will be especially pernicious in a large and important category of cases: those in which patent owners rely on the mechanisms Congress provided in the Hatch-Waxman Act to enforce their intellectual-property rights, which account for some ten percent of all patent-infringement suits in the United States. To balance the rights of patent owners against the benefits of competition, the Hatch-Waxman Act encourages patent owners to file infringement suits promptly against potential generic competitors—and rewards them for doing so with a stay of FDA approval of the generic—so that intellectual-property disputes can be resolved expeditiously before a generic drug goes to market. But the court of appeals treated the fact that AbbVie followed that statutory scheme (and thus benefited from the automatic "[e]specially" indicative of bad faith. App. 70a; see App. 50a. And the court held that the circumstances of the suit—that it was overseen by experienced lawyers familiar with the Hatch-Waxman framework and that AbbVie stood to gain financially—supported the inference of subjective bad faith. App. 70a. On that reasoning, any Hatch-Waxman suit later found to be objectively baseless will automatically be deemed a sham, unless the antitrust defendant can overcome the inference and affirmatively establish its good faith by waiving attorney-client privilege. That rule improperly shifts the burden of proof to the antitrust defendant and imperils the attorney-client privilege.

It provides little solace to patent owners and innovators that these consequences will follow only where an infringement suit is deemed objectively baseless. Patent law is notoriously complicated, hard to predict, and constantly changing. Thus, the "breathing space" that this Court has emphasized for suits that are adju-

dicated to be objectively baseless is particularly necessary, lest a defendant be subjected to antitrust liability and treble damages for incorrectly assessing the merits of enforcing a patent under inherently complex and evolving law. That is precisely why the Court established the subjective prong as an independent element of the test and why the decision below will be so damaging to First Amendment rights and innovation alike.

OPINIONS BELOW

The court of appeals' amended opinion (App. 1a-92a) is reported at 976 F.3d 327. The order denying rehearing (App. 205a-206a) is unreported. The district court's findings of fact and conclusions of law after a bench trial (App. 93a-175a) are reported at 329 F. Supp. 3d 98. The district court's decision granting partial summary judgment to the FTC (App. 177a-204a) is unpublished but is available at 2017 WL 4098688.

JURISDICTION

The court of appeals entered judgment on September 30, 2020, and denied a timely rehearing petition on December 4, 2020. On March 19, 2020, this Court extended the deadline to file petitions for writs of certiorari to 150 days from the date of the lower court judgment or order denying rehearing. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The First Amendment to the U.S. Constitution and relevant provisions of the Hatch-Waxman Act, 21 U.S.C. § 355(a), (b), (c), (j)(1)-(2), (j)(5)(A)-(B), are reproduced in the Appendix.

STATEMENT

A. *Noerr-Pennington* Immunity And The Sham-Litigation Exception

The First Amendment protects "the right of the people ... to petition the Government for a redress of grievances." U.S. Const. amend. I. The right to petition is "one of 'the most precious of the liberties safeguarded by the Bill of Rights," implied in "[t]he very idea of a government, republican in form." BE&K Const. Co. v. NLRB, 536 U.S. 516, 524-525 (2002).

To safeguard that right, this Court has long held that people may seek "anticompetitive action from the government" without fear of antitrust liability. City of Columbia v. Omni Outdoor Advert., Inc., 499 U.S. 365, 379-380 (1991). The antitrust laws, the Court has explained, do not prohibit attempts to "persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly." Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 136 (1961); accord United Mine Workers v. Pennington, 381 U.S. 657, 669 (1965).

That principle—known as the *Noerr-Pennington* doctrine—applies equally to litigation in courts. When parties "use ... courts to advocate their causes and points of view respecting resolution of their business and economic interests vis-a-vis their competitors," they are exercising their right to petition the government, and the litigation generally cannot be the basis of antitrust liability. *California Motor Transp. Co.* v. *Trucking Unlimited*, 404 U.S. 508, 510-511 (1972).

This Court has recognized a limited exception to *Noerr-Pennington* immunity for when petitioning is "a

mere sham to cover ... an attempt to interfere directly with the business relationships of a competitor," rather than a "genuine" effort to influence governmental action. Omni, 499 U.S. at 380, 382. To show that litigation was a sham, an antitrust plaintiff bears the burden of satisfying the "two-part definition" set forth in *Pro*fessional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U.S. 49, 60 (1993) ("PRE"). "First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Id. Second, the litigant must have been subjectively motivated by an improper purpose in bringing the suit. Id. The subjective element "focus[es] on whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor, through the use [of] the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." Id. at 60-61 (quotation marks and internal citations omitted).

The subjective element serves a distinct role in the sham inquiry. Whereas the objective element requires the antitrust plaintiff to "disprove the challenged lawsuit's legal viability," the subjective element requires the plaintiff to disprove the suit's "economic viability." PRE, 508 U.S. at 61. Litigation may be motivated by an improper purpose (and economically irrational) when the litigant is "indifferent to the outcome on the merits of the ... suit," when "any damages" to be recovered from the suit are "too low to justify [the litigant's] investment in the suit," or when the litigant sues "primarily for the benefit of collateral injuries inflicted through the use of legal process." Id. at 65. A "classic example" of sham litigation, this Court has noted, is where a party files suit "with no expectation of"

prevailing, "simply in order to impose expense and delay." *Omni*, 499 U.S. at 380.

By contrast, a litigant's mere "purpose of delaying a competitor's entry into the market *does not* render [the lawsuit] a sham," absent proof that "the delay is sought to be achieved only by the [litigation] process itself, and not by the governmental action that the [litigation] seeks." *Omni*, 499 U.S. at 381 (emphasis added). As the Court has explained, a litigant's "ill will" toward a competitor "does not mean" the dispute is "not genuine." *BE&K*, 536 U.S. at 534.

This Court has cautioned that the sham exception to Noerr-Pennington immunity is and must be "narrow," "to avoid chilling the exercise of the First Amendment right to petition." Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 556 (2014); see BE&K, 536 U.S. at 528-529. Particularly in the antitrust context, the threat of liability and "attendant treble damages" "significantly chills" the right to bring suit against a competitor. Octane Fitness, 572 U.S. at 556. Thus, the Court has "never held that the entire class of objectively baseless litigation may be enjoined or declared unlawful even though such suits may advance no First Amendment interests of their own." BE&K, 536 U.S. at 531. Instead, recognizing that "breathing space" is necessary for robust First Amendment protection, the Court has made clear that only those suits that are "both objectively baseless and subjectively motivated by an unlawful purpose" can give rise to antitrust liability. Id.

B. AbbVie's Hatch-Waxman Act Lawsuit

AbbVie and Besins co-own the patent that covered AndroGel, a revolutionary drug for treating low testosterone levels.² As the first topical testosterone replacement therapy offered in a convenient gel form, AndroGel offers patients numerous benefits and became a commercial success after it launched in 2000. App. 8a-10a.

In 2011, nine years before the AndroGel patent was set to expire, Teva Pharmaceuticals USA and Perrigo Company each sought FDA approval under the Hatch-Waxman Act to market generic versions of AndroGel. App. 14a-15a. Ordinarily, a manufacturer seeking to market a new drug must submit a New Drug Application (NDA) and undergo a lengthy testing process for safety and efficacy. The Hatch-Waxman Act, however, facilitates competition by permitting generic manufacturers to pursue abbreviated approval pathways by "piggy-backing on the brand's NDA" and supporting data. Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 405 (2012); see 21 U.S.C. § 355(b)(2), (j)(2)(A); 21 C.F.R. § 314.54. To protect patent rights in such cases, the Hatch-Waxman Act requires a generic manufacturer seeking abbreviated approval to certify either that the branded drug is not covered by an existing patent or—in what is commonly known as a paragraph IV certification—that any applicable patent "is invalid or will not be infringed" by the manufacture, use, or sale of the generic drug. 21 U.S.C. § 355(b)(2)(A)(iv), (j)(2)(A)(vii)(IV).

Filing a paragraph IV certification "means provoking litigation." *Caraco*, 566 U.S. at 407. To facilitate the prompt resolution of any patent disputes between generic and brand manufacturers, the patent statute deems the submission of a paragraph IV certification

 $^{^2}$ The Andro Gel patent expired in August 2020. App. 12a.

"an act of infringement" that "gives the brand an immediate right to sue" without waiting for the generic drug's manufacture or sale. *Id.* (citing 35 U.S.C. § 271(e)(2)(A)). And the Hatch-Waxman Act incentivizes brand manufacturers to file such suits quickly, by providing that if the patent owner sues for infringement within 45 days after receiving the paragraph IV certification then the FDA must withhold approval of the generic drug for 30 months or until the infringement suit ends, whichever occurs first. 21 U.S.C. § 355(e)(3)(C), (j)(5)(B)(iii).

Teva and Perrigo each submitted paragraph IV certifications asserting that their testosterone gels would not infringe the AndroGel patent because they contained an ingredient—the "penetration enhancer," which accelerates drug delivery through the skin—that differed chemically from the penetration enhancer claimed in the AndroGel patent. AbbVie promptly sued Teva and Perrigo for infringement, triggering the statutory stay of FDA approval of Teva's and Perrigo's products. App. 14a-15a.

AbbVie alleged in the infringement suits that although Teva's and Perrigo's products did not literally infringe the AndroGel patent, they infringed the patent under the "doctrine of equivalents," because the differences between the penetration enhancer claimed in the patent and the penetration enhancers used in those products were insubstantial. App. 184a, 187a-188a; see Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 732 (2002); Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997). Teva and Perrigo did not dispute the validity of the AndroGel patent or that their products were substantially equivalent. Instead, relying on the doctrine of "prosecution history estoppel," they each contended that AbbVie

had surrendered patent protection for equivalent penetration enhancers by narrowing the scope of the AndroGel patent during prosecution. App. 107a, 110a, 189a-193a; C.A.J.A. 429-440; see Festo, 535 U.S. at 739-740. AbbVie responded that no estoppel applied because the narrowing amendments it made to the patent application during prosecution were not made for purposes of patentability and were only tangentially related to the Teva and Perrigo penetration enhancers. See Festo, 535 U.S. at 735-741 (discussing tangentiality and other exceptions to prosecution-history estoppel).

Throughout the relevant period, while acknowledging some risk to AndroGel from potential market entry by Teva or Perrigo, AbbVie's internal business planning documents reflected overall confidence that AndroGel would continue to maintain market exclusivity and experience growing sales. C.A.J.A. 1827-1865, 2016-2070, 2538-2596, 2599-2662, 3378-3391, 3393-3401, 3403-3470, 3966, 3971, 3977-3982. For example, even after AbbVie received Teva's paragraph IV certification, AbbVie's Long Range Plan as of April 2011 reflected the "key assumption for the business" that AndroGel would have exclusivity through August 2015 (the date two other generics were licensed to enter the market). C.A.J.A. 3966; see C.A.J.A. 4119 (dates used in planning documents "universally c[a]me from ... our legal teams"). And even after both lawsuits began, AbbVie's annual plan for 2012 continued to reflect that confidence. C.A.J.A. 3977-3982.

Both infringement suits settled on terms favorable to AbbVie. App. 16a-17a. Although Teva and Perrigo each initially pushed for agreements that would have allowed an earlier launch of their respective products, AbbVie held firm and successfully insisted on later launch dates—dates far later than the maximum 30-

month stay that would have applied under the Hatch-Waxman Act had the lawsuits continued. *Id.* As Perrigo's in-house lawyer later explained, Perrigo accepted a later date based in part on its assessment of AbbVie's chances of winning the infringement litigation. App. 16a. *Cf. Theme Promotions, Inc.* v. *News Am. Mktg. FSI*, 546 F.3d 991, 1008 (9th Cir. 2008) (that "ongoing litigation settled suggests that the original suit was not objectively baseless").

C. The FTC's Antitrust Claim And Proceedings Below

Nearly three years after the patent-infringement suits settled, the FTC brought this antitrust action against AbbVie under the FTC Act, 15 U.S.C. §§ 45(a), 53(b). As relevant here, the FTC alleged that AbbVie engaged in monopolization by filing sham litigation against Teva and Perrigo to delay entry of their generic products. App. 19a.³

The district court held that both lawsuits were sham litigation that violated the antitrust laws and awarded the FTC nearly \$500 million in disgorgement. App. 175a; C.A.J.A. 171-172. Addressing the subjective prong of the sham exception, the district court acknowledged that "the FTC must prove that defendants had actual knowledge that the patent infringement suits here were baseless in order both to meet its bur-

³ In a separate count against AbbVie and Teva, the FTC alleged that AbbVie's settlement with Teva was an illegal restraint of trade under *FTC* v. *Actavis*, *Inc.*, 570 U.S. 136 (2013). The district court dismissed that count. App. 19a. On the FTC's appeal, Teva was dismissed as a defendant, and the court of appeals reinstated the claim against AbbVie. App. 29a-47a. That claim is not at issue in this petition.

den under" this Court's precedent "and to avoid interference with [AbbVie's] First Amendment rights." App. 123a. The court further acknowledged that there was "no direct evidence of ... subjective intent." App. 133a. The court nevertheless found the subjective element satisfied based on its view that AbbVie's lawyers were "very experienced patent attorneys" who knew the law and the prosecution history of the AndroGel patent and "knew the extensive financial benefits" that would follow if generic competition was delayed. App. 135a. Because the court had deemed the patent-infringement suits objectively baseless, the court found it "reasonable to conclude" in those circumstances that the lawyers' "subjective intent" must have been "to file sham lawsuits." *Id*.

The court of appeals affirmed in part, reversed in part, and vacated in part. App. 3a-4a, 208a. It held that AbbVie's infringement suit against Teva was not objectively baseless and therefore not a sham. App. 51a-60a. As to the suit against Perrigo, however, the court affirmed the finding of sham litigation. App. 60a-71a.

The court of appeals first stated that the district court did not err in holding that the suit was objectively baseless. App. 60a-64a.⁴ Regarding the subjective

⁴ Although this petition does not seek review of the court of appeals' determination on objective baselessness, that holding was wrong for several reasons. The patent-law doctrine of prosecution-history estoppel and the "tangentiality" exception to that doctrine are highly technical, fact-specific standards, and an objectively reasonable litigant considering the prosecution history of the AndroGel patent could have easily perceived a chance that AbbVie's patent-infringement claims would prevail—indeed, the Federal Circuit has found several infringement suits similar to AbbVie's to be not only reasonable but meritorious. See, e.g., Eli Lilly & Co. v. Hospira, Inc., 933 F.3d 1320 (Fed. Cir. 2019). That Perrigo (like Teva) made significant concessions during settlement

prong, the court of appeals "agree[d] with the FTC" that "what matters is the intent to thwart competition." App. 67a (quotation marks omitted); see App. 49a. The district court had therefore "applied an improper legal standard" by requiring evidence that AbbVie believed the suit lacked merit. App. 65a, 67a-68a. To the contrary, the court of appeals held that "evidence of [the] defendant's belief about the merits of its claims ... is not required" to establish the necessary intent to thwart competition. App. 68a.

Instead, the court held that the objective and subjective elements of the sham exception are not "distinct," but rather are "interrelated," and that a subjective intent to thwart competition could therefore be inferred from a suit's objective baselessness. App. 68a. In particular, the court of appeals endorsed the district court's "syllogism," reasoning that because "no reasonable litigant could realistically [have] expect[ed] success" in an objectively baseless suit, AbbVie's subjective motivation for pursuing such a suit "must [have] be[en] something besides success on the merits." Id. In the court's view, that inference of subjective bad faith was supported because, as the district court had emphasized, the lawyers at AbbVie who decided to sue Perrigo were "all very experienced patent attorneys" who knew that AbbVie would benefit financially if Perrigo was delayed from entering the market. App. 68a, 70a. Given those circumstances, and "the collateral injury the Hatch-Waxman Act's 30-month stay invariably inflicts," the court of appeals upheld the district court's determination that AbbVie must have been subjective-

discussions indicates that it too perceived a meaningful chance that AbbVie would win.

ly motivated "not to assert a patent in good faith, but to impose expense and delay on Perrigo." App. 70a.

The court of appeals allowed that an antitrust defendant could overcome an inference of bad faith by introducing evidence that it "subjectively (though unreasonably) expected the lawsuit to succeed." App. 69a. But the court recognized that such evidence was not available here because AbbVie had not waived attorney-client privilege. *Id.* Although AbbVie had cited business planning documents and settlement negotiation conduct showing that AbbVie believed the suits would succeed, the court rejected that evidence as not "probative" of the decisionmakers'—i.e., the attorneys'—subjective motivations. App. 66a n.4; see App. 127a. The court thus deemed the Perrigo suit a sham in violation of the antitrust laws. App. 92a.

The court of appeals affirmed the denial of injunctive relief and reversed the disgorgement award as unauthorized by § 13(b) of the FTC Act. App. 77a-90a.⁵

REASONS FOR GRANTING THE PETITION

The decision below effectively nullifies the subjective element of the sham exception to *Noerr-Pennington* immunity in conflict with this Court's precedent. Under the court of appeals' decision, a court may infer that a litigant who brings a suit that is later adjudicated to be objectively baseless must have acted for an improper purpose, without requiring the antitrust plaintiff to prove independently that the litigant was subjectively indifferent to the outcome of the suit

⁵ The question of whether equitable monetary relief is available under § 13(b) of the FTC Act is currently pending before this Court in *AMG Capital Management*, *LLC* v. *FTC*, No. 19-508 (argued Jan. 13, 2021).

and was suing only to use the litigation process to undermine competition—at least where (as is almost always the case) the litigation was directed by experienced attorneys.

That decision is irreconcilable with this Court's precedent and will have a substantial chilling effect on parties seeking to petition the government for redress of grievances. And that consequence will be particularly pronounced in the Hatch-Waxman context. Under that Act, patent owners have a short window of time in which to decide whether to assert their patent rights; given the heightened risk of antitrust liability under the decision below, a patent owner will be deterred from asserting its patent against a potentially infringing product if there is any risk that the infringement claim might later be adjudicated to be objectively baseless (unless the patent owner is willing to waive attorney-client privilege to defend itself against the sham inference). That deterrent effect will be especially strong where, as is frequently the case (including here), the patent-law doctrines in question are unsettled or are the subject of confusing or conflicting decisions by the Federal Circuit. The decision below thus undermines Congress's purpose to encourage filing such suits promptly and chills the very First Amendment rights that Noerr-Pennington was intended to protect. This Court's review is warranted.

I. THE DECISION BELOW CONFLICTS WITH THIS COURT'S PRECEDENT

A. Noerr-Pennington immunity is "broad" so as to "balance[] the risk of anticompetitive lawsuits against the chilling effect on First Amendment petitioning that might be caused by the treble-damages remedy and other distinct features of antitrust litigation." BE&K

Constr. Co. v. NLRB, 536 U.S. 516, 528-529 (2002) (quotation marks omitted). For the same reason, this Court has held that the sham exception is and must be narrow and difficult to satisfy. Id. at 530-531; see Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 556-557 (2014). The court of appeals' decision upends that balance, and in doing so it conflicts with this Court's precedent.

First, the decision below deprives the subjective element of its independent role in the sham inquiry and relieves the antitrust plaintiff of its burden to prove both elements of the two-part test. This Court has made clear that for a suit to be a sham, it must satisfy "a two-part definition": the suit must be objectively baseless, and the litigant must have been subjectively motivated by an improper purpose. PRE, 508 U.S. 49, 60 (1993); see BE&K, 536 U.S. at 526 ("For a suit to violate the antitrust laws, ... it must be a sham both objectively and subjectively."). The Court also has made clear that it is the antitrust plaintiff's burden to "defeat[] the defendant's claim to *Noerr* immunity by demonstrating both the objective and the subjective components of a sham." PRE, 508 U.S. at 61 (emphasis added). In other words, the plaintiff is "require[d] ... to disprove" both the challenged lawsuit's "legal viability" under the objective prong and "the suit's economic viability" under the subjective prong. Id.

Under the decision below, however, an antitrust plaintiff need prove only the objective element in most circumstances. The court of appeals held that the objective and subjective elements are "interrelated," not "distinct," and thus that subjective bad faith may be inferred from the suit's objective baselessness through a "syllogism," at least where experienced lawyers decided to sue. App. 68a. As the court of appeals put it,

AbbVie "must have been motivated by something other than success on the merits" because its lawyers were "very experienced patent attorneys" yet they filed a suit that was later adjudicated to be objectively meritless. App. 68a-69a.

That analysis improperly merges the objective and subjective elements, collapsing the "two-part" test into a single inquiry. But this Court's precedent requires both elements to be satisfied independently. The subjective component of Noerr-Pennington immunity protects litigation that is not motivated by an improper purpose, even when the lawsuit is not "reasonably based." BE&K, 536 U.S. at 528. Yet the decision below instructs courts to find subjective bad faith because the litigant brought an objectively baseless suit, rather than requiring an independent showing of improper purpose.

Second, the court of appeals held that "what matters" under the subjective element is a commonplace "intent to thwart competition." App. 67a (quotation marks omitted); see App. 49a. But this Court has made clear that a mere "purpose of delaying a competitor's entry into the market does not render [petitioning] activity a 'sham,' unless ... the delay is sought to be achieved only by the [petitioning] process itself, and not by the governmental action that the [petitioning] seeks." City of Columbia v. Omni Outdoor Advert., Inc., 499 U.S. 365, 381 (1991) (emphasis added). The Court thus held in *Omni* that the defendant's lobbying conduct was not a sham, even though the defendant "indisputably set out to disrupt [the plaintiff's] business relationships," because the defendant "sought to do so not through the very process of lobbying ... but rather through the ultimate product of that lobbying." Id. "If Noerr teaches anything it is that an intent to restrain

trade as a *result* of the government action sought ... does not foreclose protection." *Id*.

This Court's decisions instead focus on the litigant's abuse of process, not on the commonplace intent to undermine a competitor. A "classic example" of sham litigation, the Court has explained, is where a party files suit "with no expectation of" prevailing, "simply in order to impose expense and delay." Omni, 499 U.S. at 380. Similarly, in PRE, the Court noted that a "baseless lawsuit" is subjectively motivated by an improper purpose where it seeks to "interfere directly with the business relationships of a competitor, through the use [of] the governmental process—as opposed to the outcome of that process." 508 U.S. at 60-61 (quotation marks and citations omitted). Accordingly, a suit may be motivated by bad faith where the damages to be recovered are "too low to justify" the litigant's investment in the suit, which shows the suit was "economic[ally]" not viable. Id. at 61, 65 (emphasis omitted). And in California Motor Transport, the Court noted that a suit may be a sham where the litigant has brought "a pattern of baseless, repetitive claims" that "leads the factfinder to conclude that the administrative and judicial processes have been abused." 404 U.S. at 513.

The court of appeals' holding that a mere "intent to thwart competition" satisfies the subjective element directly conflicts with that precedent. In particular, the court of appeals' standard fails to follow this Court's instruction to distinguish between suits that seek to impede competition through a potentially successful outcome and suits that seek the same effect through the litigation process. Rather, the decision below indiscriminately imputes bad faith to all litigants that seek to stymie competition, including those that seek to do

so through a "genuine" (albeit mistaken) expectation that the prospect of a successful outcome justified the costs of suing. *Omni*, 499 U.S. at 382; see *PRE*, 508 U.S. at 61 ("genuine," in the subjective sense, means "sincerely and honestly felt or experienced").

An intent to thwart competition is a particularly proxy for bad faith inappropriate in patentinfringement suits, because "the essence of a patent grant is the right to exclude others from profiting by the patented invention," Dawson Chemical Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980)—i.e., to impede competition by asserting patent rights. In that sense, an intent to impede competition is present in virtually every intellectual-property dispute. This Court has recognized as much, noting that a suit is not a sham merely because the litigant bears "ill will" toward the competitor, BE&K, 536 U.S. at 534, or, as Justice Stevens's concurring opinion in PRE explained, because the litigant intends to harm an adversary, 508 U.S. at 69 (Stevens, J., concurring) ("We may presume that every litigant intends harm to his adversary.").

Third, the court of appeals held that an antitrust plaintiff is "not required" to show that the defendant actually knew or believed the challenged lawsuit was meritless. But this Court has held that suing with "no expectation" of success is the hallmark of subjective bad faith. *Omni*, 499 U.S. at 380. Where a litigant believed the suit was meritless or was simply indifferent to the merits but sued anyway, *see id.*, that indicates that the litigant "decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process," *PRE*, 508 U.S. at 65. By dispensing with any requirement that the antitrust plaintiff adduce such evidence, the decision below allows a litigant to be subject to antitrust liability and treble damages based on a lat-

er determination of objective baselessness even if the litigant subjectively (if mistakenly) believed its suit could prevail—or at least believed the chances of success were sufficiently plausible to warrant investment in the suit in light of the potential relief.

The court of appeals did hold that an antitrust defendant could rebut an inference of bad faith by adducing its own evidence that it "subjectively (though unreasonably) expected the lawsuit to succeed." App. 69a. But that improperly shifts the burden of proof on subjective intent to the antitrust defendant, see PRE, 508 U.S. at 61, and, in any event, the court of appeals made even that defense inaccessible unless the defendant is willing to waive attorney-client privilege. Here, AbbVie introduced business-planning documents and evidence of its settlement negotiation conduct to show that AbbVie subjectively believed the infringement suit against Perrigo could succeed, but the court of appeals rejected that evidence as not "probative" because the evidence did not reveal the views of the lawyers who made the decision to sue. App. 66a n.4; see App. 127a. Because AbbVie did not waive privilege and present direct evidence of its counsel's advice and mental impressions, the court allowed the FTC to prove subjective bad faith merely by establishing that the suit was objectively baseless.

Fourth, the Third Circuit attached the wrong significance to the AbbVie attorneys' knowledge of the financial stakes. In the court's view, their knowledge that AbbVie could benefit financially from the infringement suits supported a finding of sham because it suggested an improper purpose to delay Perrigo's market entry. But this Court has held the opposite: the subjective element turns on a suit's "economic viability." *PRE*, 508 U.S. at 61. Where a suit is economically

irrational—because any damages remedy "would be too low to justify [the antitrust defendant's] investment in the suit," *id.* at 65—that irrationality is evidence that the litigant's purpose was to interfere with a competitor through the *process* of the litigation, rather than by achieving a favorable outcome. *Id.* But where a litigant (like AbbVie here) stood to gain financially by prevailing in a suit to protect its patent that, if successful, would have kept a rival off the market, that shows the litigant had ample reason to sue in pursuit of that *outcome*—unless the antitrust plaintiff offers evidence showing that the litigant believed it had no chance to win, such that the costs of suit could not be justified. *Id.* at 65-66.

This Court's precedent thus treats a rational economic motive as evidence of a good-faith reason to bring even a long-shot claim. But the court of appeals treated it as evidence of bad faith. And by omitting any requirement of proof that the litigant subjectively believed the suit had no potential to prevail, the court excluded from the analysis the only evidence capable of distinguishing efforts to use "the government *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *PRE*, 508 U.S. at 60-61.

B. No decision of this Court supports the court of appeals' approach. The court of appeals relied principally on *Octane Fitness*, 572 U.S. 545. App. 49a, 67a. But *Octane Fitness* was not a sham-litigation case at all, and the language the court of appeals cited was dicta. *Octane Fitness* addressed the standard for awarding attorney's fees in patent litigation for "exceptional cases" under 35 U.S.C. § 285. *See* 572 U.S. at 548, 556-557. To identify "exceptional cases," the Federal Circuit had adopted *PRE*'s test, but this Court rejected that test as too restrictive for the attorney-fee context.

Id. at 548, 554-557. In one sentence, cited by the court of appeals, the Court described *PRE* as requiring that "the plaintiff must have brought baseless claims in an attempt to thwart competition (i.e., in bad faith)." Id. at 556; see App. 49a, 67a. But, as the context demonstrates, Octane Fitness had no occasion to explicate the sham-litigation standard or thoroughly define its contours—to the contrary, the Court held that *PRE* was irrelevant to the issue before it. Octane Fitness's short-hand description of *PRE* thus did not silently overrule Omni's holding that a mere intent to thwart competition "does not render [petitioning] activity a sham." 499 U.S. at 381 (emphasis added).

Indeed, to the extent Octane Fitness is relevant, it confirms the error in the court of appeals' decision. As one reason for rejecting the application of PRE to the attorney-fee context, this Court explained that "[t]he threat of antitrust liability (and the attendant treble damages, 15 U.S.C. § 15) far more significantly chills the exercise of the right to petition than does the mere shifting of attorney's fees." Octane Fitness, 572 U.S. at 556. And the Court emphasized that it had "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." Thus, far from supporting the court of appeals' decision, Octane Fitness confirms that the sham-litigation exception to Noerr-Pennington immunity is narrow and that PRE's two-part inquiry must be maintained stringently to protect First Amendment rights. The court of appeals failed to heed that warning.

II. OTHER COURTS OF APPEALS HAVE APPLIED A MORE RIGOROUS SUBJECTIVE MOTIVATION STANDARD

Unlike the court below, other courts of appeals have understood the subjective element of the sham exception to require affirmative evidence of bad faith, independent of a suit's objective baselessness. In C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340 (Fed. Cir. 1998), the Federal Circuit held that "[n]either the bringing of an unsuccessful suit to enforce patent rights, nor the effort to enforce a patent that falls to invalidity, subjects the suitor to antitrust liability." Id. at 1369. "Since 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," the court explained, "the patentee 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." *Id.* The Federal Circuit therefore concluded that to establish that a suit was a sham, an antitrust plaintiff must offer "affirmative evidence of bad faith" sufficient to overcome the presumption that "the assertion of a duly granted patent is made in good faith." Id.

When the Federal Circuit has found the sham exception to apply, the court has predicated that finding on evidence that the antitrust defendant knew the suit lacked merit. In *Tyco Healthcare Group LP* v. *Mutual Pharmaceutical Co.*, 762 F.3d 1338 (Fed. Cir. 2014), for example, the Federal Circuit vacated the district court's grant of summary judgment in favor of an antitrust defendant accused of filing a sham citizen petition with the FDA. With respect to the subjective element, the court cited evidence that was sufficient to "support a finding that [the antitrust defendant] knew the theory in its citizen petition lacked merit." *Id.* at 1348. In

contrast, in *C.R. Bard*, the Federal Circuit rejected a sham-litigation claim where the evidence that the antitrust defendant "knew its patents were not infringed when it brought the suit" was too thin to overcome the "presumption that the assertion of a duly granted patent is made in good faith." 157 F.3d at 1369; *see id.* at 1368 ("Conduct prohibited under antitrust law includes bringing suit to enforce a patent *with knowledge* that the patent is invalid or not infringed, and the litigation is conducted for anti-competitive purposes." (emphasis added)).

Other courts of appeals have taken an approach similar to the Federal Circuit's. In In re DDAVP Direct Purchaser Antitrust Litigation, 585 F.3d 677, 694 (2d Cir. 2009), the Second Circuit reinstated a shamlitigation complaint where the allegations that the defendants "knew their misconduct before the PTO had rendered the patent invalid" were "sufficient to make out a sham litigation claim." And the Ninth Circuit has held, even before PRE, that evidence that the antitrust defendant "actually knew" that the patent it asserted in litigation was invalid supports a finding of bad faith. Handgards, Inc. v. Ethicon, Inc., 743 F.2d 1282, 1288 In *Handgards*, the defendant's (9th Cir. 1984). "knowledge that its patent was invalid" was dispositive because "[a]ll that is required for a finding of bad faith in the context of an infringement suit is that the patent holder ... knew that its patent was invalid," id. at 1289, and the same showing sufficed to overcome Noerr-Pennington immunity, id. at 1294-1295.

Those decisions are in sharp tension with the decision below. They confirm that the appropriate focus of the subjective inquiry is not the mere intent to thwart competition or a bare inference from objective baselessness, but whether an antitrust plaintiff adequately

alleged or proved that the defendant actually believed its suit lacked merit or was otherwise subjectively indifferent to the outcome of the litigation, as this Court's precedent requires. By treating such evidence as unnecessary, the decision below cannot be reconciled with those other courts' decisions.

III. THE DECISION BELOW WILL HAVE SIGNIFICANT NEGATIVE CONSEQUENCES

The court of appeals' decision sets a dangerous precedent that threatens to curtail the First Amendment right to petition, erode patent rights and the Hatch-Waxman Act, and undermine the attorney-client privilege.

A. This Court has "carved out only a narrow exception for 'sham' litigation" to "avoid chilling the exercise of the First Amendment right to petition." Octane Fitness, 572 U.S. at 556; see BE&K, 536 U.S. at 528. A rigorous subjective element is critical to cabining that narrow exception and to protecting the First Amendment rights embodied in the Noerr-Pennington doctrine. Indeed, this Court has "never held that the entire class of objectively baseless litigation may be enjoined or declared unlawful even though such suits may advance no First Amendment interests of their own," but instead has required an independent showing of bad faith to ensure the necessary "breathing space," consistent with broader First Amendment principles. BE&K, 536 U.S. at 531.

The decision below, however, deprives the subjective element of an independent role in the sham inquiry, allowing it to be satisfied by a commonplace intent to thwart competition inferred from a finding of objective baselessness. As a result, litigants exercising

their First Amendment right to assert claims with uncertain prospects of success will do so at their peril.

That chilling effect will reach beyond litigation. As this Court has explained, the same sham exception "governs the approach of citizens or groups of them to administrative agencies" as to courts. California Motor Transp., 404 U.S. at 510. Thus, courts have applied PRE's sham exception to citizen petitions submitted to the FDA to oppose entry of generic products, see Tyco, 762 F.3d at 1347 (citing cases), and to petitioning conduct before state or local agencies, see Kottle v. Northwest Kidney Centers, 146 F.3d 1056, 1059, 1062 (9th Cir. 1998); CSMN Investments, LLC v. Cordillera Metropolitan District, 956 F.3d 1276, 1282 n.8, 1286 n.13 (10th Cir. 2020); see also PRE, 508 U.S. at 59 (discussing sham exception "[w]hether applying Noerr as an antitrust doctrine or invoking it in other contexts"). The decision below thus jeopardizes a broad range of First Amendment petitioning activity.

B. The chilling effect will be especially pernicious in patent cases—and, in particular, in the important context of Hatch-Waxman litigation, thwarting Congress's purposes in enacting that statute.

Congress designed the Hatch-Waxman Act to balance patent rights against the benefits of increased competition in the market for medicines. At the same time that it allowed generic manufacturers to take advantage of brand manufacturers' research and development through streamlined approval pathways, Congress also incentivized "increased expenditures for research and development" by lengthening patent protection to compensate for time lost on patent life to the FDA approval process. H.R. Rep. No. 98-857, pt. 1, at 15 (1984). In addition, Congress sought to ensure that

patent disputes could be resolved early—before the generic product goes to market—by providing for the statutory stay of FDA approval to reward patent owners that file infringement suits promptly. See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 407-408 (2012). Yet the court of appeals treated the fact that AbbVie followed and benefited from that congressional design as "[e]specially" supportive of an inference of bad faith. App. 70a. Indeed, the court went so far as to disparage the congressional design as giving rise to "a collateral injury" that a patent owner's "mere use of legal process invariably inflicts" as "an anticompetitive weapon." App. 50a; see App. 70a.

That is a perverse outcome—one that will affect nearly every litigant filing an infringement suit under the Hatch-Waxman Act. All litigants that promptly file infringement suits under the Hatch-Waxman Act benefit from the automatic stay, as Congress intended, and they invariably do so on the advice of experienced lawyers with the aim of securing a financial benefit by preventing or delaying competition from a potentially infringing product. Imputing bad faith to litigants' mere participation in that statutory scheme is particularly unfair and destructive to incentives to innovate because a patentee is presumed to assert a "duly granted patent ... in good faith." C.R. Bard, 157 F.3d at 1369 (citing Virtue v. Creamery Package Mfg. Co., 227 U.S. 8, 37-38 (1913)). The court of appeals' decision penalizes a patentee that enforces its patent against a potentially infringing competitor despite that presumption, even though such a suit may be entirely compatible with a "genuine[]" invocation of the Hatch-Waxman Act's protections. *Omni*, 499 U.S. at 382.

That expansion of the sham exception would have significant practical impact. Ten percent of all patent-

infringement suits filed in the United States are triggered by paragraph IV certifications under the Hatch-Waxman Act, and the number of such suits has been increasing. Brachmann, Hatch-Waxman Litigation: 60 Percent Increase in ANDA Lawsuits from 2016 to 2017, IPWatchdog (May 16, 2018). The court of appeals' decision will deter patentees from availing themselves of their Hatch-Waxman remedy—and enforcing their patent rights more generally—for fear that they might be subject to antitrust liability and treble damages if the suit is subsequently adjudicated to be objectively baseless notwithstanding their subjective expectation of success. And, of course, where patent-holders face uncertainty about their ability to enforce their patent rights in court, their incentive to innovate in the first place is correspondingly diminished.

It is no answer to suggest that the requirement of objective baselessness adequately protects against an undue chilling effect. As explained above, objective baselessness is only one half of the sham-litigation test—and that is so for important reasons. Supra pp. 7-9, 18-19. In addition, reasonable jurists can, and do, make errors in assessing objective baselessness or disagree about what constitutes such baselessness. That problem is highlighted by this very case: the district court ruled that AbbVie's patent-infringement suit against Teva was objectively baseless, but the court of appeals reached the opposite conclusion (even while agreeing that the similar suit against Perrigo was objectively baseless).

That is not surprising, given that patent law is notoriously technical and subject to change. See Teva Pharm. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 327 (2015); see also, e.g., KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 419 (2007) (invalidating Federal Circuit's test

for obviousness); Festo, 535 U.S. at 737-738 (rejecting Federal Circuit's "per se rule" for prosecution-history estoppel); cf. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1335-1373 (Fed. Cir. 2019) (per curiam) (eight opinions concurring in or dissenting from denial of rehearing, articulating different standards for subject-matter eligibility). Especially where, as here, the objective baselessness inquiry turns on issues of patent law, rather than disputed issues of underlying fact, it is dangerous to subject a patent litigant to antitrust liability based only on a decisionmaker's later determination that the litigant got the law wrong—without any consideration of that litigant's actual expectations in bringing suit.

C. The decision below also threatens to intrude on the attorney-client privilege. Under the court of appeals' approach, an antitrust defendant can overcome the inference of bad faith only by adducing its own evidence that it subjectively (if erroneously) expected the challenged lawsuit to succeed. App. 69a-70a. But the court also held that evidence would not be "probative" of that defense unless it bears directly on the opinions and mental impressions of the attorneys who directed the litigation. App. 66a n.4; see App. 127a (rejecting business planning documents as "not probative of the state of mind of the ... attorneys"). As an initial matter, an antitrust defendant should not have to prove anything because, as explained above, it is the plaintiff's burden to establish the objective and subjective elements of the sham exception. PRE, 508 U.S. at 61. But the court's approach is all the more problematic because its burden-shifting framework makes the antitrust defendant's defense contingent on its willingness to waive privilege, at least where the decision to sue is made by lawyers. That requirement not only impinges on an "important[]" privilege that facilitates lawyers' "candid advice and effective representation," *Mohawk Industries, Inc.* v. *Carpenter*, 558 U.S. 100, 108 (2009), but also adds to the chilling effect on First Amendment rights that *Noerr-Pennington* immunity was intended to prevent.

IV. THIS CASE IS AN APPROPRIATE VEHICLE

This case squarely frames the important question presented. The decisions below make clear that had the court of appeals applied the subjective element consistent with this Court's precedent, it could not have concluded that AbbVie sued Perrigo in bad faith, because the FTC offered no probative evidence that AbbVie actually believed the suit was meritless, was indifferent to the outcome, or misused the litigation process in any other way. App. 64a-71a, 132a-136a. The FTC did not allege, for example, that the potential economic return of a successful outcome did not justify AbbVie's investment in the suit or that AbbVie had brought a pattern of baseless suits before. See PRE, 508 U.S. at 65; California Motor Transp., 404 U.S. at 513. The issue is thus cleanly presented, and resolving it in AbbVie's favor would dispositively require reversal of the conclusion that AbbVie violated the antitrust laws.

It makes no difference that the disgorgement award was vacated and the injunction denied. As an initial matter, the availability of a disgorgement remedy under § 13(b) of the FTC Act is currently pending before this Court, see supra n.5, and if the Court holds that such a remedy is authorized, that decision would likely support any effort by the FTC to reinstate the nearly-half-billion-dollar disgorgement award. And even if this Court agrees that no monetary award was

permissible, the decision below will still have significant collateral consequences giving AbbVie an ongoing stake in reversal.

The court of appeals stated that it was "affirm[ing] the [district court's] order adjudging AbbVie and Besins liable for monopolization ... based upon its holding that the suit against Perrigo was a sham." App. 92a. A number of plaintiffs in follow-on antitrust suits challenging AbbVie's enforcement of the AndroGel patent, including Perrigo, have already indicated their intent to argue that the sham-litigation finding in this case should be preclusive of AbbVie's liability in those other cases. See Plaintiffs' Br. in Opp. to Defendants' Mot. for Judgment on the Pleadings 1, Perrigo Co. v. AbbVie, Inc., No. 3:20-cv-17560-BRM-DEA, Doc. 76 (D.N.J. Feb. 16, 2021) ("Perrigo anticipates presenting the liability phase of its case on the basis of issue preclusion resulting from the FTC litigation"); Compl. 2-3, King Drug Company of Florence, Inc. v. Abbott Labs., No. 2:19-cv-03565-HB, Doc. 1 (E.D. Pa. Aug. 7, 2019) (alleging antitrust claims based on findings in this FTC action). Moreover, if the decision below were to stand, the FTC and other plaintiffs might cite it as a basis for seeking a restrictive injunction against AbbVie in future cases. Cf. FTC C.A. Opening Br. 49-51.

Finally, AbbVie will face the chilling effects of the decision below on its own efforts to enforce its valid patents and exercise its First Amendment rights. Whenever it receives a paragraph IV certification under the Hatch-Waxman Act, AbbVie must now act at its peril in pursuing infringement claims that are uncertain to prevail, lest it face not only the potential for antitrust liability and treble damages but also the prospect of being adjudicated liable for serial sham petitioning. The legal standard that the court of appeals announced to

restrict *Noerr-Pennington* immunity will thus infringe on AbbVie's own First Amendment rights, just as it threatens to do for all litigants seeking to enforce their patent rights against a competitor or to invoke their remedies under the Hatch-Waxman Act.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

SETH P. WAXMAN

WILLIAM F. LEE
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109

JEFFREY I. WEINBERGER
STUART N. SENATOR
ADAM R. LAWTON
MUNGER, TOLLES & OLSON LLP
350 South Grand Avenue
Los Angeles, CA 90071

MEDHA GARGEYA
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
(202) 663-6000

Counsel of Record
LEON B. GREENFIELD
CATHERINE M.A. CARROLL
BRITTANY BLUEITT AMADI
CLAIRE H. CHUNG
MEDHA GARGEYA
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
(202) 663-6000
seth.waxman@wilmerhale.com

ELAINE J. GOLDENBERG MUNGER, TOLLES & OLSON LLP 601 Massachusetts Ave., NW Suite 500 East Washington, DC 20001

 $Counsel for Abb Vie Inc., Abbott \ Laboratories, and \ Unimed \\ Pharmaceuticals \ LLC$

MELINDA F. LEVITT GREGORY E. NEPPL FOLEY & LARDNER, LLP 3000 K Street, NW Washington, DC 20007

Counsel for Besins Healthcare, Inc.

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