No. 20-1293

IN THE

Supreme Court of the United States

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

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 FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION AS *AMICI CURIAE* IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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INTEREST OF *AMICI CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association of the country's leading research-based biopharmaceutical companies. PhRMA's mission is to advocate public policies encouraging innovation in life-saving and life-enhancing new medicines. PhRMA's member companies are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives, and have led the way in the search for new cures.[2] Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.[3]

The Biotechnology Innovation Organization (BIO) is the principal trade organization representing the biotechnology industry domestically and abroad. BIO has more than 1,000 members, which span the for-profit and nonprofit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. BIO's members devote billions of dollars annually to researching and developing biotechnological

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[1] Pursuant to Rule 37.6, *amici curiae* affirm that no counsel for a party authored this brief in whole or in part, and that no persons other than *amici curiae* or their counsel made any monetary contributions intended to fund the preparation or submission of this brief. The parties have consented to the filing of this brief.

[2] A complete list of PhRMA members is available at http://www.phrma.org/about/members (last visited April 16, 2021).

[3] *See* PhRMA, *About PhRMA*, www.phrma.org/about (last visited April 16, 2021).

healthcare, agricultural, environmental, and industrial products that cure diseases, improve food security, create alternative energy sources, and deliver many other benefits. However, these products typically require lengthy, costly, and resource-intensive development periods.

The key question on which Petitioners seek this Court's review—what an antitrust plaintiff must prove to establish that an innovator's patent infringement lawsuit is a "sham" and therefore excepted from *Noerr-Pennington* immunity—is of critical importance to the biopharmaceutical industry. To continue the extraordinary investments in research and development necessary to offer new life-saving and life-enhancing treatments, innovators must be able to enforce their rights under the patent laws, including through petitioning courts for redress against infringement of their patent rights. The court of appeals erred in applying the sham-litigation exception established in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993) ("*PRE*"), and all but eliminated the requirement that an innovator must subjectively intend to use the judicial process to directly interfere with a competitor's business interests in order to constitute sham litigation. The court of appeals' decision thus exposes biopharmaceutical companies to significant antitrust liability for filing good-faith patent infringement lawsuits. As a result, innovators will be deterred from enforcing their patent rights, undermining the constitutional protection of *Noerr-Pennington* immunity and weakening the robust patent protections necessary to spur the life-saving innovations that the

biopharmaceutical industry provides. For these reasons, PhRMA and BIO join Petitioners in asking this Court to grant the petition for a writ of certiorari.

INTRODUCTION AND SUMMARY OF ARGUMENT

Under the *Noerr-Pennington* doctrine, patent holders are generally immune from antitrust liability for filing lawsuits seeking to enforce their rights. *See PRE*, 508 U.S. at 56. This immunity is necessary to protect litigants' First Amendment rights to petition the government for redress of their grievances. *See id.* at 56-57. This Court has recognized a narrow exception to this rule, but that exception applies only where a litigant has initiated "sham litigation." *Id.* The decision below warrants this Court's review because it misapplied the sham-litigation test, and in so doing, substantially broadened that narrow exception in a way that threatens to encroach on patent holders' rights under both the patent laws and the First Amendment.

I. The decision below will chill innovation in the biopharmaceutical industry. Biopharmaceutical companies invest billions of dollars annually to develop new life-saving and life-enhancing treatments. These investments make financial sense only because the patent laws reward the developer of a new treatment with a period of exclusivity during which it can recoup its substantial investment. By discouraging patent holders from enforcing their rights, the court of appeals' decision reduces the incentive for biopharmaceutical companies to invest in developing new treatments, which will have serious negative consequences for scientific progress, public health, and the economy.

II. The decision below is incorrect. This Court has long held that to constitute a "sham," litigation must be *both* objectively baseless *and* subjectively motivated by bad faith. *See PRE*, 508 U.S. at 57, 61. Although the court of appeals recognized that subjective bad faith is an element of the test, it deviated from this Court's clear direction that the two prongs are separate and distinct by treating them as "distinct, but . . . interrelated." Pet. App. 68a. The court thus rendered the subjective prong meaningless by conflating it with the objective prong. In so doing, the court of appeals drastically expanded the sham litigation exception.

ARGUMENT

I. THE COURT OF APPEALS' RULING WILL CHILL INNOVATION IN THE BIOPHARMACEUTICAL INDUSTRY

If the decision below were permitted to stand, innovators would be placed in an untenable position. Faced with an entity potentially infringing on its patent rights, a patent holder would have to decide whether filing suit to protect its rights is worth the risk of incurring treble-damage liability in a subsequent antitrust lawsuit simply because an experienced attorney authorized the suit that triggered the automatic stay provision of the Hatch-Waxman Act and the lawsuit ultimately proved to be unsuccessful. Given the widely acknowledged uncertainty inherent in the outcomes of patent litigation under the Hatch-Waxman Act, patent holders will be deterred from filing suit to enforce their patent rights, undermining a critical component of patent protection. *See Octane Fitness, LLC v. ICON Health &*

Fitness, Inc., 572 U.S. 545, 556 (2014) (recognizing that the threat of antitrust liability can significantly chill patent holders' exercise of their First Amendment right to petition the government). This deterrence is also contrary to the legislative compromise embodied in the Hatch-Waxman Act, which balances patent protections for pharmaceutical innovators with the encouragement of generic entry. The consequence of discouraging Hatch-Waxman lawsuits will be to discourage the substantial investments required to innovate in the biopharmaceutical industry, with negative consequences for scientific progress, public health, and the economy.

A. Robust Patent Protection is Critical to Innovation in the Biopharmaceutical Industry

The process of developing and bringing to market a new drug is incredibly costly. On average, developing and obtaining FDA approval of a new medicine takes ten to fifteen years and costs $2.6 billion.[4] As such, biopharmaceutical companies must devote enormous resources to research and development in order to bring a new drug to market. By any measure, the biopharmaceutical industry is one of the most R&D-intensive industries in the world. It accounts for 18% of all self-funded research and development spend in

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[4] PhRMA, *Biopharmaceuticals in Perspective*, at 27 (Fall 2020), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/ChartPack_Biopharmaceuticals_in_Perspective_Fall2020.pdf; *see also* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 26 (2016).

the United States, and the United States accounts for approximately half of all global spend on biopharmaceutical R&D.[5] The biopharmaceutical industry has the highest percentage of R&D reinvestment of any U.S. industry as a percentage of revenue. In fact, on a per-employee basis, the pharmaceutical industry invests $196,000 in R&D—13 times the overall manufacturing industry average in the United States.[6] PhRMA's member companies collectively invest nearly 25% of their total annual domestic sales in research and development.[7] And small, emerging companies represented by BIO are contributing significantly to the search for new cures and therapies, conducting 70 percent of clinical trials.[8] Most of these innovative companies have no products yet on the market. Given the research-intensive nature of drug development, more than 90 percent of biopharmaceutical companies are not profitable, and must rely on private investment, not sales, to fund research and development.[9]

Such large investments in inventing and commercializing new drugs are particularly noteworthy because there is a very high likelihood that any individual drug will fail to result in a commercially viable

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[5] *Biopharmaceuticals in Perspective*, *supra* note 4, at 128.

[6] *Id.* at 130.

[7] *Id.* at 129.

[8] Biotechnology Innovation Organization, *Research and Development: Biopharmaceutical Sector, A Driver of Innovation* (May 9, 2017), https://www.bio.org/sites/default/files/legacy/bioorg/docs/BIO_RD_one%20pager%205-9-17.pdf.

[9] *Id.*

product. Pharmaceutical companies may consider tens of thousands of compounds before identifying a handful that might have a potential commercial use.[10] Even of those drugs that make it to a Phase I clinical trial, fewer than 12% are ultimately approved by the FDA.[11]

Patent protection is thus critical to incentivize the industry to continue to pursue both research and development of new drugs and improvements to existing therapies because it ensures that a certain amount of financial reward will accrue to the owner of a new or improved drug product that, against the odds, successfully navigates these obstacles. As the Federal Trade Commission ("FTC")—Respondent in this case—has explained, "[p]harmaceutical companies . . . rely on patents to prevent free riding, recoup their R&D investments, and learn about new technological breakthroughs."[12] A former Acting Chairman of the FTC recently surveyed the available empirical evidence and concluded that "[t]he strength of IP rights positively correlates with R&D investment, at least in

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[10] *See* Ingrid Torjesen, *Drug Development: The Journey of a Medicine From Lab to Shelf*, Pharmaceutical J. (May 12, 2015), https://pharmaceutical-journal.com/article/feature/drug-development-the-journey-of-a-medicine-from-lab-to-shelf.

[11] *Biopharmaceuticals in Perspective*, *supra* note 4, at 27; *see also* Henry G. Grabowski et al., *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34(2) Health Affairs 302, 303 (Feb. 2015) (approximately one in eight drug candidates survives clinical testing).

[12] Fed. Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Ch. 2 at 1 (Oct. 2003).

developed countries," and "empirical evidence that patents drive innovation in pharmaceuticals is especially strong."[13] Others have noted that "it is likely that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection."[14]

The Hatch-Waxman Act recognizes the importance of patent protection to innovation in the biopharmaceutical industry. While encouraging the manufacture of generic drugs, the Act also protects incentives for innovation, including by aiming "to create a new incentive for increased expenditures for research and development" in the pharmaceutical industry by increasing the length of patent life in order to restore some of the patent life lost due to the FDA approval process. H.R. Rep. No. 98-857, pt.1, at 15 (June 21, 1984). At a hearing on the legislation, Senator Hatch emphasized that "added research and development will flow from added patent protection" provided by the law. *Drug Price Competition and Patent Term Restoration Act of 1984: Hearing Before the S. Comm. on Labor and Human Res.*, 98th Cong. 2 (June 28, 1984). Congressman Waxman similarly recognized that the Act created "a significant incentive for the development" of new drugs, which "could mean new cures for untreatable diseases and less expensive treatments for controllable diseases." 130 Cong. Rec. 23,057 (Aug. 8, 1984).

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[13] Maureen K. Ohlhausen, *Patent Rights in a Climate of Intellectual Property Rights Skepticism*, 30 Harv. J.L. & Tech. 103, 127-31 (2016).

[14] Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1616-17 (2003).

The Act also protects innovators' hard-won patent rights by ensuring that the status quo remains in place for up to 30 months to allow the parties to litigate the patent infringement suit. Indeed, although Congress considered an 18-month stay, H.R. Rep. 98-857, pt. 1, at 27 (June 21, 1984), it ultimately decided that an automatic stay of up to 30 months was necessary to safeguard innovators' patent interest, 21 U.S.C. § 355(j)(5)(B)(iii). The Act balances this interest with the interest in efficiently resolving patent disputes by incentivizing innovators promptly to file suit to enforce their patent rights. Specifically, in order to be eligible for a stay of FDA final approval of a generic competitor for up to 30 months, an innovator must bring suit within 45 days of receiving notice of a generic manufacturer's application. *Id*.

B. The Court of Appeals' Decision Disincentivizes Innovation and Economic Growth in the Biopharmaceutical Industry

Hatch-Waxman litigation is fraught with uncertainty and is enormously costly to innovator pharmaceutical companies. *See Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.) (recognizing that "[n]o one can be *certain* that he will prevail in a patent suit") (emphasis in original). Given the technical complexities inherent in these lawsuits, the existing case law hardly provides a reliable guide for the likelihood that an innovator will ultimately succeed in enforcing its rights. *See TM Patents, L.P. v. Int'l Bus. Machs. Corp.*, 72 F. Supp. 2d 370, 378 (S.D.N.Y. 1999) (noting that "nearly 40 percent of claims constructions are changed or overturned by the Federal Circuit"); *see also, e.g.*, *Purdue Pharma L.P. v. Endo Pharm. Inc.*,

438 F.3d 1123, 1125-26 (Fed. Cir. 2006) (initially affirming a ruling in favor of a generic challenger, only to vacate and remand on reconsideration). Moreover, as discussed above, by design, the Hatch-Waxman Act incentivizes innovators to act quickly to enforce their rights in order to be eligible for a stay of up to 30 months. Consistent with this, a party bringing a patent infringement lawsuit before concluding that it is certain to win the case does not act in bad faith. *See Asahi Glass Co.*, 289 F. Supp. 2d at 993 ("It is not bad faith . . . to assert patent rights that one is not certain will be upheld in a suit for infringement . . .").

If allowed to stand, the decision below would penalize innovators for filing suit in the face of this uncertainty. The standard for subjective intent that the court of appeals applied would deter innovators faced with potential generic infringers from asserting their rights based on the prospect of treble-damage antitrust liability. While parties typically seek the advice of counsel to avoid taking any actions that could result in antitrust liability, the decision below discourages that approach by treating a patent holder's decision to rely on advice from experienced attorneys to bring ultimately unsuccessful suits as a reason for treating the suit as a sham. Pet. App. 66a-70a. Even for patent holders who decide to bring suit to enforce their rights, the decision below will serve as a powerful deterrent to making reasonable arguments for the development or modification of patent law principles. That outcome is in sharp tension with *PRE*'s statement that an "objectively good faith argument for the extension, modification, or reversal of existing law" cannot render a lawsuit baseless. 508 U.S. at 65.

Penalizing patent owners for asserting uncertain but presumptively valid patent rights undermines a critical element of the patent protections on which innovators depend to protect their enormous investments in developing life-saving drugs. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1369 (Fed. Cir. 1998) (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"). Absent robust patent protections, biopharmaceutical innovators face diminished prospects of recouping the high costs of developing new treatments, and are consequently less likely to make the necessary R&D investments.[15] As a former Acting Chairman of the FTC has observed, "innovation in the life sciences industry would suffer catastrophic decline without patent protection."[16]

Chilling biopharmaceutical innovation would come at a large cost to public health and U.S. international competitiveness, as 57% of new drug molecules, invented between 2001 and 2010 originated from biopharmaceutical companies in the United States.[17]

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[15] *See, e.g.*, Ohlhausen, *supra* note 13, at 130 ("[I]nvestment in R&D will be suboptimal if the investing firm has limited ability to internalize the ensuing value"); Grabowski, *supra* note 11, at 303 ("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.").

[16] Ohlhausen, *supra* note 13, at 117.

[17] Ross C. DeVol et al., *The Global Biomedical Industry: Preserving U.S. Leadership*, at 5 (September 2011), http://www.ncnano.org/CAMIExecSum.pdf.

Biopharmaceutical companies have been responsible for major public health advancements in recent years. The industry provides the majority of funding to discover, develop, and manufacture transformative medicines.[18] For example, innovative diagnostic techniques and treatments have reduced the death rate from cancer by 29% since 1991.[19] Pharmaceutical innovations have helped reduce the death rate from heart disease by 36% since 2000.[20] And innovative treatments for HIV/AIDS have contributed to a 90% decline in death rates since the mid-1990s, preventing over 862,000 premature deaths.[21] It is essential to continue to encourage, rather than to deter, ongoing investments from pharmaceutical companies in such research and development through robust patent protection and the ability to predictably navigate patent challenges.

II. THE COURT OF APPEALS' DECISION IS INCORRECT

To establish that Petitioners' lawsuit was a "sham"—and therefore not entitled to immunity from antitrust liability—Respondent needed to demonstrate both that the suit was objectively baseless and that Petitioners were motivated by a desire to use the litigation process as "an anticompetitive weapon." *PRE*, 508 U.S. at 61 (quoting *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380

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[18] *Biopharmaceuticals in Perspective*, *supra* note 4, at 28.

[19] *Id.* at 9.

[20] *See id.* at 11.

[21] *Id.* at 7-8.

(1991)). The court of appeals ostensibly recognized objective baselessness and subjective intent as distinct requirements under *PRE*, but its application of the subjective intent element rendered it meaningless.

The court of appeals held that Petitioners subjectively intended to file a lawsuit in bad faith based on its determination that the objective prong was satisfied and the existence of two unremarkable facts present in nearly every patent infringement suit filed by a biopharmaceutical company under the Hatch-Waxman Act: (1) the lawsuit was approved by experienced in-house patent attorneys who, the court concluded, should have known the suit was objectively baseless; and (2) the filing of the lawsuits benefited Petitioners by triggering an automatic stay of Perrigo's FDA applications under the Hatch-Waxman Act. This misconstruction of *PRE*'s subjective intent requirement greatly expands the reach of the sham litigation exception to *Noerr-Pennington* immunity and is inconsistent with the showing required under *PRE*.

A. The Sham Litigation Exception to *Noerr-Pennington* Immunity Requires Exacting Proof of Both Objective Baselessness and Subjective Bad Faith

This Court has recognized a narrow exception to *Noerr-Pennington* First Amendment immunity where the petitioning activity is a "sham"—*i.e.*, where it "is not genuinely aimed at procuring favorable government action, as opposed to a valid effort to influence government action." *PRE*, 508 U.S. at 58 (internal citation and quotation marks omitted); *Octane Fitness*,

572 U.S. at 556 (describing sham litigation as a "narrow exception" to *Noerr-Pennington* immunity). In order for litigation to be a sham, it must first "be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *PRE*, 508 U.S. at 60. This Court, however, has been clear that objective baselessness alone is insufficient to qualify litigation as a sham. *See PRE*, 508 U.S. at 60 (outlining "a two-part definition of 'sham' litigation"); *id.* (if litigation is objectively baseless, court must go on to "examine the litigant's subjective motivation"); *BE & K Constr. Co. v. NLRB*, 536 U.S. 516, 526 (2002) ("For a suit to violate the antitrust laws . . . it must be a sham *both* objectively and subjectively.") (emphasis in original). Instead, a court must also examine the defendant's subjective motivation for filing the suit to determine "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." *PRE*, 508 U.S. at 60-61 (internal citations and quotation marks omitted) (emphasis in original); *see also Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 500 n.4 (1988) (sham requires that the activity is "not genuinely aimed at procuring favorable government action" at all).

Courts of appeals have properly interpreted this Court's two-step test in *PRE* as "exacting" and as "plac[ing] a heavy thumb on the scale in favor of the defendant." *Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 180 (3d Cir. 2015); *see also U.S. Futures Exch., L.L.C. v. Bd. of Trade of Chicago*,

953 F.3d 955, 963 (7th Cir. 2020) ("The sham exception is extraordinarily narrow.") (internal citation omitted). This is particularly true with respect to patent infringement lawsuits. As courts have recognized, "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"; as such, 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." *C.R. Bard*, 157 F.3d at 1369.

To safeguard this central goal of the patent system, "[t]he law recognizes a presumption that the assertion of a duly granted patent is made in good faith." *Id.* (citing *Virtue v. Creamery Package Mfg. Co.*, 227 U.S. 8, 37-38 (1913)). Thus, to overcome this presumption and establish the subjective bad faith necessary to prove that a patent infringement lawsuit is a sham, an antitrust plaintiff must produce affirmative evidence of bad faith such as, for example, the defendant's actual knowledge that it could not have prevailed. *See, e.g.*, *C.R. Bard*, 157 F.3d at 1369 (citing *PRE*); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009) (reinstating sham litigation claim given allegations that defendants "knew their misconduct before the PTO had rendered the patent invalid"); *Handgards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282, 1288 (9th Cir. 1984) (affirming jury verdict that defendant had engaged in sham litigation based on evidence showing that defendant "actually knew that the . . . patent was invalid").

B. The Court of Appeals' Decision Vitiates *PRE*'s Subjective Intent Requirement

The subjective intent element of *PRE*'s sham litigation test requires that "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." *PRE*, 508 U.S. at 60-61 (internal citations and quotation marks omitted). While the decision below recognized the subjective intent requirement, it incorrectly held that the objective and subjective requirements are "interrelated," Pet. App. 68a, and that the district court's factual finding that Petitioners had filed these lawsuits "to impose expense and delay on Perrigo so as to block its entry into the TTRT market" was sufficient to satisfy the subjective prong. *Id.* at 67a.

The court of appeals thus affirmed that a factual finding of a motivation to block Perrigo from the market—which is a legitimate purpose of a patent infringement lawsuit—is sufficient to satisfy *PRE*'s subjective intent prong. Further, it affirmed that evidence that (1) the decisionmakers who authorized the suit were "very experienced patent attorneys," and (2) filing the lawsuit would result in "extensive financial benefits" to Petitioners because it would trigger an automatic stay of approval of Perrigo's FDA application for approval of generic versions of AndroGel for up to 30 months was sufficient to establish that anticompetitive motivation. *Id.* at 66a-69a.

The court of appeals' decision eliminates *PRE*'s subjective intent element. As an initial matter, that experienced patent attorneys authorized the lawsuit

and knew that the suit would result in financial benefits to AbbVie and Besins has no bearing on whether the attorneys intended to use the process of the lawsuit—rather than its outcome—as an anticompetitive weapon. Unlike the decisions of the Second and Ninth Circuits, summarized *supra* at 15, the court in this case did not find that the subjective intent prong had been satisfied based on evidence that AbbVie and Besins actually *knew* that the patent they brought suit to defend was invalid.

Moreover, under the court of appeals' analysis, a court's *ex post* conclusion that a suit was objectively unreasonable will be imputed as proof of the decisionmaker's *ex ante* state of mind, provided only that the decisionmaker is a knowledgeable attorney and that the company the attorney represents stands to gain from filing the lawsuit. In the biopharmaceutical industry (and in many industries heavily dependent on intellectual property), decisions to file patent infringement suits involving successful products are regularly made by experienced patent attorneys. That should be encouraged, not condemned. It simply cannot be the law that *PRE*'s subjective bad faith prong is presumptively satisfied if experienced patent lawyers approved the filing of a lawsuit. Indeed, as far as *amici curiae* are aware, no other court has ever referred to the experience level of the attorney who authorized the lawsuit as evidence supporting satisfaction of *PRE*'s subjective baselessness prong.

Similarly, the fact that filing the patent infringement suit triggered a stay of up to 30 months of the approval of Perrigo's FDA application under a federal regulatory statute does not support a finding that Appellees acted with either anticompetitive motivation

or subjective bad faith. Indeed, it is impossible to imagine that an innovator pharmaceutical company would *not* know that the filing of a patent lawsuit within 45 days of notice of the generic product's application triggers the statutorily mandated stay of up to 30 months for approval of an alleged infringer's generic product. Such an awareness cannot automatically transform every such Hatch-Waxman case into a sham, with the concomitant burdens of treble-damage antitrust liability, when a court later finds the suit to lack objective merit. *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"). Yet, the decision below accepted that the triggering of the stay and its impact on AbbVie's innovator product, accompanied only by the fact that the lawsuits were initiated by experienced counsel, was sufficient evidence to support a finding that the suits were brought with an improper subjective motivation. *See* Pet. App. 66a-69a.

Indeed, by affirming the district court's reliance on a negative inference from the fact that the litigation triggered an automatic stay that benefited the Petitioners, the court of appeals penalized conduct that Congress intended to encourage. The automatic stay provision reflects Congress's preference that disputes over patent rights be resolved before a generic product enters the market, *see* H.R. Rep. No. 98-857, pt. 1, at 28 (June 21, 1984), and Congress incentivized innovators to act promptly to enforce their rights by making the automatic stay contingent on an innovator

filing suit within 45 days of receiving notice of a generic manufacturer's application, *see* 21 U.S.C. § 355(j)(5)(B)(iii). As two courts of appeals have recognized, the Hatch-Waxman Act "incentivizes brand-name drug manufacturers to promptly file patent infringement suits by rewarding them with a stay of up to 30 months if they do so," and "to penalize a brand-name manufacturer whose litigiousness was a product of Hatch-Waxman . . . would punish behavior that Congress sought to encourage." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 157-58 (3d Cir. 2017) (internal citation and quotation marks omitted); *see also Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1047 (9th Cir. 2009) (evidence was insufficient to find that patent infringement suits filed by a party were sham lawsuits where "to some degree its litigiousness was a product of Hatch-Waxman"). The decision below, which permitted the inference that *PRE*'s subjective intent prong had been satisfied from the triggering of the automatic stay, cannot be squared with the clear Congressional intent behind the automatic stay provision.

CONCLUSION

For the reasons set forth above and in the petition, the Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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