Nos. 18-2621, 18-2748, 18-2758

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

FEDERAL TRADE COMMISION,

Plaintiff-Appellant/Cross-Appellee

v.

ABBVIE INC. et al.,

Defendants-Appellees/Cross-Appellants

On Appeals from the United States District Court
for the Eastern District of Pennsylvania, No. 2:14-cv-05151
Hon. Harvey Bartle III

BRIEF FOR THE AMERICAN ANTITRUST INSTITUTE, PUBLIC KNOWLEDGE, AND PUBLIC CITIZEN AS AMICI CURIAE IN SUPPORT OF PLAINTIFF/CROSS-APPELLEE FEDERAL TRADE COMMISSION

RANDY M. STUTZ
AMERICAN ANTITRUST INSTITUTE
1025 Connecticut Avenue, NW
Suite 1000
Washington, DC 20036
(202) 905-5420

RICHARD M. BRUNELL
Counsel of Record
HILLIARD & SHADOWEN LLP
135 W. 6th St., Suite 125
Austin, TX 787703
(202) 600-9640

Counsel for Amicus Curiae

July 26, 2019

CORPORATE DISCLOSURE STATEMENT

Pursuant to Local Appellate Rule 26.1.1, *amici* state as follows:

The American Antitrust Institute is a nonprofit, non-stock corporation. It has no parent corporations, and no publicly traded corporations have an ownership interest in it.

Public Knowledge has no parent corporation, and no publicly held corporation holds 10% or more of its stock.

Public Citizen, Inc. is a nonprofit, non-stock corporation. It has no parent corporations, and no publicly traded corporations have an ownership interest in it of any kind.

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT ii

TABLE OF AUTHORITIES iv

INTEREST OF AMICI CURIAE 1

STATEMENT OF THE CASE 2

SUMMARY OF ARGUMENT 4

ARGUMENT 6

I. SHAM HATCH-WAXMAN LITIGATION IS A SIGNIFICANT PROBLEM 6

II. THE DISTRICT COURT CORRECTLY CONCLUDED THAT THE LAWSUITS WERE SHAMS EVEN THOUGH IT APPLIED OVERLY STRICT STANDARDS FOR PROVING THE SUBJECTIVE PRONG OF THE SHAM TEST 13

A. A Suit Is Objectively Baseless if It Had No Realistic Chance of Success 13

B. The Subjective Test Does Not Require Proof That the Defendant Knew Its Claims Were Baseless 14

C. The Subjective Test Does Not Require Proof by Clear and Convincing Evidence 19

D. The Settlement Agreements Do Not Undercut the Court's Findings of Sham 23

CONCLUSION 26

CERTIFICATE OF COUNSEL

CERTIFICATE OF SERVICE

TABLE OF AUTHORITIES

CASES

Ackerman v. Nw. Mut. Life Ins. Co.,
172 F.3d 467 (7th Cir. 1999) 20

Andrix Pharms., Inc. v. Biovail Corp. Int'l,
256 F.3d 799 (D.C. Cir. 2001) 23

C.R. Bard, Inc. v. M3 Sys., Inc.,
157 F.3d 1340 (Fed. Cir. 1998) 19, 21

Fed. Trade Comm'n v. Actavis, Inc.,
570 U.S. 136 (2013) 7, 10

Fisher v. Kelly,
105 F.3d 350 (7th Cir. 1997) 24

Gov't Employees Ins. Co. v. Hazel,
No. 11-CV-410, 2014 WL 4628655 (E.D. N.Y. Aug. 11, 2014) 25

Halo Elecs., Inc. v. Pulse Elecs., Inc.,
136 S. Ct. 1923 (2016) 11, 19

Handguards, Inc. v. Ethicon, Inc.,
621 F.2d 986 (9th Cir. 1979) 20

Handguards, Inc. v. Ethicon, Inc.,
743 F.2d 1282 (9th Cir. 1984) 20

Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.,
806 F.3d 162 (3d Cir. 2015) 22

In re Flonase Antitrust Litig.,
795 F. Supp. 2d 300 (E.D. Pa. 2011) 14

In re Neurontin Antitrust Litig.,
MDL No. 1479, 2009 WL 2751029 (D. N.J. Aug. 28, 2009) 8

In re Unocal,
138 FTC 1(2004) 20

In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class,
868 F.3d 132 (3d Cir. 2017) 9, 10, 13

Kilopass Technology, Inc. v. Sidense Corp.,
738 F.3d 1302 (Fed. Cir. 2013) 17, 18, 21

King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.,
791 F.3d 388 (3d Cir. 2015) 25

Litton Systems, Inc. v. American Tel. & Tel. Co.,
700 F.2d 785 (2d Cir. 1983) 21, 22

MCI Commc'ns Corp. v. AT&T Co.,
1081 (7th Cir. 1983) 20

Microsoft Corp. v. i4i Ltd. P'ship,
564 U.S. 91 (2011) 21

N.C. State Bd. of Dental Examiners v. Fed. Trade Comm'n,
135 S. Ct. 1101 (2015) 22

New York ex rel. Schneiderman v. Actavis PLC,
787 F.3d 638 (2nd Cir. 2015) 10, 12

Octane Fitness, LLC v. ICON Health & Fitness, Inc.,
572 U.S. 545 (2014) 11, 17

Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.,
508 U.S. 49 (1993) (*PRE*) ..... passim

Takeda Chemical Industries, Ltd. v. Mylan Labs, Inc.,
549 F. 3d 1381 (D.C. Cir. 2008)..... 9

Therasense, Inc. v. Becton Dickinson & Co.,
649 F.3d 1276 (Fed. Cir. 2011) (*en banc*) 20

Tyco Healthcare Group LP v. Mut. Pharm. Co.,
762 F.3d 1338 (Fed. Cir. 2014) 21

United States v. Otter Tail Power Co.,
360 F. Supp. 451 (D. Minn. 1973)..... 15

Verizon Commc'ns Inc. v. Law Office of Curtis V. Trinko, LLP,
540 U.S. 398 (2004) 8

STATUTES AND RULES

21 U.S.C. § 355 9

21 U.S.C. § 505 7

35 U.S.C. § 271 10

35 U.S.C. § 285 17

Fed. R. Civ. P. 9(b) 20

OTHER AUTHORITIES

Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* (4th ed.) 14, 18

Am. Bar Ass'n, *Ann. Mod. Rules of Prof. Conduct* (2019) 16

Robert H. Bork, *The Antitrust Paradox* (rev. ed. 1993) 22, 23

Einer Elhauge, *Making Sense of Antitrust Petitioning Immunity*,
80 Cal. L. Rev. 1177 (1992) 6

C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*,
339 Science 1386 (2013) 12

Herbert Hovenkamp *et al.*, *IP and Antitrust* (2018) 7, 8, 10, 23

Ruben Jacobo-Rubio *et al.*, *The Distribution of Surplus in the U.S. Pharmaceutical Industry: Evidence From Paragraph (iv) Patent Litigation Decisions* (June 2, 2017) 9

Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*,
15 Yale J. Health Pol'y, L. & Ethics 293 (2015) 8, 12

Mark A. Lemley, *The Surprising Resilience of the Patent System*,
95 Tex. L. Rev. 1 (2016) 6

Restatement (Second) of Torts (1977) 13, 15

INTEREST OF AMICI CURIAE[1]

The American Antitrust Institute ("AAI") is an independent nonprofit organization devoted to promoting competition that protects consumers, businesses, and society. It serves the public through research, education, and advocacy on the benefits of competition and the use of antitrust enforcement as a vital component of national and international competition policy. AAI enjoys the input of an Advisory Board that consists of over 130 prominent antitrust lawyers, law professors, economists, and business leaders. *See* http://www.antitrustinstitute.org.[2]

Public Knowledge is a nonprofit technology policy organization that promotes freedom of expression, an open Internet, consumer rights online, and access to affordable communications tools and creative works. As part of that mission, Public Knowledge advocates on behalf of consumer interests for balanced and procompetitive media and communications policies though grassroots efforts, educating policymakers in Washington, D.C. and around the country, participating in regulatory proceedings, and where appropriate, filing amicus curiae briefs in cases

[1] All parties consent to the filing of this amicus brief. No counsel for a party has authored this brief in whole or in part, and no party, party's counsel, or any other person—other than amici or their counsel—has contributed money that was intended to fund preparing or submitting this brief.

[2] Individual views of members of the American Antitrust Institute's Board of Directors or its Advisory Board may differ from its positions.

of significance. Public Knowledge believes that antitrust and intellectual property law should work together to promote consumer welfare.

Public Citizen, Inc. is a nonprofit consumer advocacy organization that appears on behalf of its nationwide membership before Congress, administrative agencies, courts, and state governments on a wide range of issues. Among Public Citizen's longstanding concerns are promoting access to the affordable generic medications whose market entry the Hatch-Waxman Act was intended to promote, as well as maintaining the efficacy of the antitrust laws and other protections for consumers against collusive, manipulative and anticompetitive commercial practices.

STATEMENT OF THE CASE

This case raises the question whether the already narrow sham-litigation exception to the *Noerr-Pennington* doctrine—which is critically important to protect the public from excessive drug prices—will be narrowed further or rendered a nullity under the standards urged by Appellees/Cross-Appellants AbbVie Inc. and Besins Healthcare, Inc. (the Drug Companies).

The Federal Trade Commission (FTC) brought antitrust claims against the Drug Companies and their affiliates for monopolizing the market for topical testosterone replacement therapies (TTRT) by bringing baseless patent infringement suits against Teva Pharmaceuticals and Perrigo Company, which were seeking to

enter the market with a generic version of AbbVie's blockbuster drug, AndroGel. The FTC alleged that the Drug Companies were not immune from liability under the two-part test established by *Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) (*PRE*), contending that the patent suits were both objectively baseless and subjectively intended to delay entry through the collateral impact of the suits themselves. The FTC also charged the Drug Companies with entering into an unlawful reverse-payment agreement with Teva in connection with settling the patent litigation, claims that the district court dismissed under Rule 12(b)(6).

The district court granted partial summary judgment to the FTC on the issue of objective baselessness, concluding that "[t]he patent lawsuits against Teva and Perrigo were without question objectively baseless." MSJ Op. 31. Subsequently, after a bench trial, the court also found in favor of the FTC on the subjective component of the *PRE* test, concluding that "[t]he only reason for the filing of these lawsuits was to impose expense and delay on Teva and Perrigo so as to block their entry into the TTRT market with lower price generics and to delay defendants' impending loss of hundreds of millions of dollars in AndroGel sales and profits." Op. 53. Finding that the Drug Companies had engaged in unlawful monopolization, the court ordered disgorgement of their unlawful profits in the amount of $448 million.

The parties have filed cross appeals on numerous issues, but amici write here in support of the FTC primarily to stress the importance of preserving a robust sham-litigation doctrine in the Hatch-Waxman context and to address the proper standards for applying the *PRE* test in that setting.

SUMMARY OF ARGUMENT

1. The Hatch-Waxman Act provides an automatic 30-month stay of FDA approval of a generic drug application when a brand-name drug company files a patent infringement suit in response to a generic firm's certification that the brand-drug manufacturer's patent is invalid or not infringed. This creates an opportunity and incentive for unscrupulous drug companies to engage in baseless litigation because delay in generic entry can be worth hundreds of millions of dollars a year and the stay applies even if the lawsuit is entirely without merit. The robust application of the antitrust laws and the sham-litigation doctrine is essential to protect the public from such behavior, which Congress did not intend to countenance.

Sound patent policy supports a meaningful sham-litigation doctrine. Patent law seeks to discourage baseless patent suits, and innovation is promoted when generic firms can challenge or design around weak drug patents without fear that baseless infringement claims will be brought to delay generic entry.

2. *PRE*'s objective prong provides substantial protection to patentees who bring uncertain infringement claims, but it does not protect lawsuits with *any* chance of success; rather *PRE* requires a *realistic* chance of success.

Having established that the lawsuits here were objectively baseless, the FTC needed only to show that the Drug Companies filed the suits primarily to prevent competition by obtaining the automatic 30-month stay to delay their rivals' impending product launch. While reaching the correct result, the district court erred in requiring the FTC to prove that the Drug Companies had actual knowledge that the suits were baseless. The subjective test focuses on a sham litigant's economic motivations, and does not exculpate a monopolist that seeks to use the collateral injuries attributable to a lawsuit to thwart competition if the monopolist subjectively—but unreasonably—did not know the suit was baseless. And the Drug Companies' argument that actual knowledge must be shown with direct evidence of the patentee's state of mind would render sham-litigation doctrine a nullity where, as here, patent lawyers are the decisionmakers and their mental processes are shielded by privileges.

The district court also erred by requiring the subjective prong to be proved by clear and convincing evidence. The court relied on case law dealing with *Walker Process* fraud, which is inapposite, and pre-*PRE* cases that did not require objective baselessness. A higher burden of proof is particularly inapt where (as

here) the baseless patent lawsuit involves infringement, rather than validity. The normal burden of proof is sufficiently protective of the right to petition given the objective baselessness requirement, and a heightened burden of proof is insufficiently protective of the free-market system embodied by our antitrust laws.

Finally, the district court correctly concluded that the Drug Companies' settlements with Teva and Perrigo, which delayed entry slightly beyond the dates that the automatic stays would have expired, do not refute the objective or subjective elements of the *PRE* test.

ARGUMENT

I. SHAM HATCH-WAXMAN LITIGATION IS A SIGNIFICANT PROBLEM

Monopolizing or attempting to monopolize a market by bringing baseless litigation "primarily for the benefit of collateral injuries inflicted" on rivals, *PRE*, 508 U.S. at 65, can be a problem in any market. *See* Mark A. Lemley, *The Surprising Resilience of the Patent System*, 95 Tex. L. Rev. 1, 45 (2016) (discussing prevalence of patent lawsuits brought "not because the patentee hopes to win in court, but because the very act of filing the lawsuit will disadvantage a competitor"); Einer Elhauge, *Making Sense of Antitrust Petitioning Immunity*, 80 Cal. L. Rev. 1177, 1230 (1992) (noting that strategic litigation "is actually a far more useful tool for driving competitors out of business than predatory pricing"). But it is a particularly significant problem in the pharmaceutical industry under the Hatch-

Waxman Act. That is because brand-name drug manufacturers have a strong incentive to delay generic entry, as the hundreds of millions of dollars at stake in this case demonstrate. And the Hatch-Waxman regulatory regime gives them a powerful tool to do so by providing a 30-month automatic stay of FDA approval of a generic firm's pending Abbreviated New Drug Application (ANDA) if the brand-name drug manufacturer files a patent infringement lawsuit against the generic manufacturer, regardless of the merits of the suit. *See Fed. Trade Comm'n v. Actavis, Inc.*, 570 U.S. 136, 143 (2013) (describing "paragraph IV" certification process).[3]

As Hovenkamp *et al.* explain: "If the patentee files an infringement lawsuit against the generic manufacturer, the FDA cannot grant approval to the ANDA for 30 months, unless a court issues an opinion during that time holding the patent invalid, unenforceable, or not infringed." Herbert Hovenkamp *et al.*, *IP and Antitrust* § 15.03[A][2][a] (2018). "In effect, the FDA acts as though the patent were conclusively presumed valid [and infringed] unless the Federal Circuit instructs it otherwise." *Id.* "The effect of this rather remarkable rule is to delay drug price competition for several years even where a patent is clearly invalid [or not infringed], by granting what is akin to an automatic preliminary injunction whenever

[3] The stay is also applicable to generics that file a New Drug Application (NDA) under 21 U.S.C. § 505(b)(2), which is "a hybrid between an ANDA and a full NDA," and which was at issue here. Op. 4.

a pharmaceutical patent owner files suit against a generic manufacturer." *Id.*; *see also* Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 Yale J. Health Pol'y, L. & Ethics 293, 320 (2015) (noting that stay is available "no matter how weak the patent is or how peripheral the protected feature is to the underlying active ingredient, product, or use").

This procedural framework gives "unscrupulous patent owners . . . a powerful tool for excluding competitors by compelling the FDA to deny or delay approval of new generic drugs." *IP and Antitrust*, *supra*, § 15.03[A][2][a]; *see also In re Neurontin Antitrust Litig.*, MDL No. 1479, 2009 WL 2751029, at *20 (D. N.J. Aug. 28, 2009) ("The Hatch-Waxman regulatory scheme presents unique opportunities for gamesmanship by offering a 'non-refundable' 30-month stay."). A baseless infringement action brought primarily to obtain the temporary stay of FDA approval is the epitome of a sham. *See* Defendants' Post-Trial Br. (ECF 408) 10-12.

There is no dispute that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue." *Verizon Commc'ns Inc. v. Law Office of Curtis V. Trinko*, *LLP*, 540 U.S. 398, 411 (2004). But the Drug Companies argue that the incentive the Hatch-Waxman Act creates for brand-name manufacturers to file suit quickly to take advantage of the 30-month

automatic stay counsels in favor of *less* vigorous antitrust enforcement against sham litigation, rather than more vigilance. *See* Opening/Response Brief for Appellees/Cross Appellants AbbVie et al. (AbbVie Br.) 52-53; Amicus Brief of U.S. Chamber of Commerce 9; Amicus Brief of Pharm. Research & Mfgs. of America (PhRMA Br.) 11. That is plainly incorrect. While Congress may have sought to encourage patentees with *legitimate* claims to bring infringement suits quickly, it did not intend to incentivize brand-name manufactures to file *baseless* litigation, just as it did not intend to encourage generic firms to make baseless certifications that their drugs do not infringe valid patents. *See Takeda Chemical Industries, Ltd. v. Mylan Labs, Inc.*, 549 F. 3d 1381, 1388, 1390 (D.C. Cir. 2008) (attorney's fees available to prevailing patentee where generic firm files a "baseless" certification letter).[4]

[4] This Court stated in dicta that the "time limits imposed by the Hatch-Waxman Act embody a 'file-now, discover-details-later' policy." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 151 n.22 (3d Cir. 2017). But the very provision the Court cited requires an ANDA applicant to provide the patentee with a "*detailed* statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(b)(3)(D) (emphasis added). Moreover, insofar as the 45-day window for a patentee to bring suit limits the information available to a "reasonable litigant in the defendant's position" to assess the merits of a suit, the objectively baseless component of the sham test would take that into account. *PRE*, 508 U.S. at 63. *Cf.* Op. 18, 22 (noting detailed information, including confidential information, made available to Drug Companies here).

Responsible brand-drug manufacturers often do *not* sue in response to a paragraph IV challenge, as illustrated in this case when AbbVie's predecessor did not bring suit. Op. 15. *See generally* Ruben Jacobo-Rubio *et al.*, *The Distribution of*

The Supreme Court made clear in *Actavis* that antitrust has an important role to play in policing anticompetitive conduct that arises from the *unintended* consequences of Hatch-Waxman. *Actavis,* 570 U.S. at 155-56 (noting that provisions of "Hatch-Waxman's unique regulatory framework" "unintentionally[] have created special incentives for collusion"); *accord New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 658 (2nd Cir. 2015) (recognizing that "efforts to manipulate aspects of the Hatch-Waxman incentive structure to exclude competition" may state an antitrust claim). In short, antitrust law in general, and the sham-litigation doctrine in particular, should be applied to prevent the subversion of the "general procompetitive thrust" of the Hatch-Waxman Act. *Actavis*, 570 U.S. at 152.[5]

Sound patent policy also counsels in favor of a meaningful sham-litigation doctrine. Patent policy does not support the enforcement of an exclusionary right

---

Surplus in the U.S. Pharmaceutical Industry: Evidence From Paragraph (iv) Patent Litigation Decisions 19 & Table 2 (June 2, 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2481908 (in sample of 274 paragraph IV ANDAs, 18% were approved without a challenge in court).

[5] *Wellbutrin* also suggested in dicta that "[t]he already high hurdle for stating an antitrust claim for anticompetitive litigation is higher still in the context of an ANDA case because . . . the Hatch-Waxman Act states that '[i]t shall be an act of infringement to submit' an ANDA for a drug claimed in a patent." 868 F.3d at 149 (quoting 35 U.S.C. § 271(e)(2)) (second alteration in original). That position "is unsupportable" because "Congress created this technical act of infringement for jurisdictional purposes only." *IP and Antitrust*, *supra*, § 15.03[A][2][c] (internal quotation marks omitted).

when a patent is not actually valid or infringed. *See id.* at 151 (noting "patent-related policy of eliminating unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification'" (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969))). Indeed, patent law seeks to discourage meritless patent suits by awarding attorney's fees to a prevailing defendant in exceptional cases under 35 U.S.C. § 285. *See Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545 (2014). But such a discretionary award provides little deterrence against baseless lawsuits when the suit enables the patentee unlawfully to preserve a monopoly worth tens or hundreds of millions of dollars per year, particularly when the suit is designed to end in settlement (and thus avoid the strictures of 35 U.S.C. § 285).

To be sure, any rule other than absolute immunity has the potential to deter patentees from bringing some marginal suits involving weak patents or infringement claims. Even so, that potential will not result in harm to innovation, as PhRMA contends, Br. 11-20, let alone harm outweighing the harm to the economy and consumers of permitting sham litigation. Indeed, absent a meaningful sham-litigation doctrine, baseless infringement claims brought to delay generic entry would harm innovation by generics by lessening their incentive to invent around patents and challenge weak ones. *See Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1935 (2016) (noting "the importance of facilitating the 'imitation and

refinement through imitation' that are 'necessary to invention itself and the very lifeblood of a competitive economy'" (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989))).

Moreover, if brand-name drug manufacturers have to think twice about bringing dubious lawsuits, their own innovation incentives may be heightened. In recent years, brand-name drug manufacturers have focused less on developing new drug compounds or active ingredients that provide the most important advances for patients (the "transformative medicines" highlighted by PhRMA, Br. 18), and more on obtaining secondary patents on tweaks in formulations and methods of use that prolong monopoly rent collection and provide only minor benefits at best. *See* Kesselheim & Darrow, *supra*, at 320-22 (describing growth of secondary patents).

A meaningful sham-litigation doctrine may have the beneficial effect of encouraging brand-name drug companies to invest more in new drug compounds with strong patents and less on weak secondary patents that may not provide an objectively sound basis for infringement litigation against generic entrants. *See* C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 Science 1386, 1386 (2013) (noting "salutary effect on innovation" if drug companies' innovative efforts are channeled toward new chemical entities and away from secondary patents); *New York ex rel. Schneiderman*, 787 F.3d at 659 ("immunizing [patentees' anticompetitive conduct] from antitrust scrutiny may deter significant

innovation by encouraging manufacturers to focus on . . . trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations").

II. THE DISTRICT COURT CORRECTLY CONCLUDED THAT THE LAWSUITS WERE SHAMS EVEN THOUGH IT APPLIED OVERLY STRICT STANDARDS FOR PROVING THE SUBJECTIVE PRONG OF THE SHAM TEST

A. A Suit Is Objectively Baseless if It Had No Realistic Chance of Success

The objective component of the sham test provides litigants with substantial protections to pursue uncertain but ultimately meritless claims. But it does not mean, as AbbVie's brief sometimes suggests, that a lawsuit is objectively reasonable if the suit has "any chance" of succeeding, or that the FTC was required to show that the lawsuits had "no chance" of success. AbbVie Br. at 27, 58. To be sure, *PRE* stated that a suit with probable cause is not objectively baseless and observed at one point that probable causes requires "no more than a reasonable belief that there is a chance that a claim may be held valid." *PRE*, 508 U.S. at 62 (internal quotation marks and brackets omitted).[6] But the standard it adopted is whether "a

[6] The *Restatement (Second) of Torts* § 675, Comment e (1977), which the Court cited, states: "In determining probable cause for initiation of civil proceedings, all that is necessary is that the claimant reasonably believe that there is a *sound* chance that his claim may be held legally valid upon adjudication." (emphasis added). Moreover, elsewhere in *PRE*, the Court speaks of whether a "reasonable litigant could have perceived *some likelihood* of success." 508 U.S. at 65 (emphasis added); *accord Wellbutrin*, 868 F.3d at 150.

reasonable litigant in the defendant's position could realistically expect success on the merits of the challenged lawsuit." *Id.* at 63. Thus, what is called for is a *realistic* chance of success, as AbbVie's brief elsewhere concedes. *See* AbbVie Br. 50; *see also In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 317 (E.D. Pa. 2011) (suit must have at least "a *realistic* chance" of success to have objective basis); 1 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 205b (4th ed. 2013) ("As to what constitutes a meritorious claim, Justice Souter was right to remind readers that a 'chance' of success should not be understood too literally . . . .").

In any event, the district court concluded that the Drug Companies could not reasonably have believed they had "a chance to prevail," MSJ Op. 31, and thus the lawsuits were objectively baseless even under the most restrictive possible formulation of the standard.

B. The Subjective Test Does Not Require Proof That the Defendant Knew Its Claims Were Baseless

PRE instructs that the subjective component of the sham test "should focus 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 the process—as an anticompetitive weapon.'" 508 U.S. at 60-61 (quoting *E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961) and *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380 (1991)) (brackets and emphasis in original). The district court

complied with this instruction and found that "[t]he *only* reason for the filing of these lawsuits" was to delay generic entry into the TTRT market. Op. 52-53 (emphasis added).

In reaching this conclusion, however, the court held that the FTC was required to "prove that defendants had actual knowledge that the patent infringement suits here were baseless in order to meet its burden under *Omni Outdoor Advertising* and *PRE* and to avoid interference with defendants' First Amendment rights." *Id.* at 37. Although the court found actual knowledge of baselessness here, it was wrong to require such a showing. Once the FTC established that the suits were objectively baseless, it had to show only that the Drug Companies filed the suits primarily for their collateral effects—in this case, the automatic 30-month stay and resulting delay in their generic rivals' impending product launch. *E.g., United States v. Otter Tail Power C*o., 360 F. Supp. 451, 451 (D. Minn. 1973) ("use of litigation by Otter Tail was timed and designed principally to prevent the establishment of municipal electric systems and thereby to preserve defendant's monopoly"), *aff'd*, *Otter Tail Power Co. v. U.S.*, 417 U.S. 901 (1974); *cf. Restatement (Second) of Torts* § 682 (1977) ("One who uses a legal process . . . against another primarily to accomplish a purpose for which it is not designed, is subject to liability to the other for harm caused by the abuse of process"); Defendants' Post Trial Brief, *supra*, at 10-12.

A finding that a Hatch-Waxman suit is objectively baseless supports a strong inference that the suit was primarily intended to obtain the 30-month automatic stay. *See* FTC Third-Step Br. 60. After all, the 30-month stay provides a guaranteed respite from competition while the suit itself is one that no reasonable litigant would expect to win.[7] Here, moreover, the district court did not have to rely on that inference as it found substantial evidence beyond objective baselessness to show that the Drug Companies' primary purpose was to delay entry through the automatic stay, rather than ultimately to succeed on the merits.[8]

The court offered no direct authority for requiring knowledge of baselessness, actual or otherwise. As the Federal Circuit has explained, *PRE*'s "subjective

[7] It is no answer to say that the high stakes of Hatch-Waxman litigation make it rational to bring even very low probability suits with the aim of winning. *See* AbbVie Br. 57. That reasoning ignores that the subjective test looks to the "primary purpose" of the litigation, that the high stakes to the litigant involve correspondingly high stakes to the public, and that an objectively baseless suit is one that a reasonable lawyer does not (and should not) bring regardless of the stakes. *Cf.* Am. Bar Ass'n, *Ann. Mod. Rules of Prof. Conduct* § 3.1 (2019) (explaining lawyer's professional obligation "not to advance meritless or frivolous arguments" regardless of "a lawyer's state of mind").

[8] *See* FTC Third Step Br. 60-62. The FTC also showed that delay was crucial to AbbVie's strategy of transitioning patients from AndroGel 1% to AndroGel 1.62%, which was intended to and did blunt the impact of the entry of generic AndroGel 1%. *See* Op. 90; FTC Third-Step Br. 15 (noting that transition enabled by sham litigation adversely affected Teva's incentives to launch its generic). In other words, the 30-month stay was not only incredibly valuable in delaying entry while it was in effect, but it also minimized the cost of likely generic entry in the subsequent years and therefore the value of "winning" the suit.

inquiry has nothing to do with what a litigant knew or should have known regarding the merits of its claims." *Kilopass Technology, Inc. v. Sidense Corp.*, 738 F.3d 1302, 1313 (Fed. Cir. 2013).[9] Rather, as *PRE* indicates, the subjective test "depends on the existence of anticompetitive intent" and a defendant's "economic motivations in bringing suit," including whether a litigant is "indifferent to the outcome on the merits." 508 U.S. at 57 n.4, 65-66; *see Octane Fitness,* 572 U.S. at 556 ("the plaintiff must have brought baseless claims in an attempt to thwart competition (*i.e.*, in bad faith)").

Why should a monopolist that brings an objectively baseless lawsuit not to win, but to impose collateral injuries on its rival, be exculpated if it subjectively (but unreasonably) did not know the lawsuit was baseless? There is no basis for exculpation. A monopolist that brings an objectively baseless lawsuit for ulterior anticompetitive purposes cannot reasonably be characterized as acting in good faith. *Cf. Kilopass*, 738 F.3d at 1311 (in bringing meritless claims, "one's

[9] To be sure, *Kilopass* involved the standard for awarding attorney's fees to the prevailing party in patent cases under 35 U.S.C. § 285, which the Supreme Court subsequently held is not subject to the *PRE* test for sham litigation. *Octane Fitness*, 572 U.S. at 555. But *Kilopass*'s understanding of the *PRE* test is entirely consistent with *Octane Fitness*. *See id.* at 551 n.4, 556. Moreover, while *Octane Fitness* declined to import the *PRE* test partly because the threat of antitrust liability "far more significantly chills the exercise of the right to petition than does the mere shifting of attorney's fees," *id.* at 556, it is also true that baseless litigation used to maintain a monopoly imposes far more harm to the economy—especially in the Hatch-Waxman context—than "exceptional" meritless cases that warrant fee shifting.

misguided belief, based on zealousness rather than reason, is simply not sufficient" to avoid liability for attorney's fees under § 285).

Moreover, if actual knowledge of baselessness also required *direct* evidence of the patentee's state of mind, as the Drug Companies contend (but the court correctly rejected), then the sham exception would be rendered a nullity because such evidence would rarely be available to plaintiffs. *See* 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 706b (4th ed. 2015) (noting that "[o]ften reliable evidence about the infringement plaintiff's subjective state of mind will be unavailable" and that it is problematic to make an antitrust claim "dependent on the vagaries of the patentee's document retention policy or other efforts to suppress incriminating information"); *Kilopass*, 738 F.3d at 1311 ("Subjective bad faith is difficult to prove directly, essentially requiring the discovery of a smoking gun, and evidence of a lack of subjective bad faith is easy to provide . . . .").

Indeed, the Drug Companies in this case asserted the attorney-client privilege and work-product doctrine to prevent discovery into the mental process of the lawyers who made the decision to file the lawsuits, so the court quite naturally permitted the FTC to rely on circumstantial evidence to prove the decisionmakers' subjective intent. Op. 49-50. AbbVie argues that the fact that the "vast majority of suits brought under Hatch-Waxman will involve decisions made or influenced by 'experienced patent attorneys'" militates against the court's approach. Br. at 57

(quoting Op. 52). But if actual knowledge of baseless were required, the opposite would be true. The ubiquitous role of patent attorneys in determining whether to bring Hatch-Waxman cases and the scope of available privileges makes it is essential to allow intent to be provable indirectly.

C. The Subjective Test Does Not Require Proof by Clear and Convincing Evidence

The district court also required the FTC to meet an overly stringent burden of proof to satisfy the subjective prong of the sham test. Although the court recognized that the preponderance-of-the-evidence standard is "the general standard for civil antitrust claims," it required the FTC to prove the subjective prong by clear and convincing evidence. Op. 38. Such a heightened standard is neither required nor appropriate. *Cf. Halo Elecs.,* 136 S. Ct. at 1934 (reversing Federal Circuit's clear-and-convincing standard for proving willful infringement since "'patent-infringement litigation has always been governed by a preponderance of the evidence standard'" (quoting *Octane Fitness*, 572 U.S. at 557)).

The court relied on *Walker Process* cases that require clear and convincing evidence of "knowing and willful" fraud.[10] However, fraud claims are not

[10] *See* Op. 38-39 (citing *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998)). Notably, *Bard* did not say that that the clear-and-convincing standard applies to sham-litigation claims. *See Bard*, 157 F.3d at 1369. Besins also refers to the "analogous context of inequitable patent conduct," Opening/Response Br. for Appellee/Cross-Apellant Besins Healthcare, Inc. 12, but the inequitable conduct defense in patent law is largely equivalent to *Walker Process* fraud. *See*

governed by the *PRE* test for sham litigation. *See PRE*, 508 U.S. at 62 n.6. Fraud is a separate *Noerr-Pennington* exception that does not involve the outcome/process distinction. *See In re Unocal*, 138 FTC 1, 47-48 (2004). And fraud claims naturally call for a relatively high burden of proof. *E.g.*, Fed. R. Civ. P. 9(b); *Ackerman v. Nw. Mut. Life Ins. Co.*, 172 F.3d 467, 469-70 (7th Cir. 1999) (explaining that heightened burden of proving fraud protects against "defamatory and extortionate" charges).[11]

The court also referenced *Handguards*, a pre-*PRE* case reflecting the Ninth Circuit's adoption of a clear-and-convincing standard for showing that a patent suit was brought "in bad faith." *Handguards, Inc. v. Ethicon, Inc*., 743 F.2d 1282, 1284 (9th Cir. 1984). But *Handguards* is inapposite because the Ninth Circuit's test lacked an objective component.[12] More persuasive, and consistent with *PRE*, is the Second Circuit's *Litton Systems* decision, which adopted an objective

---

Therasense, Inc. v. Becton Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011) (*en banc*).

[11] Insofar as the subjective test for sham litigation does not require proof of defendants' knowledge of baselessness, *see supra* part B, it makes even less sense to apply a clear-and-convincing standard that was designed to address the "knowing, deliberate nature of" a misrepresentation. *Unocal*, 138 FTC at 48.

[12] *See Handguards, Inc. v. Ethicon, Inc.*, 621 F.2d 986, 993, 996 (9th Cir. 1979). The district court also cited *MCI Commc'ns Corp. v. AT&T Co.*, 1081, 1155 (7th Cir. 1983), but *MCI* also did not use an objective standard and in any event merely approved a jury instruction on the sham issue that had been challenged as insufficiently *protective* of the antitrust defendant.

component and rejected any heightened standard of proof. *Litton Systems, Inc. v. American Tel. & Tel. Co.,* 700 F.2d 785, 813-14 (2d Cir. 1983).[13]

AbbVie relies on the Federal Circuit's statement in *C.R. Bard* that "[t]he law recognizes a presumption that the assertion of a duly granted patent is made in good faith." *C.R. Bard*, 157 F.3d at 1369; *see* AbbVie Br. 56. But the Federal Circuit subsequently called this presumption into question and stated that, in any event, there is no basis for requiring a party to overcome that presumption by clear and convincing evidence. *Kilopass*, 738 F. 3d at 1314-15. Nor does the statutory presumption of patent validity—which places on alleged infringers the burden of proving invalidity by clear and convincing evidence, *see Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91 (2011)—provide support for applying a heightened burden in sham-litigation claims given that the presumption is already accounted for in applying the objective standard. *E.g., Tyco Healthcare Group LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1345 (Fed. Cir. 2014). Doing so makes even less sense where, as

[13] The Second Circuit rejected any heightened burden because "the Supreme Court had already struck a rough balance between the competing First Amendment and antitrust interests" "by requiring a plaintiff to prove that a defendant's conduct was a sham," which entails proof that defendant had no "reasonable expectation" of obtaining a favorable ruling. *Litton Systems*, 700 F.2d at 810, 813; *cf. PRE*, 508 U.S. at 55 n.3 (citing *Litton* as indicative of the Second Circuit's "demand that an alleged sham be proved legally unreasonable").

here, the only issue in the underlying lawsuit(s) is infringement, as to which the *patentee* has the burden of proof.[14]

A heightened standard is also not required in order to avoid chilling the First Amendment right to petition. The objective baselessness test *already* provides that protection, giving patentees free rein to seek to enforce even questionable patents as long as there is probable cause to do so. *See Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162, 180 (3d Cir. 2015) (objective-baselessness requirement "prevent[s] any undue chilling of First Amendment activity"). And there are countervailing values on the other side. As the Second Circuit highlighted in *Litton Systems*, "the antitrust laws are as important to the preservation of economic freedom and the free enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms." *Litton Systems*, 700 F.2d at 813 (citing *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972)); *see also N.C. State Bd. of Dental Examiners v. Fed. Trade Comm'n*, 135 S. Ct. 1101, 1109 (2015) ("Federal antitrust law is a central safeguard for the Nation's free market structures."). The government also has a "correlative need" to "be able to protect the integrity of its processes." Robert H. Bork, *The Antitrust Paradox* 355 (rev. ed.

[14] To the extent that the clear-and-convincing standard in *Walker Process* and other fraud cases follows from the presumption of validity, that is an additional reason not to rely on the fraud standard when the baseless claim involves the scope of the patent, as opposed to its validity.

1993). Thus, "there is no constitutional right to . . . press baseless claims for the ulterior purpose of wreaking economic injury upon a competitor." *Id* at 359.

D. The Settlement Agreements Do Not Undercut the Court's Findings of Sham

AbbVie contends that its settlement agreements with Teva and Perrigo in which the generics agreed to delay their entry to dates after the 30-month automatic stays would have expired refutes the findings that its litigation was a sham. AbbVie Br. 50-53, 58-59.[15] The argument is meritless: A private settlement agreement, enjoying no *Noerr-Pennington* immunity at all, *see, e.g., Andrix Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 817-19 (D.C. Cir. 2001), should not shelter otherwise baseless litigation.

A "favorable settlement" is not indicative of an exculpatory motivation, particularly given that "[o]ne strategic use of sham lawsuits is to drive up litigation costs to deter resistance and encourage settlement, even if the defendant believes the lawsuit is frivolous." *IP and Antitrust*, *supra*, § 11.03[B][2]. Moreover, AbbVie's use of a settlement to obtain additional months of delayed entry is

[15] Leaving aside that the settlements appear to have been pay-for-delay deals, *see infra* p. 25, it is questionable whether the settlements should be characterized as "favorable." The settlements gave the Drug Companies about 15 months of further delayed entry against Teva and 9 months against Perrigo, while permitting entry about 66 months before the expiration of the relevant patent. *See* Op. 13, 19, 23-25. In other words, the Drug Companies gained further delay amounting to about 18.5% (Teva) and 12% (Perrigo) of the remaining life of the patent.

entirely consistent with an intent to sue *primarily* to obtain the benefits of the automatic stay rather than to win the lawsuit.

Nor does a "favorable settlement" prove that a lawsuit was not objectively baselessness. A favorable settlement is not equivalent to a "winning lawsuit," and so does not "by definition" avoid condemnation as a sham. *PRE*, 508 U.S. at 60 n.5. A favorable settlement may be comparable to winning when the litigant obtains all (or perhaps most) of the relief it sought from a court, but that is not the case when a settlement merely provides some consideration for dismissing the lawsuit. As the district court explained, "Parties often settle litigation for a variety of reasons independent of the merits of the claims," noting that "[e]ven frivolous lawsuits can be very costly to defend and to take to trial, especially when plaintiffs, such as the defendants here, have extensive resources." Op. 44. And when the court, as here, can determine objective merit directly from the available legal materials, there is no reason to resort to inferior, "secondary" indicators of merit.

Even, assuming, *arguendo*, that a "favorable settlement" providing less than complete relief may in some circumstances be evidence that a suit is not objectively baseless, the burden should be on the litigant to demonstrate that the settlement was attributable to the merits of the litigation. *Cf. Fisher v. Kelly*, 105 F.3d 350, 353 (7th Cir. 1997) (given "reasons for parties to settle that are wholly unrelated to the substance" of the litigation, a plaintiff that obtains an agreed

judgment is not a prevailing party under 42 U.S.C. § 1988(b) without showing that the relief was "obtained because of the potential merit of plaintiff's position") (internal quotation marks omitted). AbbVie provided no such evidence here.

Indeed, beyond avoiding litigation costs, there is another, even more obvious reason to believe that Teva's agreement to delay its entry beyond the 30-month stay had nothing to do with the merits of AbbVie's claim: the side deal to supply Teva with generic TriCor entered contemporaneously with the patent settlement.[16] *See Gov't Employees Ins. Co. v. Hazel*, No. 11-CV-410, 2014 WL 4628655 (E.D. N.Y. Aug. 11, 2014) (favorable settlement did not undermine claim of objective baselessness where settlement was "not an arm's-length transaction"); *cf. King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 405 n.23 (3d Cir. 2015) (combining "an early-entry date plus valuable consideration" is a concern because "the generic manufacturer may be willing to accept a later early-entry date without any corresponding benefit to consumers"). Regardless of whether this Court reverses the district court's dismissal of the FTC's reverse-payment claim based on the TriCor deal, that deal provides further reason for rejecting AbbVie's "favorable settlement" argument.

[16] Perrigo also obtained side benefits in the form of an acceleration clause that allowed it to enter as soon as any other generic came to market and a $2 million payment from the Drug Companies. Op. 24-25.

CONCLUSION

The Court should affirm the district court's findings of a sham under the reasonable standards set forth above.

Respectfully submitted,

/s/ Richard M. Brunell
RICHARD M. BRUNELL
HILLIARD & SHADOWEN LLP
1135 W. 6th St.
Suite 125
Austin, TX 787703
(202) 600-9640

RANDY M. STUTZ
AMERICAN ANTITRUST INSTITUTE
1025 Connecticut Avenue, NW
Suite 1000
Washington, DC 20036
(202) 905-5420

Dated: July 26, 201

CERTIFICATE OF COUNSEL

I, Richard M. Brunell hereby certify that:

1. Pursuant to Third Circuit Local Appellate Rule 46.1, I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

2. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6381 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

3. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5)(A) and the type styles requirements of Fed. R. App. P. 32(a)(6) because the brief has been prepared in a proportionally spaced typeface using Microsoft Word, in 14 point Times New Roman font.

4. Pursuant to Third Circuit Local Appellate Rule 31.1(c), the PDF file and the text of the paper version of the brief are identical. The electronic version of the brief has been scanned for viruses by McAfee Virus Scan (current version) and no viruses were found.

/s/ Richard M. Brunell

Dated: July 26, 2019

CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of July, 2019, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

s/ Richard M. Brunell

Dated: July 26, 2019