PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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Nos. 15-2875/3559/3591/3681/3682

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IN RE: WELLBUTRIN XL ANTITRUST LITIGATION

Indirect Purchaser Class,
Appellants in 15-2875

Aetna Health of California Inc.; IBEW-NECA Local 505 Health
and Welfare Plan; Bricklayers and Masons Union Local Union
No. 5 Ohio Health and Welfare Fund; Mechanical Contractors-United
Association Local 119 Health and Welfare Plan; Painters District
Council No. 30 Health and Welfare Fund; Plumbers and Pipefitters
Local 572 Health and Welfare Fund; Aetna, Inc.,
Appellants in 15-3559

Professional Drug Company, Inc., individually and on behalf
of the Direct Purchaser Class,
Appellant in 15-3591

SmithKline Beecham Corporation d/b/a
GlaxoSmithKline

and GlaxoSmithKline plc,
Appellants in 15-3681/3682

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Nos. 2-08-cv-2431 and 2-08-cv-2433)
District Judge: Hon. Mary A. McLaughlin

Argued
September 7, 2016

Before: JORDAN, VANASKIE, and NYGAARD, *Circuit Judges*.

(Filed: August 9, 2017)

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OPINION OF THE COURT

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JORDAN, *Circuit Judge*.

This appeal lies at the confluence of intellectual property and antitrust law. Following the Supreme Court's decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), we are tasked with balancing a patent owner's right to exclude and the public's right to benefit from fair and open competition.

The Appellants in this case are the direct and indirect purchasers of Wellbutrin XL, a drug designed to treat depression. (Consolidated Brief of Appellees/Cross-Appellants ("Ans. Br.") 6, 19.) The direct-purchaser Appellants bring claims under federal antitrust law, alleging that the Appellee, GlaxoSmithKline ("GSK"),[1] violated Sections One and Two of the Sherman Antitrust Act by entering into an unlawful conspiracy with a company called Biovail,[2] GSK's partner in the development of Wellbutrin XL, to delay the launch of generic versions of the drug. (Consolidated Brief of Direct Purchaser and End-Payor Class

[1] "GlaxoSmithKline," or "GSK," refers collectively to SmithKline Beecham Corporation and GlaxoSmithKline PLC, the producers and distributors of Wellbutrin XL.

[2] "Biovail" refers collectively to Biovail Corporation (n/k/a Valeant Pharmaceuticals International, Inc.) and Biovail Laboratories International SRL (n/k/a Valeant International Bermuda). Biovail was originally a defendant in the case but settled with the Appellants prior to the appeal.

Plaintiffs-Appellants ("Op. Br.") 2; JA 11465-68.) The indirect-purchaser Appellants assert similar theories, but under state, rather than federal law. They also allege that GSK's actions violated common law principles and state statutes mandating fair trade practices.

According to the Appellants, GSK is liable under two theories. First, the Appellants claim that GSK delayed the launch of generic versions of Wellbutrin XL by supporting baseless patent infringement suits and a baseless FDA Citizen Petition aimed at generic drug companies. Second, they claim that GSK delayed the launch of those generic drugs by entering into an unlawful reverse payment settlement agreement with its potential competitors.[3] The District Court granted summary judgment on the merits to GSK with respect to both of those theories. It concluded that there was insufficient evidence that GSK's patent litigation was a sham or that the settlement delayed the launch of generic versions of Wellbutrin XL. At the same time, the Court granted GSK's *Daubert* motion to exclude the testimony of the Appellants' economic expert. The Court also granted a motion to decertify the indirect-purchaser class for lack of

[3] Ordinarily, when a plaintiff sues a defendant, one expects that, if there is a settlement, it will involve a payment from the defendant to the plaintiff. A so-called "reverse payment" settlement takes place when the plaintiff settles the case by paying the defendant. *See FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013) ("Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a 'reverse payment' settlement agreement.").

ascertainability and dismissed the indirect-purchaser claims brought under the laws of any state that was not the home of a named class representative.[4] Finally, the Court denied a motion filed by Aetna, Inc. to intervene on the side of the indirect purchasers.[5]

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[4] The District Court had certified both the direct-purchaser and indirect-purchaser classes in August 2011. The indirect purchasers allege antitrust claims under the laws of Arizona, California, the District of Columbia, Florida, Hawaii, Iowa, Kansas, Louisiana, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, North Carolina, North Dakota, South Dakota, Tennessee, Utah, Vermont, West Virginia and Wisconsin. They assert violations of consumer protection laws in Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Washington and West Virginia, as well as the District of Columbia. The District Court concluded that the indirect-purchaser Appellants only have standing to bring their claims under the laws of states where their members reside – that is, California, Florida, Illinois, Nevada, New York, Ohio, Pennsylvania, Tennessee, Texas, and Wisconsin.

[5] Aetna, an insurance provider, had purchased brand and generic versions of Wellbutrin XL in all 50 states. It sought to intervene in order to save the indirect purchasers' claims from dismissal.

This appeal followed. Both the direct-purchaser and indirect-purchaser Appellants seek review of the District Court's summary judgment and *Daubert* rulings. The indirect-purchaser Appellants also contest the order decertifying their class and the denial of Aetna's motion to intervene. GSK filed a conditional cross-appeal challenging on numerosity grounds the certification of the direct-purchaser class. GSK filed a second conditional cross-appeal with respect to the indirect-purchaser class, asking that, if we were to disagree with the District Court's decertification on ascertainability grounds, we nevertheless affirm on numerosity grounds. The direct-purchaser and indirect-purchaser Appellants filed a joint brief addressing the summary judgment orders and the order denying Aetna's intervention; the indirect-purchaser Appellants also filed a separate brief addressing the decertification order.

We agree with the District Court's conclusions that the Appellants have failed to establish a genuine dispute of fact either as to whether GSK engaged in sham litigation or whether GSK's actions delayed the launch of any generic version of Wellbutrin XL. Consequently, we will affirm the District Court's grant of summary judgment and do not reach the remaining issues on appeal.

I. Background

A. The Hatch-Waxman Act

To better explain the antitrust issues in this case, we first describe the regulatory scheme that governs the testing and approval of new drugs in the United States. That framework was established by the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, as amended, which is commonly known as the Hatch-Waxman Act ("the Act"), or simply Hatch-Waxman. *Actavis*, 133 S. Ct. at 2227-28.

A drug manufacturer seeking to market a new drug "must submit a New Drug Application [(NDA)] to the federal Food and Drug Administration (FDA) ... and undergo a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive marketing approval from the FDA." *Id.* at 2228 (citing 21 U.S.C. § 355(b)(1)). One of the goals of Hatch-Waxman is to increase competition between generic and brand-name drugs. To that end, the Act allows the manufacturers of generic drugs to obtain FDA approval without having to endure the gauntlet of procedures associated with NDAs.

> [O]nce the FDA has approved a brand-name drug ... a manufacturer of a generic drug can obtain similar marketing approval through the use of abbreviated procedures. The [Act] permits a generic manufacturer to file an Abbreviated New Drug Application [(ANDA)] specifying that the generic has the "same active ingredients as," and is "biologically equivalent" to, the already-approved brand-name drug. ... [B]y allowing the generic to piggy-back on the pioneer's approval efforts, [the Act] "speed[s]

> the introduction of low-cost generic drugs to market," thereby furthering drug competition.

Id. (last alteration in original) (internal citations omitted) (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012)).

In addition to streamlining the drug approval process, the Hatch-Waxman Act provides specialized procedures for brand-name and generic drug manufacturers to resolve intellectual property disputes. The Act "requires the ... brand-name manufacturer to list in its [NDA] the number and the expiration date of any relevant patent. And it requires the generic manufacturer in its [ANDA] to assure the FDA that the generic will not infringe the brand-name's patents." *Id.* (internal quotation marks and citations omitted). One way for generic manufacturers to make that assurance is to "certify that any listed, relevant patent 'is invalid or will not be infringed by the manufacture, use, or sale' of the drug described in the [ANDA]." *Id.* (quoting 21 U.S.C. § 355(j)(2)(A)(vii)). That assurance is referred to as a paragraph IV certification. *Id.* To facilitate the filing of infringement suits, a paragraph IV certification "automatically counts as patent infringement."[6] *Id.* (citation

[6] The "infringement" in those circumstances is a legal construct that permits a patent holder to initiate suit without having to wait for the generic manufacturer to actually make, use, or sell a generic version of the patented drug. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (explaining that "the defined act of infringement [is] artificial" and exists to "enable the judicial adjudication upon which the ANDA ... scheme[] depend[s]"). Because a paragraph IV certification

omitted). Hatch-Waxman further states that "[i]t shall be an act of infringement to submit an [ANDA] for a drug claimed in a patent[.]" 35 U.S.C. § 271(e)(2)(A).

The Act also encourages brand-name manufacturers to file patent infringement suits quickly. If a patentee files an infringement suit against a generic manufacturer within 45 days of receiving notice of the filing of a paragraph IV certification, the patentee is rewarded with some breathing space before competition can begin: the FDA is required to withhold approval of the generic drug for 30 months or until the infringement case is resolved, whichever comes first. 21 U.S.C. § 355(j)(5)(B)(iii).

Finally, the Act "provides a special incentive for a generic to be the first to file an [ANDA] taking the paragraph IV route." *Actavis*, 133 S. Ct. at 2228-29. The first applicant is entitled to an exclusivity period during which no generic drug other than the first-filer's can compete with the brand-name drug. More specifically, the Act prohibits the FDA from approving any ANDA other than the one first filed until 180 days after the first-filer starts marketing its drug. 21 U.S.C. § 355(j)(5)(B)(iv). In effect, that allows the first-filing generic to exclude other generics from the market for

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is defined as a technical act of infringement, it allows a patent owner to sue, but it does not speak to whether the disclosed generic drug does, in fact, infringe the cited patent. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) ("The occurrence of the defined 'act of infringement' does not determine the ultimate question whether what will be sold will infringe any relevant patent.").

longer than 180 days because it may delay or decline to launch its drug.[7]

B. Factual and Procedural Background

In 1985, GSK obtained FDA approval for bupropion hydrochloride, a drug for the treatment of major depressive disorders. The drug became branded as "Wellbutrin." Over the years, several companies, including GSK, sought to develop an extended release formulation of bupropion hydrochloride. While GSK was unsuccessful, at least two companies – Biovail and Andrx Pharmaceuticals, LLC – found success and obtained patents covering extended release

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[7] While the exclusivity period can be forfeited if the first-filer fails to market its drug, it can take time to trigger the forfeiture. "Forfeiture applies only upon the satisfaction of two statutory conditions. The first condition [(i.e., the failure to market the drug either within 75 days of the date the ANDA was approved or within 30 months of the date the ANDA was submitted, whichever comes earlier)] is relatively easy to satisfy. The second is triggered only if an appeals court rules that the relevant patents are invalid or not infringed, or if a settlement reaches a similar result." C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 660-61 (2009) (footnotes omitted). That rule "allows first-filers to retain their exclusivity by settling." Chika Seidel, Comment, *Settlement Should be the End of Story: A Proposed Procedure to Settle Hatch-Waxman Paragraph IV Litigations Modeled After Rule 23 Class Action Settlement Procedure*, 46 Seton Hall L. Rev. 697, 706-07 (2016) (footnote omitted).

formulations of the drug.[8] To gain access to an extended release formulation, GSK obtained an exclusive license to certain of Biovail's patents. Then, in August 2002, GSK filed an NDA for that new formulation, which was approved the following year. The extended release Wellbutrin was named "Wellbutrin XL."

Between September 2004 and May 2005, four generic manufacturers filed ANDAs seeking approval to market generic versions of Wellbutrin XL. Each of the four companies – Anchen, Abrika, Impax, and Watson – filed a paragraph IV certification.[9] Of those companies, Anchen was the first to file its ANDA, and, as a result, was entitled to the 180-day period of exclusivity.

Biovail filed patent infringement suits against all four generic companies. With one exception, it filed its several suits within 45 days of receiving each of the would-be

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[8] Biovail obtained U.S. Patents 6,096,341 and 6,143,327 (the '341 and '327 patents), while Andrx obtained U.S. Patent 6,905,708 (the '708 patent). At the time that Biovail and Andrx were conducting their research, it appears that most or all of the information relating to bupropion hydrochloride and its delivery mechanisms was in the public domain. Neither Biovail nor Andrx needed to obtain a license from GSK in order to conduct its research.

[9] The companies' full names are Anchen Pharmaceuticals, Inc., Abrika Pharmaceuticals, LLP, Impax Laboratories, Inc., and Watson Pharmaceuticals, Inc., respectively.

competitors' paragraph IV certifications. As explained above, that triggered a stay that generally prevented the FDA from approving the ANDAs for 30 months, or until the resolution of the respective patent suits, whichever came first. Biovail did not file suit within the required 45-day period against Impax's 300 mg dosage of extended release bupropion hydrochloride. Impax was therefore not subject to the 30-month stay with respect to that product. GSK joined Biovail's suits against Anchen and Abrika but not the suits against Impax and Watson.[10]

In addition to its lawsuits, Biovail filed a "Citizen Petition" with the FDA on December 20, 2005.[11] Biovail asked the FDA to impose certain requirements for approval of any generic version of Wellbutrin XL. The FDA issued a final response to the Petition in December 2006, granting it in part and denying it in part.

On December 21, 2005, Andrx filed suit against GSK, alleging that Wellbutrin XL, in 150 mg dosages, violated Andrx's '708 patent, *see supra* n.8. Andrx also filed suit

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[10] GSK's CEO, Jean-Pierre Garner, explained that GSK elected not to join the suits against Impax or Watson because it did not believe it would have sufficient control over the litigation.

[11] Interested citizens may "petition the Commissioner [of the FDA] to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25. GSK elected not to join Biovail's FDA petition.

against Anchen for infringing the same patent with a generic version of Wellbutrin XL. In both cases, Andrx sought damages and an injunction against the sale of infringing products. In February 2007, all of the parties involved in the Wellbutrin-related patent litigation, except for Abrika, entered into a settlement.[12]

The next year, in May 2008, this litigation began. Two putative classes – a class of direct purchasers (e.g., entities like pharmacies that purchased Wellbutrin XL directly from GSK) and a class of indirect purchasers (e.g., consumers) – filed suits against Biovail and GSK.[13] As noted at the outset

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[12] Abrika settled with Biovail a few months later, after GSK had withdrawn from the suit.

[13] The direct-purchaser class includes "[a]ll persons or entities in the United States ... who purchased Wellbutrin XL directly from any of the Defendants at any time during the period November 14, 2005 through August 31, 2009... ." (JA 3.) In total, the class contains over 30 members. When certified, the indirect-purchaser class included "[a]ll persons or entities who purchased an [appropriately FDA- rated] generic bioequivalent of Wellbutrin XL ... at any time [between November 14, 2005 and April 29, 2011] in California, Florida, Nevada, New York, Tennessee and Wisconsin; and ... [a]ll entities that purchased 150 mg or 300 mg Wellbutrin XL before an [appropriately FDA-rated] generic bioequivalent was available for such dosages AND purchased generic XL in the same state after generic XL became available in California, Florida, Nevada, New York, Tennessee and Wisconsin." (Appendix for 15-2875 at 6.)

of this opinion, both sets of plaintiffs alleged that Biovail and GSK conspired to prevent generic versions of Wellbutrin XL from entering the market. The instrumentalities of the alleged conspiracy were, according to the Plaintiffs, sham lawsuits, a sham FDA petition, and an unlawful reverse payment settlement. The direct purchasers brought their claims under federal law, while the indirect purchasers brought their claims under various state laws. Biovail settled with both classes in November 2012, so only GSK has remained as a defendant.[14]

The District Court had earlier granted summary judgment for GSK on the merits on all of the claims. First, the Court granted summary judgment on the sham petition claims. Shortly after that, it stayed both the direct-purchaser and indirect-purchaser cases while the Supreme Court considered potentially relevant petitions for writs of certiorari. The District Court continued the stay in anticipation of the Supreme Court's decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). After the *Actavis* opinion issued, the District Court granted summary judgment for GSK on the reverse payment claims.

The District Court also rendered decisions regarding class certification. It at first certified both putative classes. Later, however, it concluded that the indirect-purchaser class only had standing "under the laws of those states where the plaintiffs are located or their members reside." (JA 243.) The Court thus dismissed the claims arising under the laws of states that were not represented by one of the named plaintiffs. In response, Aetna moved to intervene in the

[14] The two cases proceeded independently in the District Court, but were consolidated on appeal.

indirect-purchaser suit. It alleged that it had purchased brand and generic Wellbutrin XL in all fifty states, and that, consequently, its intervention would alleviate the standing issues. The Court denied Aetna's motion. In June 2015, the Court granted a motion to decertify the indirect-purchaser class on ascertainability grounds.

Before us on appeal are the following rulings: the grant of summary judgment to GSK on all claims, the exclusion of the testimony of the Appellants' economic expert, the decertification of the indirect-purchaser class, the dismissal of certain of the indirect-purchaser Appellants' claims for lack of standing, and the denial of Aetna's motion to intervene. GSK also conditionally challenges the certification of the direct-purchaser class. And, should the indirect purchasers succeed in overcoming the ascertainability objection to certification of their class, GSK also conditionally appeals any certification of that class, citing problems with numerosity.

II. Discussion[15]

A. Sham Litigation

The first broad issue on appeal is whether the District Court erred in granting summary judgment on the sham litigation claims. The Appellants argue that GSK violated antitrust laws by conspiring with Biovail to prosecute sham lawsuits against Anchen, Abrika, Impax, and Watson, and to file a sham petition with the FDA. According to the Appellants, GSK and Biovail worked together to press the infringement lawsuits in order to exploit the mandatory 30-month stay created by the Hatch-Waxman Act. The Appellants also allege that, but for the lawsuits and the FDA petition, the FDA would have approved Anchen's ANDA immediately and likewise would have approved the other three ANDAs at the end of Anchen's 180-day exclusivity

[15] The District Court had subject matter jurisdiction over the direct purchasers' claims under 15 U.S.C. § 15(a) and 28 U.S.C. §§ 1331, 1332, and 1337. The District Court had subject matter jurisdiction over the indirect purchasers' claims under 28 U.S.C § 1332(d)(2). We have jurisdiction over the appeal pursuant to 28 U.S.C. § 1291.

"We exercise plenary review over a district court's order granting summary judgment, applying the same standard as the district court. We will affirm only if drawing all reasonable inferences in favor of the nonmoving party, there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." *Young v. Martin*, 801 F.3d 172, 177 (3d Cir. 2015) (internal quotation marks, citations, and modifications omitted).

period. The assertion is that, without the delay in ANDA approvals, Anchen and the other generics would have launched their products sooner, resulting in increased competition and lower drug prices for pharmacies and consumers.

1. Applicable Law

A plaintiff claiming that a lawsuit is, by its very existence, anticompetitive and unlawful faces an uphill battle. It is well-established that the First Amendment protects the right to petition the government and to have access to the courts. *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56-57 (1993);[16] *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 515 (1972); *see also* U.S. Const. amend. I ("Congress shall make no law ... abridging ... the right of the people ... to petition the Government for a redress of grievances."). That protection is the basis of the *Noerr-Pennington* doctrine, which holds that "[t]hose who petition [the] government for redress are generally immune from antitrust liability."[17] *PRE*, 508 U.S.

[16] We will refer to *Professional Real Estate Investors v. Columbia Pictures Industries*, 508 U.S. 49 (1993), throughout this opinion as "*PRE*."

[17] The *Noerr-Pennington* doctrine "takes its name from *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) (holding that railroads' publicity campaign to promote support for laws harmful to trucking interest was immune from antitrust liability), and *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965) (joint efforts by miners' union and large coal companies to

at 56. *Noerr-Pennington* immunity, however, is not absolute. "[A]ctivity 'ostensibly directed toward influencing governmental action' does not qualify for [first amendment] immunity if it 'is a mere sham to cover ... an attempt to interfere directly with the business relationships of a competitor.'" *Id.* at 51 (third alteration in original) (quoting *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961)).

To determine whether a lawsuit qualifies as a "sham," courts apply a two-part test:

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part ..., the court 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 that process—as an anticompetitive

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have federal agency impose higher minimum wage for coal suppliers to TVA were immune from antitrust liability)." *Mercatus Grp., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 841 (7th Cir. 2011).

> weapon. This two-tiered process requires the plaintiff to disprove the challenged lawsuit's *legal* viability before the court will entertain evidence of the suit's *economic* viability.

PRE, 508 U.S. at 60-61 (internal quotation marks, citations, alteration, and footnote omitted).[18]

The Supreme Court has explained that "[t]he existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation." *Id.* at 62. In selecting "probable cause" as the standard by which to judge objective baselessness, the Court said that it was drawing from "[t]he notion of probable cause, as understood and applied in the common law tort of wrongful civil proceedings[.]" *Id.* A litigant has probable cause to initiate a suit if the litigant has "a reasonable belief that there is a chance that a claim may be held valid upon adjudication." *Id.* at 62-63 (internal citations, quotation, and alterations omitted); *see also* Restatement (Second) of Torts § 675. In other words, the essential question is not whether

[18] The Supreme Court in *PRE* indicated that the plaintiff in an antitrust suit has the burden of proving that the defendant is not entitled to immunity under the *Noerr-Pennington* doctrine. *See PRE*, 508 U.S. at 61 (explaining that a plaintiff must "demonstrat[e] both the objective and the subjective components of a sham"). The Court was silent, however, as to the standard of proof (i.e., clear and convincing evidence, or preponderance of the evidence) needed to show objective baselessness. Because our decision in this case does not hinge on the standard of proof, we leave that question for another day.

the suit succeeds, but whether the suit was a sham at the time it was filed. *See PRE*, 508 U.S. at 60 n.5 (cautioning that "when the antitrust defendant has lost the underlying litigation, a court must resist the ... temptation to engage in *post hoc* reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation" (internal quotations omitted)).

In addition, it is not enough for a plaintiff to show that a defendant engaged in sham litigation. "[A] plaintiff who defeats the defendant's claim to *Noerr* immunity ... must still prove a substantive antitrust violation." *Id.* at 61. That includes proving the challenged lawsuit is "causally linked" to an antitrust injury. *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977) (describing antitrust injury as "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful").

As noted earlier, the Appellants argue that each of the patent infringement suits relating to generic versions of Wellbutrin XL (that is, each of the suits against Anchen, Abrika, Watson, and Impax), as well as the Citizen Petition, was an instance of anticompetitive sham litigation or sham petitioning that caused antitrust injury by delaying the entry of generic versions of Wellbutrin XL into the market. The District Court granted summary judgment to GSK with respect to each of the five challenged actions. We agree that the sham litigation claims fail, for reasons we now endeavor to explain.

2. The Anchen Lawsuit

The sham litigation claim relating to the Anchen suit fails for the simple reason that an act of infringement plainly occurred. The already high hurdle for stating an antitrust claim for anticompetitive litigation, *PRE*, 508 U.S. at 56, is higher still in the context of an ANDA case because, as described above, 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, 35 U.S.C. § 271(e)(2). Since the submission of an ANDA is, by statutory definition, an infringing act, an infringement suit filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification. *See AstraZeneca AB v. Mylan Labs., Inc.*, No. 00-cv-6749, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010) ("[A]t the outset of Astra's case, Mylan gave Astra an objectively reasonable basis to sue: Mylan provided Astra notice of its Paragraph IV certification."), *aff'd sub nom. In re Omeprazole Patent Litig.*, 412 Fed. App'x 297 (Fed Cir. 2011). It suffices here to say that this case does not present such a circumstance. Anchen filed an ANDA for a drug that was claimed in Biovail's '341 patent. There is nothing in the record indicating that Biovail, the patentee, and GSK, the exclusive licensee,[19] were less than objectively reasonable in

[19] "Because the legally protected interests in a patent are exclusionary rights created by the Patent Act, a party holding one or more of those exclusionary rights—such as an exclusive licensee—suffers a legally cognizable injury when an unauthorized party encroaches upon those rights and

acting on that technical act of infringement, and that alone provides a sufficient basis for us to affirm the District Court's grant of summary judgment.

The content of the ANDA bolsters that conclusion. As explained above, Wellbutrin XL used a formulation of bupropion hydrochloride described in Biovail's '341 patent. That patent discloses, among other things, "a core comprising bupropion hydrochloride and conventional excipients, *free of stabilizer*" (JA 3117, '341 patent at 9:50-51 (emphasis added).) Anchen's paragraph IV certification asserted that "Anchen's proposed product cannot be deemed literally to infringe [the patent] because it includes a stabilizing amount of hydrochloric acid in the core[,]" and thus does not satisfy the "free of stabilizer" limitation. (JA 35714); *see also Pfizer, Inc. v. Teva Pharm., USA, Inc.*, 429 F.3d 1364, 1376 (Fed. Cir. 2005) (explaining that a product must satisfy *each* of a claim's limitations in order to infringe). But Anchen's ANDA suggested otherwise. It included several tables listing the ingredients that would be present in Anchen's drug, along with the relative percentages of each. While the tables listed hydrochloric acid, which can serve as a stabilizer,[20] they indicated that the acid would compose 0% of the final product. To the same effect, the percentages associated with the other listed ingredients summed to 100%. As if to emphasize that point, the tables explicitly stated that the

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therefore has standing to sue." *WiAV Solutions LLC v. Motorola, Inc.*, 631 F.3d 1257, 1264-65 (Fed. Cir. 2010).

[20] Hydrochloric acid is a stabilizing agent. (*See* Anchen's paragraph IV certification, JA 35714 (referring to hydrochloric acid as a stabilizing agent).)

hydrochloric acid had been "removed" or "evaporated" from the drug. (JA 11748-52.) That language provided GSK and Biovail with sufficient probable cause to file its infringement suit, and no reasonable jury – i.e., no jury considering the sham litigation claim – could conclude otherwise. *See Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) (holding that the ANDA specification governs the infringement inquiry).

The parties and the District Court invested considerable effort in addressing two subsidiary questions – whether FDA regulations required Anchen to quantify the amount of stabilizer present in its drug, and whether Biovail asserted a frivolous claim construction position. Those disputes are ultimately irrelevant. The question here is whether GSK and Biovail could have perceived "some likelihood of success" in their case at the time of filing. *PRE*, 508 U.S. at 65; *Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1093 (Fed. Cir. 1997) (concluding that courts should evaluate the question of objective baselessness "in light of ... information [available] at the time of filing"). At that time, the only information they had access to was an excerpt of Anchen's ANDA – an excerpt that, under a plain reading, suggested the non-infringement theory offered in Anchen's paragraph IV certification was, or at least could be, infirm. Viewed in that light, the FDA's rules regarding quantification are insufficient to override the probable cause provided in the ANDA. Again, the fact that one might conclude, after a thorough investigation, that Anchen's ANDA did not definitively exclude the presence of hydrochloric acid does not mean it was unreasonable for GSK and Biovail to file their suit, as it was not unreasonable for them to take the

ANDA at face value.[21] Similarly, the fact that a court (in the underlying patent litigation) rejected Biovail's later proposed claim construction does not bear on whether the patent infringement suit was objectively baseless from the outset.[22]

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[21] As explained above, Anchen's ANDA quantified the amount of hydrochloric acid in its drug as "--" and indicated that the other ingredients summed to 100%. The Appellants argue that, under standard industry convention, "--" denotes a residual quantity greater than zero. However, they do not point to any evidence showing that GSK and Biovail's interpretation of either "--" or "100%" was unreasonable. More to the point, they have not demonstrated that it was unreasonable to view the claim language "free of stabilizer" as covering a residual amount so small as to not register in the tables they provided.

[22] It is worth noting that GSK withdrew from the case well before claim construction began. While it is no doubt important to think about possible constructions for patent claims before filing a case, it would be unfair to require parties to divine the outcome of claim construction before filing. That is especially true in the Hatch-Waxman context, where many details about the potentially infringing drug (details that could shape a plaintiff's claim construction position) cannot be known at the time a suit is filed and where there are congressionally designed pressures to file suit quickly. *See* 21 U.S.C. § 355(b)(3)(D) (stating that an ANDA applicant is required to provide notice to patentees "includ[ing] a detailed statement of the factual and legal basis of the opinion of the applicant that the patent[s] [are] invalid or will not be infringed," but refraining from requiring ANDA applicants to submit any additional information). The

See Rohm & Haas Co., 127 F.3d at 1092 (explaining that "[p]atent litigation is complex, long, and difficult" and that parties and courts rely on "discovery procedures, partial or complete summary judgment, and evidentiary rules to narrow the issues").

The Appellants also argue that the District Court "usurp[ed] the role of the jury" by "find[ing] facts." (Op. Br. 53-54.) We disagree. In *PRE*, the Supreme Court held that courts can grant summary judgment on the issue of objective baselessness if "there is no dispute over the predicate facts of the underlying legal proceeding." 508 U.S. at 63. Here, the predicate facts include the content of Anchen's ANDA. The existence of that content – as opposed to its accuracy – is not in dispute. Instead, the parties disagree about whether that content was sufficient to establish probable cause for the

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time limits imposed by the Hatch-Waxman Act embody a "file-now, discover-details-later" policy, and while the merit of that policy may make for an interesting debate, Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Redesigned Approach for the Modern Era?*, 15 Yale J. Health Pol'y, L. & Ethics 293 (2015) (describing the debate over whether the Act is good policy), it is not our place – nor was it GSK's – to take that debate on. We decline to apply the antitrust laws in a way that would undermine the operation of Hatch-Waxman.

It is likewise a painful stretch to say that Biovail's claim construction arguments show GSK was wrong to join in the initial decision to file against Anchen. At the time the suit was filed, GSK was not obligated to know the details of claim construction arguments that Biovail would later present.

objective baselessness inquiry. *PRE*, 508 U.S. at 62. That, however, is a legal question, not a factual one. *Highmark, Inc. v. Allcare Health Mgmt. Sys., Inc.*, 701 F.3d 1351, 1353 (Fed. Cir. 2012) ("Under *PRE*, the reasonableness of a legal position … is itself a question of law[.]"); *Stewart v. Sonneborn*, 98 U.S. 187, 194 (1878) ("[P]robable cause is a question of law in a very important sense. ... Whether the circumstances alleged to show it probable are true, and existed, is a matter of fact; but whether, supposing them to be true, they amount to a probable cause, is a question of law."). In granting summary judgment, the District Court decided that GSK's suit "[did] not fit the profile of objectively baseless sham litigation." (JA 72, 95.) It was entitled to reach that legal conclusion.[23]

There is an additional problem with the Appellants' argument that warrants discussion. As we noted earlier, to establish an antitrust claim for anticompetitive litigation, the Appellants had to show not only that GSK's litigation was a sham, but also that it caused an antitrust injury by delaying generic competition. Based on the current record, they would have difficulty making such a showing, for at least two reasons. First, generic entry would have been blocked by Biovail's continuing litigation against Anchen, in which GSK did not participate. Under Hatch-Waxman, the rule requiring the FDA to delay approving an ANDA is based not simply on the filing of a lawsuit but on the ongoing presence of a lawsuit. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (stating that the FDA may approve an ANDA as soon as "the district court

[23] That the Court elected at times to use the verb "find" instead of "conclude" does not change our decision.

decides that the patent is invalid or not infringed"). GSK withdrew from the underlying litigation just a few months after the case was filed. Biovail, however, continued to pursue the suit. That is significant, as it means that the delay in competition based on the lawsuit should likely be attributed to Biovail rather than to GSK.[24]

Second, and perhaps more formidably, generic entry would have been blocked by the '708 patent owned by Andrx. We address the Andrx patent in more detail in the context of the reverse payment settlement. The implications for causation, however, apply just as much to the Appellants' sham litigation claims as they do to their reverse payment claims.

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[24] GSK and Biovail filed their suit against Anchen on December 21, 2004. GSK withdrew from the case exactly four months later, on April 21, 2005, long before the 30-month stay expired. In order to prevail against GSK, the Appellants must show that at least some delay can be attributed to GSK's actions in the case – that is, they must show that at least some delay can be attributed to the first four months of the litigation. There is no evidence in the record indicating that any delay can be linked to that period of time.

In a heading in their statement of undisputed facts, the Appellants state that "GSK Withdrew From the Anchen and Abrika Cases But Not the Conspiracy[.]" It takes some chutzpah to use that language, as GSK plainly disputes that it was ever in a conspiracy with Biovail. We consider the conspiracy argument in more detail below.

3. The Abrika Lawsuit

The Appellants contend that GSK and Biovail's suit against Abrika was another instance of anticompetitive litigation. As before, they argue that GSK and Biovail are not entitled to *Noerr-Pennington* immunity because the lawsuit was a sham. The District Court granted summary judgment to GSK based on its conclusion that there was insufficient evidence to show that the litigation delayed Abrika's entry into the market. Again, we agree.

As an initial matter, we note that two of the arguments that defeated the Appellants' claim relating to the Anchen litigation also justify affirming the District Court on this point. First, Abrika's ANDA, including the paragraph IV certification, provided GSK with an objectively reasonable basis to file its suit.[25] Additionally, as in the Anchen case, GSK initially joined with Biovail in the infringement suit, but then withdrew, and Biovail continued to litigate. That means that any delay attributable to the litigation would have existed even without GSK's involvement.

Moreover, there is an independent problem with the causation theory as it relates to the Abrika litigation. The Appellants argue that the infringement suit against Abrika delayed Abrika's entry into the market because the suit

[25] Without parsing the Abrika ANDA in the same detail as we did Anchen's, it suffices to say that the Appellants have not provided evidence to demonstrate that it was objectively unreasonable for Biovail and GSK to act on the technical act of infringement that the ANDA and paragraph IV certification provided.

imposed a 30-month stay on the FDA's approval of Abrika's ANDA. There is, however, no evidence that Abrika could have launched even in the absence of the 30-month stay. To the contrary, it is undisputed that the FDA could not have approved Abrika's ANDA until the end of Anchen's 180-day first-filer exclusivity period, a period that would not even start until Anchen launched its drug. Thus, it should surprise no one to learn that, while the 30-month stay imposed by GSK's suit expired on June 21, 2007, Abrika's ANDA was not approved until over a year later, after Anchen's exclusivity period came to an end. In responding to those facts, the Appellants in their Reply Brief appear to abandon their argument that it was the Abrika lawsuit that caused delay. Instead, they argue that the delay was caused by the suit against Anchen. That argument, however, is unavailing for the reasons already stated. Because there is no evidence showing that GSK's lawsuit against Abrika actually delayed Abrika's entry into the market, the District Court rightly rejected it as a basis of liability.

4. The Impax and Watson Lawsuits and the Appellants' Conspiracy Theory

In contrast with the Anchen and Abrika lawsuits, GSK never joined the infringement litigation against Impax and Watson. Biovail pursued those suits on its own. Nevertheless, the Appellants argue that all of Biovail's Wellbutrin-related litigation was brought in furtherance of a conspiracy with GSK. Once again, their arguments are wanting.

To avoid an adverse summary judgment on an antitrust conspiracy claim, a plaintiff must "present evidence 'that

tends to exclude the possibility' that the alleged conspirators acted independently." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986) (quoting *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 764 (1984)). "[A] plaintiff must offer enough evidence that the inference of conspiracy is reasonable in light of the competing inferences of independent action ... ." *Cosmetic Gallery, Inc. v. Schoeneman Corp.*, 495 F.3d 46, 51 (3d Cir. 2007) (internal quotation marks and citation omitted). Mere communication between alleged co-conspirators, without more, is not sufficient to defeat the presumption of independent action. *See In re Baby Food Antitrust Litig.*, 166 F.3d 112, 133 (3d Cir. 1999) (concluding that courts reject conspiracy claims that "seek to infer agreement from … communications despite a lack of independent evidence tending to show an agreement" (citation omitted) (alteration in original)); *Alvord-Polk, Inc. v. F. Schumacher & Co.*, 37 F.3d 996, 1014 (3d Cir. 1994) ("Plaintiffs … seek to infer an agreement from those communications despite a lack of independent evidence tending to show an agreement and in the face of uncontradicted testimony that only informational exchanges took place. Without more, they cannot do so.").

The Appellants have markedly failed to offer meaningful evidence that excludes the possibility that Biovail acted independently. With respect to the suits against Impax and Watson, the evidence that the Appellants do point to is a "common interest agreement" between Biovail and GSK,[26] a

[26] GSK and Biovail did not produce the common interest agreement. Instead, the parties stipulated that "[u]pon receiving [Anchen's] Paragraph [IV] certification ... GSK and Biovail reached a common interest agreement with respect to

communication between Biovail and GSK in which GSK forwarded Impax's paragraph IV certification, and an email from Biovail to GSK's outside counsel stating that Biovail had not heard from GSK with respect to the Impax litigation and that Biovail "[did] not want to let the 45-day clock expire without consciously dealing with the issue."[27] (JA 2347.) That evidence is insufficient. Biovail was the patentee and GSK the exclusive licensee on directly relevant technology, so communication between them acknowledging a common interest is hardly surprising and does not come close to supporting an inference that there was an unlawful conspiracy to stifle competition. Likewise, it is not surprising to see that the companies exchanged e-mails relating to their shared interest. The e-mails containing Impax's paragraph IV certification and acknowledging Hatch-Waxman's 45-day litigation window are the sort one would expect from two companies that share an interest in a pharmaceutical patent. That communication does not amount to a conspiracy to engage in sham litigation. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 56 (1st Cir. 2016) (explaining that pharmaceutical companies have valid reasons for

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their common legal interest in potential infringement of [the '341 and '327 patents] by Anchen or the filers of any additional ANDAs and related Paragraph [IV] notices ... ." (JA 11513.) GSK and Biovail further stipulated that the common interest agreement "related to the Paragraph [IV] certifications of [Anchen, Abrika, and Impax]" as well as the Anchen and Abrika actions. (*Id.*)

[27] The Appellants do not have any evidence regarding communication between Biovail and GSK with respect to the Watson suit.

communicating with each other, and concluding that evidence of such communication, without more, is not enough to establish an unlawful conspiracy).

The Appellants do not fare any better with respect to their claim that the Impax and Watson suits were brought as part of a larger conspiracy involving all four infringement actions, the Citizen Petition filed with the FDA, and the overall settlement agreement. Bare allegations cannot defeat summary judgment, and the Appellants have not pointed to any evidence to support their theory that there was a larger, overarching conspiracy.

5. The FDA Citizen Petition

Biovail (but not GSK) filed a Citizen Petition with the FDA, expressing concern regarding the sufficiency of the FDA's bioequivalence criteria for generic versions of Wellbutrin XL.[28] Biovail requested the FDA to require all generic manufacturers of the drug to do the following four things:

[28] As already discussed, for a generic manufacturer to obtain FDA approval of an ANDA, the manufacturer must demonstrate that its drug is bioequivalent to a drug that went through the rigorous NDA approval process. *Actavis*, 133 S. Ct. at 2228. "Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. § 314.3 (2016).

> (1) demonstrate that the generic formulation of [the drug] is bioequivalent to Wellbutrin ... Wellbutrin SR ... and Wellbutrin XL;
>
> (2) calculate and evaluate parameters in all of its bioequivalence trials based on concentrations of the patent drug and active metabolites; ...
>
> (3) conduct its bioequivalence trials at steady-state... [; and]
>
> [(4)] ... provide in vitro data demonstrating the absence of *dose dumping* if generic bupropion HCl extended-release tablets are consumed with alcohol.

(JA 37509.) Six months after receiving the Petition, the FDA issued an interim response stating that the FDA "has been unable to reach a decision on [the] petition because it raises complex issues requiring extensive review and analysis by Agency officials." (JA 37507.)

Another six months passed and, on December 14, 2006, the FDA issued its final response to the Petition, granting it in part, and denying it in part. The final response came on the same day that the FDA approved Anchen's ANDA. The Appellants allege that Biovail's Citizen Petition was anticompetitive and unlawful because, again, it was filed in furtherance of a conspiracy with GSK to delay generic entry. The District Court rejected that contention, concluding that the Appellants failed to "raise[] a genuine issue of material fact as to whether the unsuccessful and allegedly sham requests[(among the four requests Biovail made to the FDA)] caused any delay beyond the non-sham requests[.]"

(JA 127.) The Court also concluded that the Appellants failed to show that Biovail filed the Petition as part of a conspiracy with GSK.

On appeal, the Appellants argue that each of the four requests in the Petition was a sham, that there is no requirement to show the extent to which the delay was caused by sham requests (as opposed to meritorious requests), and that there was evidence to show that the Petition was filed as part of a conspiracy between Biovail and GSK. Those arguments, though, are no more persuasive now than they were before the District Court.

The most straightforward basis for affirmance is, once more, that the Appellants have failed to identify evidence showing that there was a conspiracy between Biovail and GSK, in this instance relating to the FDA petition. Just as with the sham litigation conspiracy claims, the Appellants must "present evidence 'that tends to exclude the possibility' that the alleged conspirators acted independently[,]" *Matsushita*, 475 U.S. at 588 (quoting *Monsanto Co.*, 465 U.S. at 764), and must "offer enough evidence that the inference of conspiracy is reasonable in light of the competing inferences of independent action … ." *Cosmetic Gallery*, 495 F.3d at 51 (internal quotation marks omitted). They have not met that burden. There is no evidence in the record showing that Biovail and GSK collaborated, let alone illegally conspired, on Biovail's Citizen Petition, and there is no evidence showing that Biovail filed the Petition at the direction of GSK or in furtherance of a plan involving GSK. On the contrary, the record indicates that GSK was not aware of Biovail's

specific plans to file a petition,[29] that neither GSK nor Biovail wanted to collaborate on a petition,[30] that GSK refused to share its data with Biovail for use in a petition,[31] and that GSK disagreed with the general premise of Biovail's Petition.[32]

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[29] Eight days before Biovail filed its Petition, GSK employees sent an internal email expressing uncertainty as to whether Biovail had filed a petition.

[30] GSK sent a fax to Biovail indicating that it "[did] not wish to participate in or be associated with ... Biovail explorations, deliberations, strategizing, decision-making, or ultimate advocacy with the FDA." (JA 12356.) Biovail responded and confirmed that it "[did] not seek the participation of GSK[.]" (JA 12358.)

[31] In e-mail correspondence, GSK employees acknowledged that "Biovail is curious if we have any information on metabolites that might form the basis of a challenge to the standard bioequivalence testing/standards." (JA 13281.) In response, Stan Hull, a GSK employee, explained that "[the] information is available internally, but has not been shared with Biovail, and it is our recommendation not to share metabolite data with Biovail." (JA 13282.)

[32] Indeed, in a heading in their statement of undisputed facts, the Appellants state that "GSK concluded that the bioequivalence ... argument was wrong."

In arguing otherwise, the Appellants point to an e-mail between two Biovail employees noting that "David [S]tout [who, at the time, was the President of U.S. Pharmaceutical Operations for GSK ... said that a generic to Wellbutrin XL would have to prove bioequivalence to [Wellbutrin IR] not to [Wellbutrin XL] to get approved." (JA 12621.) Assuming the relevance of that statement, however, simple communication does not establish a conspiracy. The Appellants claim that the e-mail shows that "GSK developed the [bioequivalence argument] and gave it to Biovail to put in the petition." (JA 2383.) But the e-mail does not support that claim. Nothing in the e-mail indicates that GSK wanted Biovail to include the bioequivalence argument in a Citizen Petition – the e-mail does not mention a petition and, in fact, there was no petition to which GSK could refer – the e-mail was written over a year and a half before any FDA petition was filed.

The Appellants also point to an e-mail from David Stout to several GSK employees that asked the employees to "coordinate with Biovail on ... [d]eveloping an agreement for [the concerns relating to bioequivalence, steady-state testing, and dose-dumping] and formulat[ing] a plan for the filing of the petition." (JA 13261.) At the same time, though, the Appellants ignore a follow-up e-mail indicating that GSK did not want to move forward with the Petition. A week after Stout sent his e-mail, he received a response concluding that "a Citizen's Petition requesting that all generic versions of Wellbutrin extended-release products be required to demonstrate a lack of food effect appears unnecessary as these are current confirmed requirements." (JA 13279.) The evidence is thus inadequate to support the Appellants' claim that GSK and Biovail collaborated on Biovail's Petition,

much less that they conspired to use the Petition to suppress competition.[33] Because we can affirm the District Court on that basis, we do not need to consider whether GSK is entitled to *Noerr-Pennington* immunity with respect to the Petition.[34]

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[33] As was the case with each of the four sham lawsuit claims, there is another causation problem. As we will explain in more detail below, Anchen's launch would have been delayed by a blocking patent owned by Andrx. That means that any delay caused by Biovail's FDA Petition is irrelevant – the blocking patent would have prevented a lawful launch even in the absence of Biovail's Petition.

[34] In evaluating Biovail's Petition, the District Court considered the Petition as a series of four requests. The Court concluded that two of the four requests were successful, and thus not baseless, and that two of the four requests were potentially baseless. The Court then concluded that GSK was entitled to summary judgment because the Appellants had failed to show that their injury was attributable to the unsuccessful (and potentially sham) requests, rather than to the successful requests.

We have doubts about that reasoning. The flaw is in viewing the Petition as four independent requests, rather than as a single petition. When considering whether a petition is entitled to immunity, courts should consider whether the petition as a whole is objectively baseless. *See Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1347 (Fed. Cir. 2014); *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 123 (3d Cir. 1999) ("[W]e will determine whether Ethyl's *petition* was objectively baseless ... ." (emphasis added)). While the District Court considered the merit of each of the Petition's constituent requests, it did not reach any

6. Serial Petitioning

In addition to arguing that GSK engaged in sham litigation with respect to each of the four suits against generic manufacturers and the Citizen Petition, the Appellants contend that GSK engaged in serial petitioning, and thus in an abuse of the opportunity to litigate. They say that we should vacate and remand to allow the District Court to evaluate GSK's actions in light of *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162 (3d Cir. 2015), an opinion we issued after the District Court's final judgment. GSK responds that the serial petitioning argument was waived and that, even if we consider it, *Hanover* is readily distinguishable. We decline to vacate and remand because the Appellants have not demonstrated that GSK engaged in serial petitioning.[35]

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conclusions regarding whether the Petition, in toto, was objectively baseless. As a result, the Court's consideration of causation and delay was premature.

[35] GSK argues that the Appellants did not properly preserve the serial petitioning claim below, despite the fact that the Supreme Court precedent on which *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162 (3d Cir. 2015), relied was decided "more than 40 years ago," and that the Appellants' trial counsel was familiar with it from a prior case. (Ans. Br. 64.) The Appellants respond that asserting a general theory of sham litigation was sufficient because in doing so, they "recounted a series of meritless petitions filed to frustrate competition and prolong the defendants' monopoly." (Consolidated Reply Brief of Direct Purchaser and End-Payor Class Plaintiffs-Appellants 74.) In

In *Hanover*, we held that a plaintiff could more easily overcome *Noerr-Pennington* immunity when the defendant had engaged in multiple legal actions against the plaintiff. 806 F.3d at 180. We explained that, "[w]here there is only one alleged sham petition, [*PRE*]'s exacting two-step test properly places a heavy thumb on the scale in favor of the defendant." *Id.* at 180. "In contrast, a more flexible standard is appropriate when dealing with a pattern of petitioning." *Id.* In the latter context, we ask "whether a series of petitions were filed with or without regard to merit and for the purpose of using the governmental process (as opposed to the outcome of that process) to harm a market rival and restrain trade." *Id.* To determine whether a practice of petitioning the government without regard to merit was used, "a court should perform a holistic review that may include looking at the defendant's filing success—i.e., win-loss percentage—as circumstantial evidence of the defendant's subjective motivations." *Id.*

At the outset, we reject the contention that GSK engaged in serial petitioning through "four lawsuits and a petition[.]" (Op. Br. 116.) GSK was only involved in two of

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Hanover, we rejected an argument that the plaintiffs had waived a serial litigation claim where the plaintiffs "consistently" argued "that the sham exception applie[d]" and "alleg[ed] an 'illegal scheme' through a 'series of sham litigations,' [that] put Defendants on notice of the relevant facts[.]" 806 F.3d at 179 n.13. Although the Appellants did not independently articulate the "series" claim in the District Court, we conclude that, as in *Hanover*, the recitation of sequential litigious activity was sufficient to preserve the claim.

the suits, and then only briefly. GSK did not file suit against Impax or Watson, nor did it join the Citizen Petition that was filed with the FDA. Biovail took those steps alone. And we have already rejected the Appellants' arguments that GSK was engaged in a conspiracy with Biovail. When the Appellants' serial petitioning claim is reduced to only the lawsuits against Anchen and Abrika, both of which GSK withdrew from, it must fail. The test for serial petitioning announced in *Hanover* explicitly applies to "a series of legal proceedings" or "a pattern of petitioning[,]" 806 F.3d at 180, and two proceedings – each against an independent defendant – does not constitute a pattern.

The serial petitioning charge is particularly inapt because GSK's actions were consistent with the design and intent of Hatch-Waxman. The 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. 21 U.S.C. § 355(j)(5)(B)(iii). We are not inclined to penalize a brand-name manufacturer whose "litigiousness was a product of Hatch-Waxman." *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1047 (9th Cir. 2009). Doing so would punish behavior that Congress sought to encourage. *See id.* (recognizing that the "volume of ... suits" filed by a brand-name manufacturer is "dependent on the number of generic companies attempting to enter the … marketplace, a matter over which the [brand-name manufacturer] ha[s] no control"). For that reason too, we agree with the District Court's rejection of the Appellants' serial petitioning argument.

B. Reverse Payment Settlement Agreement

The second major point of contention on appeal relates to a set of agreements that resolved Biovail's infringement suits against Anchen, Impax, and Watson, and Andrx's infringement suits against GSK and Anchen. Each of the agreements was entered into on February 9, 2007, and together they settled many of the patent disputes related to Wellbutrin XL. The Appellants argue that the overall settlement was unlawful and anticompetitive. Before delving into the details of the agreements, we give some background on the events leading to the settlement.

1. Events Leading to the Settlement

In January 2006, in anticipation of the FDA's approval of Impax's ANDA, Anchen, Impax, and Teva Pharmaceuticals U.S.A entered into an agreement under which Anchen would waive its first-filer exclusivity to allow Teva to market Impax's 300 mg version of Wellbutrin XL.[36] Pursuant to that agreement, Impax and Teva launched a generic version of 300 mg Wellbutrin XL in December 2006.

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[36] This is Teva's first appearance in this case. It is another producer and distributor of generic drugs.

As explained above, because Biovail filed its suit against Anchen promptly, it was able to delay the approval of Anchen's ANDA for 30 months. However, Biovail did not file against Impax within 45 days of receiving Impax's paragraph IV certification. As a result, the only barrier to the approval of Impax's ANDA was Anchen's first-filer exclusivity period.

That same month, Anchen's ANDA was approved, and Anchen and Teva entered into a "Distribution and Supply Agreement," under which Teva would launch Anchen's 150 mg version of Wellbutrin XL. At that point, GSK, Biovail, and Teva (as the distributor for Anchen and Impax) entered into a "'standstill' agreement under which Teva, Anchen, and Impax agreed not to launch any more 300 mg generic product or any 150 mg generic product, and Biovail ... agreed not to launch any authorized generic version of either dosage strength."[37] (JA 2435.)

In the midst of that standstill, in February 2007, the parties entered into the series of agreements constituting the settlement. By that time, Biovail had lost its infringement suit against Anchen in district court and had an appeal pending in the United States Court of Appeals for the Federal Circuit.[38] Each of the other infringement cases was pending in district court. Also pending was a federal case filed by Biovail against the FDA challenging the FDA's treatment of Biovail's Citizen Petition.

[37] An "authorized generic" is a non-branded version of a brand-name drug that is produced by the brand-name company itself.

[38] The appeals process was at an early stage – Biovail filed its notice of appeal on September 13, 2006, and its opening brief on December 14, 2006.

2. The Settlement

Five agreements constituting the overall settlement are relevant here. The first was between GSK and Andrx and provided that GSK would settle with Andrx, "paying $35 million to cover past use of the technology described in Andrx's patent, plus an ongoing royalty rate in exchange for a license to the patent." [39] (Ans Br. 14; *see also* JA 34043.) GSK also obtained the right to sublicense the Andrx patent.

The second agreement was a license between Teva and Biovail. It contained three relevant provisions. First, it granted Teva a 180-day exclusive license to certain Biovail patents,[40] so that Teva could sell a 150 mg version of generic Wellbutrin XL beginning on May 30, 2008, or earlier if Biovail lost its appeal in the Anchen case.[41] Second, the agreement granted Teva an exclusive license to Biovail patents so that it could sell a 300 mg version of generic

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[39] In November 2006, Andrx was acquired by Watson. For simplicity, we will continue to refer to Andrx by that name.

[40] To ensure that the license would, in fact, be exclusive, Biovail amended its development agreement with GSK. To facilitate the settlement, GSK agreed to refrain from launching an authorized generic version of 150 mg Wellbutrin XL for the duration of Teva's exclusive license.

[41] The agreement contained five other "trigger" provisions that would allow Teva to market generic versions of Wellbutrin. None of the other provisions is relevant here.

Wellbutrin XL.[42] The license ran from December 13, 2006 through June 12, 2007.[43] Finally, the agreement required Biovail to provide Teva with a supply of 150 mg and 300 mg generic Wellbutrin XL.[44] Specifically, Biovail agreed to supply Teva with 75 million tablets of the 150 mg dosage. The agreement also contained two unlimited supply provisions (one for the 150 mg dosage and one for the 300 mg dosage), obligating Biovail to provide Teva with an unlimited supply of Wellbutrin XL in the event that Biovail's Citizen Petition ended up interfering with Teva's launch.

The third agreement was between Anchen and Biovail. In that agreement, Biovail granted Anchen a sublicense to Andrx's '708 patent – the patent that had been the subject of litigation involving Anchen's 150 mg generic version of Wellbutrin XL.[45] The parties also acknowledged that the

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[42] Biovail and GSK similarly amended their development agreement to preclude GSK from launching an authorized generic version of 300 mg Wellbutrin XL.

[43] The license was written to retroactively authorize the sales that Teva had made prior to entering the license agreement. The Appellants contend that the license was meaningless and that "Teva did not need a license to make and sell the product because Teva was already doing so." (JA 2635.)

[44] The agreement specified that the tablets must be "Generic NDA Equivalent." (JA 34081.)

[45] The agreement explains that Biovail was an assignee of the license agreement between Andrx and GSK, and thus

agreement did not "settle or otherwise end the Biovail Anchen lawsuit." (JA 3697.)

The fourth agreement was between Biovail and Impax, in which Biovail agreed to dismiss its infringement suit against Impax and agreed not to sue Impax for selling or manufacturing generic versions of Wellbutrin XL outside of Anchen's 180-day exclusivity period.

The fifth agreement was an "omnibus" one in which the several parties acknowledged that the second through fifth agreements were related to each other and agreed to submit those agreements to the FTC for approval. The parties further agreed to modify the agreements in response to any FTC concerns.[46]

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that Biovail had the ability to grant a sublicense to Andrx's patent.

[46] By statute, the parties were required to submit their several settlement agreements to the FTC within 10 days. *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, Pub. L. No. 108-173, § 1112(a), 117 Stat 2066, 2461-62 (2003). The omnibus agreement required the parties to submit the agreements to the FTC within two days and to either revise or terminate the agreement in response to any FTC concerns. In addition to the five agreements described above, Andrx sent a letter to Anchen explaining that, in light of the license agreement between GSK and Andrx, Andrx would dismiss its infringement suit against Anchen. That same day, Biovail and GSK amended their development agreement (the agreement that granted GSK an exclusive license to Biovail's

Pursuant to the terms of the agreements, Anchen waited until May 2008 to launch its 150 mg generic version of Wellbutrin XL, and GSK waited 180 days to launch authorized generic versions of both 150 mg and 300 mg Wellbutrin XL.

3. The Appellants Cannot Prevail on Their Antitrust Claims Pertaining to the Alleged Reverse Payment

In order to prevail on an antitrust claim, a private plaintiff must establish antitrust standing, *Ethypharm S.A. France v. Abbott Laboratories*, 707 F.3d 223, 232-33 (3d Cir. 2013), and must show that the defendant's actions violated antitrust law. Phillip E. Areeda & Herbert Hovenkamp, Fundamentals of Antitrust Law 3-16 (4th ed. 2015). In this case, there is an additional threshold question – whether the challenged agreements are immune from antitrust scrutiny as the valid exercise of patent rights. *See Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) (explaining that "the essence of a patent grant is the right to exclude others from profiting by the patented invention"); *Actavis*, 133 S. Ct. at 2238 (Roberts, C.J., dissenting) ("A patent grants the right to exclude others from profiting by the patented invention. In doing so it provides an exception to antitrust law, and the scope of the patent ... forms the zone within which the patent

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patents) to bring it into compliance with the substance of the Teva-Biovail agreement. Finally, Biovail agreed to dismiss its suit against Watson. There was no payment (reverse or otherwise) associated with the Biovail-Watson settlement.

holder may operate without facing antitrust liability." (internal quotation marks and citation omitted)).

a) The Agreements Are Not Immune from Antitrust Scrutiny; the Rule of Reason Test Applies

The Supreme Court considered the legality of reverse payment settlements in *FTC v. Actavis*, 133 S. Ct. 2223. In that case, a brand-name drug manufacturer sued an ANDA applicant. *Id.* at 2229. After litigating the case for several years, the parties entered into a settlement agreement whereby the brand manufacturer paid the generic manufacturer tens of millions of dollars in exchange for the generic's agreement to delay its entry into the market for nine years. *Id.* at 2229-30. The FTC filed suit challenging the settlement agreement. *Id.* at 2227. Although the United States Court of Appeals for the Eleventh Circuit held that reverse payment settlements should be immune from antitrust liability, as long as they fall within the scope of the relevant patents, *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012), the Supreme Court saw it differently. It said that "reverse payment settlements ... can sometimes violate the antitrust laws" and that "courts reviewing such agreements should ... apply[] [the] 'rule of reason' [test]." *Actavis*, 133 S. Ct. at 2227, 2237.[47] In reaching that conclusion, the Court observed that "it would be incongruous to determine antitrust legality by measuring the

[47] The Supreme Court explicitly rejected the claim that reverse payment settlement agreements are "presumptively unlawful" and concluded that it would also be improper to evaluate reverse payment agreements via a "quick-look" approach. *Id.* at 2237.

settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." *Id.* at 2231. The Court then explained that reverse payments can generate "genuine adverse effects on competition" by allowing brand manufacturers to "avoid the risk of patent invalidation or a finding of noninfringement." *Id.* at 2235-36. Ultimately, the Court concluded that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects[.]" *Id.* at 2237.

In *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015), we considered whether antitrust scrutiny under *Actavis* was limited to reverse payments of cash, or whether other "transfers of value" would also be subject to scrutiny. Like the agreement at issue in this case, *King* involved a settlement in which a brand manufacturer agreed not to produce an "authorized generic" version of its drug – a so-called "no-AG agreement." *Id.* at 394. The antitrust plaintiffs in that case alleged that the no-AG agreement qualified as a reverse payment under *Actavis*. *See id.* We agreed and held that "*Actavis*'s holding [could not] be limited to reverse payments of cash." *Id.* at 403. We explained:

> [A] brand's commitment not to produce an authorized generic means that it must give up the valuable right to capture profits ... . The no-AG agreement transfers the profits the patentee would have made from its authorized generic to the settling generic—plus potentially more ... because there will now be a generic monopoly instead of a generic duopoly.

Id. at 405. As a result, we concluded that "no-AG agreements are likely to present the same types of problems as reverse payments of cash" and that "[t]he anticompetitive consequences of [a no-AG agreement] may be as harmful as those resulting from reverse payments of cash." *Id.* at 404-05.

When evaluating the challenged settlements in this case, the District Court suggested, but did not hold, that they might be beyond the reach of antitrust law. According to the Court, "the Wellbutrin Settlement does not present the same antitrust concerns that motivated the court in *Actavis* to subject the settlement to antitrust scrutiny" because "the Wellbutrin Settlement required the underlying patent litigation to continue, maintaining the risk of a finding of patent invalidity or non-infringement[.]" (JA 182-83.) Despite that intimation, the Court declined to hold that "any reverse payment that allows the underlying patent litigation to continue is automatically exempt from the antitrust laws." (JA 184.) Instead, the Court analyzed the settlement using the rule of reason. On appeal, GSK echoes the initial intimation of the District Court and maintains that "[t]he settlement did not pose the anticompetitive harm the Supreme Court identified in *Actavis*[.]" (Ans. Br. 67.) We disagree.

In light of *Actavis* and our decision in *King*, the agreements at issue in this case, as they relate to Anchen's generic version of 150 mg Wellbutrin XL, must be evaluated under the rule of reason test. As explained above, the agreements include an alleged reverse payment and pay-for-delay scheme: in exchange for a 180-day no-AG agreement from Biovail and GSK (the reverse payment), Anchen agreed not to launch a generic version of 150 mg Wellbutrin XL until

the occurrence of a triggering event. Moreover, there is some support in the record for the assertion that the reverse payment is large and unjustified, *see Actavis*, 133 S. Ct. at 2237 (suggesting that reverse payments are especially problematic if they are "large and unjustified"). First, the payment can be said to be large. According to the Appellants' economic expert,[48] the no-AG agreement was worth $233 million to Anchen, Teva, and Impax – an amount that would qualify as large in most any context. *See Actavis*, 133 S. Ct. at 2237 (explaining that "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size [and] scale in relation to the payor's anticipated future litigation costs"). The "payment," i.e., the no-AG agreement, could also be said to be unjustified in the sense of being unexplained.[49] In particular, it was not tied to the merits of the litigation between Biovail and Anchen. We know that the

[48] The District Court granted a *Daubert* motion to exclude that expert's opinion relating to the rule of reason analysis. However, the *Daubert* motion did not appear to challenge the expert's opinions with respect to the value associated with the no-AG agreement. And, in *Actavis*, the Supreme Court recognized the immense value associated with market exclusivity. *See Actavis*, 133 S. Ct. at 2229 (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)).

[49] We intend no comment on whether a no-AG promise could be justified in the sense of being a sound exercise of business judgment and consonant with good public policy.

no-AG agreement was not linked to the merits of the litigation because its value did not depend on the outcome of the appeal before the Federal Circuit. The duration of the no-AG promise was fixed at 180 days, regardless of who prevailed in the case, and that duration provided value to Anchen, as well as to Teva and Impax.[50] Because the

[50] It is worth noting that this case differs from *Actavis* and *King* in at least one important respect: in both *Actavis* and *King*, the challenged agreements ended litigation between the brand-name manufacturer and the generic manufacturer. In this case, however, the agreements allowed Biovail's appeal to continue. (*See* JA 3697 (explicitly noting that the agreement did not "settle or otherwise end the Biovail Anchen lawsuit").) In acknowledging that difference, the District Court concluded that the agreements in this case "do[] not present the same antitrust concerns that motivated the court in *Actavis* to subject the settlement to antitrust scrutiny." (JA 183.) We question that conclusion. While there is language in *Actavis* that describes the premature termination of litigation as an anticompetitive harm, *see* 133 S. Ct. at 2236 (explaining that a patentee should not be allowed to "us[e] its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement"), the Supreme Court's holding was not so narrow. Instead, *Actavis* stands for the broader proposition that both "patent and antitrust policies are ... relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." *Id.* at 2231. In other words, the Court took issue with reverse payments not simply because they could lead to the premature termination of litigation, but rather because they eliminate the risk of competition. *Id.* at 2236; *King*, 791 F.3d at 405.

agreements at issue here are such as to implicate the concerns identified in *Actavis*, they are not immune from antitrust scrutiny and must, to a degree, be evaluated under the rule of reason test.

That "to a degree" qualifier is added because our conclusion is limited to the agreements as they relate to Anchen's generic version of 150 mg Wellbutrin XL. We reach a different conclusion with respect to the agreements as they relate to Anchen's 300 mg Wellbutrin XL.[51] As

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While the agreements at issue here did not end the litigation between Biovail and Anchen, they nevertheless implicate the kinds of concerns articulated in *Actavis* by delaying the entry of 150 mg generic Wellbutrin XL and by delaying the entry of an authorized generic version of both 150 and 300 mg Wellbutrin XL. That conclusion follows directly from *Actavis* and *King* and is also supported by the FTC, which filed an amicus brief in this case. (*See* FTC Br. 15 ("An agreement that forecloses the possibility of at-risk entry into the market (in exchange for shared monopoly profits) can also be anticompetitive under that analysis.").) The view of the law espoused by the FTC, adopted by the majority in *Actavis*, and followed by our Court in *King*, has been subject to cogent criticism, *see, e.g.*, *Actavis*, 133 S. Ct. at 2240-47 (Roberts, C.J., dissenting), but the controlling precedent is what it is.

[51] It does not appear that the Appellants have presented any arguments relating exclusively to Anchen's generic version of 300 mg Wellbutrin XL. As a result, any arguments the Appellants might have regarding the 300 mg product could be viewed as waived. *Nagle v. Alspach*, 8 F.3d 141,

explained above, Anchen, in partnership with Impax and Teva, launched a 300 mg version of Wellbutrin XL in December 2006 – as soon as its ANDA was approved. The agreements reached in February 2007 allowed Teva to continue marketing that product. As a result, there was no delay associated with the 300 mg product and the analysis in *Actavis* does not apply. As a result, any pay-for-delay claim unique to Anchen's 300 mg product must fail.[52]

b) The Appellants Do Not Have Antitrust Standing

In order to maintain an antitrust suit, a plaintiff must establish antitrust standing, which is distinct from Article III standing. While Article III standing is rooted in the Constitution, antitrust standing is a judge-made doctrine.[53]

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143 (3d Cir. 1993). However, for the reasons stated above, the Appellants would not prevail on that issue even if it were not waived.

[52] One could argue that the no-AG agreement relating to the 300 mg product was part of the payment used to persuade Anchen to delay its launch of the 150 mg product. If one adopts that view, then the 300 mg no-AG agreement would be subject to the same analysis as the 150 mg no-AG agreement and there would not be any claim unique to the generic 300 mg product.

[53] Though judge-made, federal antitrust standing is rooted in federal statutory law, and antitrust standing under state law is likewise rooted in the respective statutes of the several states represented within the ranks of the indirect-

Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 534-35 & n.31 (1983); *Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 232 n.17 (2013) ("[A]ntitrust standing is based on prudential principles."). It is not a jurisdictional requirement. *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 263 n.30 (3d Cir. 2016). And while "[h]arm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact," courts must also consider "whether the plaintiff is a proper party to bring [the] private antitrust action." *Associated Gen. Contractors*, 459 U.S. at 535 n.31. In that sense, antitrust standing is more properly viewed as an element of an antitrust claim that can be resolved at summary judgment. *Ethypharm S.A. France*, 707 F.3d at 232 n.15

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purchaser Appellants. The state requirements for antitrust standing are functionally identical to the federal requirements in this respect – each of the state antitrust laws asserted in this case requires antitrust plaintiffs to prove that they have suffered an antitrust injury. Moreover, the standards for proving antitrust injury under the state laws appear to be identical to the standards under federal law. *See Breakdown Servs., Ltd. v. Now Casting, Inc.*, 550 F. Supp. 2d 1123, 1141 (C.D. Cal. 2007); *Boulware v. State of Nev., Dept. of Human Res.*, 960 F.2d 793, 800-01 (9th Cir. 1992) (Nevada); *Benjamin of Forest Hills Realty, Inc. v. Austin Sheppard Realty, Inc.*, 823 N.Y.S.2d 79, 94 (App. Div. 2006); *Lerma v. Univision Commc'ns, Inc.*, 52 F. Supp. 2d 1011, 1016 (E.D. Wis. 1999); *Rockholt Furniture, Inc. v. Kincaid Furniture Co.*, 1998 WL 1661384, at *7 (E.D. Tenn. July 6, 1998). As a result, our standing and causation analysis on this issue applies equally to the direct purchasers' claims and the indirect purchasers' claims.

(indicating that antitrust standing is a "merits issue"); *see also Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 182 (3d Cir. 1997) (considering the question of antitrust standing at summary judgment, and determining whether the plaintiff "adduced sufficient evidence to permit a reasonable factfinder to conclude that it competed in the market in which trade was allegedly restrained, such that its alleged injury would constitute 'antitrust injury'"); *McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 852-54 (3d Cir. 1996) (resolving the question of antitrust standing at summary judgment).

To establish antitrust standing, a plaintiff must show that it has suffered an antitrust injury[54] – that is, an "injury of

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[54] "The Supreme Court ... [has] articulated several factors to be considered when deciding whether a complainant has antitrust standing." *Ethypharm S.A. France*, 707 F.3d at 232 (3d Cir. 2013) (internal quotation marks and citations omitted). Those factors include:

> (1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative

the type the antitrust laws were intended to prevent and that flows from that which makes [the] defendants' acts unlawful." [55] *Ethypharm S.A. France*, 707 F.3d at 233 (3d

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> recovery or complex apportionment of damages.

Id. at 232-33 (internal citations omitted). Because "[t]he second factor, antitrust injury, is a necessary but insufficient condition of antitrust standing[,] ... if it is lacking, we need not address the remaining ... factors." *Id.* at 233 (internal quotation marks and citation omitted); *see also City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 265 ("[B]ecause there is no causal connection and no antitrust injury, we need not examine the other ... standing factors.").

[55] In *Illinois Brick Co. v. Illinois*, the Supreme Court held that indirect purchasers do not have standing to bring antitrust suits under federal law. 431 U.S. 720, 730-31 (1977); *see also In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1163 n.10 (3d Cir. 1993) ("[In *Illinois Brick Co.*,] [t]he Court held that § 4 [of the Clayton Act] did not permit ... indirect purchasers ... to recover for the overcharge passed through the chain of distribution."). However, indirect purchasers do have standing to assert antitrust claims in each of the state causes of action asserted here. Nev. Rev. Stat. § 598A.210 (Nevada statute granting standing to indirect purchasers to recover for antitrust violations); *In re Dynamic Random Access Memory (Dram) Antitrust Litig.*, 516 F. Supp. 2d 1072, 1094-95 (N.D. Cal. 2007) (recognizing that indirect purchaser suits are permitted in Arizona, Kansas, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, North Carolina,

Cir. 2013) (alteration in original) (quoting *Brunswick Corp.*, 429 U.S. at 489).

In order to establish antitrust injury here, the Appellants must show that the harm they say they experienced – increased drug prices for Wellbutrin XL (and its generic equivalents) – was caused by the settlement they are complaining about. *See Zenith Radio Corp. v. Hazeltine Res., Inc.*, 395 U.S. 100, 114 n.9 (1969) (explaining that, under the Clayton Act, a plaintiff must prove that it has suffered at least "some damage flowing from the unlawful conspiracy"). The Appellants attempt to meet their burden by pointing to evidence showing that, in the absence of the agreements, Anchen (partnering with Teva) would have launched its 150 mg generic no later than the middle of 2007.

At first glance, that argument seems appealing. Indeed, the District Court found that there was at least a question of fact as to whether Anchen would have launched the drug in June 2007. The problem with the argument, however, is that it does not take into account Andrx's blocking patent, the '708 patent. It is not enough for the Appellants to show that Anchen wanted to launch its drug; they must also show that the launch would have been legal. After all, if the launch were stopped because it was illegal, then the Appellants' injury (if it could still be called that)

North Dakota, South Dakota, and Wisconsin); *Indirect Purchaser Lawsuits: A State-by-State Survey* 27, 215, 287, 337 (Eric McCarthy et al., eds., 2010) (explaining that California, New York, Tennessee, and Wisconsin each allow indirect purchasers to assert antitrust claims).

would be caused not by the settlement but by the patent laws prohibiting the launch. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 62-63 (1st Cir. 2016) ("[T]he argument that [the generic manufacturer] would have incurred the risk of launching at risk or that [it] would have won its ... suit against [the patent holder] depends on the theory that ... [the] patents were invalid or not infringed by a generic version."); Phillip E. Areeda & Herbert Hovenkamp, Fundamentals of Antitrust Law § 3.04[B] (rev. 4th ed. Supp. 2015) ("[A] plaintiff cannot be injured in fact by private conduct excluding it from the market when a statute prevents the plaintiff from entering that market in any event.").[56]

That a regulatory or legislative bar can break the chain of causation in an antitrust case is beyond fair dispute. For example, in *RSA Media, Inc. v. AK Media Grp., Inc.*, 260 F.3d 10, 15 (1st Cir. 2001), the First Circuit decided that the plaintiff was excluded from the outdoor billboard market not because of the defendant's actions but rather "because the Massachusetts regulatory scheme ... [prevented] new billboards from being built." Similarly, in *In re Canadian Import Antitrust Litigation*, 470 F.3d 785, 790-91 (8th Cir. 2006), the Eighth Circuit held that the plaintiffs faced higher drug prices not because drug companies excluded cheaper

[56] GSK also argues that Anchen's launch would have been blocked by FDA regulations relating to Anchen's production facilities. We do not consider that argument because, even if it were given full weight, it would only show that Anchen would have had to wait until June 12, 2007 to launch – a date that was almost a year prior to its actual launch. In other words, the argument relates to the length of delay, rather than the existence of a delay.

Canadian drugs from the market but because federal law excluded the cheaper Canadian drugs. *See City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998) (applying the same principle and concluding that any injury suffered by the plaintiff resulted from "the realities of the regulated environment" rather than from the defendants' actions). In this case, the launch of Anchen's 150 mg version of Wellbutrin XL was effectively blocked by federal patent law, which, through Andrx's '708 patent, would have prevented market entry.

The Appellants offer two arguments to fend off that conclusion – one legal and one factual. Their legal argument is that the reasoning just given was repudiated by our decision in *Consolidated Express, Inc., v. New York Shipping Association*. 602 F.2d 494 (3d Cir. 1979), *vacated* 448 U.S. 902 (1980), *remanded and affirmed*, 641 F.2d 90 (3d Cir. 1981). They misread that case. In *Consolidated Express*, we held that an antitrust *plaintiff's* improper conduct did not preclude that plaintiff from asserting an antitrust claim unrelated to the improper conduct. *Id.* at 508. By contrast, our holding in this case is that the antitrust claim fails because the actions of GSK, the *defendant*, did not actually cause the Appellants' claimed injury. But even if the Appellants had a correct reading of *Consolidated Express*, their argument would still fail because that case predates significant developments in antitrust standing jurisprudence. *Consolidated Express* was decided in 1979, before the Supreme Court established its antitrust standing "factors" in *Associated General Contractors* four years later. *See Merican, Inc. v. Caterpillar Tractor Co.*, 713 F.2d 958, 965 (3d Cir. 1983) (applying the Supreme Court's decision in *Associated General Contractors*). We later adopted the very

argument that the Appellants now claim is not good law. In *City of Pittsburgh* we said that no antitrust standing exists when a plaintiff's grievance is caused by a regulatory scheme rather than by the defendant's actions. 147 F.3d at 266. We decline to deviate from the well-reasoned path marked in *City of Pittsburgh*.

The Appellants' factual response is that, but for the challenged agreements, Anchen would have been able to launch its 150 mg version of Wellbutrin XL without running afoul of Andrx's patent. They offer two scenarios. First, they argue that, in the absence of the challenged agreements, Anchen would have obtained a license to Andrx's patent. We will refer to that as the license-based scenario. Alternatively, they argue that, in the absence of the challenged agreements, Anchen would have prevailed against Andrx in litigation. We will refer to that as the litigation-based scenario. The record supports neither.

(1) License-Based Scenario

The Appellants contend that, for at least three reasons, Anchen would have obtained a license from Andrx. First, they say that GSK failed to produce evidence "showing [that] … GSK's no-AG payment or the generic delay … were necessary in order [for Anchen] to secure a ... license [to Andrx's patent]." (Op. Br. 74.) That argument, however, flips the burden of proof. As the plaintiffs, the Appellants have the burden of proving that they have been injured. In order to withstand summary judgment, they must point to evidence affirmatively showing that Anchen could have launched. *See W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 101 (3d Cir. 2010) ("[T]he plaintiff must

establish that it suffered an antitrust injury."). It is no good saying that the defendants have failed to disprove causation. *See id.*

Second, the Appellants say that Andrx had "an independent economic interest" in providing a license to Anchen. (Op. Br. 74.) Their reasoning is that Andrx was a non-practicing entity and thus "could only profit from its '708 patent through licenses." (*Id.* at 74.) That argument is both incorrect and insufficient. The argument is incorrect because, as noted above, *supra* n.39, Watson acquired Andrx in November 2006. That means that Andrx was, by that time, not a non-practicing entity and in fact had a reason to deny Anchen a license. If Anchen were precluded from launching its product, then Anchen would waive its exclusivity period, allowing Watson (a/k/a Andrx) to enter the market earlier. *See* 21 U.S.C. § 355(j)(5)(D)(i) (outlining the conditions in which a first-filer waives its exclusivity). But, even if the Appellants' argument were better rooted in reality, it would be insufficient. In order to withstand summary judgment, the Appellants must produce evidence from which a reasonable jury could conclude that it is more likely than not that Anchen *would* have obtained a license. Evidence showing that Anchen *may* have been able to obtain a license does not meet that standard. A plaintiff cannot satisfy the summary judgment burden based on speculation alone. *See Halsey v. Pfeiffer*, 750 F.3d 273, 287 (3d Cir. 2014) ("[A]n inference based upon a speculation or conjecture does not create a material factual dispute sufficient to defeat [entry of] summary judgment." (quoting *Robertson v. Allied Signal, Inc.*, 914 F.2d 360, 382 n.12 (3d Cir. 1990))); *Fedorczyk v. Caribbean Cruise Lines, Ltd.*, 82 F.3d 69, 76 (3d Cir. 1996) (affirming a grant of summary judgment because "[b]ased on

the evidence presented, a jury could only speculate" as to whether the defendant's actions actually caused the claimed injury).[57]

Third, the Appellants argue that Anchen was negotiating a license agreement with Andrx in the days preceding the agreements and had agreed on all but one term. Based on those negotiations, the Appellants argue, a

[57] The Appellants point to our recent decision in *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, 852 F.3d 268 (3d Cir. 2017), to support their claim that juries are "'routinely' given questions that permissibly require them to 'predict the outcome of a hypothetical scenario' or to 'speculate' or 'guess what could have happened in a counterfactual setting' by assessing corporate motives and thought processes or by 'evaluat[ing] inference[s] about human behavior.'" (March 27, 2017 28(j) letter at 2 (alterations in original) (quoting *Fosamax*, 852 F.3d at 289, 297, 299).) Their argument is correct, but irrelevant. The fact that juries may predict the outcome of hypothetical scenarios says nothing about the type or amount of evidence that is needed for a plaintiff to withstand summary judgment on a claim involving a counterfactual scenario. As explained above, the Appellants have not presented sufficient evidence upon which a reasonable jury could rely to conclude that it is more likely than not that Anchen and Andrx would have entered into a license agreement in the counterfactual world. While it may be better than speculative that Anchen and Andrx would have had an incentive to talk, it is, on this record, pure speculation that they would have reached an agreement.

reasonable jury could infer that the two companies would have reached an agreement. But this argument too is completely speculative. It is certainly possible that Anchen and Andrx would have reached an agreement, but it is also certainly possible that the negotiations would have stalled and failed. Many a contract has foundered on a single deal-breaker point. Without more specific or concrete evidence, the jury in this case would be left with nothing on which it could rely to reach a conclusion one way or the other. Summary judgment was thus appropriate.

(2) Litigation-Based Scenario

The Appellants' litigation-based scenario is premised on the idea that Anchen would have prevailed in Andrx's infringement suit. If Andrx's '708 patent were invalid, or if it did not cover Anchen's product, then patent law would not have prevented Anchen's launch. In order to evaluate the merit of the litigation-based scenario, we must consider the substance of that underlying litigation.[58]

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[58] In the *Actavis* decision, there was a debate between the majority and the Chief Justice on whether lower courts would be required to resolve substantive patent questions in order to adequately assess the merits of reverse payment antitrust claims. Writing for the majority, Justice Breyer asserted that "it is normally not necessary to litigate patent validity to answer the antitrust question ... ." *Actavis*, 133 S. Ct. at 2236. The Chief Justice disagreed:

> [S]ettling a patent claim *cannot possibly* impose unlawful anticompetitive harm if the patent holder is acting within the scope of a valid

The Appellants make two arguments relative to the merits of the patent litigation. First, they say that we should view the size of the reverse payment as "a surrogate for [the] patent's weakness" and conclude that GSK "knew [that Andrx's patent] could *not* prevent generic competition." (Op. Br. 86.) While the size of a reverse payment may have some relevance in determining how confident a litigant is in the strength of its case, *Actavis*, 133 S. Ct. at 2236-37 ("In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness ... ."), it is far from dispositive. That is especially so when, as in this case, the settlement is complex and multi-faceted. For

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> patent and therefore permitted to do precisely what the antitrust suit claims is unlawful. This means that in any such antitrust suit, the defendant (patent holder) will want to use the validity of his patent as a defense—in other words, he'll want to say "I can do this because I have a valid patent that lets me do this." I therefore don't see how the majority can conclude that it won't normally be "necessary to litigate patent validity to answer the antitrust question[.]"

Id. at 2244 (Roberts, C.J., dissenting). The present case appears to vindicate the Chief Justice's analysis. As he predicted, GSK argues that the Andrx patent (which was a central component of the agreements) defeats the Appellants' suit, and, as he predicted, we cannot resolve this aspect of the case without considering the merits of the underlying patent dispute.

example, GSK and Biovail may have offered the reverse payment not because they thought Andrx had a weak patent but rather because they thought Anchen would improperly evaluate the patent and launch at-risk.[59] In that scenario, GSK would lose substantial revenue from having a generic competitor and would not be entitled to damages if the patent were vindicated because the patent belonged to Andrx, not to GSK. That there are multiple plausible ways to interpret the reverse payment in this case means that the payment alone tells us less about the merits of the underlying case than the Appellants wish.

We are also persuaded by an argument raised in the amicus brief filed by a group of antitrust economists ("the Economists"). That group explains why risk aversion makes it difficult to use the size of a settlement as a proxy for the brand-name's likelihood of success in litigation:

> To explore why risk aversion could lead to the exchange of consideration having nothing to do with delayed entry, consider a lottery ticket with a 50% chance of a $0 payoff and a 50% chance of a $100 million payoff—*i.e.*, the lottery ticket has an expected payoff of $50 million. Most people holding such a ticket would be willing to accept less than the expected payoff amount to

[59] In the context of patent litigation, a launch is said to be "at-risk" if it takes place before the questions of infringement and validity are resolved, either through litigation or a license. *See In re Modafinil Antitrust Litig.*, 837 F.3d at 244.

> achieve certainty. If a person would trade the aforementioned lottery ticket for a certain outcome of $20 million, he or she would essentially be willing to pay $30 million dollars to eliminate the risk of holding the lottery ticket that might result in the $0 payoff. Accepting the certain outcome of $20 million dollars, however, does not reflect a belief that a $0 payoff is anything more than [a] 50% [risk].

(Antitrust Economists Br. 11 (internal citation omitted).) We think that reasoning serves as an effective rebuttal to the Appellants' claim that the size of the reverse payment is a "surrogate" for the weakness of the '708 patent.

The Appellants' second argument relating to the litigation-based scenario relies on testimony provided by Martin Adelman, GSK's expert. Adelman estimated that Andrx had an 80% chance of prevailing with respect to infringement, a 50% chance of prevailing with respect to validity, and a 90% chance of prevailing with respect to inequitable conduct.[60] Because Andrx would have to prevail with respect to all three issues in order to win the case, Adelman concluded that "Andrx had approximately a one out of three chance of winning the cases."[61] (JA 38717.)

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[60] Adelman's estimates and analysis are uncontested.

[61] The probability that Andrx would prevail on all three issues was calculated by multiplying the probability of success on each issue. 0.8*0.9*0.5=0.36, which is approximately 1/3.

However, in a bit of historical irony, it was Anchen's founder and CEO who made the invention disclosed in the '708 patent, and he assigned his rights in it to Andrx. Accordingly, it is highly likely that assignor estoppel would have prevented Anchen from arguing that the '708 patent was invalid or that the patent was unenforceable because of inequitable conduct.[62] *Mentor Graphics Corp. v. Quickturn Design Sys., Inc.*, 150 F.3d 1374, 1378-79 (Fed. Cir. 1998) (describing the doctrine of assignor estoppel and explaining that the doctrine "also prevents parties in privity with an estopped assignor from challenging the validity of the patent"); *Shamrock Techs., Inc. v. Med. Sterilization, Inc.*, 903 F.2d 789, 793 (Fed. Cir. 1990) (same). As a result, the only topic left for litigation would be whether Anchen infringed. On that point, Adelman's unrebutted analysis was that Andrx would have an

[62] "Assignor estoppel prevents a party who assigns a patent to another from later challenging the validity of the assigned patent. This doctrine prevents the unfairness and injustice of permitting a party to sell something and later to assert that what was sold is worthless. ... [A]n assignment contains an implicit representation by the assignor that the patent rights that he is assigning ... are not worthless." *Mentor Graphics Corp., v. Quickturn Design Sys., Inc.*, 150 F.3d 1374, 1378 (Fed. Cir. 1998) (internal quotation marks and citations omitted); *see Shamrock Techs., Inc. v. Med. Sterilization, Inc.*, 903 F.2d 789, 793 (Fed. Cir. 1990) (explaining assignor estoppel also applies to those who are in privity with the assignor). Because the estoppel applies not only to the individual inventor but also to those in privity, Anchen itself, and not just its founder and CEO, would likely have been estopped.

80% chance of proving infringement – or, in other words, that Anchen would only have a 20% chance of winning the suit.[63] Neither the Appellants nor GSK identify any other evidence in the record that speaks to the possible outcomes of the Anchen-Andrx litigation. On this record, then, no reasonable jury could conclude that Anchen would have been more likely than not to prevail.

Because both of the scenarios advanced by the Appellants fail to show that Anchen would have been able to launch its 150 mg version of Wellbutrin XL without running afoul of the Andrx patent, we conclude that the Appellants have also failed to show that their injuries were caused by the overall settlement. Because the Appellants thus do not have antitrust standing, we will affirm the District Court's grant of summary judgment.[64]

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[63] The Appellants' only response to that analysis is that GSK never moved for summary judgment on inventor estoppel and that Anchen had not raised the issue of assignor estoppel before it settled the case. Even if those assertions are true, they do not show that Andrx would not have asserted the estoppel argument as the case progressed.

[64] Having concluded that the Appellants lack antitrust standing, we do not need to consider the District Court's application of the rule of reason. We note, however, that the rule of reason inquiry is fact intensive and is not easy to resolve at the summary judgment stage. *See Poller v. Columbia Broad. Sys., Inc.*, 368 U.S. 464, 473 (1962) ("[S]ummary procedures should be used sparingly in complex antitrust litigation where motive and intent play leading roles, the proof is largely in the hands of the alleged conspirators,

C. Class Certification, *Daubert*, and Intervention Issues

Because we affirm the District Court's grant of summary judgment on the merits, we need not address those other issues on appeal.[65] *Cf. Bowen v. Owens*, 476 U.S. 340, 344 n.4 (1986) ("Because we reject the equal protection claim, we do not reach the class certification issue."); *Wilson v. Quadramed Corp.*, 225 F.3d 350, 353 n.3 (3d Cir. 2000) ("We do not reach the class certification issue raised by Wilson since we [will] affirm the District Court's dismissal of the complaint ... .").

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and hostile witnesses thicken the plot."); *W. Penn Allegheny Health Sys.*, 627 F.3d at 99 (describing the rule-of-reason as "fact intensive"); *cf. King*, 791 F.3d at 411 n.36 (describing the significance of fact finding in the rule of reason analysis).

[65] To recap, those issues are the decisions excluding the testimony of their economic expert and denying Aetna's motion to intervene. Additionally, the indirect-purchaser Appellants challenge the District Court orders decertifying the indirect-purchaser class and dismissing certain of the indirect purchasers' claims for lack of standing. Finally, GSK conditionally cross-appeals the Court's certification of the direct-purchaser class as well as the Court's conclusion that the indirect purchasers satisfy the predominance requirement of Rule 23.

III. Conclusion

For the foregoing reasons, we will affirm the District Court's grant of summary judgment.