PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 18-2621

FEDERAL TRADE COMMISSION,
Appellant

v.

ABBVIE INC.; ABBOTT LABORATORIES; UNIMED PHARMACEUTICALS, LLC; BESINS HEALTHCARE, INC.; *TEVA PHARMACEUTICALS USA, INC.

(*Dismissed Pursuant to Court's 3/12/19 Order.)

No. 18-2748

FEDERAL TRADE COMMISSION

v.

ABBVIE INC.; ABBOTT LABORATORIES; UNIMED PHARMACEUTICALS, LLC; BESINS HEALTHCARE, INC.; *TEVA PHARMACEUTICALS USA, INC.

Abbvie Inc.; Abbott Laboratories; Unimed Pharmaceuticals, LLC,
Appellants

(*Dismissed Pursuant to Court's 3/12/19 Order.)

No. 18-2758

FEDERAL TRADE COMMISSION

v.

ABBVIE INC.; ABBOTT LABORATORIES; UNIMED PHARMACEUTICALS, LLC;
BESINS HEALTHCARE, INC.; *TEVA PHARMACEUTICALS USA, INC.

Besins Healthcare, Inc.,
Appellant

(*Dismissed Pursuant to Court's 3/12/19 Order.)

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. No. 2-14-cv-05151)
District Judge: Honorable Harvey Bartle, III

Argued on January 15, 2020

Before: HARDIMAN, PORTER and PHIPPS, *Circuit Judges*.

(Filed: September 30, 2020)

Mark S. Hegedus
Federal Trade Commission
MS-582
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Matthew M. Hoffman [Argued]
Joel R. Marcus
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Attorneys for Federal Trade Commission

Brittany Amadi
Catherine M.A. Carroll
Leon B. Greenfield
Seth P. Waxman [Argued]
WilmerHale
1875 Pennsylvania Avenue, N.W.
Washington, DC 20006

Elaine J. Goldenberg
Munger Tolles & Olson
601 Massachusetts Avenue, N.W.
Suite 500e
Washington, DC 20001

Adam R. Lawton

Stuart N. Senator
Jeffrey I. Weinberger
Munger Tolles & Olson
350 South Grand Avenue
50th Floor
Los Angeles, CA 90071

William F. Lee
WilmerHale
60 State Street
Boston, MA 02109

Paul H. Saint-Antoine
John S. Yi.
Faegre Drinker Biddle & Reath
One Logan Square
Suite 2000
Philadelphia, PA 19103

Attorneys for AbbVie Inc, Abbott Laboratories, and Unimed Pharmaceuticals LLC

Melinda F. Levitt
Gregory E. Neppl [Argued]
Foley & Lardner
3000 K Street, N.W.
Suite 600
Washington, DC 20007

Paul H. Saint-Antoine
John S. Yi
Faegre Drinker Biddle & Reath
One Logan Square

Suite 2000
Philadelphia, PA 19103

Attorneys for Besins Healthcare, Inc.

William A. Rivera
AARP Foundation Litigation
B4-230
601 E Street, N.W.
Washington, DC 20049

Attorney for Amici AARP and AARP Foundation

Ilana H. Eisenstein
DLA Piper
1650 Market Street
One Liberty Place, Suite 5000
Philadelphia, PA 19103

Attorney for Amicus Chamber of Commerce of the United States of America

Bradford J. Badke
Sidley Austin
787 Seventh Avenue
New York, NY 10019

Attorney for Amicus Amgen Inc

Andrew D. Lazerow
Covington & Burling
850 10th Street, N.W.
One City Center

Washington, DC 20001

Attorney for Amicus Pharmaceutical Research and Manufacturers of America

Richard M. Brunell
Hilliard & Shadowen
1135 West 6th Street
Suite 125
Austin, TX 78703

Attorney for Amici American Antitrust Institute, Public Citizen Inc, and Public Knowledge

---

OPINION OF THE COURT

HARDIMAN, *Circuit Judge*.

TABLE OF CONTENTS

I. FACTUAL BACKGROUND 9
A. FDA Approval under the Hatch-Waxman Act 9
B. Patent disputes under the Hatch-Waxman Act 11
C. Therapeutic equivalence ratings 12
D. Hypogonadism and testosterone replacement therapies 13
E. AndroGel 14

F. The ’894 patent’s prosecution history....15
G. AndroGel’s competitors....18
H. The lawsuits against Teva and Perrigo....18
I. The settlements with Perrigo and Teva....21
J. Teva and Perrigo’s generic versions of AndroGel....23
II. PROCEDURAL HISTORY....24
III. JURISDICTION....26
IV. LIABILITY....35
A. The District Court erred by rejecting the reverse-payment theory....35
B. The District Court erred in concluding AbbVie and Besins’s litigation against Teva was a sham; it did not err in concluding the Perrigo litigation was a sham....53
C. The District Court did not err in concluding AbbVie and Besins had monopoly power in the relevant market....77
V. REMEDIES....83
A. The District Court erred in ordering disgorgement....83
B. The District Court did not abuse its discretion in denying injunctive relief....93
C. Remand on the reverse-payment theory is not futile....97

This appeal involves a patented drug called AndroGel. A blockbuster testosterone replacement therapy that generated billions of dollars in sales, AndroGel caught the attention of the Federal Trade Commission. The FTC sued the owners of an AndroGel patent—AbbVie, Inc., Abbott Laboratories, Unimed Pharmaceuticals LLC, and Besins Healthcare, Inc.—under Section 13(b) of the Federal Trade Commission Act in the United States District Court for the Eastern District of Pennsylvania. The FTC alleged that Defendants filed sham patent infringement suits against Teva Pharmaceuticals USA, Inc. and Perrigo Company, and that AbbVie, Abbott, and Unimed entered into an anticompetitive reverse-payment agreement with Teva. The FTC accused Defendants of trying to monopolize and restrain trade over AndroGel.

The District Court dismissed the FTC's claims to the extent they relied on a reverse-payment theory but found Defendants liable for monopolization on the sham-litigation theory. The Court ordered Defendants to disgorge $448 million in ill-gotten profits but denied the FTC's request for an injunction. The parties cross-appeal.

We hold the District Court erred by rejecting the reverse-payment theory and in concluding Defendants' litigation against Teva was a sham. The Court did not err, however, in concluding the Perrigo litigation was a sham and that Defendants had monopoly power in the relevant market. Yet the FTC has not shown the monopolization entitles it to any remedy. The Court did not abuse its discretion in denying injunctive relief; and the Court erred by ordering disgorgement because that remedy is unavailable under Section 13(b) of the FTC Act. Accordingly, we will reinstate the FTC's dismissed claims and remand for further proceedings consistent with this opinion. We will also affirm in part and reverse in part the

Court's order adjudging Defendants liable for monopolization. Finally, we will affirm the Court's order denying injunctive relief and reverse the Court's order requiring Defendants to disgorge $448 million.

I. FACTUAL BACKGROUND

A. FDA Approval under the Hatch-Waxman Act

The Food, Drug, and Cosmetic Act (the FDC Act), 21 U.S.C. § 301 *et seq.*, empowers the Food and Drug Administration (FDA) to regulate the manufacture and sale of drugs in the United States. Before a pharmaceutical company can market a drug, it must obtain FDA approval. *Id.* § 355(a). Under the FDC Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), 21 U.S.C. § 355 and 35 U.S.C. § 271, a company can apply for FDA approval in one of three ways:

1. *Section 505(b)(1) New Drug Application (NDA)*. This is a "full-length" application. *FTC v. AbbVie Inc.*, 329 F. Supp. 3d 98, 107 (E.D. Pa. 2018). The "gauntlet of procedures" associated with it is "long, comprehensive, and costly." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 143 (3d Cir. 2017) (citation omitted). It includes "full reports of investigations" into whether the drug is safe and effective, a "full list of . . . [the drug's] components," a "full description of the methods used in . . . the manufacture, processing, and packing" of the drug, samples of the drug, and specimens of the labeling the company proposes to use. 21 U.S.C. § 355(b)(1). A company must also list any relevant patents. *See Wellbutrin*, 868 F.3d at 144 (citation omitted). We refer

to drugs approved through this process as "brand-name" drugs.

2. *Section 505(j) Abbreviated New Drug Application (ANDA)*. This streamlined application is appropriate for a company seeking to market a generic version of a brand-name drug. The company need not produce its own safety and efficacy data. 21 U.S.C. § 355(j)(2)(A)(vi). But it must show that the generic drug is "the same" as the brand-name drug in certain relevant respects. *Id.* § 355(j)(2)(A). It also must "assure the FDA that its proposed generic drug will not infringe the brand's patents." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012). It can do so by certifying that the manufacture, use, or sale of the generic will not infringe patents relating to the brand-name drug, or that those patents are invalid. 21 U.S.C. § 355 (j)(2)(A)(vii)(IV). This certification is known as a "paragraph IV notice." *AbbVie*, 329 F. Supp. 3d at 108.

   The first company to seek FDA approval in this way enjoys "a period of 180 days of exclusivity," during which "no other generic can compete with the brand-name drug." *FTC v. Actavis, Inc.*, 570 U.S. 136, 143–44 (2013) (citing 21 U.S.C. § 355 (j)(5)(B)(iv)). "[T]his 180-day period . . . can prove valuable, possibly worth several hundred million dollars." *Id.* at 144 (internal quotation marks and citation omitted). One exception is that during the 180-day exclusivity period, the brand-name company can produce a generic version of its own drug or license a third party to do so. *See Mylan Pharm., Inc. v. FDA*, 454 F.3d 270, 276–77 (4th Cir. 2006). These "authorized generics" can decrease the value an

applicant receives from the 180-day exclusivity period to the extent they share the generic drug market and depress prices. *See id.* at 273.

3. *Section 505(b)(2) New Drug Application (hybrid NDA).* This application is appropriate for a company seeking to modify another company's brand-name drug. For example, a company might seek FDA approval of "a new indication or new dosage form." 21 C.F.R. § 314.54(a). This application is like an ANDA because the company need not produce all safety and efficacy data about the drug and because it must assure the FDA that its generic drug will not infringe the brand's patents. *See* 21 U.S.C. § 355(b)(2)(A)(iv). But it differs from an ANDA because the company must produce some data, including whatever "information [is] needed to support the modification(s)." 21 C.F.R. § 314.54(a).

The latter two pathways "speed the introduction of low-cost generic drugs to market" and promote competition in the pharmaceutical industry. *Actavis*, 570 U.S. at 142 (internal citation omitted).

B. Patent disputes under the Hatch-Waxman Act

The Hatch-Waxman Act also has provisions that encourage the quick resolution of patent disputes. *See Wellbutrin*, 868 F.3d at 144. A paragraph IV notice "automatically counts as patent infringement." *Id.* (quoting *Actavis*, 570 U.S. at 143 (citing 35 U.S.C. § 271(e)(2)(A))). After receiving this notice, a patentee has 45 days to decide whether to sue. 21 U.S.C. § 355(j)(5)(B)(iii).

To help a patentee make that decision, the company seeking approval of a generic drug often allows the patentee's outside counsel to review the company's application in secret. If the patentee sues within the time limit, the FDA cannot approve the company's application for a generic drug until one of three things happens: (1) a court holds that the patent is invalid or has not been infringed; (2) the patent expires; or (3) 30 months elapse, as measured from the date the patentee received the paragraph IV notice. 21 U.S.C. § 355(j)(5)(B)(iii).

The automatic, 30-month stay creates tension with the Hatch-Waxman Act's procompetitive goals. Simply by suing, a patentee can delay the introduction of low-cost generic drugs to market and impede competition in the pharmaceutical industry. *Cf. Actavis*, 570 U.S. at 142.

C. Therapeutic equivalence ratings

After the FDA approves a company's generic drug, the company can seek a therapeutic equivalence (TE) rating. "Products that are determined to be therapeutically equivalent [to the brand] are assigned an 'A' or 'AB' rating. Generic products for which therapeutic equivalence cannot be determined are assigned a 'B' or 'BX' rating." *AbbVie*, 329 F. Supp. 3d at 107. Generic drug companies usually prefer A or AB ratings because every state's law "either permit[s] or require[s] pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug." *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd.*, 838 F.3d 421, 428 (3d Cir. 2016) (internal quotation marks and citations omitted).

D. Hypogonadism and testosterone replacement therapies

Hypogonadism is a clinical syndrome resulting from low testosterone in the human body. *See AbbVie*, 329 F. Supp. 3d at 108. It affects an estimated 2-6 percent of the adult male population in the United States and causes "decreases in energy and libido, erectile dysfunction, and changes in body composition." *Id.*

Doctors treat hypogonadism with testosterone replacement therapies (TRTs). TRTs include injectables, topical/transdermals (TTRTs), and other therapies. Companies first marketed injectables in the 1950s. Because generic injectables have been available for decades, they are the least expensive. They involve dissolving testosterone in a liquid and injecting it into the patient's body every one to three weeks. Some patients administer injections to themselves at home, while others receive injections at their doctor's office or a specialized testosterone clinic. By contrast, TTRTs first appeared in the 1990s and are more expensive. They deliver testosterone to the patient's body through a patch or gel applied to the patient's skin. Gels are applied daily.

TRTs have different benefits and drawbacks. Some patients dislike injectables because the injection is painful, or because the "peak in testosterone level" after the injection causes "swings in mood, libido, and energy." *Id.* at 109. Many of these patients prefer TTRTs because they release testosterone steadily. Other patients dislike TTRT gels. Common complaints include skin irritation and the inconvenience of having to apply the gel daily. And patients sometimes transfer the testosterone gel to others inadvertently through skin-to-skin contact. Finally, some patients dislike

TTRT patches, which can irritate the skin and are visible to other people, depending on where the patch is applied.

E. AndroGel

In the 1990s, Laboratoires Besins International S.A.S. (LBI)—a corporate affiliate of Besins's parent company—developed the TTRT gel that became AndroGel. In 1995, LBI licensed to Unimed certain intellectual property relating to the gel, and Unimed assumed responsibility for marketing the gel in the United States. In exchange, Unimed agreed to pay LBI a royalty on the gel's net sales. Unimed secured FDA approval for the gel in 2000. That same year, Unimed and Besins filed a joint U.S. patent application, and, in 2003, U.S. Patent No. 6,503,894 (the '894 patent) issued.

Today, Besins and AbbVie co-own the '894 patent. AbbVie acquired Unimed's interest in the patent as follows: in 1999, Unimed was acquired by Solvay; in 2010, Solvay was acquired by Abbott; in 2013, Abbott separated into two companies—Abbott and AbbVie—with AbbVie assuming all of Abbott's propriety pharmaceutical business, including its interest in AndroGel.

Solvay brought AndroGel to market in 2000. At the time, AndroGel was available only in a sachet form at 1% strength. From 2004-2013, Solvay and its successors marketed AndroGel in a metered-dose pump form. And in 2011, Abbott started marketing AndroGel at 1.62% strength. Sales of AndroGel 1.62% grew more slowly than anticipated, but by June 2012, they comprised most of AndroGel's total sales.

AndroGel has been a huge commercial success. Its annual net sales sometimes surpassed a billion dollars and

remained strong even after generic versions of AndroGel entered the market in 2015. From 2009-2015, it generated a high profit margin of about 65 percent.

F. The ’894 patent’s prosecution history

TTRT gels use “penetration enhancers” to accelerate the delivery of testosterone through a patient’s skin. AndroGel’s penetration enhancer is isopropyl myristate.

Unimed and Besins’s joint patent application was U.S. Patent Application Serial No. 09/651,777. As originally drafted, claim 1 of the patent application claimed *all* penetration enhancers:

> A pharmaceutical composition useful for the percutaneous delivery of an active pharmaceutical ingredient, comprising:
>
> (a) a C1-C4 alcohol;
>
> (b) *a penetration enhancer*;
>
> (c) the active pharmaceutical ingredient; and
>
> (d) water.

App. 909 (emphasis added). The penetration enhancers then in existence numbered in the tens of millions.

In June 2001, the patent examiner rejected this claim as obvious over two prior art references—Mak in view of Allen. Mak disclosed the penetration enhancer oleic acid used in a transdermal testosterone gel. Allen disclosed isopropyl myristate, isopropyl palmitate, and three other penetration

enhancers used in a nitroglycerin cream. The examiner explained that "since all composition components herein are known to be useful for the percutaneous delivery of pharmaceuticals, it is considered prima facie obvious to combine them into a single composition useful for the very same purpose." App. 1014–16.

In October 2001, Unimed and Besins amended the patent application's claim 1 to recite at least one of 24 penetration enhancers, including isopropyl myristate and isostearic acid. Isopropyl palmitate was not among the 24. Unimed and Besins also added several new claims. Claim 47 recited "a penetration enhancer selected from the group consisting of isopropyl myristate and lauryl alcohol." App. 1022. And claims 61 and 62 recited only isopropyl myristate as a penetration enhancer.

Unimed and Besins sought "reconsideration and withdrawal of the [obviousness] rejections and allowance of the[se] claims." App. 1039. In support, they cited AndroGel's commercial success. *See id.*; *see generally Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966) (holding commercial success is a "secondary consideration" suggesting nonobviousness). They also argued "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." App. 1030–31 (citations omitted). For three reasons, they said, the prior art did not suggest combining Mak and Allen. First, Mak "[taught] away from using the presently claimed penetration enhancers by focusing on the superiority of oleic acid." App. 1032. Second, the claimed penetration enhancers had an "unexpected and unique pharmacokinetic and phamacodynamic profile." *Id.* And third, "the prior art recognize[d] the chemical and

physiologic/functional differences of penetration enhancers, including the differences between oleic acid and the claimed enhancers, such as isopropyl myristate." App. 1037–38.

Attorneys for Unimed and Besins then met with the examiner for an interview. The examiner opined that "claims 61-62 are . . . allowable over the prior art." App. 1084. She also noted that the attorneys "argued claim 47 is novel [and] nonobvious over the prior art because the prior art does not teach the composition with particular concentrations [of isopropyl myristate and lauryl alcohol]." *Id.*

In December 2001 and February 2002, Unimed and Besins twice more amended the patent application. They cancelled claims 1 and 62, amended claim 47 to cover only a composition comprising isopropyl myristate, and modified the concentration ranges for isopropyl myristate in claim 61. With each amendment, they sought "reconsideration and withdrawal of the [obviousness] rejections and allowance of the[se] claims." App. 1095, 1129.

The examiner issued a notice of allowability. She wrote that "[t]he claimed pharmaceutical composition consisting essentially of the particular ingredients herein in the specific amounts, is not seen to be taught or fairly suggested by the prior art." App. 1152. She clarified that she considered the amendments "all together," and they sufficed to "remove the prior art rejection . . . over [Mak in view of Allen]." *Id.*

In January 2003, the '894 patent issued. It expired on August 30, 2020.

G. AndroGel's competitors

When Solvay brought AndroGel to market in 2000, its only competitors were injectables and two TTRT patches (*i.e.*, Testoderm and Androderm). Since then, companies have marketed four other TTRT gels (*i.e.*, Testim, Axiron, Fortesta, and Vogelxo). Companies have also developed other TRTs, including Striant (a buccal tablet applied twice daily to a patient's gums), Testopel (a pellet surgically inserted into a patient's body every three to six months), and Natesto (a nasal spray administered three times a day).

H. The lawsuits against Teva and Perrigo

In December 2008, Perrigo filed two ANDAs for a generic 1% testosterone gel in sachet and pump forms, and in June 2009 it served paragraph IV notices on Unimed and Besins. It asserted that because its gel used the penetration enhancer isostearic acid instead of isopropyl myristate, the gel would not literally infringe the '894 patent. It also argued the gel would not infringe the patent under the doctrine of equivalents, which provides that "[t]he scope of a patent . . . embraces all equivalents to the claims described." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. ("Festo VIII")*, 535 U.S. 722, 732 (2002). Perrigo explained the '894 patent's prosecution history would estop Unimed and Besins from claiming equivalency between isostearic acid and isopropyl myristate, because they originally claimed isostearic acid before excluding it in response to a rejection. This limitation on the doctrine of equivalents is known as prosecution history estoppel. *Id.* at 733–34.

Solvay, Unimed, and Besins retained outside counsel to review Perrigo's ANDAs. In July 2009, Solvay and Unimed

issued a press release stating that they had carefully evaluated the ANDAs and decided not to sue Perrigo, in part because Perrigo's gel "contains a different formulation than the formulation protected by the AndroGel patent." *AbbVie*, 329 F. Supp. 3d at 111. Besins also decided not to sue.

That same year, the FDA learned that patients were accidentally transferring TTRT gels to children through skin-to-skin contact. AndroGel's new owner Abbott petitioned the FDA to require Perrigo to resubmit its 2009 ANDAs as hybrid NDAs. *See* 21 C.F.R. § 10.30 (FDA citizen petition form). That would require Perrigo to investigate whether isostearic acid poses a higher risk of accidental transfer than isopropyl myristate. Abbott also asked the FDA to require Perrigo to serve new paragraph IV notices on Abbott and Besins, thereby reopening the 45-day window for them to decide whether to sue. The FDA granted Abbott's petition in relevant part.

In January 2011, Teva filed a hybrid NDA for a generic 1% testosterone gel in sachet and pump forms, and in March 2011 it served paragraph IV notices on Abbott, Solvay, Unimed, and Besins. Teva asserted its gel would not literally infringe the '894 patent because it used isopropyl palmitate instead of isopropyl myristate. It also explained that the '894 patent's prosecution history would estop Abbott and Besins from claiming infringement on the ground that isopropyl palmitate is equivalent to isopropyl myristate. Abbott and Besins retained outside counsel to review Teva's hybrid NDA.

On April 29, 2011, Abbott, Unimed, and Besins sued Teva for patent infringement in the United States District Court for the District of Delaware. They argued that isopropyl myristate and isopropyl palmitate were equivalent. The lawsuit triggered the Hatch-Waxman Act's automatic, 30-month stay

on FDA approval for Teva's gel. Teva responded that prosecution history estoppel applied because Unimed and Besins's October 2001 amendment—which narrowed the application's claim 1 from all penetration enhancers to a list of 24—surrendered isopropyl palmitate. Abbott, Unimed, and Besins disagreed. They cited an exception to prosecution history estoppel—known as "tangentiality"—that applies if "the rationale underlying the amendment [bore] no more than a tangential relation to the equivalent in question." *Festo VIII*, 535 U.S. at 740. Abbott, Unimed, and Besins argued the October 2001 amendment sought to overcome Mak's use of oleic acid and was thus tangential to isopropyl palmitate, which Allen disclosed. The Court set trial for May 2012.

In July 2011, Perrigo filed a hybrid NDA for generic 1% testosterone gel, and in September 2001, it served new paragraph IV notices on Abbott, Unimed, and Besins. It again asserted its gel would not infringe the '894 patent. And it added that "a lawsuit asserting the '894 patent against Perrigo would be objectively baseless and a sham, brought in bad faith for the improper purpose of, *inter alia*, delaying Perrigo's NDA approval." *AbbVie*, 329 F. Supp. 3d at 114. A bad faith motive for suing would be "particularly apparent," Perrigo said, in light of Solvay's July 2009 press release. *Id.* Abbott, Unimed, and Besins retained outside counsel to review Perrigo's hybrid NDA.

In August 2011, Abbott petitioned the FDA not to grant therapeutic equivalence ratings to hybrid NDAs referencing AndroGel. Alternatively, it asked the FDA to assign such products BX ratings.

On October 31, 2011, Abbott, Unimed, and Besins sued Perrigo in the United States District Court for the District of

New Jersey. That lawsuit triggered the Hatch-Waxman Act's automatic, 30-month stay on FDA approval for Perrigo's gel.

Four in-house patent attorneys in AbbVie's intellectual property group and AbbVie's general counsel decided to sue Teva and Perrigo. Those attorneys had "extensive experience in patent law and with AbbVie." *See id.* at 113. However, "[n]o business persons at AbbVie were involved in the decision to sue." *Id.* As for Besins, its in-house counsel Thomas MacAllister decided to sue. MacAllister is an experienced intellectual property attorney and a former patent examiner.

I. The settlements with Perrigo and Teva

In December 2011, Abbott and Perrigo settled. They agreed to dismiss all claims and counterclaims with prejudice; Abbott agreed to pay Perrigo $2 million as reasonable litigation expenses; and Abbott agreed to license Perrigo to market its generic 1% testosterone gel on either January 1, 2015 or when another generic version came to market, whichever was sooner. **(**The last provision is known as an acceleration clause). Perrigo unsuccessfully pushed for an earlier market entry date in settlement negotiations. Its assistant general counsel Andrew Solomon later said he predicted the acceleration clause would provide Perrigo with an earlier entry date, because he saw "a very good probability Teva could prevail" against Abbott and Besins at trial in the other lawsuit. *AbbVie*, 329 F. Supp. 3d at 115. He also said he advised Perrigo that it had a 75 percent chance of success, had the litigation proceeded to trial. He explained this figure meant Perrigo felt "very, very strongly about [its] chances for success, recognizing that there is [an] inherent uncertainty . . . any time a case gets in front of an arbiter." App. 4071.

Abbott and Teva also settled in December 2011, soon after the court set a trial date. Abbott agreed to license Teva to market its generic 1% testosterone gel on December 27, 2014—almost six years before the '894 patent expired. Teva pushed unsuccessfully for an earlier market–entry date in settlement negotiations.

On the same day Abbott and Teva settled the infringement suit, they also made a deal involving a popular brand-name cholesterol drug named TriCor. A previous settlement between Abbott and Teva had set Teva's entry in the TriCor market for July 2012. And because Teva was the first generic challenger to TriCor, Teva was entitled to 180 days of marketing exclusivity. Teva was struggling to capitalize on the exclusivity period, though, because it could not secure FDA approval. In the December 2011 deal, Abbott agreed to grant Teva a license to sell a generic version of TriCor, which Abbott would supply to Teva at Teva's option, for a four-year term beginning in November 2012. This supply agreement provided for Teva to pay Abbott the costs of production, an additional percentage of that cost, and a royalty.

According to the FTC, the December 2011 settlement agreement and TriCor deal were an illegal reverse payment. A reverse payment occurs when a patentee, as plaintiff, pays an alleged infringer, as defendant, to end a lawsuit. *See Wellbutrin*, 868 F.3d at 142 n.3 (citing *Actavis*, 570 U.S. at 140–41). Such agreements can be anticompetitive if they allow a brand-name company to split its monopoly profits with a generic company in exchange for the generic agreeing to delay market entry. As applied here, the FTC alleges Abbott calculated that it would sacrifice about $100 million in TriCor sales, but that was a small fraction of the billions of dollars in AndroGel revenue it protected by deferring competition in the

TTRT market for three years. Deferring competition also gave Abbott time to shift sales to Androgel 1.62%, for which there were no generic competitors. As for Teva, it "concluded that it would be better off by sharing in AbbVie[']s monopoly profits from the sale of AndroGel than by competing." App. 4418.

Teva's settlement triggered the acceleration clause in Perrigo's settlement agreement, so Perrigo's licensed entry date became December 27, 2014.

J. Teva and Perrigo's generic versions of AndroGel

In February 2012, the FDA approved Teva's hybrid NDA for the sachet form of its generic 1% testosterone gel. Teva withdrew the pump form from its application after the FDA identified a safety concern with the packaging. But the FDA allowed Teva to resubmit the pump form as a post-approval amendment.

In January 2013, the FDA approved Perrigo's hybrid NDA for generic 1% testosterone gel. It then considered the gel's therapeutic equivalence rating. Perrigo sent the FDA three letters to expedite the FDA's consideration. AbbVie petitioned the FDA to issue Perrigo's product a BX rating.

In March 2014, Perrigo sued the FDA, accusing it of unreasonable delay. The FDA responded that "Perrigo has itself obviated the need for a prompt decision by reaching an agreement with [Abbott] not to market until December 2014." *AbbVie*, 329 F. Supp. 3d at 116. It said it expected to rate Perrigo's gel "by July 31, 2014—some five months before Perrigo's planned product launch." *Id.* On July 23, 2014, the FDA issued the gel an AB rating, and Perrigo dismissed its lawsuit against the FDA. *See id.* at 116, 116 n.9. Perrigo

brought its gel to market on December 27, 2014, its licensed entry date.

Also on July 23, 2014, the FDA issued Teva's gel a BX rating. Teva never marketed the product.

II. PROCEDURAL HISTORY

The FTC sued AbbVie, Abbott, Unimed, Besins, and Teva under Section 13(b) of the FTC Act in the United States District Court for the Eastern District of Pennsylvania. 15 U.S.C. § 53(b). We refer to AbbVie, Abbott, Unimed, and Solvay as "AbbVie" for simplicity.

In Count I of the complaint, the FTC alleged AbbVie and Besins willfully maintained a monopoly through a course of anticompetitive conduct, including sham patent litigation against Teva and Perrigo. In Count II, the FTC alleged AbbVie restrained trade by entering into an anticompetitive reverse-payment agreement with Teva. The FTC requested that the Court enjoin AbbVie and Besins "from engaging in similar and related conduct in the future," and that the Court "grant such other equitable [monetary] relief as [it] finds necessary, including restitution or disgorgement." App. 4454.

AbbVie and Besins moved to dismiss "Count I to the extent it [wa]s premised on the" alleged reverse payments, under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Dkt. 2:14-cv-05151, ECF No. 38 at 1. AbbVie also moved to dismiss Count II in its entirety, as it was based only on the reverse-payment theory. The District Court granted both motions.

The FTC moved for reconsideration after our decision in *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015). But the District Court distinguished *King Drug* and denied the motion.

The FTC then moved for partial summary judgment on the sham-litigation theory supporting Count I. AbbVie and Besins sought summary judgment as well.

The sham-litigation theory required the FTC to prove (1) that AbbVie had monopoly power in the relevant market and (2) that AbbVie willfully acquired or maintained that power through sham litigation. *See Mylan*, 838 F.3d at 433. Sham litigation has two prongs. "First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Prof'l Real Estate Invs., Inc. v. Columbia Pictures Indus., Inc. ("PRE")*, 508 U.S. 49, 60 (1993). And second, the lawsuit must conceal an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process as an anticompetitive weapon. *See id.* at 60–61. The FTC sought summary judgment only on the objective baselessness prong.

The District Court granted the FTC partial summary judgment and denied AbbVie and Besins's motions. The Court held a sixteen-day bench trial on sham litigation's subjective prong and monopoly power, and it found for the FTC on both. *See AbbVie*, 329 F. Supp. 3d at 146. The Court awarded "equitable monetary relief in favor of the FTC and against [AbbVie and Besins] in the amount of $448 million, which represent[ed] disgorgement of [their] ill-gotten profits." *Id.* It

declined to enter an injunction. The FTC, AbbVie, and Besins now appeal.

The FTC argues the District Court erred in dismissing its claims to the extent they relied on a reverse-payment theory; abused its discretion in calculating the amount of disgorgement; and abused its discretion in denying the FTC injunctive relief.

AbbVie and Besins argue the District Court erred in concluding the infringement suits against Teva and Perrigo met either prong of the sham-litigation standard, and that AbbVie had monopoly power in the relevant market. They also argue the Court erred in ordering disgorgement because Section 13(b) of the FTC Act does not authorize disgorgement, the disgorgement is a penalty rather than an equitable remedy, and the FTC failed to prove statutory preconditions for injunctive relief. Finally, they argue the Court abused its discretion in calculating the amount of disgorgement

III. JURISDICTION

The District Court had jurisdiction under 28 U.S.C. § 1331. The parties to this appeal agree that we have jurisdiction. Yet we have a "continuing obligation to . . . raise the issue of subject matter jurisdiction if it is in question." *Bracken v. Matgouranis*, 296 F.3d 160, 162 (3d Cir. 2002) (citations omitted).

Our jurisdiction under 28 U.S.C. § 1291 extends to "appeals from all final decisions of the district courts of the United States." But there is an exception. The United States Court of Appeals for the Federal Circuit has "exclusive jurisdiction . . . of an appeal from a final decision of a district

court of the United States . . . in any civil action *arising under* . . . any Act of Congress relating to patents." 28 U.S.C. § 1295(a)(1) (emphasis added).

A civil action "aris[es] under" federal patent law if "a well-pleaded complaint" shows either that "federal patent law creates the cause of action," or "the plaintiff's right to relief *necessarily depends* on resolution of a *substantial* question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988) (emphasis added). In this appeal, the former basis for the Federal Circuit's jurisdiction does not apply because "[f]ederal . . . antitrust law, not federal patent law, creates [the FTC's] claims." *In re Lipitor Antitrust Litig.*, 855 F.3d 126, 145 (3d Cir. 2017) (emphasis omitted). So "[t]his case . . . turns on the [latter basis]" for the Federal Circuit's exclusive jurisdiction. *Id.*

The latter basis applies only if two requirements are met. First, federal patent law must be a "necessary" element of one of the plaintiff's well-pleaded claims. Here, the word "necessary" takes its strict, logical meaning: "a claim supported by alternative theories in the complaint may not form the basis for [the Federal Circuit's exclusive jurisdiction] unless patent law is *essential to each* of those theories." *Christianson*, 486 U.S. at 810 (emphasis added). And the patent-law issues must be "substantial." *Id.* at 809.

The Supreme Court has yet to interpret the substantiality requirement in a case involving 28 U.S.C. § 1295(a)(1) in its current form. But it has addressed the requirement in cases involving 28 U.S.C. § 1338(a), which is analogous because it gives district courts exclusive jurisdiction over "any civil action *arising under* any Act of Congress

relating to patents." (emphasis added). In *Gunn v. Minton*, 568 U.S. 251 (2013), the Court held a state legal malpractice claim arising out of a patent infringement proceeding did not present a "substantial" federal issue vesting federal district courts with exclusive jurisdiction. *Id.* at 261. The Court first clarified that whether a question is "substantial" turns not on the "importance of the issue to the plaintiff's case and to the parties," but instead on "the importance of the issue to the federal system as a whole." *Id*. at 260. Applying that standard, it emphasized that because the legal malpractice claim was "backward-looking" and the issue it raised was "hypothetical," the state court could not change the patent's invalidity as determined by the prior federal patent litigation. *Id.* at 261. Nor could the state court undermine the uniformity of federal patent law going forward, because federal courts "are of course not bound by state court . . . patent rulings" and "state courts can be expected to hew closely to the pertinent federal precedents." *Id.* at 261–62 (citations omitted). Moreover, any preclusive effect the state court's ruling might have "would be limited to the parties and patents that had been before the state court." *Id.* at 263. Finally, the mere possibility that the state court might misunderstand patent law and incorrectly resolve a state claim was not "enough to trigger the federal courts' exclusive patent jurisdiction." *Id.*

This appeal meets neither of the requirements for the latter basis of the Federal Circuit's exclusive jurisdiction. Thus, the Federal Circuit does not have exclusive jurisdiction here. First, federal patent law is not a "necessary" element of one of the FTC's well-pleaded claims. In its complaint, the FTC "challenges a course of anticompetitive conduct," which the complaint defines to include AbbVie and Besins's "sham patent infringement litigation" and "[AbbVie's] . . . illegal

[reverse-payment] agreement." App. 4416. The complaint then asserts two counts. Count II (Restraint of Trade) claims AbbVie violated federal antitrust law by entering into an anticompetitive reverse-payment agreement with Teva. App. 4453–54. We have held that "reverse-payment antitrust claims do not present a question of patent law." *Lipitor*, 855 F.3d at 146 (citing *Actavis*, 570 U.S. at 158 ("[T]he size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.") (citation omitted)). Thus, patent law is not a necessary element of Count II.

The same reasoning applies to Count I (Monopolization). It first "reallege[s] and incorporate[s] by reference" all of the complaint's allegations. App. 4453. It then asserts that AbbVie and Besins willfully maintained a monopoly "through a course of anticompetitive conduct, including filing sham patent litigation against Teva and Perrigo." *Id.* By its terms, Count I challenges a "course of anticompetitive conduct," which the complaint earlier defines to include not only sham litigation, but also the reverse-payment agreement. Because reverse-payment theories do not present a question of patent law, patent law is not a necessary element of Count I either.

Our reasoning is consistent with the Supreme Court's decision in *Christianson* and our decision in *Lipitor*. In both cases, the presence of "non-patent-law theories of liability supporting the . . . plaintiffs' monopolization claims vest[ed] jurisdiction over their appeals" in the regional circuit, "not the

Federal Circuit." *Lipitor*, 855 F.3d at 146 (citing *Christianson*, 486 U.S. at 812).

The parties' conduct before the District Court also supports our interpretation. AbbVie and Besins moved to dismiss "Count I to the extent it [wa]s premised on the" alleged reverse payments. Dkt. 2:14-cv-05151, ECF No. 38 at 1. The District Court granted that motion. Because Count I is premised, at least in part, on this non-patent-law theory, the Federal Circuit does not have exclusive jurisdiction over this action.

It is true that the FTC pleads in Count I that the course of conduct "includ[es]" sham patent litigation. App. 4453. And a sham-litigation theory does present patent-law questions because it requires us to review the objective reasonableness of AbbVie and Besins's patent-infringement litigation against Teva and Perrigo. *See PRE*, 508 U.S. at 60. But that fact does not undermine our jurisdiction because the sham-litigation theory is one of two theories supporting Count I. And the other theory—the reverse-payment theory—does not present a question of patent law. *See Christianson*, 486 U.S. at 810.

We also note that the FTC has not contended that Besins and Teva entered into an independent reverse-payment agreement. Thus, it might be argued the FTC's right to relief *as against* Besins necessarily depends on resolution of patent-law questions.[1] We disagree because the FTC's complaint may be read to allege that Besins participated in AbbVie's settlement with Teva. The complaint notes "[t]he sham lawsuits did not

[1] Judge Phipps would have accepted this argument and held we have jurisdiction because the patent-law issues the FTC's sham-litigation theory presents are not substantial.

eliminate the threat of Teva's and Perrigo's products to AbbVie Defendants and Besins's monopoly." App. 4441. It then asserts "AbbVie . . . and Besins . . . turned to other ways to preserve their monopoly," including AbbVie's settlement with Teva. App. 4442. As mentioned above, the parties' conduct before the District Court supports our reading because both AbbVie *and Besins* moved to dismiss "Count I to the extent it [wa]s premised on the" alleged reverse payments.

Thus, patent law is not a "necessary" element of one of the FTC's well-pleaded claims, so the latter basis for the Federal Circuit's exclusive jurisdiction does not apply.

Second, the patent-law issues that the FTC's sham-litigation theory presents are not "substantial," in the sense that they are important to the "federal system as a whole." *Gunn*, 568 U.S. at 260. So even if federal patent law were a "necessary" element of one of the FTC's well-pleaded claims, the latter basis for the Federal Circuit's exclusive jurisdiction still would not apply. Like the state legal malpractice claim in *Gunn*, the sham-litigation theory here is purely backward looking: just as the state court's adjudication of the legal malpractice claim could not change the result of the prior federal patent litigation, our adjudication of the FTC's sham-litigation theory cannot change the settlement that resulted from AbbVie and Besins's infringement suits against Teva and Perrigo. *See id.* at 261.[2]

Nor would adjudicating the sham-litigation theory undermine the uniformity of federal patent law. *See id.* at 261–

[2] It might be argued the patent-law issues *Gunn* presented are less substantial than the ones we face here because the patent litigation in *Gunn* led to the patent's

62. The reasons for this are general and case specific. Generally, much like the state court's decision in *Gunn* could not bind federal courts, the parts of our decision in this appeal that interpret patent law cannot bind the Federal Circuit or district courts outside the Third Circuit. *See id.* And like the state court in *Gunn*, we must hew closely to the Federal Circuit's precedents. *See id.* If the patent-law issues we decide arise frequently, they "will soon be resolved within [the Federal Circuit], laying to rest any contrary . . . precedent." *Id.* at 262. Otherwise, they are "unlikely to implicate substantial federal interests." *Id.*

There are two additional, case-specific reasons that adjudicating the sham-litigation theory would not undermine the uniformity of federal patent law. First, litigation is a sham only if it is objectively baseless, meaning "no reasonable litigant could realistically expect success on the merits." *PRE*, 508 U.S. at 60. Our application of this standard poses no threat to the uniformity of federal patent law. Consider our choices in this appeal: AbbVie and Besins's lawsuits were or were not shams. If the former, it must be true that the patent law we apply is so clear that AbbVie and Besins were unreasonable in suing Teva or Perrigo for infringement and expecting to

---

invalidation, *see id.* at 255, whereas the '894 patent has not been invalidated. Indeed, while the '894 patent expired on August 30, 2020, AbbVie and Besins may sue for infringement for up to six years after that date. *See* 35 U.S.C. § 286. We think this distinction is immaterial under *Gunn*, which emphasized that state-court adjudication of the legal malpractice claim would not change the result of the prior federal patent litigation, rather than emphasizing the result itself. *See* 568 U.S. at 261.

succeed. Such a holding would effectively adjudicate the merits of an infringement claim but at no cost to uniformity. And the latter holding would mean only that AbbVie and Besins were not unreasonable in expecting success in their infringement suits. That conclusion would not undermine uniformity because it would not adjudicate the merits of the infringement claims.

Moreover, whether AbbVie and Besins's infringement lawsuits were shams depends on whether the tangentiality exception to prosecution history estoppel applies. But the Federal Circuit has cautioned against applying analogical reasoning in determining tangentiality. *See Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1332 n.5 (Fed. Cir. 2019) ("[W]e find the analogies to other cases less helpful than a direct consideration of the specific record of this case and what it shows about the reason for amendment and the relation of that reason to the asserted equivalent."). Because the Federal Circuit limits reliance on its own precedents in determining tangentiality, it follows that our decision in this appeal will have limited effect on the uniformity of patent law. Even setting *Eli Lilly* aside, however, the rarity of the patent-law issues these appeals present counsels in favor of our jurisdiction: the issues are not ones whose resolution will control numerous other cases. *See Gunn*, 568 U.S. at 262 (quoting *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 700 (2006)).

Finally, here, as in *Gunn*, the preclusive effect of our ruling "would be limited to the parties and patents" before us. *See* 568 U.S. at 263. And the mere possibility that we might misunderstand patent law is not dispositive. *See id.* So the patent-law issues that the FTC's sham-litigation theory presents are not "substantial." Even if federal patent law were

a "necessary" element of one of the FTC's well-pleaded claims, the latter basis for the Federal Circuit's exclusive jurisdiction still would not apply.

Before concluding, we note a prudential consideration supporting our jurisdiction: "[u]nder the Federal Circuit's choice-of-law rules, it would apply *Third Circuit* antitrust jurisprudence . . . when reviewing whether [the FTC] states[s a] plausible claim[] for relief under" a reverse-payment theory. *Lipitor*, 855 F.3d at 148 (citing *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998) (the Federal Circuit "appl[ies] the law of the appropriate regional circuit to issues involving other elements of antitrust law such as relevant market, market power, damages, etc., as those issues are not unique to patent law")). The Federal Circuit would also apply our precedent when reviewing the District Court's judgment on the sham-litigation theory, except when the judgment raised issues unique to patent law. *See id.* Needless to say, we are as capable of applying our own law as the Federal Circuit. And it makes eminent sense for this Court to develop our own law in this area.

In summary, neither basis for the Federal Circuit's exclusive jurisdiction applies: federal patent law does not create the FTC's cause of action, and the FTC's right to relief does not necessarily depend on resolution of a substantial question of federal patent law. So this civil action does not "aris[e] under" federal patent law within the meaning of 28 U.S.C. § 1295(a)(1). We have jurisdiction under 28 U.S.C. § 1291.

IV. LIABILITY

Having assured ourselves of our jurisdiction, we turn to the merits of these cross-appeals. We hold the District Court erred by rejecting the reverse-payment theory and in concluding AbbVie and Besins's litigation against Teva was a sham. The Court did not err, however, in concluding the Perrigo litigation was a sham and that AbbVie and Besins had monopoly power in the relevant market.

A. The District Court erred by rejecting the reverse-payment theory.

We review the District Court's dismissal order de novo. *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 230 (3d Cir. 2008) (citation omitted). We must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Id.* at 231 (internal citation and quotation marks omitted). A plaintiff relying on a reverse-payment theory must "allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 252 (3d Cir. 2017) (citation omitted).

1. *Actavis*

A reverse payment occurs when a patentee pays an alleged infringer to end a lawsuit. *See Wellbutrin*, 868 F.3d at 142 n.3 (citing *Actavis*, 570 U.S. at 140–41). A typical reverse payment happens this way: "Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce

the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars." *Actavis*, 570 U.S. at 140.

Reverse payments can be anticompetitive in violation of the antitrust laws. Absent the reverse payment in the previous example, Company B might have prevailed by proving Company A's patent invalid. Even if the patent were valid, Company B might prevail by showing it did not infringe. In either case, generic drugs would have entered the market before Company A's patent was set to expire, and consumers would have benefited from lower drug prices.

In *Actavis*, the Supreme Court held reverse payments "can sometimes unreasonably diminish competition in violation of the antitrust laws." *Id.* at 141. That case, like this one, involved AndroGel. *See id.* at 144. Solvay sued Actavis, Inc., a company seeking to market a generic version of the gel. *See id.* at 145. Solvay and Actavis settled under the following terms: (1) "Actavis agreed that it would not bring its generic to market until . . . 65 months before Solvay's patent expired (unless someone else marketed a generic sooner)"; (2) "Actavis also agreed to promote AndroGel to urologists"; and (3) "Solvay agreed to pay . . . an estimated $19–$30 million annually, for nine years, to Actavis." *Id.* "The companies described these payments as compensation for other services [Actavis] promised to perform." *Id.* at 145. The FTC was unpersuaded. It sued Solvay and Actavis, contending the services had little value and the payments actually compensated the generics for delaying their market entry. *See id.*

The district court dismissed the FTC's complaint, and the United States Court of Appeals for the Eleventh Circuit

affirmed. *See id.* at 145–46. Both courts applied the "scope of the patent" test, which provides that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Id.* at 146 (citation omitted). This "categorical rule . . . relied on the premise that, because a patentee possesses a lawful right to keep others out of its market, the patentee may also enter into settlement agreements excluding potential patent challengers from entering that market." *Lipitor*, 868 F.3d at 250 (citing *Actavis*, 570 U.S. at 146). The Eleventh Circuit was also concerned that antitrust review of reverse payments would undermine the general policy in favor of settlements and "require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement." *Actavis*, 570 U.S. at 153.

The Supreme Court reversed. It first rejected the scope of the patent test. The infringement suit Solvay and Actavis settled "put the patent's validity at issue, as well as its actual preclusive scope." *Actavis*, 570 U.S. at 147. And the parties' settlement was both "unusual" and potentially anticompetitive, because the FTC alleged Solvay "agreed to pay [Actavis] many millions of dollars to stay out of its market, even though [Actavis] did not have any claim that [Solvay] was liable . . . for damages." *Id.* at 147–48. These factors persuaded the Court it would be "incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than measuring them against procompetitive antitrust policies as well." *Id.* at 148.

The Court then held that for five reasons, the district court erred by dismissing the FTC's complaint. *See id.* at 153.

First, reverse payments can be anticompetitive because they allow a brand-name company to split its monopoly profits with a generic company willing to delay market entry. *See id.* at 153–56. Second, reverse payments' "anticompetitive consequences will at least sometimes prove unjustified." *Id.* at 156. A defendant might show that "traditional settlement considerations, such as avoided litigation costs or fair value for services" justified the reverse payment. *Id.* Alternatively, antitrust review could reveal "a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement," in which case the payment is not justified. *Id.* Third and fourth, the "size of [an] unexplained reverse payment can provide a workable surrogate for a patent's weakness" and a patentee's market power, "all without forcing a court to conduct a detailed exploration of the patent itself." *Id.* at 157–58 (citation omitted). Fifth, subjecting reverse payments to antitrust review does not violate the general legal policy in favor of settlements, because companies can settle in other ways. *See id.* at 158. For example, a brand-name company may "allow[] the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.* Thus, the Court concluded, "a reverse payment, where *large and unjustified*," can violate the antitrust laws. *Id.* at 158–60 (emphasis added).

2. *King Drug* and *Lipitor*

Since the Supreme Court decided *Actavis*, we have applied its teachings on three occasions. *See King Drug*, 791 F.3d at 393; *Lipitor*, 868 F.3d at 239; *Wellbutrin*, 868 F.3d at 158. The parties to this appeal rely on *King Drug* and *Lipitor*.

In *King Drug*, we reinstated a complaint challenging a settlement agreement in which the alleged reverse payment took a form other than cash. *See* 791 F.3d at 393. There, direct purchasers of the brand-name drug Lamictal sued its producer (GlaxoSmithKline (GSK)) and generic applicant (Teva) over their settlement of Teva's challenge to the validity and enforceability of GSK's patents on Lamictal's active ingredient (lamotrigine). *See id.* Teva agreed to "end its challenge to GSK's patent in exchange for early entry into the $50 million annual lamotrigine chewables market and GSK's commitment not to produce its own, 'authorized generic' version of Lamictal tablets for the market alleged to be worth $2 billion annually." *Id.* at 393–94. The purchasers claimed this "no-AG agreement" was a reverse payment under *Actavis* because it "was designed to induce Teva to abandon the patent fight and thereby agree to eliminate the risk of competition in the $2 billion lamotrigine tablet market." *Id.* at 394.

Reversing the district court, we held the no-AG agreement was actionable under *Actavis*. *See id.* The district court had reasoned that "when the Supreme Court said 'payment' it meant a payment of money." *Id.* at 405 (quotation marks and citation omitted). We doubted "the Court intended to draw such a formal line." *Id.* at 405–06. We explained that even though GSK did not pay Teva cash under the agreement, it was "likely to present the same types of problems as reverse payments of cash." *Id.* at 404. The no-AG agreement could have been worth millions of dollars, if not hundreds of millions of dollars, to Teva. *See id.* Conversely, GSK's commitment not to produce an authorized generic transferred to Teva "the profits [GSK] would have made from its authorized generic." *Id.* at 405. Thus, the agreement may have been "something

more than just an agreed-upon early entry"—it may have been "pay-for-delay." *Id.*

We also rejected the defendants' counterargument that the purchasers' "allegations [were] far too speculative to satisfy their burden of plausibly alleging that the settlement was anticompetitive." *Id.* at 409 (quotations and citation omitted). Specifically, the defendants argued the purchasers needed to plead that without the reverse payment: GSK and Teva would have negotiated an alternative, more competitive agreement; continued litigation ending in settlement would have yielded a more competitive result; and Teva would have launched its generics. *See id.*

We held the purchasers stated a claim. They alleged: GSK agreed not to launch an authorized generic during Teva's 180-day exclusivity period; the agreement was worth "many millions of dollars of additional revenue"; GSK would otherwise be incentivized to launch an authorized generic; Teva likely would have launched alongside GSK; and GSK's patent was likely to be invalidated. *See id.* at 409–10. "And although [the purchasers] concede[d] that Teva entered the lamotrigine chewables market about 37 months early . . . the chewables market, allegedly worth only $50 million annually, was orders of magnitude smaller than the alleged $2 billion tablet market the agreement [was] said to have protected." *Id.* at 410. Because the purchasers had plausibly alleged that "any procompetitive aspects of the chewables arrangement were outweighed by the anticompetitive harm from the no-AG agreement," they were entitled to discovery. *Id.*

We also rejected the district court's alternative holding that "the settlement . . . would survive *Actavis* scrutiny and [was] reasonable." *Id.* at 410–11. The purchasers were entitled

to discovery because they plausibly alleged the settlement was anticompetitive. *See id.* at 411. And "[i]f genuine issues of material fact remain[ed] after discovery, the rule-of-reason analysis [would be] for the finder of fact, not the court as a matter of law." *Id.*

Next, in *Lipitor*, we addressed consolidated appeals concerning two drugs: Lipitor and Effexor XR. *See* 868 F.3d at 239. In the Lipitor litigation, we reinstated a complaint alleging a generic applicant delayed entry into the market in exchange for the brand-name producer settling a damages claim for much less than the claim was really worth. *See id.* at 253–54. There, the plaintiffs were a putative class of direct purchasers, a putative class of end payors, and several individual retailers. *See id.* at 241. They sued Lipitor's brand-name producer (Pfizer Inc.) and its generic applicant (Ranbaxy Inc.) over a "near-global" litigation settlement addressing "scores of patent litigations [between Pfizer and Ranbaxy] around the world." *Id.* at 244. One part of that settlement resolved Ranbaxy's challenge to the validity and enforceability of Pfizer's patents on Lipitor. *See id.* at 242. It provided Ranbaxy would delay its entry, "thus extending Pfizer's exclusivity in the Lipitor market" past the expiration of its patents. *Id.* at 244–45. Another part of the settlement resolved Pfizer's claim against Ranbaxy for allegedly infringing Pfizer's patents on Accupril, a different drug. *Id.* at 243–44. Before settling, Pfizer had reason to believe its claim was worth hundreds of millions of dollars: Accupril's annual sales were "over $500 million"; Ranbaxy's generic entry "decimated" those sales; Pfizer sought treble damages for willful infringement; and the district court granted Pfizer a preliminary injunction and Pfizer posted a $200 million bond. *Id.* Pfizer had also "expressed confidence that it would succeed

in obtaining a substantial monetary judgment from Ranbaxy." *Id.* at 244. Nevertheless, Pfizer agreed to settle this claim for a mere $1 million. *See id.*

Reversing the district court, we held these two, otherwise-unrelated parts of the global settlement agreement were actionable under *Actavis*. *See id.* at 248, 253. The court had required the plaintiffs to plead a "reliable" monetary estimate of the dropped Accupril claims so it could determine whether the reverse payment was large and unjustified. *See id.* at 254. We rejected that requirement, explaining it "heightened [the] pleading standard contrary to *Bell Atlantic v. Twombly*, [550 U.S. 544 (2007)], and *Ashcroft v. Iqbal*, [556 U.S. 662 (2009)]." *Id.* Moreover, we said neither *Actavis* nor *King Drug* "demanded [that] level of detail." *Id.* at 254.

In fact, the plaintiffs' allegations "easily match[ed], if not exceed[ed], the level of specificity and detail of those in *Actavis* and *King Drug*." *Id.* at 253, 255. As relevant here, the plaintiffs alleged:

> Ranbaxy launched a generic version of Pfizer's brand drug Accupril "at risk" [of infringement] . . . ; Pfizer had annual Accupril sales over $500 million prior to Ranbaxy's launch . . . ; Pfizer brought suit and sought to enjoin Ranbaxy's generic sales . . . ; the District Court granted the injunction halting Ranbaxy's sales of generic Accupril, which the Federal Circuit affirmed . . . ; Pfizer posted 'a $200 million bond in conjunction with' the injunction and informed the Court that Ranbaxy's generic sales 'decimated' its Accupril sales . . . ; Pfizer's suit was likely to be successful . . . ; and Pfizer

> itself made statements about Ranbaxy's exposure . . . .

Id. at 253. The plaintiffs also alleged the release of the Accupril claims was unjustified because the "potential liability in *Accupril* 'far exceeded' any of Pfizer's saved litigation costs or any services provided by Ranbaxy." *Id.* Thus, we held the plaintiffs "sufficiently allege[d] that Pfizer agreed to release the *Accupril* claims against Ranbaxy, which were likely to succeed and worth hundreds of millions of dollars, in exchange for Ranbaxy's delay in the release of its generic version of Lipitor." *Id*.

The defendants countered that the plaintiffs did not address other parts of the global litigation settlement that might well have justified the alleged reverse payment. But because the defendants had the burden of justifying a reverse payment, *Actavis* did not "require antitrust plaintiffs to come up with possible explanations for the reverse payment and then rebut those explanations." *Id.* at 256. The defendants also countered that because Ranbaxy paid Pfizer $1 million, it was a commonplace settlement to which *Actavis* does not apply. *Id.* at 257. We said this argument "[could not] be squared with *Actavis*" because "[i]f parties could shield their settlements from antitrust review by simply including a token payment by the purportedly infringing generic manufacturer, then otherwise unlawful reverse payment settlement agreements attempting to eliminate the risk of competition would escape review." *Id.* at 258.

Similarly, in the Effexor XR litigation, we reinstated a complaint alleging a generic applicant delayed entry into the Effexor market in exchange for the brand-name producer's agreement not to market an authorized generic—even though

the generic agreed to pay some royalties to the brand. *See id.* at 254, 247. There, the plaintiffs were a putative class of end payors, two third-party payors, and several retailers. *See id.* at 246. They sued Effexor's generic applicant (Teva) and brand-name producer (Wyeth, Inc.) over their settlement of Teva's challenge to the validity and enforceability of Wyeth's patents on Effexor. *See id.* at 247. Under the settlement, Teva and Wyeth agreed to vacate a district court ruling construing the patent claims unfavorably to Wyeth. *See id.* They further agreed that Teva could market the extended-release version of its generic nearly seven years before Wyeth's patent expired, and its instant-release version at some point before the patent expired. *See id.* In exchange, Wyeth agreed it would not market authorized generics during Teva's 180-day exclusivity period. *See id.* In return, Teva agreed to pay Wyeth royalties. *See id.*

Reversing the district court, we held the no-AG agreement was actionable under *Actavis*. Given the similarities between *King Drug* and the Effexor litigation, we will not repeat the Effexor plaintiffs' allegations here. *See id.* at 258–59. We mention the Effexor litigation only to highlight two counterarguments the defendants made. First, the defendants argued "the reverse payment was not large because the complaints failed to sufficiently allege that Wyeth would have released an authorized generic but for its settlement agreement with Teva." *Id.* They explained that "Wyeth has rarely introduced authorized generics in response to the entry of a generic into one of their branded drugs' markets." *Id.* at 260. We rejected this argument because the mere fact that "Wyeth does not typically introduce authorized generics into the market" did not "render[] [the plaintiffs'] allegations about the value of the no-AG agreement implausible." *Id.* at 260–61. Second, the defendants argued the royalties Teva agreed to pay

Wyeth justified the reverse payment. *See id.* We responded that "[a]lthough the royalty licensing provisions will perhaps be a valid defense, they require factual assessments, economic calculations, and expert analysis that are inappropriate at the pleading stage." *Id.* at 261. In sum, we said, "*Effexor* plaintiffs need not have valued the no-AG agreement beyond their allegations summarized above . . . Nor were they required to counter potential defenses at the pleading stage." *Id.* at 262 (citation omitted).

3. Application

Two principles emerge from *King Drug* and *Lipitor*. First, a reverse payment's legality depends mainly on its economic substance, not its form. The alleged reverse payment in *Actavis* was made in cash. Yet the alleged reverse payments in *King Drug* and *Lipitor* included two no-AG agreements and the settlement of a valuable damages claim. The reverse payment in *Actavis* was part of a single settlement agreement addressing one drug (AndroGel). Yet the reverse payment in the Lipitor litigation spanned two parts of a "near-global" litigation settlement addressing two different drugs (Lipitor and Accupril); and in *King Drug*, the challenged settlement addressed a drug in two different forms (chewable and tablet). Finally, the settlement in *Actavis* did not provide for cash to flow from the generic entrant to the brand-name producer. Yet the settlements in *Lipitor* provided for Ranbaxy to pay Pfizer $1 million and for Teva to pay Wyeth royalties.

However meaningful these formalisms may be in other areas of the law, they are disfavored in antitrust. The purpose of antitrust law is "to protect consumers from arrangements that prevent competition in the marketplace." *King Drug*, 791 F.3d at 406 (citations omitted). Because of that unique purpose,

"economic realities rather than a formalistic approach must govern." *United States v. Dentsply, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005). Accordingly, in *King Drug* and *Lipitor*, we read *Actavis* practically; we read it to apply to potentially anticompetitive reverse payments regardless of their form.

The second principle emerging from *King Drug* and *Lipitor* is that the law of pleading applies to reverse-payment theories. To survive a motion to dismiss, a plaintiff must "allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*." *Lipitor*, 868 F.3d at 252 (citation omitted). A plaintiff can meet this pleading standard without describing in perfect detail the world without the reverse payment, calculating reliably the payment's exact size, or pre-empting every possible explanation for it. Moreover, a district court must accept a plaintiff's well-pleaded allegations as true. If a plaintiff plausibly alleges that an agreement's anticompetitive effects outweigh its procompetitive virtues, the district court must accept that allegation and allow the plaintiff to take discovery. If genuine issues of material fact remain, the rule-of-reason analysis is for the factfinder, not the court.

Applying these precedents here, the District Court erred by dismissing the FTC's claims to the extent they relied on a reverse payment theory. The FTC plausibly alleged an anticompetitive reverse payment. It alleged AbbVie and Besins filed sham lawsuits against Teva and Perrigo in order to trigger the automatic, 30-month stay of FDA approval on its generic version of AndroGel. App. 4440 ¶ 99. But those suits "did not eliminate the threat of Teva's . . . products to [AbbVie] and Besins's monopoly," because AbbVie and Teva both expected Teva would win the infringement suit against it and would

introduce its generic in 2012—before 30 months had passed. App. 4441 ¶¶ 107–09. So "[AbbVie] and Besins . . . turned to other ways to preserve their monopoly." App. 4442 ¶ 111. Specifically, AbbVie "approached Teva to discuss a potential settlement" that would give "[AbbVie] time to shift sales to its reformulated product, AndroGel 1.62%." *Id.* ¶ 112. Teva agreed to "drop its patent challenge and refrain from competing with [AndroGel] until December 2014." App. 4443 ¶ 115. In exchange, it asked AbbVie to sell it a "supply of . . . TriCor." *Id.* ¶ 113. AbbVie agreed. It authorized Teva to sell a generic version of TriCor, which AbbVie would supply to Teva at Teva's option, for a four-year term beginning in November 2012. *Id.* ¶ 117. The supply agreement provided for Teva to pay AbbVie the costs of production, an additional percentage of that cost, and a royalty. *See id.*

The payment was plausibly "large." The FTC alleges the supply of TriCor was "extremely valuable" to Teva. App. 4444 ¶ 120. A previous settlement between AbbVie and Teva had set Teva's entry in the TriCor market for July 2012. App. 4442 ¶ 114. And because Teva was the first generic challenger to TriCor, Teva was entitled to 180 days of marketing exclusivity. *See id*. Teva was struggling to capitalize on the exclusivity period, though, because it could not secure FDA approval for its generic drug. *See id*. The TriCor deal enabled Teva "to secure generic TriCor revenues in 2012 and its first mover advantage." App. 4444–45 ¶¶ 121, 124. Teva expected its "net sales of authorized generic TriCor sales would be nearly $175 million over a four-year period." App. 4444 ¶ 120. In fact, Teva's actual sales were much higher. *Id*. They "far exceed[ed]" the litigation costs that AbbVie, Besins, or Teva saved by settling. App. 4445 ¶ 122. And they exceeded what Teva had projected it was likely to earn by winning the

infringement suit and marketing its generic version of AndroGel. *Id.* ¶ 123.

The payment was also plausibly "unjustified." The FTC alleges the TriCor deal "cannot be explained as an independent business deal from Abbott's perspective." App. 4445 ¶ 125. AbbVie "had no incentive to increase . . . generic competition from Teva on another of its blockbuster products." App. 4443 ¶ 115. And the TriCor deal was "highly unusual" in other respects. App. 4445 ¶ 126. For example, it did not condition Teva's launch on the launch of an independent generic. App. 4445–46 ¶ 126. It actually accelerated generic entry, because "Teva's launch triggered provisions in [AbbVie's] agreements with other generic TriCor ANDA filers allowing them to launch their own generic[versions]." App. 4446–47 ¶ 129. Moreover, the royalty terms were "significantly worse for [AbbVie]" than is usual in authorized-generic agreements, including contemporaneous agreements that AbbVie entered. App. 4447 ¶ 130. AbbVie expected to lose roughly $100 million in TriCor revenues as a result of the deal, and its "modest income from the . . . deal did not come close to making up this significant loss of revenue." *Id.* ¶ 132.

Finally, it is plausible that the anticompetitive effects of AbbVie's settlement with Teva outweighed any procompetitive virtues of the TriCor deal. The FTC alleges AbbVie calculated that it would sacrifice $100 million in TriCor sales, but that was a small fraction of the billions of dollars in AndroGel revenue it protected by deferring competition in the TTRT market for three years. *See id.*; *cf. King Drug*, 791 F.3d at 410 (purchasers were entitled to discovery because they plausibly alleged that "any procompetitive aspects of the chewables arrangement were

outweighed by the anticompetitive harm from the no-AG agreement").

These allegations, if true, would "support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment." *Lipitor*, 868 F.3d at 252. So the District Court erred by dismissing the FTC's claims to the extent they relied on a reverse-payment theory.

The District Court ruled that "when two agreements are involved . . . the court must determine separately whether each promotes competition." *AbbVie*, 107 F. Supp. 3d at 437 (citing *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438 (2009)). The Court then reasoned AbbVie's settlement with Teva promoted competition and was distinguishable from the settlement in *Actavis*. In *Actavis*, the patentee paid the alleged infringer. But here, the Court said, AbbVie and Besins "did not make any payment, reverse or otherwise, to . . . Teva." *Id.* at 436. Instead, they "simply allow[ed] Teva to enter the AndroGel market almost six years prior to the expiration of the '894 patent." *Id.* It further stated that because "*Actavis* specifically states that such an agreement does not run afoul of the antitrust laws," the settlement was procompetitive and unactionable. *Id.* (citation omitted).

The District Court next reasoned the TriCor deal promoted competition because "[i]t allow[ed] Teva to enter the cholesterol drug market with a generic product to compete with Abbott's product and thus advantage[d] the purchasers of cholesterol drugs." *Id.* The Court stressed that while "something of large value passed from [AbbVie] to Teva, it was not a reverse payment under *Actavis*" because AbbVie was "not making any payments to Teva." *Id.* Rather, Teva was "paying [AbbVie] for the supply of TriCor." *Id.* And even

though the FTC alleged AbbVie was "charging a price that is well below what is customary in such situations," it did not allege AbbVie "agreed to sell TriCor . . . for less than its cost." *Id.* Thus, the Court held the deal was procompetitive. *Id.*

The District Court's reasoning is unpersuasive. The Court cited *Linkline* for the proposition that if a settlement involves two agreements, a court must determine separately whether each promotes competition. But *Linkline* held "two antitrust theories cannot be combined to form a new *theory of antitrust liability*." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 280 (3d Cir. 2012) (emphasis added) (citing *Linkline*, 555 U.S. at 457). The FTC's complaint does not allege such a combination, so *Linkline* does not apply.

Nor do our precedents support the rule that "when two agreements are involved . . . [a] court must determine separately whether each promotes competition." *AbbVie*, 107 F. Supp. 3d at 437 (citation omitted). That rule violates two principles from our precedents. It elevates form over substance because companies could avoid liability for anticompetitive reverse payments simply by structuring them as two separate agreements—one in which the generic company agrees to delay entry until patent expiration, and the other in which the brand-name company agrees to split monopoly profits. In effect, *Actavis* would become a penalty for bad corporate lawyering instead of anticompetitive conduct. The rule also contradicts pleading law. Here, the FTC plausibly alleged that AbbVie's settlement with Teva and the TriCor deal were linked. The Court had to accept that allegation as true. *See Phillips*, 515 F.3d at 230–31.

We are also unpersuaded by the District Court's economic analyses of the TriCor deal and AbbVie's settlement

with Teva. As to the TriCor deal, the Court acknowledged that "something of large value passed from [AbbVie] to Teva." *AbbVie*, 107 F. Supp. 3d at 436. Yet it said that transfer could not be a reverse payment under *Actavis* because AbbVie was not "making any payments to Teva." *Id.* This reasoning cannot be reconciled with *King Drug*, where we held a plaintiff may base a reverse-payment theory on any "unexplained large *transfer of value* from the patent holder to the alleged infringer." *King Drug*, 791 F.3d at 403 (emphasis added).

Moreover, the Court emphasized that Teva paid AbbVie for the supply of TriCor. But in *Lipitor*, we held that parties cannot "shield their settlements from antitrust review by simply including a token payment by the purportedly infringing generic manufacturer." 868 F.3d at 258. Although Teva's payments "will perhaps be a valid defense, they require factual assessments, economic calculations, and expert analysis that are inappropriate at the pleading stage." *Id.* at 261. Finally, the Court intimated the result might be different if the FTC had alleged AbbVie agreed to sell TriCor below-cost. But the FTC did not have to allege the TriCor deal would appear as a loss on AbbVie's balance sheets; it needed only to allege that through the deal, AbbVie unjustifiably transferred to Teva an opportunity, and the profits associated with the opportunity were large. *See King Drug*, 791 F.3d at 405 (GSK's commitment not to produce an authorized generic transferred to Teva "the profits [GSK] *would have made* from its authorized generic") (emphasis added). So without expressing an opinion whether the District Court correctly concluded the TriCor deal was procompetitive, we think it analyzed incorrectly the deal's economic substance.

As to AbbVie's settlement with Teva, the District Court erred in concluding it was procompetitive as a matter of law.

Granted, the District Court was right that under *Actavis*, "an agreement does not run afoul of the antitrust laws" if it simply allows a generic company to enter a market before patent expiration. *AbbVie*, 107 F. Supp. 3d at 436 (citing *Actavis*, 570 U.S. at 158 ("[Parties] may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, *without the patentee paying the challenger to stay out prior to that point*.") (emphasis added)). And it was reasonable for the Court to think this exception reflects the Supreme Court's view that such agreements are so often procompetitive they should be legal per se. Still, the exception applies only if a patentee does not "pay[] the challenger to stay out [before patent expiration]," and the District Court erred in concluding this condition was met here. *Actavis*, 570 U.S. at 158. The Court said AbbVie "did not make any payment, reverse or otherwise, to . . . Teva." *AbbVie*, 107 F. Supp. 3d at 436. But that finding rested on the Court's erroneous ruling that it had to analyze the settlement separately from the TriCor deal, which even the Court acknowledged involved a transfer of value from AbbVie to Teva. Because the FTC plausibly alleged the TriCor deal was a reverse payment, the settlement may have been "something more than just an agreed-upon early entry"—it may have been "pay-for-delay." *King Drug*, 791 F.3d at 405. And pay-for-delay is anticompetitive even if the delay does not continue past patent expiration. It was this same anticompetitive potential that led the Supreme Court to reject the scope of the patent test in *Actavis*. *See* 570 U.S. at 147–48.

For these reasons, the District Court erred by dismissing the FTC's claims to the extent they relied on a reverse-payment theory.

B. The District Court erred in concluding AbbVie and Besins's litigation against Teva was a sham; it did not err in concluding the Perrigo litigation was a sham.

1. *Noerr-Pennington* immunity

Under the *Noerr-Pennington* doctrine, "[t]hose who petition [the] government for redress are generally immune from antitrust liability." *PRE*, 508 U.S. at 56. That includes the right to sue in federal court. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510, 515 (1972) (holding "the right to petition extends to all departments of the Government," including the courts).

Noerr-Pennington immunity is not absolute. *Wellbutrin*, 868 F.3d at 148. An exception arises if a lawsuit is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961). In *PRE*, the Supreme Court held this exception has two prongs:

> 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 of our definition of sham, 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 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.

508 U.S. at 60–61 (internal quotation marks, citations, alteration, and footnote omitted). Under the objective baselessness prong, a "probable cause determination irrefutably demonstrates" a defendant's immunity. *Id.* at 63. Probable cause is a "reasonable belief that there is a chance that a claim may be held valid upon adjudication." *Id.* at 62–63 (internal quotation marks, citations, and alterations omitted); *see also id.* at 65 (defendant was immune because "[a]ny reasonable [litigant] in [its] position could have believed that it had some chance of winning"). In determining reasonableness, a court should consider the state of the law at the time of a defendant's suit. *See id.* at 65; *see also Wellbutrin*, 868 F.3d at 150. Generally, the more "unsettled" the law is, the more reasonable is a belief that a claim will be held valid. *PRE*, 508 U.S. at 64–65 (probable cause supports a claim if it is "arguably 'warranted by existing law'") (quoting FED. R. CIV. P. 11). Even if the law was settled against the defendant, however, that is not dispositive. Then, a court should ask whether the defendant's claim "at the very least was based on an objectively 'good faith argument for the extension, modification, or reversal of existing law.'" *Id.* at 65 (quoting FED. R. CIV. P. 11).

Under the subjective motivation prong, a plaintiff must show the defendant "brought baseless claims in an attempt to thwart competition (*i.e.*, in bad faith)." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 556 (2014). Some factors relating to a defendant's "economic motivations" in bringing suit include whether the defendant was "indifferent to the outcome on the merits of the . . . suit, whether any damages for infringement would be too low to justify . . . investment in the suit, or whether [the defendant] had decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process." *PRE*, 508 U.S. at 65–66 (citation omitted).

Generally, a plaintiff seeking to show the sham litigation exception faces "an uphill battle." *Wellbutrin*, 868 F.3d at 147. And in some respects, the hill is steeper "in the context of an ANDA case." *Id.* at 149. "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." *Id.* (citation omitted). Moreover, the number of lawsuits a brand-name drug manufacturer files will sometimes reveal little about its subjective motivation for suing, because the Hatch-Waxman Act "incentivizes [brands] to promptly file patent infringement suits by rewarding them with a stay of up to 30 months if they do so." *Id.* at 157–58 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). For that reason, we have declined to apply a related exception to *Noerr-Pennington* immunity—serial petitioning—in the Hatch-Waxman context. *Id.* (citing *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162 (3d Cir. 2015)).

Yet in other respects, the ANDA context may help a plaintiff. The automatic, 30-month stay is a collateral injury the defendant's mere use of legal process invariably inflicts. And though the stay ends if a court holds the defendant's patent is invalid or has not been infringed, it does not otherwise depend on a suit's outcome. Thus, a plaintiff may be able to show a defendant was indifferent to the outcome of its infringement suit, and the automatic, 30-month stay was an anticompetitive weapon the defendant tried to wield.

In sum, applying the sham-litigation standard is a delicate task. The defendant's First Amendment right "to petition the Government for a redress of grievances" is at stake. U.S. Const. amend. I. So too is congressional policy, as expressed in both the Hatch-Waxman Act and the antitrust laws. We must not "penalize a brand-name manufacturer whose 'litigiousness was a product of Hatch-Waxman.'" *Wellbutrin*, 868 F.3d. at 158 (citing *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." *Id.* (citation omitted). At the same time, we must not immunize a brand-name manufacturer who uses the Hatch-Waxman Act's automatic, 30-month stay to thwart competition. Doing so would excuse behavior that Congress proscribed in the antitrust laws.

2. Objective Baselessness

The District Court granted the FTC summary judgment on sham litigation's objective baselessness prong. We review that judgment de novo. *See Morgan v. Covington Twp.*, 648 F.3d 172, 177 (3d Cir. 2011).

a. Patent law's doctrine of equivalents, prosecution history estoppel, and tangentiality

Under the doctrine of equivalents, "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." *Festo VIII*, 535 U.S. at 732. There are at least two reasons for this doctrine. First, because "the nature of language makes it impossible to capture the essence of a thing in a patent application," it is unrealistic to expect a patentee to "capture every nuance of [his or her] invention or describe with complete precision the range of its novelty." *Id.* at 731. Second, "[i]f patents were always interpreted by their literal terms," rival inventors might "defeat the patent" simply by making "unimportant and insubstantial" changes. *Id.* This would diminish the scientific and artistic progress that the patent system seeks to foster. *See id.*

Although the doctrine of equivalents counters the threat that literal interpretation of patents poses to scientific and artistic progress, it creates another problem. One function of patents is to notify would-be inventors about the scope of the patentee's property right. *See id.* ("A patent holder should know what he owns, and the public should know what he does not."). Notice allows inventors to innovate without fear that the patentee will sue them for infringement. *See id.* at 732. But because the doctrine of equivalents untethers a patentee's property right from a patent's literal terms, it tends to undermine notice. *See id.* So the doctrine risks dampening inventors' innovative spirit.

Thus, patent law must balance "the needs of patentees for adequate protection of their inventions" on the one hand, and "the needs of would-be competitors for adequate notice of the scope of that protection" on the other. *Festo Corp. v.*

Shoketsu Kinzoku Kogyo Kabushiki Co. ("*Festo IX*"*)*, 344 F.3d 1359, 1385 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part).

Recognizing the need for balance, the Supreme Court has limited the doctrine of equivalents. One limitation—known as prosecution history estoppel—applies when "the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection." *Festo VIII*, 535 U.S. at 733. The patentee "may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent." *Id.* at 733–34.

Prosecution history estoppel "ensures that the doctrine of equivalents remains tied to its underlying purpose." *Id.* at 734. "The doctrine of equivalents is premised on language's inability to capture the essence of innovation." *Id.* But that premise is unsound if a patent's prosecution history shows that the patentee "turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter." *Id.* at 734–35. In that case, the patentee's competitors could reasonably infer the patentee's property right extended only so far as the narrower claim.

Courts use a three-part test to determine whether prosecution history estoppel applies:

1. The first question in a prosecution history estoppel inquiry is whether an amendment filed in the Patent and Trademark Office (PTO) has narrowed the literal scope of a claim. . . . If the

> amendment was not narrowing, then prosecution history estoppel does not apply.
>
> 2. If the accused infringer establishes that the amendment was a narrowing one, then the second question is whether the reason for that amendment was a substantial one relating to patentability. . . . When the prosecution history record reveals no reason for the narrowing amendment, [the Supreme Court's decision in] *Warner–Jenkinson* [*Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997)] presumes that the patentee had a substantial reason relating to patentability; consequently, the patentee must show that the reason for the amendment was not one relating to patentability if it is to rebut that presumption. . . . In this regard, . . . a patentee's rebuttal of the *Warner–Jenkinson* presumption is restricted to the evidence in the prosecution history record. . . . If the patentee successfully establishes that the amendment was not for a reason of patentability, then prosecution history estoppel does not apply.
>
> 3. If, however, the court determines that a narrowing amendment has been made for a substantial reason relating to patentability . . . then the third question in a prosecution history estoppel analysis addresses the scope of the subject matter surrendered by the narrowing amendment. . . . At that point *Festo VIII* imposes the presumption that the patentee has surrendered all territory between the original claim limitation and the amended claim

> limitation. . . . *The patentee may rebut that presumption* of total surrender by demonstrating that it did not surrender the particular equivalent in question . . . Finally, if the patentee fails to rebut the *Festo* presumption, then prosecution history estoppel bars the patentee from relying on the doctrine of equivalents for the accused element. If the patentee successfully rebuts the presumption, then prosecution history estoppel does not apply and the question whether the accused element is in fact equivalent to the limitation at issue is reached on the merits.

Festo IX, 344 F.3d at 1366–67 (internal citations omitted) (emphasis added). To rebut the presumption of total surrender, a patentee "must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Festo VIII*, 535 U.S. at 741.

One way a patentee can meet this high standard is by showing "the rationale underlying the narrowing amendment [bore] no more than a tangential relation to the equivalent in question." *Festo IX*, 344 F.3d at 1369 (internal citation omitted). This is the tangentiality exception to prosecution history estoppel. In determining whether an amendment was tangential to an equivalent, a court does not consider the patentee's subjective motivation for narrowing his claims. That approach would overlook "the public notice function of a patent and its prosecution history." *Id.* (citations omitted). Instead, the court considers the "objectively apparent" motivation as suggested by the prosecution history. *Id.* Although the tangentiality exception generally cannot be reduced to hard-and-fast rules, *see id.* at 1368, one rule is clear:

"an amendment made to avoid prior art that contains the equivalent in question is not tangential," *id.* at 1369 (citation omitted).

Like prosecution history estoppel, the tangentiality exception balances the needs of patentees and would-be competitors. It also ensures the doctrine of equivalents remains tied to its underlying purpose. If the rationale for an amendment is tangential to the alleged equivalent, "one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Festo VIII*, 535 U.S. at 741. Thus, a patentee's competitors could not infer the patentee "turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter." *Id.* at 734–35. By the same token, however, the tangentiality exception does not apply if the rationale for an amendment is to avoid prior art that contains the alleged equivalent. Then the prior art itself teaches the patentee how to draft a claim that literally encompasses the equivalent. And because the patentee turned his attention to the prior art in order to avoid it, the patentee's competitors could infer the patentee affirmatively chose the narrower claim.

b. The District Court erred in concluding AbbVie and Besins's suit against Teva was objectively baseless.

Teva's paragraph IV notice asserted that because its gel used the penetration enhancer isopropyl palmitate instead of isopropyl myristate, the gel did not literally infringe the '894 patent. It also argued the '894 patent's prosecution history estopped AbbVie and Besins from claiming infringement on

the ground that isopropyl palmitate is equivalent to isopropyl myristate.

On appeal, AbbVie and Besins concede the October 2001 amendment—which narrowed the patent application's claim 1 from all penetration enhancers to a list of 24 not including isopropyl palmitate—was narrowing and was made for a substantial reason related to patentability. *See Festo IX*, 344 F.3d at 1366 (citation omitted). Thus, we presume AbbVie and Besins "surrendered all territory between the original claim limitation and the amended claim limitation," which includes isopropyl palmitate. *Id.* at 1367 (citing *Festo VIII*, 535 U.S. at 740). To rebut this presumption, AbbVie and Besins would have had to show that "at the time of the [October 2001] amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed [isopropyl palmitate]." *Festo VIII*, 535 U.S. at 741. AbbVie and Besins argue they could make this showing. They contend the reason for the October 2001 amendment was to overcome Mak's use of oleic acid—not Allen's disclosure of isopropyl palmitate or other penetration enhancers. So, they claim, the rationale for the amendment was tangential to isopropyl palmitate. *See Festo IX*, 344 F.3d at 1369 (internal citation omitted).

The FTC has not shown that no reasonable litigant in AbbVie and Besins's position would believe it had a chance of winning. *See PRE*, 508 U.S. at 65. AbbVie and Besins's argument has support in the prosecution history record. Allen disclosed isopropyl myristate—the penetration enhancer used in AndroGel—and yet the October 2001 amendment retained isopropyl myristate. Moreover, AbbVie and Besins gave three reasons why the prior art did not suggest combining Mak and Allen. Every one of those reasons distinguished the claimed

penetration enhancers from oleic acid, the penetration enhancer Mak used. Finally, expert testimony could have supported AbbVie and Besins's interpretation of the prosecution history. *See Festo IX*, 344 F.3d at 1369–70. The District Court heard testimony from Dr. Jonathan Hadgraft, Emeritus Professor of Biophysical Chemistry at University College London School of Pharmacy. He testified the "chemical and functional differences identified by the patent applicants in their rationale for distinguishing the penetration enhancers listed in the claims in the [October 2001] amendment . . . from oleic acid would apply equally to isopropyl palmitate." App. 4511. For these reasons, AbbVie and Besins could reasonably have argued that at the time of the October 2001 amendment, one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed isopropyl palmitate. *See Festo VIII*, 535 U.S. at 741. In that case, prosecution history estoppel would not apply. *See id.*

The FTC presents three main counterarguments.

First, the District Court concluded the rationale for the October 2001 amendment was not tangential to isopropyl palmitate because "[i]f AbbVie and Besins merely sought to relinquish oleic acid and no other penetration enhancer in October 2001, they easily could have said so." *AbbVie*, 2017 WL 4098688, at *8. Relatedly, the FTC argues that because AbbVie's "oleic acid rationale does not explain the entire [October 2001] amendment," the rationale for the amendment was not tangential to isopropyl palmitate as a matter of law. FTC Resp. Br. 39–40 (citing *Felix v. Am. Honda Motor Co.*, 562 F.3d 1167, 1184 (Fed. Cir. 2009) and *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1315 (Fed. Cir. 2006)). But negative claim limitations of the sort the Court

mentioned are usually impermissible. *See In re Schechter*, 205 F.2d 185, 188 (C.C.P.A. 1953). Put differently, AbbVie and Besins probably could not have claimed all penetration enhancers "except oleic acid." And the law is not as well-settled as the FTC suggests. Granted, in the cases the FTC cites, the Federal Circuit held the tangentiality exception did not apply in part because the patentee's rationale failed to explain the entire amendment. But because the Federal Circuit has refused to reduce the tangentiality exception to hard-and-fast rules, *see Festo IX*, 344 F.3d at 1368, a reasonable litigant in AbbVie and Besins's position would not necessarily see those decisions as foreclosing its claim.

More persuasive is the District Court's reasoning that the October 2001 amendment sought to overcome the Allen prior art, which "listed isopropyl palmitate as one of five penetration enhancers." *AbbVie*, 2017 WL 4098688, at *8. The FTC also argues Allen's disclosure of isopropyl palmitate "precludes a tangentiality finding," because "an amendment made to avoid prior art that contains the equivalent in question is not tangential." FTC Resp. Br. 38 (quoting *Festo IX*, 344 F.3d at 1369 (*Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1357 (Fed. Cir. 2003))). This argument is more persuasive because the rule the FTC cites is a well-settled exception to the Federal Circuit's case-by-case approach to the tangentiality exception. *See id*. But the argument is not so strong as to make the suits objectively unreasonable. AbbVie and Besins could reasonably have argued the rule did not apply or should be modified, because even though Allen disclosed isopropyl palmitate, AbbVie and Besins made the October 2001 amendment "to avoid" Mak's use of oleic acid, not Allen's disclosure of isopropyl palmitate or other penetration enhancers. *PRE*, 508 U.S. at 65 (quoting FED. R. CIV. P. 11).

Thus, a reasonable litigant in AbbVie and Besins's position would not necessarily see this rule as foreclosing its claim.

Finally, the District Court reasoned that the "entire prosecution history"—not just the October 2001 amendment—is relevant to determine whether estoppel applies. *AbbVie*, 2017 WL 4098688, at *6 (citing *Wang Labs, Inc. v. Toshiba Corp.*, 993 F.2d 858, 867 (Fed. Cir. 1993) and *Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1174 (Fed. Cir. 1993)). Likewise, the FTC argues that "[e]ven if the October 2001 amendment had not excluded isopropyl palmitate, the later amendments would have." FTC Resp. Br. 41. And those amendments "plainly could not have been intended to distinguish oleic acid, which (as AbbVie concedes) had already been excluded by the October 2001 amendment." FTC Resp. Br. 42. Again, the law is not as well-settled as the FTC would have us believe. AbbVie and Besins could reasonably have argued only the October 2001 amendment was relevant under existing law. *See Festo IX*, 344 F.3d at 1369 (tangentiality "focuses on the patentee's objectively apparent reason *for the narrowing amendment*") (emphasis added); *see also Felix*, 562 F.3d at 1182–83; *PRE*, 508 U.S. at 64–65 (probable cause supports a claim if it is "arguably 'warranted by existing law'") (quoting FED. R. CIV. P. 11).

Thus, the District Court erred in concluding AbbVie and Besins's suit against Teva was objectively baseless. Accordingly, we will not consider the subjective motivation prong as to Teva. *See PRE*, 508 U.S. at 60–61.

c. The District Court did not err in concluding AbbVie and Besins's suit against Perrigo was objectively baseless.

Perrigo's first paragraph IV notice asserted that because its gel used the penetration enhancer isostearic acid instead of isopropyl myristate, the gel did not literally infringe the '894 patent. It also explained that the '894 patent's prosecution history estopped AbbVie and Besins from claiming infringement on the ground that isostearic acid is equivalent to isopropyl myristate.

AbbVie and Besins concede the December 2001 amendment narrowed the patent application's claims from 24 penetration enhancers including isostearic acid to isopropyl myristate. But they argue it was not for a substantial reason relating to patentability and, if it was, the rationale for the amendment was tangential to isostearic acid.

No reasonable litigant in AbbVie and Besins's position would believe it had a chance of winning on these arguments. First, AbbVie and Besins argue the December 2001 amendment was not for a substantial reason relating to patentability, both because "the claims pending at the time of the December 2001 amendment . . . were never rejected or threatened with rejection," and because they "amended the claims in December 2001 to expedite the timing of patent protection." AbbVie Br. 47–48. This argument is untenable. "[A] voluntary amendment may give rise to prosecution history estoppel." *Festo IX*, 344 F.3d at 1366 (internal quotations and citation omitted). And expediting prosecution is not a legitimate basis on which to avoid prosecution history estoppel. *See Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1142 (Fed. Cir. 2003) ("[C]laims that were deliberately limited

in order to expedite prosecution by avoiding examination cannot regain that scope for infringement purposes.") (citing *Genentech, Inc. v. Wellcome Found. Ltd.*, 29 F.3d 1555, 1564 (Fed. Cir. 1994)). Regardless, no court would hold the December 2001 amendment's purpose was to expedite prosecution. "[A] patentee's rebuttal of the *Warner–Jenkinson* presumption" that a narrowing amendment was made for a substantial reason relating to patentability "is restricted to the evidence in the prosecution history record." *Festo IX*, 344 at 1367 (citations omitted). But nothing in the prosecution history supports AbbVie and Besins's claim that the December 2001 amendment's purpose was to expedite prosecution. AbbVie and Besins cite the amendment's concluding sentence, which reads: "The Examiner is urged to call the undersigned with any questions or *to otherwise expedite prosecution*." App. 1095 (emphasis added). But that boilerplate statement reveals nothing about the amendment's purpose. AbbVie and Besins also argue that even if the purpose to expedite prosecution did not appear in the prosecution history, it was clear "as a matter of law." Abbvie Br. 48 n.3. This argument fails even as an argument "for the extension, modification, or reversal of existing law." *PRE*, 508 U.S. at 65 (quoting FED. R. CIV. P. 11). As we have explained, the rule that a patentee's rebuttal of the *Warner-Jenkinson* presumption is restricted to the prosecution history is fundamental; it balances "the needs of patentees for adequate protection of their inventions" on the one hand, and "the needs of would-be competitors for adequate notice of the scope of that protection" on the other. *Festo IX*, 344 F.3d at 1385 (Newman, J., concurring in part, dissenting in part).

To the extent the prosecution history reveals the December 2001 amendment's purpose, it shows the amendment related to patentability. In June 2001, the patent

examiner rejected the application's claim 1. In October 2001, AbbVie and Besins unsuccessfully tried to overcome the rejection by amending the application. Their attorneys then had an interview with the patent examiner in which she opined that the application's claims to isopropyl myristate were allowable over the prior art. As the District Court found, these facts were "a telling signal to any reasonable person that patentability required the narrowing of any claim so that it disclosed isopropyl myristate at a particular concentration as the sole penetration enhancer." *AbbVie*, 2017 WL 4098688, at *11. AbbVie and Besins followed that signal in their December 2001 amendment: in the amendment's conclusion—immediately before the boilerplate discussed above—they sought "reconsideration and withdrawal of *the outstanding rejections* and allowance of the . . . claims." App. 1095. (emphasis added).

AbbVie and Besins also argue the rationale for the December 2001 amendment was to overcome Mak's use of oleic acid, so it was tangential to isostearic acid. That argument contradicts the prosecution history. AbbVie and Besins narrowed their claims to exclude oleic acid in October 2001, so that could not have been the purpose of the December 2001 amendment.

AbbVie and Besins counter that the District Court erred by "assessing . . . whether [they] had a winning case against Perrigo" instead of whether a reasonable litigant would believe it had a chance of winning. AbbVie Br. 50. We disagree. While the Court did assess whether they had a winning case, it also assessed whether a reasonable litigant would believe it had a chance of winning. *See AbbVie*, 2017 WL 4098688, at *9 ("[A]ny reasonable person who reads the prosecution history of the '894 patent can reach no other conclusion than that the

defendants have purposefully and not tangentially excluded . . . isostearic acid.").

Finally, AbbVie and Besins argue "[t]he favorable settlements [they] obtained in both suits foreclose the proposition that no reasonable person could have perceived a chance of success for the infringement claims." AbbVie Br. 50–51. They note Perrigo agreed to "continued market exclusivity for AndroGel until late 2014—'far beyond the maximum 30-month Hatch-Waxman stay[]' that would have applied had the lawsuits continued." *Id.* at 51. We think that, ordinarily, settlement on terms favorable to a plaintiff suggests a suit is not objectively baseless. *See, e.g.*, *Theme Promotions, Inc. v. News Am. Mktg. FSI*, 546 F.3d 991, 1008 (9th Cir. 2008); *New W., L.P. v. City of Joliet*, 491 F.3d 717, 722 (7th Cir. 2007). But that is not the situation here. To start, the settlement with Perrigo was not especially favorable to AbbVie and Besins. AbbVie paid Perrigo $2 million as reasonable litigation expenses and agreed to let Perrigo enter the market for AndroGel at the same time as Teva—almost six years before the '894 patent expired. Even if the settlement was favorable, however, that is not dispositive, since the record is clear that Perrigo did not settle because it doubted its litigation position. In Perrigo's paragraph IV notice, it opined that "a lawsuit asserting the '894 patent . . . would be objectively baseless and a sham, brought in bad faith for the improper purpose of, *inter alia*, delaying Perrigo's NDA approval." *AbbVie*, 329 F. Supp. 3d at 114. And Perrigo's assistant general counsel estimated it had a 75 percent chance of victory, which, given the uncertainties inherent in litigation, is a strong probability. Thus, as the District Court found, Perrigo settled for reasons "independent of the merits of [AbbVie and

Besins's] claims," including especially the cost of litigating. *Id*. at 123.

Thus, the District Court did not err in concluding AbbVie and Besins's suit against Perrigo was objectively baseless.

3. The District Court did not err in concluding AbbVie and Besins's suit against Perrigo met sham litigation's subjective motivation prong.

The District Court's evaluation of the subjective motivation prong of the sham litigation test required it to make findings of fact. We review those factual findings under the deferential clear-error standard. *See VICI Racing, LLC v. T-Mobile USA, Inc.*, 763 F.3d 273, 282–83 (3d Cir. 2014). A finding is clearly erroneous when "although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948). "Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 574 (1985) (citations omitted). Clear error review exists to prevent a reviewing court from "overstep[ping] the bounds of its duty . . . [by] duplicat[ing] the role of the lower court." *Id.* at 573 (citing FED. R. CIV. P. 52(a)).

The District Court ruled the FTC "must prove [by clear and convincing evidence] that defendants had actual knowledge that the patent infringement suits here were

baseless." *AbbVie*, 329 F. Supp. 3d at 120.[3] In support, it cited *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365 (1991), in which the Supreme Court said "*[a] classic example* [of sham litigation] is the filing of frivolous objections to the license application of a competitor, with no expectation of achieving denial of the license but simply in order to impose expense and delay." *Id.* at 380 (emphasis added).

The District Court then determined certain evidence submitted to show AbbVie and Besins's knowledge was not probative. This evidence included: (1) Solvay's 2009 press release, because "[n]one of the in-house AbbVie attorneys identified as the decision-makers regarding the 2011 suit[] against . . . Perrigo was previously employed by Solvay or Unimed," *AbbVie*, 329 F. Supp. 3d at 121; (2) business planning documents, because "none of the[] documents . . . was created by or influenced anyone who played a role in the decision[] to sue . . . Perrigo," *id.* at 122;

[3] In a footnote in its response brief, the FTC challenges the District Court's requirement of proof by clear-and-convincing evidence. We have not decided what standard of proof applies to sham litigation's subjective motivation prong. *Cf. Wellbutrin*, 868 F.3d at 148 n.18 (referencing the objective baselessness prong). But in discussing *Noerr-Pennington* cases involving Section 1983 claims, we have explained that a higher standard of proof is needed in *Noerr-Pennington* cases involving patent disputes. *See Campbell v. Pa. Sch. Bd. Ass'n*, 2020 WL 5049051, at *7 (3d Cir. 2020). We need not adopt that dicta today because "arguments raised in passing (such as, in a footnote), but not squarely argued," are forfeited on appeal. *John Wyeth & Bro. Ltd. v. CIGNA Intern. Corp.*, 119 F.3d 1070, 1076 n.6 (3d Cir. 1997).

(3) the settlement agreements, because "[p]arties often settle litigation for a variety of reasons independent of the merits of the claims," *id.* at 123; and (4) AbbVie's citizen petitions, because the petitions "were [all] found to be at least partially meritorious," *id.*[4]

Finally, the Court "zoom[ed] in on the individuals at AbbVie and Besins who made the decision[] to file the infringement action[] against . . . Perrigo [to] discern what these individuals knew." *Id.* at 123–24. Because AbbVie and Besins invoked attorney-client privilege and the attorney work product doctrine, the trial produced "no direct evidence of [these individuals'] subjective intent." *Id.* at 125. The Court refused to draw any negative inference as a result. *See id.* Instead, it considered "the surrounding circumstances and the natural and probable consequences of [AbbVie and Besins's] knowing acts." *Id.* The Court considered two pieces of circumstantial evidence. First, because AbbVie and Besins's decisionmakers were all "very experienced patent attorneys" who had reviewed Perrigo's paragraph IV notices and consulted outside counsel, they knew the lawsuit against Perrigo was objectively baseless. *Id.* at 126. And second, the decisionmakers—some of whom were long-time employees—"knew the extensive financial benefits to [AbbVie and Besins] if generic versions of AndroGel were kept or delayed from entry into the market." *Id.* The Court concluded "[t]he only

[4] AbbVie and Besins argue the District Court erred by not considering the business planning documents and settlement agreements. The FTC argues the Court erred by not considering Solvay's 2009 press release. The Court correctly concluded that none of this evidence is probative of the decisionmakers' subjective motivations.

reason for the filing of these lawsuits was to impose expense and delay on . . . Perrigo so as to block [its] entry into the TTRT market." *Id.*

AbbVie and Besins argue the District Court erred by merging sham litigation's objective baselessness and subjective motivation prongs. They claim "the relevant inquiry under the subjective element [is] whether [the] decisionmakers actually believed the lawsuits had no possibility of success" and were therefore "subjective[ly] baseless[]." AbbVie Br. 56.

The FTC counters that the District Court required it to prove more than was necessary, because the subjective inquiry "has nothing to do with what a litigant knew or should have known regarding the merits of its claims." FTC Resp. Br. 57 (quoting *Kilopass Tech., Inc. v. Sidense Corp.*, 738 F.3d 1302, 1313 (Fed. Cir. 2013)). Instead, the FTC argues, what matters is the intent to "thwart competition." *Id.* (citing *Octane Fitness*, 572 U.S. at 556).

We agree with the FTC that the District Court applied an improper legal standard. The ultimate inquiry under sham litigation's subjective prong is a defendant's subjective motivation, not its subjective belief about the merits of its claims. *See PRE*, 508 U.S. at 60–61; *Octane Fitness*, 572 U.S. at 556. Thus, the term "subjective baselessness" is a misnomer. That said, we disagree that the inquiry into a defendant's motivation has "nothing to do" with a defendant's belief about the merits of its claims. *But cf. Kilopass*, 738 F.3d at 1313. Evidence that a defendant knew its claims were meritless may help a plaintiff to show a defendant was "indifferent to the outcome on the merits of the . . . suit" and "decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process." *PRE*, 508 U.S. at 65 (citation

omitted). It is therefore unsurprising that evidence of a defendant's belief about the merits of its claims appears in a "classic example" of sham litigation, *Omni*, 499 U.S. at 380, or that it appeared in this case. So while evidence of a defendant's belief about the merits of its claims may be relevant to determining a defendant's motivation, it is not required in every case. In short, a defendant can be ambivalent about the merits while filing litigation for an improper purpose (*i.e.*, in bad faith).

We also reject AbbVie and Besins's argument that the District Court improperly merged sham litigation's objective baselessness and subjective motivation prongs. That argument assumes the two prongs are distinct, but they are interrelated. To see how, consider the following syllogism: (1) A lawsuit is objectively baseless if "no reasonable litigant could realistically expect success on the merits," *PRE*, 508 U.S. at 60; (2) and a litigant who files an objectively baseless lawsuit must have had some subjective motivation for suing; (3) but because the lawsuit was objectively baseless, the litigant's subjective motivation could not have been success on the merits, unless the litigant was unreasonable; (4) thus, a reasonable litigant's subjective motivation for filing an objectively baseless lawsuit must be something besides success on the merits. The District Court merely applied this syllogism. It first held that AbbVie and Besins's lawsuits were objectively baseless. It then reasoned that because AbbVie and Besins's decisionmakers were all very experienced patent attorneys who had reviewed Perrigo's paragraph IV notices and consulted outside counsel, they knew the lawsuits were baseless. Finally, it reasoned that because the decisionmakers knew the lawsuits were baseless, they must have been motivated by something

other than success on the merits. The District Court's logic is valid.

AbbVie and Besins respond that, under the District Court's analysis, "in virtually every Hatch-Waxman suit in which a court finds objective baselessness, a finding of subjective baselessness would necessarily follow." AbbVie Br. 57. Not so. The syllogism the Court applied establishes only that a reasonable litigant's subjective motivation must have been something besides success on the merits. It does not necessarily follow that the motivation was to thwart competition. For example, a company might file an objectively baseless lawsuit because it subjectively (though unreasonably) expected the lawsuit to succeed. In that case, a finding of "subjective baselessness" would not necessarily follow from a finding of objective baselessness.

AbbVie and Besins next argue that the circumstantial evidence the Court considered was insufficient to establish the subjective motivation prong by clear and convincing evidence, especially given the presumption that "the assertion of a duly granted patent is made in good faith." AbbVie Br. 56 (quoting *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1369 (Fed. Cir. 1998)).

We disagree. Because AbbVie and Besins invoked attorney-client privilege and the attorney work product doctrine, the Court properly considered the surrounding circumstances and the natural and probable consequences of AbbVie and Besins's intentional acts to make its findings. *Cf. Howard Hess Dental Labs. Inc. v. Dentsply Intern., Inc.*, 602 F.3d 237, 257–58 (3d Cir. 2010) ("Specific intent in the antitrust context may be inferred from a defendant's unlawful conduct.") (citing *Advo, Inc. v. Phila. Newspapers, Inc.*, 51

F.3d 1191, 1199 (3d Cir. 1995)). The Court noted that AbbVie and Besins's decisionmakers were all experienced patent attorneys who had reviewed Perrigo's paragraph IV notices and consulted outside counsel. They also knew the extensive financial benefits AbbVie and Besins would receive if generic versions of AndroGel were kept or delayed from entry into the market. Especially given the collateral injury the Hatch-Waxman Act's 30-month stay invariably inflicts, the Court was permitted to conclude from this evidence that in filing an objectively baseless lawsuit against Perrigo, the decisionmakers were motivated not to assert a patent in good faith, but to impose expense and delay on Perrigo to delay its entry into the TTRT market. *Anderson*, 470 U.S. at 574.

Besins lastly argues the District Court clearly erred because the FTC presented "no evidence" about "who in 2011 were the decisionmakers at Besins . . . and what those people knew." Besins Br. 14. It also argues the trial testimony "neither addressed nor established who made the 2011 decisions to sue. Nor did the FTC ask [Besin's in-house counsel] MacAllister who at Besins made those decisions." *Id.* at 15.

The District Court did not clearly err. MacAllister testified at trial that: he is a former patent examiner; he was "the highest ranking attorney in-house at Besins," App. 3672; he "oversaw the global intellectual property group," *id.*; and he "advised on litigations concerning Besins'[s] patents," App. 3673. An attorney for the FTC asked MacAllister whether he was "involved in the decision to file patent litigation against Perrigo in 2011." App. 3690. He responded that he conferred with AbbVie's in-house counsel "related to the decision whether or not to proceed with the lawsuit," and that Besins's outside counsel provided him and others with advice that "informed our decision as to whether or not to proceed with the

lawsuit." *Id.* It was "permissible" for the Court to conclude from this testimony that MacAllister decided to sue on Besins's behalf. *Anderson*, 470 U.S. at 574.

Thus, the District Court did not err in concluding AbbVie and Besins's suit against Perrigo concealed an attempt to interfere directly with its business relationships, through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon.

C. The District Court did not err in concluding AbbVie and Besins had monopoly power in the relevant market.

To prove monopolization, a plaintiff must establish that the defendant had monopoly power in the relevant market. *See Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306–07 (3d Cir. 2007). Monopoly power is "the ability to control prices and exclude competition in a given market." *Id.*

The FTC relied on indirect evidence to establish AbbVie's monopoly power. "To support a claim of monopoly power through indirect evidence, [a plaintiff] must show that (1) [d]efendants had market power in the relevant market and (2) that there were barriers to entry into the market." *Mylan*, 838 F.3d at 435. Market power is "the ability to raise prices above those that would otherwise prevail in a competitive market." *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 210 (3d Cir. 2005) (citation omitted). A court can infer market power from a market share significantly greater than 55 percent. *See Dentsply*, 399 F.3d at 187. "Other germane factors include the size and strength of competing firms, freedom of entry, pricing trends and practices in the industry, ability of consumers to substitute comparable goods, and consumer demand." *Id.* A

defendant's ability to maintain market share is also relevant. *See id.* at 188–89 (citing *United States v. Syufy Enters.*, 903 F.2d 659, 665–66 (9th Cir. 1990)). Barriers to entry include "regulatory requirements, high capital costs, or technological obstacles, that prevent new competition from entering a market in response to a monopolist's supracompetitive prices." *Broadcom Corp.*, 501 F.3d at 307.

The parties agreed that the relevant geographic market is the United States, so the District Court had to define only the product market.

> To determine if two products are in the same market, we ask if they are readily substitutable for one another, an inquiry that requires us to assess the reasonable interchangeability of use between a product and its substitute. We also look to their cross-elasticity of demand, which is defined as a relationship between two products, usually substitutes for each other, in which a price change for one product affects the price of the other.

Mylan, 838 F.3d at 435–36 (internal quotation marks, citations, and alterations omitted); *see also SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1064 (3d Cir. 1978) (requiring "significant" cross-elasticity of demand).

The District Court defined the product market as "the market for all TTRTs, that is all transdermal testosterone replacement therapies within the United States." *AbbVie*, 329 F. Supp. 3d at 134. It found that all TTRTs were "reasonably interchangeable" and exhibited cross-elasticity of demand. *See id.* at 131–32. By contrast, in considering the market for

TTRTs and injectables, the Court found that while TTRTs were reasonably interchangeable with injectables, they exhibited "little cross-elasticity of demand." *Id.* at 133. It relied on the following evidence:

- Injectables are much cheaper than AndroGel, yet AbbVie has "consistently raised AndroGel's wholesale acquisition cost."

- AbbVie executive James Hynd testified that AbbVie does not price AndroGel against injectables and did not offer rebates to match the price of injectables.

- AndroGel's Director of Marketing Frank Jaeger testified that AbbVie did not consider injectables to be competition. He identified other TTRTs "such as Axiron, Fortesta, and Testim as AndroGel's competitors."

Id. The Court discounted an internal AbbVie document stating that a rise in AndroGel's copay was correlated with an increase in injectables' sales. It explained that factors besides price drove the correlation, including "patient preference, the existence of [specialized testosterone clinics], and the disproportionate negative publicity testosterone gels received after reports associating TTRTs with heightened cardiovascular risk." *Id.* For the same reason, the Court also discounted a "patient switching study" that AbbVie and Besins's expert conducted. *See id.*

The District Court also found that AbbVie and Besins had "a dominant share of the TTRT market in the relevant period and that significant barriers existed for entry into that

market." *Id.* at 136. It relied on the following evidence in finding that AbbVie and Besins had a dominant share:

- "In the TTRT market, AndroGel was by far the most-prescribed product and was widely-recognized as the 'market leader' from before 2011 through 2014."

- In April 2011 (when AbbVie and Besins sued Teva), AndroGel's share of the TTRT market was 71.5 percent. In October 2011 (when they sued Perrigo), AndroGel's share was 63.6 percent. AndroGel's share "remained above 60[percent] until the end of 2014, when Perrigo's generic 1% testosterone product entered the market."

- No other TTRT product ever held 10 percent or more of the market during this period, and AndroGel's market share was always more than three times larger than the market share of any of its brand-name competitors.

- "AbbVie was able to maintain its share of the TTRT market with a profit margin of over 65[percent]" during this period, "even with huge rebates."

- AbbVie increased the wholesale acquisition cost for AndroGel during this period.

Id. at 134–35. Finally, the Court found significant barriers to entry because "a generic drug has significant capital, technical, regulatory, and legal barriers to overcome." *Id.* at 135–36. It explained that, although three brand-name TTRT products (*i.e.*, Fortesta, Axiron, and Vogelxo) entered the market between 2011 and 2014, "they did not pose significant

competition to [AbbVie and Besins's] monopolistic conduct" because they held a low market share. *Id.* at 136.

AbbVie and Besins claim the District Court clearly erred by excluding injectables from the product market for two reasons. First, the record contained "voluminous evidence, including expert testimony, showing substantial cross-elasticity between topical TRTs and injectables." AbbVie Br. 64. And second, the FTC's expert conceded "some cross-elasticity . . . between AndroGel and injectables" and "presented no cross-elasticity study to support" the market the Court defined. *Id.* at 64–65 (citation omitted). In sum, AbbVie and Besins argue that the Court "defined the relevant antitrust market in terms no expert had endorsed." *Id.* at 29.

We disagree for several reasons. First, the mere fact that the record contained evidence tending to show substantial cross-elasticity between topical TRTs and injectables does not mean the Court clearly erred. AbbVie employees conceded at trial that AndroGel does not compete against injectables, so it was at least "permissible" for the Court to exclude injectables from the product market. *Anderson*, 470 U.S. at 574. Second, while the FTC's expert conceded *some* cross-elasticity between AndroGel and injectables, he did not concede *significant* cross-elasticity, which is required to find clear error. *See SmithKline Corp.*, 575 F.2d at 1064. Finally, the FTC's expert did study whether AndroGel and injectables exhibited cross-elasticity of demand. App. 3862 ("I looked at the data on what happened over time to a number of injectable prescriptions and looked to see whether significant changes in the price of the transdermal products, whether we could see an effect on injectables . . . [The data] indicates a low cross-elasticity of demand between AndroGel and injectables . . . ."). While the expert did not "endorse" the market the Court

ultimately defined, his testimony supported the Court's market definition, and the FTC argued for that definition in the alternative. App. 3491 ("[E]ven if the relevant market included all other TRT products except injections, the market share has established that AndroGel still possessed monopoly power.").

AbbVie and Besins also contend the District Court committed legal error by misapplying the legal standard as to the existence of market power and barriers to entry. They argue the Court gave dispositive weight to market share data and Hatch-Waxman's technical and regulatory requirements while ignoring real-world evidence. They emphasize that three new competing brand-name TTRTs entered the market between 2011 and 2014. We are unpersuaded.

The Court did not give dispositive weight to market share data; it also considered consumer demand for AndroGel, the durability of AndroGel's market share, the size and strength of AndroGel's competitors, and AndroGel's pricing trends and practices. *See Dentsply*, 399 F.3d at 187–89 (explaining these are relevant factors). And the Court did not ignore new entrants; it explained the three brand-name TTRT products that entered the market between 2011 and 2014 were not meaningful competitors to AndroGel because of their modest market shares. So the District Court did not err in concluding AbbVie and Besins had monopoly power in the relevant market.

For all the reasons stated, we hold the District Court erred by rejecting the reverse-payment theory and in concluding AbbVie and Besins's litigation against Teva was a sham. We also hold that the Court did not err when it concluded the Perrigo litigation was a sham and that AbbVie and Besins had monopoly power in the relevant market.

V. REMEDIES

We turn finally to remedial issues. The District Court erred in requiring AbbVie and Besins to disgorge $448 million because district courts lack the power to order disgorgement under Section 13(b) of the FTC Act. But it did not abuse its discretion in denying injunctive relief. Nor is it futile to remand the reverse-payment theory.

A. The District Court erred in ordering disgorgement.

The District Court ordered AbbVie and Besins to disgorge $448 million in ill-gotten profits. It reasoned "[t]he weight of authority . . . supports the conclusion that the grant of authority in section 13(b) to provide injunctive relief includes the full range of equitable remedies, including the power to order a defendant to disgorge illegally obtained funds." *AbbVie*, 329 F. Supp. 3d at 137 (citation omitted). It also said a contrary interpretation would "eviscerate the FTC Act" because a monopolist would "be able to retain its ill-gotten gains and simply face an injunction against future wrongdoing." *Id.*

Reviewing the District Court's interpretation de novo, *see Kaufman v. Allstate N.J. Ins. Co.*, 561 F.3d 144, 151 (3d Cir. 2009), we conclude it erred in ordering disgorgement because district courts lack the power to do so under Section 13(b).

"The FTC has multiple instruments in its toolbox to combat unfair methods of competition" and unfair or deceptive acts or practices. *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147, 155 (3d Cir. 2019). First is the FTC's "traditional enforcement tool," Section 5 of the FTC Act. *Id.* (citing 15 U.S.C. § 45(b)).

That section allows the FTC to initiate an administrative proceeding to obtain a cease-and-desist order against an unfair method of competition or an unfair or deceptive act or practice. *See* 15 U.S.C. § 45(b). The FTC can then sue in federal district court to get "limited monetary remedies" for violations of the order. *Shire*, 917 F.3d at 155. A respondent who violates an order is liable for no more than $10,000 per violation. *See* 15 U.S.C. § 45(*l*). The FTC can also seek "mandatory injunctions" and "such other and further equitable relief" as the court deems appropriate. *Id.* Violators other than the respondent are also liable for up to $10,000 per violation, but only if they violate the order knowingly. *See id.* § 45(m)(1)(A).

Second, under Section 19 of the FTC Act, the FTC can promulgate "rules which define with specificity acts or practices which are unfair or deceptive." *Id.* § 57a(a)(1)(B). Alternatively, it can initiate an administrative proceeding to obtain a cease-and-desist order. *Id.* § 57a(a)(2). In either case, it can sue violators in federal district court. *See id.* § 57a(a)(1)–(2). If the FTC promulgated a rule, the court can "grant such relief as the court finds necessary to redress injury," including but not limited to "the refund of money or return of property" and "the payment of damages." *Id.* § 57b(b). Otherwise, the FTC can obtain such relief only if it shows "a reasonable man would have known under the circumstances" his conduct was "dishonest or fraudulent." *Id.* § 57b(a)(2).

A third enforcement tool is Section 13(b) of the FTC Act. "Unlike Section 5, Section 13 was not part of the original FTC Act." *Shire*, 917 F.3d at 155. "Rather, [it] was added later [in 1973] in an effort to solve one of the main problems of the FTC's relatively slow-moving administrative regime—the need to quickly enjoin ongoing or imminent illegal conduct." *Id.*

The question presented in this appeal is whether a district court has the power to order disgorgement under Section 13(b). We start with the text, for where "the words of the statute are unambiguous, the judicial inquiry is complete." *Desert Palace, Inc. v. Costa*, 539 U.S. 90, 91 (2003) (internal quotation marks and citation omitted). Section 13(b) states:

> Whenever the Commission has reason to believe—
>
> (1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
>
> (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—
>
> the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: *Provided, however*, That if a complaint is not filed within such period

> (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: *Provided further*, That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction.

15 U.S.C. § 53(b). Section 13(b) authorizes a court to "enjoin" antitrust violations. It says nothing about disgorgement, which is a form of restitution, *see Liu v. SEC*, 140 S. Ct. 1936, 1940–41 (2020), not injunctive relief, *see, e.g.*, *Meghrig v. KFC W., Inc.*, 516 U.S. 479, 484 (1996) ("[N]either [a mandatory nor prohibitory injunction] contemplates the award of . . . 'damages' or 'equitable restitution.'"); *Owner-Operator Indep. Drivers Ass'n v. Landstar Sys., Inc.*, 622 F.3d 1307, 1324 (11th Cir. 2010) ("Injunctive relief constitutes a distinct type of equitable relief; it is not an umbrella term that encompasses restitution or disgorgement."). Thus, Section 13(b) does not explicitly empower district courts to order disgorgement.

This interpretation is even stronger in context. Section 13(b) says that, in order to sue, the FTC must have reason to believe an antitrust violation is imminent or ongoing. *See Shire*, 917 F.3d at 156 (holding requirement applies to request for permanent injunction). This requirement makes perfect sense as applied to injunctive relief, which prevents or mandates a future action. *See Injunction*, BLACK'S LAW DICTIONARY (rev. 4th ed. 1968). So if a violator's conduct is neither imminent nor ongoing, there is nothing to enjoin, and the FTC cannot sue under Section 13(b). By contrast, the requirement makes little sense as applied to a disgorgement

remedy. Disgorgement deprives a wrongdoer of *past* gains, *see Liu*, 140 S. Ct. at 1940–41, meaning that even if a wrongdoer's conduct is not imminent or ongoing, he may have gains to disgorge. If Congress contemplated the FTC could sue for disgorgement under Section 13(b), it probably would not have required the FTC to show an imminent or ongoing violation. That requirement suggests Section 13(b) does not empower district courts to order disgorgement.

The FTC's other enforcement powers also support our interpretation. Both distinguish between injunctions and other forms of equitable relief. *See* 15 U.S.C. § 45(*l*) (FTC can seek "mandatory injunctions" and "such other and further equitable relief" as the court deems appropriate); *Id.* § 57b(b) (court can "grant such relief as the court finds necessary to redress injury," including but not limited to "the refund of money or return of property" and "the payment of damages"). The timing of the enactment of these powers is also instructive. Congress amended Section 5 to allow "such other and further equitable relief" at the same time it enacted Section 13(b). *See* Trans-Alaska Pipeline Authorization Act, Pub. L. No. 93-153, § 408, 87 Stat. 576, 591 (1973). And it enacted Section 19—which allows disgorgement only under certain conditions—after Section 13(b). *See* Magnuson-Moss Warranty Act, Pub. L. No. 93-637, § 206, 88 Stat. 2183, 2201–02 (1975). Thus, Sections 5 and 19 both show that when Congress wants to empower a district court to order more expansive equitable relief than injunctions, it does so. Yet Congress did not do so in Section 13(b).

A contrary conclusion would undermine the FTC Act's statutory scheme. Section 13(b) was added in 1973 because the FTC's administrative regime moved slowly. *See Shire*, 917 F.3d at 155. But it is slow-moving for a reason: it affords

defendants valuable procedural protections. For example, Section 5 conditions relief to defendants on an administrative proceeding and a cease-and-desist order. *See* 15 U.S.C. § 45(b). It also limits the monetary relief the FTC can obtain. *See* 15 U.S.C. § 45(*l*); *see also id.* § 45(m)(1)(A). Section 19 likewise requires the FTC to promulgate "rules which define with specificity acts or practices which are unfair," or initiate an administrative proceeding to obtain a cease-and-desist order. *Id.* § 57a(a)(1)(B)–(2). By contrast, Section 13(b) does not incorporate these same protections: it grants the FTC a cause of action to seek a preliminary injunction in federal court without first pursuing administrative adjudication or rulemaking; and it imposes no limits on the amount of any monetary relief the FTC may be able to obtain. Thus, our interpretation does not "eviscerate" the FTC Act; it harmonizes its provisions.

The FTC counters that Section 19 has a savings clause. That clause states: "Remedies provided in this section are in addition to, and not in lieu of, any other remedy or right of action provided by State or Federal law. Nothing in this section shall be construed to affect any authority of the Commission under any other provision of law." 15 U.S.C. § 57b(e). But "[t]he saving clause preserves only those remedies that exist. It does not inform the question whether section 13(b) contains an implied power to award restitution." *FTC v. Credit Bureau Ctr., LLC*, 937 F.3d 764, 775 (7th Cir. 2019).

The FTC argues the interpretation we adopt goes against the weight of precedent. It notes that seven of our sister courts have held courts may order disgorgement under Section 13(b), and we acknowledged as much in the footnote of a not-precedential decision. FTC Reply Br. 88 (quoting *FTC v. Magazine Sols., LLC*, 432 F. App'x 155, 158 n.2 (3d Cir.

2011)). That is true, but until recently, "[n]o circuit ha[d] examined whether reading a restitution remedy into section 13(b) comports with the FTCA's text and structure." *Credit Bureau*, 937 F.3d at 785 (describing the precedents); *see also id.* (quoting *United States v. Hill*, 48 F.3d 228, 232 (7th Cir. 1995) ("We are not merely to count noses. The parties are entitled to our independent judgment.")). Moreover, today's result is consistent with the recent ruling of the United States Court of Appeals for the Seventh Circuit, which, in a thorough and well-reasoned opinion, overturned its precedent authorizing restitution under Section 13(b). *Credit Bureau Center*, 937 F.3d at 764; *see also FTC v. AMG Capital Mgmt., LLC*, 910 F.3d 417, 429 (9th Cir. 2018) (O'Scannlain, J., specially concurring). Finally, our decision in *Magazine Solutions* does not bind us. *See* I.O.P. 5.7. Even if it did, the part of the footnote on which the FTC relies was dictum because the litigant forfeited the issue by failing to raise it in the district court. *See* 432 F. App'x at 158 n.2.

Next, the FTC argues Congress has "twice ratified the consistent understanding of the courts of appeals"—first in 1994, when Congress expanded the venue and service-of-process provisions of Section 13(b), *see* FTC Act Amendments of 1994, Pub. L. No. 103-312, § 10, 108 Stat. 1691, 1695–96 (1994); and second in 2006, when Congress made "[a]ll remedies available to the Commission . . . *including restitution to domestic or foreign victims*" available for certain unfair practices abroad, *see* U.S. Safe Web Act of 2006, Pub. L. No. 109-455, § 3, 120 Stat. 3372, 3372 (2006) (amending 15 U.S.C. § 45(a)(4)(B)) (emphasis added). FTC Reply Br. 93. We disagree. The 1994 amendment did not change the remedies available to the Commission. So it can hardly be seen as ratifying our sister courts' precedents on that issue. And the

2006 amendment's reference to restitution does not mean restitution is available under Section 13(b); the availability of restitution under Sections 5 and 19 is well-settled, and the amendment could have referred to those sections instead.

The crux of the FTC's counterargument is a pair of Supreme Court decisions on which our sister courts and the District Court relied—*Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946), and *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288 (1960). According to the FTC, these decisions mean Section 13(b)'s use of the word "injunction" impliedly empowers district courts to order equitable relief in addition to injunctions. Once again, we disagree.

In *Porter*, the Supreme Court held a district court could order restitution under the Emergency Price Control Act of 1942, which authorized the Administrator of the Office of Price Administration to seek "a permanent or temporary injunction, restraining order, or *other order*" in court. 328 U.S. at 397 (emphasis added). The Court reasoned:

> Unless otherwise provided by statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction. And since the public interest is involved . . . , those equitable powers assume an even broader and more flexible character than when only a private controversy is at stake. Power is thereby resident in the District Court, in exercising this jurisdiction to do equity and to mould each decree to the necessities of the particular case. It may act so as . . . to accord full justice to all the real parties in interest . . . . In addition, the court may . . . give whatever other

> relief may be necessary under the circumstances. Only in that way can equity do complete rather than truncated justice.
>
> Moreover, the comprehensiveness of this equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command. Unless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied.

Id. at 398 (internal citations and quotations omitted). The Court concluded that "the term 'other order' contemplates a remedy other than that of an injunction or restraining order, a remedy entered in the exercise of the District Court's equitable discretion." *Id.* at 399. It noted that no "other provision of the Act . . . expressly or impliedly precludes a court from ordering restitution." *Id.* at 403.

In *Mitchell*, the Supreme Court extended *Porter*. The Court held a district court could order wage reimbursement under the Fair Labor Standards Act, which gave courts jurisdiction "to restrain violations" of the Act. *Mitchell*, 361 U.S. at 289. The Court said:

> When Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in light of the statutory purposes. As this Court long ago recognized, there is inherent in the Courts of Equity a

> jurisdiction to . . . give effect to the policy of the legislature.

Id. at 291–92 (alteration in original) (citation and internal quotations omitted). It was immaterial that the Act lacked language, like "other order" in *Porter*, that confirmed the court's power to order reimbursement. *See id.* at 291 (citations omitted).

We interpreted *Porter* and *Mitchell* in *United States v. Lane Labs-USA Inc.*, 427 F.3d 219 (3d Cir. 2005). There, we held a court could order restitution under the FDC Act in part because the Act empowered district courts to "restrain violations." *See id.* at 223; 21 U.S.C. § 332(a). We explained *Porter* and *Mitchell* "charted an analytical course that seems fairly easy to follow: (1) a district court sitting in equity may order restitution unless there is a clear statutory limitation on the district court's equitable jurisdiction and powers; and (2) restitution is permitted only where it furthers the purposes of the statute." *Id.* at 225. We noted "[n]umerous courts have followed this approach in opining about a court's power to order . . . disgorgement under several different statutes." *Id.* In support, we cited, among other authorities, a decision holding disgorgement is available under Section 13(b). *See id.* (citing *FTC v. Gem Merch. Corp.*, 87 F.3d 466, 470 (11th Cir. 1996)).

Following the analytical course that *Lane Labs* described, we conclude Section 13(b) does not implicitly empower district courts to order disgorgement. Unlike the statutes at issue in *Porter*, *Mitchell*, and *Lane Labs*, Section 13(b) limits the district court's equitable jurisdiction and powers because it specifies the form of equitable relief a court may order. *Compare Porter*, 328 U.S. at 397–98 ("a permanent or temporary injunction, restraining order, or other order" in

court), *Mitchell*, 361 U.S. at 289 ("restrain violations"), *and Lane Labs*, 427 F.3d at 223 (same) *with* 15 U.S.C. § 53(b) ("enjoin"). Moreover, as we have explained, the context of Section 13(b) and the FTC Act's broader statutory scheme both support "a necessary and inescapable inference" that a district court's jurisdiction in equity under Section 13(b) is limited to ordering injunctive relief. *Porter*, 328 U.S. at 398. So our interpretation is consistent with *Lane Labs* and faithful to *Porter* and *Mitchell.*

The FTC counters that in *Lane Labs*, we cited *Gem Merchandising*, which held disgorgement is available under Section 13(b). But we cited that case solely to support our approach to applying *Porter* and *Mitchell*, and the other cases we cited involved three different statutes. *Lane Labs*, 427 F.3d at 225. We were not interpreting statutes en masse.

For these reasons, we hold district courts lack the power to order disgorgement under Section 13(b) of the FTC Act. So the District Court erred in requiring AbbVie and Besins to disgorge $448 million.

B. The District Court did not abuse its discretion in denying injunctive relief.

To obtain an injunction, the FTC must show there is a "cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). An injunction that implicates a defendant's First Amendment rights must "burden no more speech than necessary to serve a

significant government interest." *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (citations omitted).

> The FTC sought an injunction:
>
> > (1) to prohibit the filing of any claims of patent infringement based on the '894 patent by a product that does not include about 0.1% to about 5% isopropyl myristate; (2) to prohibit defendants from filing any other sham litigation; (3) to prohibit defendants from engaging in any action that misuses government processes for anticompetitive purposes; and (4) to require defendants to certify that any patent infringement litigation or other use of governmental processes has an objectively reasonable basis.

AbbVie, 329 F. Supp. 3d at 144. It also sought an injunction to "restore competitive market conditions" by compelling AbbVie and Besins to license AndroGel 1.62% to one or more generic competitors, and to sell them a supply of the gel until they could manufacture it themselves. *Id.* at 145. At oral argument on appeal, the FTC stated that because the '894 patent would soon expire, on remand it would not seek to prohibit the filing of patent infringement claims based on the '894 patent, Oral Argument January 15, 2020 at 19:15–35; however, it reaffirmed its interest in a certification requirement, *id*. at 15:05–17:55.

The District Court found no basis on which to conclude AbbVie and Besins's sham litigations were likely to recur. It explained the FTC proved only "that defendants filed two sham infringement lawsuits," which do not establish a "pattern or

practice." *Id.* And though the FTC advised the Court that since suing Teva and Perrigo in 2011, AbbVie and Besins have filed "numerous other patent infringement suits against competitors, including seven lawsuits related to the '894 patent," the FTC presented no evidence those lawsuits were shams. *See id.* at 145 n.31. Moreover, the Court noted generic versions of AndroGel had been on the market for over three years. *See id.* at 145. Finally, the Court held that because the proposed injunction would have limited AbbVie and Besins's ability to file patent infringement suits with respect to any patent, it was so "overbroad and punitive" that it would violate their First Amendment rights. *See id.* (citing *Madsen*, 512 U.S. at 765).

On appeal, the FTC argues the District Court abused its discretion because, under the likelihood-of-recurrence test that governs SEC cases, AbbVie and Besins are likely to engage in further sham litigation. FTC Br. 48–49 (citing *SEC v. Bonastia*, 614 F.2d 908, 912 (3d Cir. 1980)). The FTC also argues the Court's First Amendment concerns rested on a mischaracterization of the injunctive relief it requested. Although its "pretrial brief used broader language," its proposed order did not seek to prohibit AbbVie and Besins from engaging in any action that misuses government processes. FTC Br. 52 n.13. In any event, the FTC argues its injunction is constitutional because the certification requirement and prohibition on sham litigation implicate no First Amendment rights. *Id.* at 54. It also cites the "well-settled" rule that "once the Government has . . . establish[ed] a violation of law, all doubts as to the remedy are to be resolved in its favor." *Id.* at 55 (citing *United States v. E. I. du Pont de Nemours & Co.*, 366 U.S. 316, 334 (1961)).

We disagree. Under *Grant*, the District Court had to determine whether the likelihood of AbbVie and Besins

engaging in sham litigation was a cognizable danger or merely possible. *See* 345 U.S. at 633. Even resolving doubts in the FTC's favor, for the reasons the Court stated it was well within its discretion to conclude the FTC had shown a mere possibility.

Nor did the District Court abuse its discretion by failing to apply the *Bonastia* factors, which we have never applied in FTC Act cases. *See* 614 F.2d at 908. And we are disinclined to extend *Bonastia* here for two reasons. First, our review of the voluminous record on appeal did not uncover any indication the FTC argued the District Court should extend *Bonastia* outside the SEC context. To the contrary, the FTC's proposed findings of fact and conclusions of law relied solely on *Grant*, which the District Court applied. To the extent the FTC did not raise this argument in the District Court, it is forfeited on appeal. *See In Re: J & S Props., LLC*, 872 F.3d 138, 146 (3d Cir. 2017) (citing *United States v. Joseph*, 730 F.3d 336, 341–42 (3d Cir. 2013)).

Second, we would not find an abuse of discretion even if *Bonastia* applied. Under that decision, courts look to:

> [1] the degree of scienter involved on the part of the defendant, [2] the isolated or recurrent nature of the infraction, [3] the defendant's recognition of the wrongful nature of his conduct, [4] the sincerity of his assurances against future violations, and [5] the likelihood, because of defendant's professional occupation, that future violations might occur.

Bonastia, 614 F.2d at 912 (citation omitted). Although the Court did not recite these factors mechanically, its rationale accounted for the substance of all but the third and fourth. And the antitrust laws afford no relief on the basis of those factors alone. *Cf. Howard Hess*, 602 F.3d at 251 (citing *Bonastia*, 614 F.2d at 912).

Thus, the District Court did not abuse its discretion in denying injunctive relief.

C. Remand on the reverse-payment theory is not futile.

AbbVie and Besins argue that remand to allow the FTC to proceed on the reverse-payment theory would be futile for several reasons. None is persuasive.

First, AbbVie and Besins argue the FTC will not be able to show they "[are] violating, or [are] about to violate" the antitrust laws. AbbVie Br. 91 (quoting 15 U.S.C. § 53(b)). But in *Shire*, we held that whereas Section 13(b) of the FTC Act requires a plaintiff to plead the defendant "is violating" or is "about to violate" the antitrust laws, the likelihood-of-recurrence standard "applies when a court is considering whether to grant or deny injunctive relief." 917 F.3d at 158. Second, AbbVie and Besins argue disgorgement would be inappropriate, both because Section 13(b) does not authorize it and because the District Court found, in calculating the amount of disgorgement, that Teva would not have marketed its generic gel even without the sham litigation. *See AbbVie*, 329 F. Supp. 3d at 140 ("[T]he FTC has not established that, but for defendants' sham litigation, Teva would have launched its product on June 2012 or at any time thereafter."). We agree that disgorgement is inappropriate because Section 13(b) does

not authorize it. But because we cannot say, based on the pleadings alone, that the Court would abuse its discretion by granting the FTC injunctive relief, remand is not futile. Consistent with our holding in *Shire*, the District Court should apply the likelihood-of-recurrence standard. *See* 917 F.3d at 158. Apart from that instruction, the District Court retains discretion to determine whether the FTC is entitled to an injunction if it ultimately succeeds on the reverse-payment theory.

Finally, at oral argument before our Court, counsel for AbbVie argued for the first time that the District Court's finding that Teva would not have marketed its generic gel without the sham litigation means that, on remand, the FTC will be unable to show antitrust injury, which is an element of every antitrust claim. *See generally Wellbutrin*, 868 F.3d at 164–65; Oral Arg. 29:10–36:25. Arguments not briefed are forfeited on appeal. *See Griswold v. Coventry First LLC*, 762 F.3d 264, 274 n.8 (3d Cir. 2014) (citation omitted). Regardless, we think that on remand, the Court must consider anew its finding that Teva would not have marketed its generic gel without the sham litigation. The FTC plausibly alleged AbbVie paid Teva a large, unjustified reverse payment to delay its entry into the market for AndroGel.

* * *

For the reasons stated, we will reverse the District Court's order granting the motion to dismiss Count I in part and to dismiss Count II. We will also affirm the Court's order adjudging AbbVie and Besins liable for monopolization under Count I based upon its holding that the suit against Perrigo was a sham. Finally, we will affirm the Court's order denying

injunctive relief, reverse the Court's disgorgement order, and remand for further proceedings consistent with this opinion.