APPENDIX

APPENDIX A

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
(Filed September 30, 2020)

OPINION OF THE COURT

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

HARDIMAN, *Circuit Judge*.

* * *

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 af-

firm 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 An-

droGel 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 empha-

sized 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 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.

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[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.

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 261-62. 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

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[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 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 the 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.

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 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 re-

verse 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 compe-

tition 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 agree-

ment 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 explana-

tions 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* in-

cluded 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 al-

lowing 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 ex-

tends 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 grievanc-

es" 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 tan-

gential 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 exist-

ing 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 re-

viewing 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,"

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[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).

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) 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 ver-

[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.

sions of AndroGel were kept or delayed from entry into the market." *Id.* The Court concluded "[t]he only 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 be-

cause 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 anti-competitive 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 ex-

hibited 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 fol-

lowing 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 in-

jectables ….”). 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 peri-

> od (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 wrong-

doer 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 timely 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.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

NO. 14-5151
CIVIL ACTION

FEDERAL TRADE COMMISSION,

v.

ABBVIE INC., ET AL.,

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Bartle, J. June 29, 2018

The Federal Trade Commission ("FTC") has sued defendants AbbVie Inc., Abbott Laboratories, and Unimed Pharmaceuticals LLC (collectively, "AbbVie"), as well as Besins Healthcare, Inc. ("Besins"), for violation of section 5(a) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(a), which prohibits "[u]nfair methods of competition in or affecting commerce."

AbbVie and Besins together own U.S. Patent No. 6,503,894 ("'894 patent") for a brand-name testosterone replacement drug, AndroGel 1%. In Count I of the complaint, the FTC alleges that AbbVie and Besins maintained an illegal monopoly through the filing of sham patent infringement lawsuits against two poten-

tial competitors, Teva Pharmaceuticals USA, Inc. ("Teva") and Perrigo Company ("Perrigo"), to delay entry into the market of their generic versions of AndroGel.[1]

To prevail in this antitrust litigation, the FTC must prove that defendants possessed monopoly power in the relevant market and that defendants willfully acquired or maintained that power. *See Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd.*, 838 F.3d 421, 433 (3d Cir. 2016). Here, the FTC asserts that defendants maintained their AndroGel monopoly through the filing of sham litigation against Teva and Perrigo. To prove its case, the FTC must establish: (1) the lawsuits filed by defendants against Teva and Perrigo were objectively baseless; (2) defendants subjectively intended to file such lawsuits; and (3) that defendants possessed monopoly power in the relevant market. *See Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993) ("*PRE*"); *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 148-49 (3d Cir. 2017).

On September 15, 2017, this court ruled that defendants' infringement lawsuits against Teva and Perrigo were objectively baseless and entered summary judgment in favor of the FTC on this issue. *See FTC v. AbbVie Inc.*, No. 14-5151, 2017 WL 4098688, at *11 (E.D. Pa. Sept. 15, 2017) (Doc. # 300). Thereafter the

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[1] In count II of the complaint, the FTC alleged that the settlement between Teva and the other defendants constituted an improper restraint of trade in violation of the FTC Act. On May 6, 2015, this court granted the motion of defendants to dismiss count II of the complaint, as well as count I to the extent it was premised on the settlement agreements with Teva. As a result, Teva was dismissed as a defendant in this action and only the claim involving sham lawsuits in Count I remains.

court held an approximately three-week nonjury trial on the issues of subjective intent and monopoly power. The court now makes the following findings of fact and conclusions of law.

I

To understand the claim presented in this action, we first set forth the regulatory scheme that governs the testing and approval of new drugs in the United States. That framework is governed by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, which is commonly known as the Hatch-Waxman Act, 21 U.S.C. § 355 and 35 U.S.C. § 271. *See* Pub. L. No. 98-417, 98 Stat. 1585.

A drug manufacturer seeking to market a new drug must obtain approval from the U.S. Food and Drug Administration ("FDA"). *See* 21 U.S.C. § 355(a). There are three pathways established by the FDCA and Hatch-Waxman: (1) a section 505(b)(1) New Drug Application ("NDA"); (2) a section 505(b)(2) NDA; and (3) a section 505(j) Abbreviated New Drug Application ("ANDA").

An NDA is a full-length application containing information on the drug's safety and efficacy, an explanation of the drug's ingredients, a description of the methods used in the manufacture and packaging of the drug, samples of the proposed labeling, and samples of the drug itself. *See id.* § 355(b)(1). The NDA must also contain a list of any patents covering the drug. *Id.*

Once the FDA has approved a new brand-name drug, an applicant with a generic version of that drug can obtain approval through the use of abbreviated

procedures. *See* 21 U.S.C. § 355(j). Most commonly, the applicant will file a section 505(j) ANDA stating, among other things, that the generic has the same active ingredients and is biologically and pharmacologically equivalent to the brand-name drug. *Id.* § 355(j)(2)(A). The applicant may then rely on the safety and efficacy data contained in the NDA for the brand-name drug. *Id.*

In the alternative, the applicant with a generic drug may file a section 505(b)(2) NDA, which is a hybrid between an ANDA and a full NDA. A section 505(b)(2) NDA is used for generics that have slight modifications from the brand-name drug. *See* 21 C.F.R. § 314.54. The applicant must submit additional data to the FDA demonstrating that any differences between the brand-name drug and the generic will not affect safety and efficacy but can otherwise avoid the other studies necessary for a full NDA application. *Id.*; *see also Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 227 (3d Cir. 2013). Because the Hatch-Waxman Act allows the applicant to "piggy-back" on the efforts for the approval of the brand-name drug, its provisions "speed the introduction of low-cost generic drugs to market" and thereby promote drug competition. *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (alteration omitted)).

Once the FDA approves a generic drug, the applicant may request from the FDA a therapeutic equivalence ("TE") rating. A TE rating is a code that reflects the FDA's determination regarding whether a generic product is pharmaceutically and biologically equivalent to the reference-listed brand-name drug. Products that are determined to be therapeutically equivalent are assigned an "A" or "AB" rating. Generic products for

which therapeutic equivalence cannot be determined are assigned a "B" or "BX" rating.[2] An "A" or "AB" rating is extremely desirable. Every state in the United States has generic substitution laws. *See Mylan Pharm. Inc.*, 838 F.3d at 428. These laws "either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be dispensed as written." *Id.* (internal quotation marks and citations omitted).

The Hatch-Waxman Act also provides specialized procedures for parties to resolve intellectual property disputes. In submitting an ANDA or section 505(b)(2) NDA, an applicant must certify that any patent currently in force for the referenced brand-name drug "is invalid or will not be infringed by the manufacture, use, or sale" of the proposed generic. 21 U.S.C. § 355(j)(2)(A)(vii). This certification is commonly referred to as a paragraph IV notice. *Actavis*, 570 U.S. at 143.

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[2] "A" and "B" are the two general categories into which the FDA sorts drugs when evaluating therapeutic equivalence. Within these two categories are various subcategories depending on the type of product (i.e., oral, injectable, solution, or powder) and other factors. For our purposes we will focus on "AB," which means "actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence," and "BX," which is "specific drug products for which the data that have been reviewed by the Agency are insufficient to determine therapeutic equivalence." *See* U.S. Food & Drug Admin., Center for Drug Evaluation & Research, *Approved Drug Products with Therapeutic Equivalence Evaluations*, at xiii, xx (38th ed. 2018), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#_ftn4.

The paragraph IV notice "automatically counts as patent infringement" and thus often leads to an infringement suit by the patentee. *Id.* (citing 35 U.S.C. § 271(e)(2)(A)). Upon receiving the paragraph IV notice, the patentee has 45 days to determine whether to file suit for infringement. 21 U.S.C. § 355(j)(5)(B)(iii). The notice often includes an offer of confidential access whereby outside counsel for the patentee may review the application submitted to the FDA by the generic applicant to facilitate a determination regarding infringement litigation. If the patentee files an infringement suit against a generic entity within this 45-day period, the FDA is required to withhold approval of the generic drug for 30 months from receipt of the paragraph IV notice or until the infringement action is resolved in the district court, whichever occurs first. *Id.*

II

AndroGel is a brand-name transdermal testosterone gel product approved by the FDA for the treatment of hypogonadism, a clinical syndrome that results from failure of a man's body to produce adequate amounts of testosterone. It is estimated that this condition affects 2-6% of the adult male population in the United States. Hypogonadism is a lifelong condition which causes decreases in energy and libido, erectile dysfunction, and changes in body composition including decreased bone density. Patients with hypogonadism are typically treated with testosterone replacement therapy ("TRT") whereby exogenous testosterone is administered.

The first TRTs approved by the FDA were injectables in which testosterone is dissolved in a liquid and then injected into a muscle of the body. Injectable testosterones were introduced in the 1950s and have been

available in generic form for decades. They are administered every one to three weeks. While many patients receive injections at their doctors' office, some patients opt to self-administer injections at home or visit clinics specializing in TRT commonly known as "Low-T" centers. Because they are available in generic form, injectables generally require a five to ten dollar patient copay on most insurance plans and thus are the least expensive treatment method for hypogonadism.

Testosterone injections typically require two needles: a withdrawal needle and an injection needle. The withdrawal needle is typically a 20-gauge wide bore and 1-inch long needle required to withdraw the testosterone from the glass vial. After withdrawal, the patient must switch to a 21- or 22-gauge narrow bore and 1.5-inch long needle to administer the injection. This needle must then be inserted deep into a muscle, typically the buttocks or thigh, until the needle is no longer visible. Because a deep intramuscular injection is required, this treatment method may cause pain and discomfort which will vary from patient to patient. Injectables generally provide an initial peak in testosterone level at the time of injection followed by troughs or valleys as the injection wears off. This variation in testosterone level may cause swings in mood, libido, and energy.

TRTs may also be administered through a gel or patch which is applied to the skin and thereby absorbed into the bloodstream. This group of products is known as topical testosterone replacement therapies or transdermal testosterone replacement therapies ("TTRTs"). Androderm, the first testosterone patch, was released in the 1990s. It is applied once a day to the back, abdomen, thighs, or upper arms. The patch formulation delivers a steady level of testosterone without the peaks

or valleys associated with injectables. It is relatively easy to apply, although the patch may cause skin irritation in some patients and may be visible depending on where it is applied. Testoderm, a testosterone patch worn on the scrotum, was also introduced in the 1990s.

AndroGel was launched in 2000 as the first FDA-approved testosterone gel. It is applied once a day to one or more application sites, including the upper arms, shoulders, and abdomen. AndroGel comes in two strengths: (1) 1%, which was the original formulation launched in June 2000; and (2) 1.62%, which was first sold in May 2011. At the time AndroGel 1% came on the market in 2000, it was available only in sachets. In 2004 it became available in a metered-dose pump. AbbVie discontinued manufacture of the AndroGel 1% pump in December 2013.

AndroGel 1% was developed through a collaboration between Unimed and various subsidiaries of Besins' parent company. At the time of its launch, AndroGel 1% was marketed and distributed by Solvay Pharmaceuticals, Inc. ("Solvay"), the parent company of Unimed. Abbott Laboratories acquired Solvay and Unimed in February 2010. At that time Solvay was renamed Abbott Products Inc. In January 2013, AbbVie assumed all of Abbott's proprietary pharmaceutical business, including AndroGel 1%.

As the first gel in the market, AndroGel achieved great commercial success and quickly became one of Solvay's "flagship" products. In 2009, AndroGel's U.S. net sales were approximately $604 million and in 2010, that number grew to $726 million. After AbbVie[3] ac-

[3] As stated above, AbbVie acquired all of Abbott's proprietary pharmaceutical business in 2013. Hereafter we will refer to Abbott as "AbbVie."

quired Solvay and Unimed in 2010, sales of AndroGel continued to grow, and AndroGel became one of AbbVie's blockbuster drugs. In 2011, U.S. net sales for AndroGel reached $874 billion and in 2012, U.S. net sales surpassed $1.15 billion. In 2013, AndroGel's U.S. net sales were approximately $1.035 billion while in 2014, net sales totaled $934 million. After entry of generic versions of AndroGel 1%, AndroGel U.S. net sales fell to $694 million in 2015. Throughout this time, AbbVie maintained a high profit margin of approximately 65% on AndroGel.

Transdermal gels have several advantages over the other forms of TRTs. A gel is relatively easy for a patient to apply without the potential for pain or discomfort associated with an injection. It also allows the patient to maintain a steady testosterone level without peaks and troughs. As compared to the patch form of testosterone, it has a lower rate of irritation and is not visible.

Gels such as AndroGel, however, are not without some drawbacks. There is a serious but rare risk of secondary exposure associated with gels, whereby testosterone may be transferred from a patient to others, including women and children, through skin-to-skin contact. Precautions such as washing hands after application and covering the application site with a t-shirt can prevent such exposure. Gels may also cause skin irritation in some patients. Finally, some patients may dislike having to apply the gel daily.

After AndroGel was released in 2000, several other brand-name TTRTs were launched by competing pharmaceutical companies. Testim, a 1% gel available in a five gram tube, was approved in 2002. In 2011, two brand-name testosterone 2% gels were brought to

market: (1) Fortesta, a metered-dose pump product applied to the thighs; and (2) Axiron, a solution that is dispensed from a metered-dose pump and is applied to the underarms using a silicon applicator. And in 2014 Vogelxo, another brand-name low-volume testosterone gel, was launched along with an authorized generic version of the same product.

In addition to injectables and TTRTs, several other forms of TRT have been approved by the FDA. Striant, a buccal testosterone tablet that is applied twice daily to gums, was released in 2003. Testopel, a pellet that is surgically inserted in the hip, buttocks, or thigh every three to six months, was approved in 2008. And in 2014 the FDA approved Natesto, a nasal testosterone spray that is administered three times a day.

AndroGel 1% is protected by the '894 patent. That patent is owned by Besins and by Unimed, which as discussed above, was a wholly-owned subsidiary of Solvay until 2010. Laboratoires Besins Iscovesco SA, a subsidiary ultimately owned by Besins' parent company and now known as Laboratoires Besins Iscovesco SAS ("LBI SAS"), licensed to Unimed certain intellectual property rights to AndroGel. In return, Unimed was obligated to pay a royalty on net sales of AndroGel. Under a separate supply agreement, LBI SAS agreed to manufacture and to sell to Unimed AndroGel products for sale and distribution by Unimed in the United States.[4]

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[4] AbbVie and Besins later amended the license and supply agreements to include AndroGel 1.62%. Royalties on U.S. sales of AndroGel 1.62% are paid to LBI SAS or Besins Healthcare Luxembourg SARL ("BHL SARL").

We have previously discussed the prosecution history of the '894 patent in our September 15, 2017 Memorandum (Doc. # 300) and therefore need not restate it in detail here. *See AbbVie*, 2017 WL 4098688, at *1-4. In summary, the initial patent application that resulted in the '894 patent claimed a pharmaceutical composition of a testosterone gel including a penetration enhancer, which according to the patent application "is an agent known to accelerate the delivery of the drug through the skin into the bloodstream." *Id.* at *1-2. The patent application claimed all penetration enhancers including isopropyl myristate, the penetration enhancer actually used in AndroGel. *Id.* at *2. The patent examiner at the U.S. Patent and Trademark Office ("PTO") rejected the claim which included all penetration enhancers. *Id.* Thereafter, Unimed and Besins submitted an amendment narrowing their claim encompassing all penetration enhancers to a claim naming only twenty-four specific penetration enhancers, including isopropyl myristate. *Id.* at *2-3. After a series of additional amendments, Unimed and Besins further narrowed their claim to one penetration enhancer, isopropyl myristate, only. *Id.* at *3. On this basis, the '894 patent was issued on January 7, 2003. *Id.* at *4. It is scheduled to expire on January 6, 2020.

As is often the case with successful pharmaceutical products, generic manufacturers sought entry into the market to compete with AndroGel. In December 2008, Perrigo submitted to the FDA two ANDAs for a generic testosterone 1% gel in both pump and packet form. The ANDAs referenced AndroGel and the '894 patent. However, the Perrigo product contained isostearic acid as its penetration enhancer rather than AndroGel's isopropyl myristate claimed in the '894 patent.

Pursuant to the procedures established by the Hatch-Waxman Act, Perrigo in June 2009 served paragraph IV notices on both Unimed and Besins as co-owners of the '894 patent. In those notices, Perrigo disclosed the filing of its ANDAs for a generic 1% testosterone gel. Perrigo further asserted that its ANDAs would not infringe the '894 patent for AndroGel because the Perrigo products did not contain "about 0.1% to about 5% isopropyl myristate," the sole penetration enhancer formulation claimed in the patent. Perrigo also stated in its notices that the prosecution history of the '894 patent would estop Unimed and Besins from filing a patent infringement claim. Finally, Perrigo offered to provide to outside counsel representing Unimed and Besins confidential access to the full ANDAs.

Thereafter Unimed and Besins, along with Unimed's parent Solvay, jointly retained the law firm of Finnegan, Henderson, Farabow, Garrett and Dunner, LLP ("Finnegan, Henderson") to assess the Perrigo paragraph IV notices and the Perrigo ANDAs. Finnegan, Henderson obtained confidential access to the full ANDAs and confirmed that Perrigo's ANDAs contained isostearic acid, not isopropyl myristate. Besins also separately retained the law firm of Foley and Lardner LLP ("Foley and Lardner"). Outside counsel at Foley and Lardner did not receive confidential access to the ANDAs.

On July 17, 2009, Solvay and Unimed issued a press release announcing that "[a]fter careful evaluation" the companies had decided not to file a patent infringement suit against Perrigo. The press release explained that the Perrigo product "contains a different formulation than the formulation protected by the AndroGel patent." It further stated that "[t]his distinction played a

role in the company's decision not to file patent infringement litigation at this time" but "the company does not waive its right to initiate patent infringement litigation at a later stage based on new or additional facts and circumstances." The ultimate decision not to file suit was made by Solvay in-house attorneys Shannon Klinger, Peter Edwards, and Dominique Dussard. Besins also determined that it was "standing down" from bringing an infringement suit but did not join in the Solvay press release or issue its own public announcement.

Sometime in 2009, the FDA became aware of cases of accidental secondary exposure of children to TTRTs due to skin-to-skin transference from patients using these products. Based on this information, the FDA required safety-related labeling changes and a Risk Evaluation and Mitigation Strategy ("REMS") for transdermal testosterone gel products currently on the market. Thereafter Auxilium Pharmaceuticals, Inc., the manufacturer of Testim, submitted a citizen petition to the FDA regarding a generic version of Testim. To facilitate the drug approval process, the FDA permits private entities to provide comments and opinions by filing citizen petitions. 21 C.F.R. § 10.30. A petition can request that the FDA "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." *Id.*

In response to the Auxilium citizen petition, the FDA directed on August 26, 2009 that any application for a generic testosterone gel product containing a penetration enhancer different from the referenced brand-name drug would be required to be submitted as a section 505(b)(2) NDA rather than an ANDA. The application must also include certain additional safety studies regarding the risk of secondary exposure.

On April 9, 2010, AbbVie, now the owner of AndroGel, filed its own citizen petition with the FDA. In that petition, AbbVie noted the FDA's ruling in response to the Auxilium citizen petition regarding all generic testosterone products containing penetration enhancers different than those contained in the reference-listed brand-name drug. AbbVie thus sought assurance from the FDA that Perrigo would be required to resubmit its 2009 ANDAs referencing AndroGel as section 505(b)(2) NDAs. AbbVie also requested that Perrigo be directed to provide to the AndroGel patent holders a new paragraph IV notice. Finally, it asked that Perrigo be required to conduct transfer and handwashing studies as set forth in the FDA's response to the Auxilium petition.

On October 4, 2010, the FDA granted in part and denied in part AbbVie's citizen petition. The FDA directed that any application by a generic manufacturer for a product referencing AndroGel that contained a different penetration enhancer must be submitted as a section 505(b)(2) NDA. It also agreed that the applicants would be required to submit new paragraph IV notices.

On January 13, 2011, Teva filed a section 505(b)(2) NDA for its generic version of AndroGel 1% which described a different penetration enhancer, isopropyl palmitate, than AbbVie used in its brand-name AndroGel. The application sought approval to manufacture and to distribute the product in two different sachet sizes as well as in a pump form. This application superseded an ANDA for generic testosterone that Teva had filed on December 29, 2008, prior to the FDA's ruling on the Auxilium citizen petition.

On March 16, 2011, Teva sent to Solvay, AbbVie, Unimed, and Besins a paragraph IV notice regarding its section 505(b)(2) NDA. Teva asserted that its product did not infringe the '894 patent because "the Teva formulation does not contain isopropyl myristate," the penetration enhancer claimed in the '894 patent. Teva laid out the prosecution history of the '894 patent and its position that, because the claims of the '894 patent were narrowed to disclose only isopropyl myristate, "the prosecution history estops the patentees from asserting infringement under the doctrine of equivalents." Teva also offered confidential access to certain information regarding its section 505(b)(2) NDA to allow the patent holders to assess whether an infringement action would have merit.

AbbVie retained outside counsel at the law firm of Munger, Tolles and Olson LLP ("Munger Tolles") to evaluate the Teva paragraph IV notice. Counsel at Munger Tolles was provided with access to the Teva section 505(b)(2) NDA and provided in-house counsel at AbbVie with its opinion. Besins again retained Foley and Lardner to evaluate the notice. Foley and Lardner was supplied with confidential access to the NDA and submitted its analysis to Besins.

On April 29, 2011, within 45 days after receiving the paragraph IV notice, AbbVie, Unimed, and Besins commenced an action in the U.S. District Court for the District of Delaware alleging the Teva's product infringed the '894 patent.[5] *See Abbott Prods., Inc. v. Teva Pharm. USA, Inc.*, No. 11-384 (D. Del. Apr. 29, 2011). The suit against Teva triggered the Hatch-Waxman

[5] As one witness explained at trial, most patent infringement suits are filed in either the District of Delaware or the District of New Jersey because "they tend to be slow-moving dockets."

automatic stay of FDA approval of the Teva product. Consequently, the FDA could not approve Teva's generic testosterone drug for 30 months after March 16, 2011 or until September 17, 2013 unless the district court resolved the lawsuit sooner.

The intellectual property ("IP") litigation group at AbbVie had direct accountability for patent litigation. Four in-house patent attorneys in that group had final responsibility for evaluating the Teva paragraph IV notice and made the decision to file the patent infringement suit against Teva: (1) Johanna Corbin; (2) Adam Chiss; (3) Anat Hakim; and (4) Jose Rivera. All of these attorneys had extensive experience in patent law and with AbbVie. Corbin is currently vice president of the IP group and the lead IP attorney at AbbVie who has worked in that group since 2005. Chiss was divisional vice president of IP litigation and before that had served as senior counsel in IP litigation. Anat Hakim was divisional vice president and associate general counsel of IP litigation at AbbVie and previously had been a partner at Foley and Lardner. Finally, Rivera was a divisional vice president of the IP group and had previously worked in private practice. The general counsel of AbbVie, Laura Schumacher, also signed off on the final decision. Schumacher has been with AbbVie since 2005. No business persons at AbbVie were involved in the decision to sue. At trial, AbbVie presented evidence that the decision whether to file a complaint is always made solely by the legal department and does not require approval from management.

As for Besins, the decision to sue was made by Thomas MacAllister, its in-house counsel. MacAllister is an experienced intellectual property attorney who previously worked as a patent examiner at the U.S. Pa-

tent and Trademark Office. Besins conferred with outside counsel as well as AbbVie about the Teva product and potential litigation. Like AbbVie, Besins or its agents had confidential access to the portions of Teva's NDA that disclosed the formulation of its product prior to filing the complaint against Teva. In addition, in-house counsel for Besins conferred with in-house counsel for AbbVie before making the decision to initiate the lawsuit.

Around this time AbbVie also was preparing for FDA approval and launch of its low-volume formulation of AndroGel, known as AndroGel 1.62%. The FDA issued final approval of brand-name AndroGel 1.62% on April 29, 2011, and AbbVie began selling it in May 2011. The 1.62% formulation is indicated for the same condition and has the same active ingredient but less total gel. Sales of AndroGel 1.62% grew more slowly after launch in 2011 than defendants initially anticipated but by June 2012 constituted the majority of total AndroGel sales. AndroGel 1.62% accounted for total AndroGel sales as follows: 57% during the last 7 months of 2012, 67% in 2013, 76% in 2014, and 83% in 2015.

In June 2011, Teva submitted a case status report proposing a schedule for early summary judgment proceedings in the patent infringement suit in the District of Delaware. AbbVie, Unimed, and Besins filed a supplemental case status report opposing any summary judgment proceedings. On August 1, 2011, before discovery had commenced, Teva filed a motion for summary judgment. Teva asserted that based on prosecution history estoppel there could be no viable claim of infringement of the '894 patent. On October 25, 2011, the court set trial on the issue of prosecution history estoppel for May 21, 2012.

On August 18, 2011, AbbVie filed a citizen petition with the FDA requesting that it refrain from granting a therapeutic equivalence rating to section 505(b)(2) products referencing AndroGel, including Teva's testosterone product, or in the alternative, requesting that it assign the product a BX rating. If a BX rating was assigned, there could be no automatic substitution at the pharmacy under state law.

Meanwhile, on July 4, 2011 Perrigo re-filed with the FDA its application for approval of a generic testosterone 1% gel as a section 505(b)(2) NDA. On September 20, 2011, Perrigo sent AbbVie, Unimed, and Besins a new paragraph IV notice. As in its 2009 notice, Perrigo certified that the '894 patent was not infringed because its generic testosterone product did not contain "about 0.1% to 0.5% isopropyl myristate," the penetration enhancer claimed in the patent.

Perrigo's letter also explained that the prosecution history of the '894 patent precluded any valid infringement claim. Perrigo stated 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." It further asserted that "a bad faith motive for bringing such a suit would be particularly apparent in light of representations and admissions made, *inter alia*, in [Solvay's] Friday, July 17, 2009 press release." Perrigo offered confidential access to certain information regarding the NDA. Again, AbbVie and Unimed retained Munger Tolles as outside counsel to analyze Perrigo's NDA. Foley and Lardner evaluated Perrigo's NDA on behalf of Besins and also issued its opinion to Besins.

On October 31, 2011, AbbVie, Unimed, and Besins filed suit in the District of New Jersey alleging that Perrigo's 1% testosterone gel infringed the '894 patent. *See Abbott Prods., Inc. v. Perrigo Co.*, 11-6357 (D.N.J. Oct. 31, 2011). As in the Teva litigation, the filing of the complaint against Perrigo triggered an automatic 30-month stay under the Hatch-Waxman Act. Thus, absent a court ruling or settlement resolving the litigation, the stay would preclude final FDA approval of the Perrigo generic testosterone product until March 20, 2014.

The same four AbbVie in-house attorneys as had made the decision to sue Teva again made the decision to file the suit against Perrigo with approval from the same general counsel. They conferred with outside counsel, who had confidential access to the Perrigo section 505(b)(2) NDA. No AbbVie business person was involved in the decision to file the Perrigo action. After consultation with AbbVie and outside counsel, Besins' same in-house attorney made the decision that it would join in bringing the Perrigo litigation.

AbbVie reached out to Teva to discuss an amicable resolution of the dispute before the complaint was filed in April 2011. Perry Siatis, an in-house attorney for AbbVie, was the main negotiator on behalf of AbbVie.[6] At that time, Siatis was Divisional Vice President of the IP strategy group and head intellectual property attorney at AbbVie. Although that initial contact did not lead to a settlement, AbbVie again raised the subject with Teva during an in-person meeting on October 28, 2011, three days after the court in the Teva litiga-

[6] Siatis had no involvement in the decision to sue either Teva or Perrigo for patent infringement.

tion had set a trial date. Although Teva at the outset pushed for an entry date as early as September 17, 2013, the final date of the 30-month Hatch-Waxman stay, AbbVie countered with an entry date of January 1, 2015. AbbVie thereafter agreed to an entry date of December 27, 2014, which would allow Teva to make some sales in 2014. On December 20, 2011 the parties reached a final settlement in the Teva litigation, in which Teva received a license to launch its product beginning December 27, 2014.[7]

While the Teva negotiations were ongoing, settlement negotiations were taking place in the Perrigo litigation. Sometime on or before November 3, 2011, Siatis approached Perrigo to initiate settlement negotiations. On December 8, 2011 the parties executed a binding term sheet, which included the dismissal of all claims and counterclaims with prejudice. In addition, AbbVie agreed to pay Perrigo $2 million dollars as reasonable litigation expenses.

During the negotiations Perrigo pushed for an earlier entry date but was unsuccessful and ultimately accepted an offer from defendants of January 1, 2015. However, the settlement contained an acceleration clause whereby Perrigo would be permitted to launch if another generic came to market. Andrew Solomon, general counsel for Perrigo, explained that the company had been monitoring the Teva litigation and thought there was "a very good probability Teva could prevail"

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[7] During this time AbbVie was negotiating with Teva regarding disputes related to two other drugs, Simcor and TriCor. Agreements related to Simcor and TriCor were executed on the same day as the AndroGel settlement. However, there is no evidence that these negotiations were linked to the AndroGel settlement.

at the trial scheduled for May 2012 and thereafter launch its product, so "that would provide a much earlier Perrigo license date." As a result of the Teva settlement, Perrigo's licensed entry date was moved up to December 27, 2014 under the acceleration clause.

On February 14, 2012, the FDA approved Teva's section 505(b)(2) NDA for the packet presentation of its TTRT product. During review of the application, the FDA had identified a potential safety concern with the packaging used in the pump presentation of the drug.[8] In response to this concern, Teva withdrew the pump presentation from its application. As a result, the FDA approved Teva's product in sachet form only.

After receiving FDA approval, Teva waited for the FDA Office of Generic Drugs to assign a TE rating for its product. On December 21, 2012, AbbVie filed a citizen petition supplement requesting that the FDA refrain from granting a TE rating to Teva's product or, in the alternative, grant it a BX rating.

Later, on January 31, 2013, the FDA approved Perrigo's section 505(b)(2) NDA for its generic version of AndroGel 1%. Thereafter the FDA considered a TE rating for Perrigo's generic product. During this period, AbbVie filed an additional citizen petition on December 11, 2013. The December 11, 2013 citizen petition supplemented the August 18, 2011 citizen petition and requested that the FDA issue a BX rating for Perrigo's product.

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[8] Specifically, during a meeting on June 27, 2011, the FDA recommended that Teva withdraw its pump configuration with the option to resubmit it as a post-approval amendment once the issue was resolved.

In the months before its December 27, 2014 licensed entry date approached, Perrigo took a number of steps to follow up with the FDA regarding its TE rating. Perrigo sent three letters to the FDA. It received no response other than being informed that the FDA needed more time to evaluate the therapeutic equivalence of the product.

Perrigo filed a lawsuit against the FDA in the United States District Court for the District of Columbia on March 21, 2014. *See Perrigo Israel Pharm. Ltd. v. U.S. Food & Drug Admin.*, No. 14-475 (D.D.C. Mar. 21, 2014). Perrigo asserted that the FDA had engaged in unreasonable delay. It requested that the court enter a mandatory injunction compelling the FDA to publish a TE rating for Perrigo's NDA product as soon as possible. On April 10, 2014, the FDA filed its first response to the lawsuit. The FDA contended that "Perrigo has itself obviated the need for a prompt decision by reaching an agreement with the innovator not to market until December 2014." The FDA further represented that it expected to issue a TE rating for Perrigo's product "by July 31, 2014—some five months before Perrigo's planned product launch."

Prior to the deadline, on July 23, 2014, the FDA determined that Perrigo's section 505(b)(2) NDA product was therapeutically equivalent to AndroGel and issued it an AB rating.[9] That same day, however, the FDA assigned a BX rating to Teva's product. Specifically, the FDA concluded that the data submitted by Teva was "insufficient to determine TE [therapeutic equivalence] to AndroGel 1%." As a result, under all state

[9] Perrigo voluntarily dismissed the lawsuit on July 24, 2014, one day after the FDA issued its TE rating to Perrigo.

laws the Perrigo generic testosterone product would be auto-substitutable at the pharmacy for brand-name AndroGel 1% prescriptions, but the Teva product would not.

Perrigo launched its AB-rated generic version of AndroGel 1% on December 27, 2014, its licensed entry date under the settlement agreement with defendants. Perrigo would not have entered the market without first receiving a decision from the FDA on its TE rating. Perrigo achieved its goal to obtain an AB rating for its product and would have challenged the FDA had it received only a BX rating.

Teva, in contrast, never set in motion the sale of its generic testosterone replacement product. Timothy Crew, Teva's Commercial Operations Officer from the time that Teva filed its NDA until late 2012, was a strong proponent of bringing the Teva product to market even absent an AB rating. Crew identified a "'brand' push through managed care" marketing strategy in which Teva would go directly to managed care organizations and pharmacy benefit managers in an attempt to negotiate preferential formulary placement for a non-AB rated product and thereby influence physicians' prescribing decisions.[10] Crew considered the Teva generic testosterone product his "pet project."

Teva underwent management changes in November 2012. Crew left the company, and Alan Oberman

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[10] A formulary is a "listing of medications for which an insurer or managed care organization provides coverage." *See Saltzman v. Indep. Blue Cross*, 384 F. App'x 107, 109 n.3 (3d Cir. 2010) (citations omitted). Formularies generally divide medications into tiers with different copays for each tier. *See id.* at 109. Typically, the first tier includes generic medications with the lowest copay, while higher tiers include brand-name drugs with higher copays. *See id.*

became the new Chief Executive Officer of Teva. Shortly thereafter, Maureen Cavanaugh, Vice President of Customer Operations and Marketing for Teva, recommended to Oberman that Teva not launch the BX rated product. Cavanaugh explained that Teva's generic group had no sales force and had never launched a non-AB rated retail pharmacy product. She further opined that a BX-rated product with no perceived advantage over brand-name AndroGel would capture only 10-11% of the brand-name product's sales and perhaps less than 5%.

Teva faced other obstacles to launching its BX-rated product. Teva had contracted with Cipla, an India-based company, to manufacture its generic testosterone replacement drug. Before it could begin the manufacturing process, Cipla required a $10 million capital expenditure from Teva, which could be paid up front or over time through a 35% royalty on sales. Cipla projected that it would require 12-24 months or more to achieve operational readiness. Pursuant to another contract, Teva was also required to pay a royalty of 5-7.5% on sales to a third company, BioSante.

As discussed above, Teva had received FDA approval for the sachet presentation of its product only. At the time that Teva withdrew the pump presentation from consideration by the FDA, pump sales made up 40-50% of AndroGel sales. Thus the failure to obtain approval for a pump product had a negative impact on the commercial viability of Teva's product.

Ultimately, on May 1, 2015, Teva transferred ownership of the 505(b)(2) NDA product and all intellectual property necessary to market the product to ANI Pharmaceuticals, Inc. ("ANI"), its development partner.

III

To prevail on its claim of illegal monopolization, the FTC must establish that defendants filed sham litigation against Teva and Perrigo as outlined by the Supreme Court in *PRE*. Whether litigation is a sham involves a two part test. We have already resolved the first part of the test, that is, that the lawsuits were objectively baseless in the sense that "no reasonable litigant could realistically expect success on the merits." *AbbVie Inc.*, 2017 WL 4098688, at *4 (quoting *PRE*, 508 U.S. at 60). The second part of the test requires the court to decide whether defendants subjectively intended to interfere directly with a competitor's business interests by using the government process as an anticompetitive weapon. *PRE*, 508 U.S. at 60-61. Only if the lawsuits were both objectively and subjectively baseless will the FTC have demonstrated that defendants engaged in sham litigation.

As stated above, we have already determined that the lawsuits against Teva and Perrigo in 2011 were objectively baseless as a matter of law in light of the undisputed facts concerning the prosecution history of the '894 patent. *See AbbVie Inc.*, 2017 WL 4098688, at *1-4, *11. We found that Unimed and Besins secured the '894 patent only by amending their patent application from an initially broad claim covering all penetration enhancers to a narrow claim covering only one penetration enhancer-isopropyl myristate at a particular concentration. *See id.* at *6-8, *10. Instead of isopropyl myristate, Teva used isopropyl palmitate and Perrigo used isostearic acid as a penetration enhancer in their generic versions of AndroGel. We concluded that "any reasonable person who reads the prosecution history of the '894 patent can reach no other conclusion than that the applicants have purposefully and not tangentially

excluded isopropyl palmitate and isostearic acid as penetration enhancers equivalent to isopropyl myristate." *Id.* at *11.

We emphasized that "the purpose of prosecution history estoppel is to protect the patentees' competitors from patent infringement litigation based on the doctrine of equivalents if the prosecution history demonstrates that an equivalent not specifically disclosed in the patent has been purposefully and not tangentially excluded from its scope." *Id.* at *11. Given the patent prosecution history for the '894 patent, AbbVie and Besins did not tangentially exclude all other penetration enhancers and could not reasonably have expected success on the merits in their suits against Teva and Perrigo alleging patent infringement under the doctrine of equivalents.[11] *Id.*

Defendants cannot have it both ways. They cannot, as they did here, purposely surrender claims to all penetration enhancers except one to obtain a patent and then claim infringement when a party uses a penetration enhancer that they deliberately surrendered. *See id.* at *10-11.

We now focus our inquiry on the subjective component of the FTC's sham litigation claim, which was one of the issues litigated in the nonjury trial held in this action. At the outset, we readily acknowledge that a plaintiff claiming that a lawsuit was a sham faces an uphill battle. The First Amendment to the United States Constitution prohibits Congress from making any law respecting "the right of the people … to peti-

[11] Defendants have moved for reconsideration of that decision. On June 27, 2018, we denied the motion in a separate order (Doc. # 438).

tion the Government for a redress of grievances." U.S. Const. amend. I. It is well-established that the First Amendment right to petition the government includes the right to have access to the courts. *PRE*, 508 U.S. at 56-57; *see also* U.S. Const. amend. I. Under the *Noerr-Pennington* doctrine articulated by the Supreme Court, "[t]hose who petition [the] government for redress are generally immune from antitrust liability."[12] *PRE*, 508 U.S. at 56. *Noerr-Pennington* immunity, however, is not absolute. "[A]ctivity 'ostensibly directed toward influencing governmental action' does not qualify for [First Amendment] immunity if it 'is a mere sham to cover … an attempt to interfere directly with the business relationships of a competitor.'" *Id.* at 51 (quoting *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961) (alterations in original)).

Later, in *City of Columbia v. Omni Outdoor Advertising, Inc.*, the Supreme Court explained:

> The 'sham' exception to *Noerr* encompasses situations in which persons use the governmental process-as opposed to the outcome of the process-as an anticompetitive weapon. A clas-

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[12] The *Noerr-Pennington* doctrine originated from two separate antitrust cases, *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965) and *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961). *Pennington* involved efforts by several companies and a union to lobby the Secretary of Labor regarding minimum wage regulations. 381 U.S. at 660. In *Noerr*, a group of railroads engaged in a publicity campaign designed to foster the adoption of certain laws and regulations harmful to the trucking industry. 365 U.S. at 129-30. The doctrine has since been extended to persons who petition the courts, in addition to legislatures and administrative agencies. *See Ca. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 509-10 (1972).

> sic example is the filing of frivolous objections to the license application of a competitor, with no expectation of achieving denial of a license but simply in order to impose expense and delay.

499 U.S. 365, 380 (1991) (emphasis omitted).

We must initially decide not only the type of proof but also the burden of proof which are required to establish subjective intent. The parties disagree regarding both. According to defendants, the FTC must show that they brought the patent infringement actions with actual knowledge that actions were baseless. The FTC, in contrast, asserts that actual knowledge or bad faith is not required under PRE. Instead, the FTC argues that the subjective baselessness inquiry concerns only "whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor." *See PRE*, 508 U.S. at 60-61 (internal citation and quotation marks omitted). Accordingly, the FTC urges the court to focus on the "economic viability" of the lawsuit and whether defendants "sue[d] primarily for the benefit of collateral injuries inflicted through the use of legal process." *Id.* at 65.

Unfortunately, the Supreme Court in *PRE* did not elaborate on this issue. In that case, the Court of Appeals had affirmed an order granting summary judgment for the plaintiff on the defendant's counterclaim alleging a sham lawsuit. *Id.* at 62-65. The Supreme Court agreed with the Court of Appeals that the lawsuit was not objectively baseless and thus did not reach the subjective intent question. *Id.* at 65-66.

In support of its position, the FTC cites *Kilopass Techology, Inc. v. Sidense Corp.*, 738 F.3d 1302 (Fed. Cir. 2013). That case, however, involved a motion for

attorneys' fees under 35 U.S.C. § 285, which provides that a court "in exceptional cases may award reasonable attorneys' fees to the prevailing party." 738 F.3d at 1304, 1312. The Federal Circuit held that "actual knowledge of baselessness is not required" and that "a defendant need only prove reckless conduct to satisfy the subjective component of the § 285 analysis." *Id.* at 1310. It further explained that courts may "dra[w] an inference of bad faith from circumstantial evidence thereof when a patentee pursues claims that are devoid of merit" and that "[o]bjective baselessness alone can create a sufficient inference of bad faith to establish exceptionality under § 285, unless the circumstances as a whole show a lack of recklessness on the patentee's part." *Id.* at 1311, 1314.

Since then, the Supreme Court has expressly distinguished the standard for a claim of sham litigation from that applicable to motions for attorneys' fees under § 285. *See Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1757-58 (2014). The Court reasoned that the *Noerr-Pennington* doctrine was created as "a narrow exception for 'sham litigation'—to avoid chilling the exercise of the First Amendment right to petition the government for the redress of grievances." *Id.* at 1757. It further observed that "[t]he threat of antitrust liability … far more significantly chills the exercise of the right to petition than does the mere shifting of attorney's fees." *Id.* Thus the standard for fee-shifting, which is governed by the statutory language of 35 U.S.C. § 285, is irrelevant to the subjective intent standard for sham litigation under *PRE*. *Id.*

Many of the authorities cited by the FTC are not helpful to our analysis regarding subjective intent. For

example, in *In re Flonase Antitrust Litigation*, the defendant conceded that there was sufficient evidence for plaintiffs to survive summary judgment on subjective intent and as a result the court did not address the issue. 795 F. Supp. 2d 300, 311 (E.D. Pa. 2011). Other authorities cited by the FTC dealt with motions to dismiss and do not contain a fulsome analysis of the evidence required to support the subjective intent prong of *PRE*. *See Moldex Metric, Inc. v. 3M Co.*, No. 14-1821, 2015 WL 520722, at *7, *9 (D. Minn. Feb. 9, 2015); *TransWeb, LLC v. 3M Innovative Props. Co.*, No. 10-4413, 2011 WL 2181189, at *15 (D.N.J. June 1, 2011); *Rochester Drug Coop., Inc. v. Braintree Labs.*, 712 F. Supp. 2d 308, 316, 319-21 (D. Del. 2010); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 643-44 (E.D. Mich. 2000).

After review of the decisions cited by both parties, we conclude that the subjective intent required to overcome *Noerr-Pennington* immunity is not merely the intent to thwart competition. It is well-established that "the essence of a patent grant is the right to exclude others from profiting by the patented invention" and thereby to interfere with a competitor's business. *See Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). As our Court of Appeals has recognized, the Hatch-Waxman Act "incentivizes brand-name drug manufacturers to promptly file patent infringement suits by rewarding them with a stay of up to 30 months if they do so" and therefore "[w]e are not inclined to penalize a brand-name manufacturer whose litigiousness was a product of Hatch-Waxman." *In re Wellbutrin*, 868 F.3d at 157-58 (internal quotation marks and citation omitted). Knowledge that the filing of a lawsuit would trigger the automatic stay is not by itself evidence of a bad-faith motive. *Id.*; *see also In re*

Terazosin Hydrochloride Antitrust Litig., 335 F. Supp. 2d 1336, 1365 (S.D. Fla. 2004).

As the Supreme Court noted in *Omni Outdoor Advertising*, a classic example of "sham" activity is the filing of frivolous objections to a license application with no expectation of prevailing but simply in order to impose expense and delay. *See* 499 U.S. at 380. Clearly, a frivolous lawsuit under those same circumstances is also a sham. The sham exception under *Noerr-Pennington*, of course, is narrow so as not to infringe on a party's constitutional right to petition the government for redress of grievances. Consequently, we conclude that the FTC must prove that defendants had actual knowledge that the patent infringement suits here were baseless in order both to meet its burden under *Omni Outdoor Advertising* and *PRE* and to avoid interference with defendants' First Amendment rights.

The parties, as noted above, further disagree as to the burden of proof required to establish subjective intent. The FTC contends that it must simply satisfy a preponderance of the evidence standard, the general standard for civil antitrust claims. *See*, *e.g.*, *LePage's Inc. v. 3M*, 324 F.3d 141, 166-69 (3d Cir. 2003). Defendants counter that a finding of subjective intent demands clear and convincing evidence.

The Supreme Court has not addressed this question. Nor has our Court of Appeals. The Courts of Appeals for the Ninth and Seventh Circuits in decisions that predate *PRE* have both required clear and convincing evidence that defendants prosecuted actions in bad faith to satisfy the subjective prong of a sham litigation claim. *See Handgards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282, 1288-93 (9th Cir. 1984); *MCI Commc'ns*

Corp. v. Am. Tel. & Tel. Co., 708 F.2d 1081, 1155 (7th Cir. 1983).

In support of their position that clear and convincing evidence is required, defendants point to *Walker Process Equipment, Inc. v. Food Machinery and Chemical Corp.*, 382 U.S. 172 (1965). There, the Supreme Court held that an allegation that the defendant "knowingly and willfully" obtained a patent through fraudulent representations to the Patent Office would not be entitled to *Noerr-Pennington* immunity for a subsequent lawsuit alleging infringement of that patent. 382 U.S. at 177-78. The Federal Circuit has since specified that clear and convincing evidence is needed to establish a *Walker Process* monopolization claim. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998). It observed that "[t]he road to the Patent Office is so tortuous and patent litigation is usually so complex," that there must be "no less than clear, convincing proof of intentional fraud involving affirmative dishonesty." *Id.* (internal citation omitted).

The authorities cited by the FTC to support its position that a preponderance of the evidence is sufficient are not on point. Those cases concern the standard for an award of attorneys' fees in a patent case under 35 U.S.C. § 285, not the subjective intent standard for sham litigation antitrust claims. *See, e.g., Kilopass Tech., Inc.*, 738 F.3d at 1315-16. As stated above, the Supreme Court has expressly distinguished sham litigation in the *Noerr-Pennington* context from motions brought under § 285. *See Octane Fitness, LLC*, 134 S. Ct. at 1757-58.

We conclude that the FTC must prove by clear and convincing evidence the subjective intent element of a sham litigation. We do so in light of the Federal Cir-

cuit's decision in *C.R. Bard* as well as the importance of the First Amendment right to petition the government for a redress of grievances as explained in *Noerr*, *Pennington*, and *California Motor Transport Co.*

Having determined that the FTC has the burden to establish by clear and convincing evidence that defendants had actual knowledge that their infringement suits against Teva and Perrigo were baseless, we now consider the evidence presented at trial and the reasonable inferences to be drawn therefrom.

The FTC puts great emphasis on the 2009 press release by Solvay on behalf of its subsidiary Unimed, co-owner of the '894 patent, before Solvay and Unimed were acquired by AbbVie in February 2010. The press release announced the companies' decision not to sue Perrigo for infringement of the '894 patent after Perrigo filed with the FDA its ANDA for a generic version of AndroGel. Solvay gave as its reason that the Perrigo product "contains a different formulation than the formulation protected by the AndroGel patent." The FTC also presented evidence regarding a July 2009 email written by MacAllister, in-house counsel for Besins, stating that Besins, the co-owner of the '894 patent, was "standing down" from pursuing Perrigo for infringement.

None of the in-house AbbVie attorneys identified as the decision-makers regarding the 2011 suits against Teva and Perrigo was previously employed by Solvay or Unimed. As for Besins, it did not explain whether its decision not to pursue a patent infringement suit was based on the merits or was simply recognizing the reality that it alone could not initiate such a suit without Unimed, the co-owner of the '894 patent. *See, e.g.*, *Int'l Nutrition Co. v. Horphag Research Ltd.*, 257 F.3d

1324, 1331 (Fed. Cir. 2001). While Solvay and its in-house attorneys certainly got it right in 2009, this evidence is not probative as to the subjective intent of defendants' decision-makers here some two years later in 2011.

Both parties also rely on various business planning documents to support their positions on subjective intent. The FTC, for example, points to an August 8, 2011 meeting attended by Jeffrey Stewart, then Vice President of U.S. Proprietary Pharmaceuticals at AbbVie, and several other AbbVie executives and in-house attorneys to discuss AndroGel. This meeting took place shortly after Teva filed its motion for summary judgment in the patent infringement case in which AbbVie had sued it. During that meeting Stewart, looking into the future, drew a chart depicting a dramatic erosion of AndroGel sales following entry of an AB-rated generic after a "lost case" eight months hence in April 2012, the month in which this court had scheduled a hearing to take place on Teva's summary judgment motion.

Thereafter, AbbVie created "AndroGel Scenarios" with various potential dates for generic entry, including: (1) November 2011, the date by which the FDA had agreed to review Teva's section 505(b)(2) NDA[13]; (2) April 2012, the date on which the summary judgment motion could be decided in the Teva matter; and (3) April 2013, an estimate of the date on which a trial on the merits may have concluded in the Teva matter.

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[13] This is commonly known as the Prescription Drug User Fee Act ("PDUFA") date. Under that Act, the FDA collects a fee from companies applying for drug approval and, in exchange, the FDA provides a "goal date" by which it will review the application. *See* 21 U.S.C. § 379h.

In an email on September 30, 2011, James Hynd, one of the AbbVie executives responsible for the AndroGel franchise, characterized the April 2012 entry date as "[t]he most likely scenario."

Defendants, meanwhile, point to the official 2012 annual plan for AbbVie's U.S. Proprietary Pharmaceuticals Division. AbbVie began work on that plan in summer of 2011 and finalized it in late fall of 2011. In that plan, AbbVie forecasted increased sales for AndroGel. It also projected an increase in total "Selling, General, and Administrative" ("SG&A") spending for AndroGel from 2011 to 2012. While the plan "assumed LOE [loss of exclusivity]" for several other products, it made no mention of any loss of exclusivity for AndroGel. Defendants also highlight the AbbVie long range plan ("LRP") that was created in 2011. The LRP is a five to ten year business plan that is updated every year through a planning process that generally begins in January and ends in May. The LRP created in 2011 uses as the loss of exclusivity date for AndroGel August 31, 2015, the licensed entry date granted to two other generic competitors, Par Pharmaceutical and Watson Pharmaceuticals, Inc.

We do not find these and other similar business documents to be persuasive or even relevant to the issue of subjective intent. Significantly, none of these corporate documents, as far as we know, was created by or influenced anyone who played a role in the decisions to sue Teva and Perrigo for patent infringement. Nor is there any evidence in the record as to what, if anything, the decision-makers in the legal department told the business people or vice versa about the merits or prospects of the litigation. These corporate documents are simply not probative of the state of mind of the in-house attorneys who made the decisions to sue.

As evidence of their subjective good faith, defendants also rely on the fact that they obtained favorable settlements in their lawsuits against Teva and Perrigo. Specifically, defendants point out that they initially proposed to both Teva and Perrigo a market entry date of January 1, 2015, a date which extended far beyond the maximum 30-month Hatch-Waxman stays applicable to the two lawsuits. Although Teva and Perrigo countered on several occasions with earlier entry dates, defendants held firm to their initial offers in both negotiations. In the end, Teva and Perrigo secured an entry date of December 27, 2014 for their products, just days earlier than defendants' first proposals.[14] Defendants maintain that they would not have insisted on such a late entry date if they knew the infringement suits were frivolous or if they otherwise were motivated only to use the litigation process itself and the automatic Hatch-Waxman stay as an anti-competitive weapon. We find this argument unpersuasive.

Parties often settle litigation for a variety of reasons independent of the merits of the claims. It is true that the settlements prevented Teva and Perrigo from entering the market until after the automatic Hatch-Waxman stays would have expired. On the other hand, the settlements permitted Teva and Perrigo to enter the market years before the '894 patent was set to expire and before any other generic competitor could come to market. They also permitted Teva and Perrigo to limit their litigation costs, and Perrigo obtained $2 million from AbbVie for reasonable litigation expenses. Even frivolous lawsuits can be very costly to defend

[14] As stated above, Perrigo ultimately agreed to an entry date of January 1, 2015 but this date was moved to December 27, 2014 pursuant to an acceleration clause in the contract.

and to take to trial, especially when plaintiffs, such as the defendants here, have extensive resources.

Charles Cotesworth Pinckney's steadfast response, "not a six-pence, sir," in rejecting a request of French officials for a payment of money in the XYZ Affair, and Representative Robert Goodloe Harper's now famous toast in a similar vein, "Millions for Defense but not a Cent for Tribute," at a dinner in 1798 in Philadelphia, while admirable in many spheres of life, generally have no applicability in the real world when lawsuits are being settled. We find that the terms of the Teva and Perrigo settlements here do not support defendants' subjective good faith.

The FTC points to the various citizen petitions filed by AbbVie regarding the applications submitted by Teva and Perrigo for FDA approval and for TE ratings for its products. For all of these petitions, the FDA granted in part the relief requested by AbbVie. Because they were found to be at least partially meritorious, we do not consider the citizen petitions as evidence of any improper subjective intent by defendants.

The FTC further points to evidence that AbbVie attempted to accelerate the transition of patients from AndroGel 1% to AndroGel 1.62% in summer 2011. Again, there is no evidence that those who decided to bring the infringement actions against Teva and Perrigo played any role in this process.

It is, of course, the FTC which bears the burden of proof by clear and convincing evidence that defendants had the subjective intent to file sham infringement actions against Teva and Perrigo. In determining subjective intent, the court must zoom in on the individuals at AbbVie and Besins who made the decisions to file the infringement actions against Teva and Perrigo and dis-

cern what these individuals knew. The state of mind of individual decision-makers is of course imputed to the corporations for which they act. *See, e.g.*, *In re Color Tile Inc.*, 475 F.3d 508, 513 (3d Cir. 2007).

The individuals, as noted above, who made the decision on behalf of AbbVie on whether to file the objectively baseless lawsuits against Teva and Perrigo were four experienced patent attorneys with sign-off from the general counsel of AbbVie. The record reflects that no business executives were in any way involved—not even with a perfunctory sign-off. As for Besins, the decision to sue was likewise made by in-house counsel for the company. Again no business people participated in the decisions to sue or were otherwise involved.

As the finder of fact, the court may consider both direct and circumstantial evidence when evaluating defendants' subjective intent. *See Howard Hess Dental Labs. Inc. v. Dentsply Intern., Inc.*, 602 F.3d 237, 257-58 (3d Cir. 2010) (citing *Advo, Inc. v. Phila. Newspapers, Inc.*, 51 F.3d 1191, 1199 (3d Cir. 1995)). We may determine what weight and credence to give this evidence and may also draw reasonable inferences therefrom. *See id.* In making findings of fact, the court, like jurors, should not leave common sense at the courthouse steps.

Triers of fact are routinely called upon to determine a party's state of mind. *U.S. Postal Serv. Bd. of Governors v. Aikens*, 460 U.S. 711, 716-17 (1983). As our Supreme Court has recognized:

> The law often obliges finders of fact to inquire into a person's state of mind. … The state of a man's mind is as much a fact as the state of his digestion. It is true that it is very difficult to prove what the state of a man's mind at a par-

> ticular time is, but if it can be ascertained it is as much as fact as anything else.

Id. (internal citations and quotations omitted). We routinely instruct juries to decide a person's intent in both criminal and civil proceedings:

> Often the state of mind … with which a person acts at any given time cannot be proved directly, because one cannot read another person's mind and tell what he or she is thinking. However, [defendants'] state of mind can be proved indirectly from the surrounding circumstances. Thus, to determine [defendants'] state of mind … at a particular time, you may consider evidence about what [defendants] said, what [defendants] did and failed to do, how [defendants] acted, and all the other facts and circumstances shown by the evidence that may prove what was in [defendants'] mind at that time. …
>
> You may also consider the natural and probable results or consequences of any acts [defendants] knowingly did, and whether it is reasonable to conclude that [defendants] intended those results or consequences. You may find, but you are not required to find, that [defendants] knew and intended the natural and probable consequences or results of acts [defendants] knowingly did. This means that if you find that an ordinary person in [defendants'] situation would have naturally realized that certain consequences would result from [defendants'] actions, then you may find, but you are not required to find, that [defendants] did know and did intend that those conse-

> quences would result from [defendants'] actions.

Third Circuit Model Criminal Jury Instructions § 5.01. This explanation is also reflected in our Circuit's model jury instructions for civil cases where intent is relevant, such as those under civil rights statutes. Those model instructions state that a plaintiff "is not required to produce direct evidence of intent" and that intent "may be inferred from the existence of other facts." *See, e.g.*, Third Circuit Model Civil Jury Instructions § 5.1.2. Because of the difficulty of proving a person's state of mind, intent is usually a matter of inference from evidence in the record both in civil and criminal cases. *See Herman & MacLean v. Huddleston*, 459 U.S. 375, 391 n.30 (1983); *Resolution Tr. Corp. v. Fid. & Deposit Co. of Md.*, 205 F.3d 615, 642-43 (3d Cir. 2000); *McLean v. Alexander*, 599 F.2d 1190, 1198 (3d Cir. 1979).

None of the attorneys who was a decision-maker at AbbVie testified at the trial. While in-house counsel for Besins did testify, he did not say a word about his reasoning for bringing suit against Teva and Perrigo. Defendants invoked the attorney-client privilege as well as the attorney work product doctrine and did not assert reliance on advice of outside counsel as an affirmative defense.[15] Defendants have cited authority

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[15] The FTC has not challenged the general proposition that attorney-client privilege or the attorney work product doctrine applies but did engage in motion practice regarding whether certain documents were in fact shielded from discovery by these privileges. It also asserted in various pretrial motions and trial briefs that defendants waived these privileges to the extent defendants asserted that the in-house counsel who made the decision to sue acted in good faith.

that we may not draw adverse inferences on subjective intent from a party's justifiable reliance on these privileges. We agree. We do not and will not draw any negative inference as to subjective intent based on defendants' decision to invoke the attorney-client privilege and the attorney work product doctrine and thereby to shroud certain information from view.[16] *See Freedom Card, Inc. v. JPMorgan Chase & Co.*, 432 F.3d 463, 479-80 n.25 (3d Cir. 2005).

With no direct evidence of the subjective intent of the decision-makers, we must decide whether their subjective intent to file a sham lawsuit has been proven by clear and convincing evidence from the surrounding circumstances and the natural and probable consequences of their knowing acts. It is unrefuted that the attorneys who decided to sue Teva and Perrigo for patent infringement were aware of the paragraph IV notices from Teva and Perrigo. In the paragraph IV notices, Teva and Perrigo declared that their products did not contain as a penetration enhancer isopropyl myristate in the particular concentration claimed in the '894 patent. Outside counsel for defendants had confidential access to the section 505(b)(2) NDAs of Teva and Perrigo, which included the penetration enhancers used by Teva and Perrigo. Both paragraph IV notices called to the attention of the decision-makers that any infringement actions by defendants would be barred by

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[16] This is not an unusual situation. It is no different from that faced by courts every day in criminal trials, in which juries are instructed to make findings about intent but not to draw a negative inference based on a defendant's failure to testify. *See United States v. Waller*, 654 F.3d 430, 435-38 (3d Cir. 2011). We also note that juries in criminal cases may rely on circumstantial evidence to find intent beyond a reasonable doubt, a standard higher than the clear and convincing standard applicable here. *See id.* at 436.

prosecution history estoppel. Perrigo went so far as to assert that any infringement suit against it would be a sham.

The decision-makers at AbbVie and Besins in 2011 knew that Teva and Perrigo used penetration enhancers for their generic products which were distinct from the one penetration enhancer claimed in the '894 patent. We reasonably infer that the decision-makers also were aware of the prosecution history of the '894 patent and specifically that the patent application originally claimed all penetration enhancers including those in the Teva and Perrigo products and that those penetration enhancers used by Teva and Perrigo were ultimately excluded from the protection of the '894 patent. The prosecution history detailed that the original claims covered all penetration enhancers but were ultimately reduced to one, isopropyl myristate. This history is outlined in our prior summary judgment decision. *See AbbVie Inc.*, 2017 WL 4098688, at *4-11. As we found there, "any reasonable person who reads the prosecution history of the '894 patent" would know that all penetration enhancers other than isopropyl myristate in particular concentrations were surrendered. *Id.* at *11.

The reason and motivation for the lawsuits against Teva and Perrigo are also proper considerations which inform our decision on subjective intent. *See Omni Outdoor Advertising, Inc.*, 499 U.S. at 380. Regardless of what the business people knew or had in mind or what any of AbbVie's specific corporate documents or business people revealed, we reasonably infer that the patent attorneys, some of whom were long-time employees, were generally aware of the extensive financial success of AndroGel. It was no secret that AndroGel was a blockbuster product for defendants. It was

bringing in hundreds of millions of dollars annually as of 2011 with a very high profit margin. Sales of AndroGel were $604 million, $726 million, and $874 million in 2009, 2010, and 2011 respectively. The patent attorneys also clearly recognized that the entry of generic versions of AndroGel with their much lower prices would quickly and significantly erode this ideal financial picture. Their reason and motivation for the filing of these objectively baseless actions against potential competitors was to staunch, at least for a time, this looming reversal of fortune.

In sum, all of the decision-makers, we reiterate, were very experienced patent attorneys, who also knew the extensive financial benefits to defendants if generic versions of AndroGel were kept or delayed from entry into the market. It is a compelling inference that they knew the law concerning the prosecution history estoppel and related principles and understood that prosecution history estoppel barred the infringement suits against Teva and Perrigo. They decided to file these lawsuits anyway. Since these experienced patent attorneys filed objectively baseless infringement lawsuits, it is reasonable to conclude that they intended the natural and probable consequences of acts they knowingly did. This leads ineluctably to an inference that the subjective intent of the decision-makers was to file sham lawsuits. We find by clear and convincing evidence that these attorneys had actual knowledge that the infringement lawsuits they initiated in 2011 against Teva in the United States District Court for the District of Delaware and against Perrigo in the United States District Court for the District of New Jersey were baseless and that they acted in bad faith. The only reason for the filing of these lawsuits was to impose expense and delay on Teva and Perrigo so as to block

their entry into the TTRT market with lower price generics and to delay defendants' impending loss of hundreds of millions of dollars in AndroGel sales and profits. They had no expectation of prevailing in the lawsuits. *See Omni Outdoor Advertising, Inc.*, 499 U.S. at 380. All the findings concerning subject intent are by clear and convincing evidence. The actions and intent of these AbbVie and Besins attorneys, of course, are binding on the defendants.

Again, we recognize the importance of the constitutional right to petition the Government for redress of grievances through the filing of lawsuits. For those reasons, this court understands its responsibility to act with caution before finding that any lawsuit was a sham. Regrettably, this is that exceptional case compelling such a finding.

IV

The FTC alleges that defendants have violated section 5 of the FTC Act, which prohibits "[u]nfair methods of competition in or affecting commerce." 15 U.S.C. § 45(a). The prohibitions under the FTC Act include, but are not limited to, conduct that violates the Sherman Act, 15 U.S.C. §§ 1 et seq. *See, e.g.*, *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454-55 (1986). Specifically, the FTC claims that defendants had monopoly power in the TTRT market throughout the United States and unlawfully sought to maintain that power through the filing of the sham lawsuits against Teva and Perrigo so as to prevent or delay the entry into the market of much less expensive generic versions of AndroGel to the detriment of the consuming public.

Thus, to prove its claim the FTC must establish not only that defendants engaged in sham litigation but also that the sham litigation was used to maintain mo-

nopoly power in the relevant market. *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007). Monopoly power is "the ability to control prices and exclude competition in a given market." *Id.* "[A] patent does not necessarily confer market power upon the patentee" and therefore the FTC must prove that defendants in fact possessed monopoly power. *See Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 45 (2006). Monopoly power is assessed as of the time of the anticompetitive conduct. *See Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 472-73, 481 (3d Cir. 1992).

The Supreme Court has ruled that questions of monopoly power must be resolved according the particular facts of each case and that "formalistic distinctions rather than actual market realities are generally disfavored in antitrust law." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466-67 (1992). Monopoly power may be proven through direct evidence of supra competitive prices and restricted output. *Mylan Pharm. Inc.*, 838 F.3d at 434. In the alternative, monopoly power may be proven through indirect evidence. *Id.* at 435. Here, the FTC has presented no direct evidence of monopoly power but instead relies on indirect evidence to establish this part of its claim.[17]

To support a finding of monopoly power through indirect evidence, the FTC must show that: (1) defendants had market power in the relevant market; and (2) barriers existed to entry into that market. *Id.* Market

[17] Direct evidence of monopoly power is "rare" and would require, among other things, evidence that defendants maintained abnormally high price-cost margins on AndroGel and that they restricted output. *See Mylan Pharm. Inc.*, 838 F.3d at 434-35 & n.53. The FTC has not presented such evidence.

power is in turn defined as "the power to raise prices above competitive levels without losing so many sales that the price increase is unprofitable." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 445 n.2 (3d Cir. 1997) (internal citation omitted). Market power can be inferred from a market share significantly greater than 55%. *Dentsply Intern., Inc.*, 399 F.3d at 187 (citing *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 201 (3d Cir. 1992)). As our Court of Appeals has explained, the size of market share is a primary determinant of whether monopoly power exists. *Pa. Dental Ass'n v. Med. Serv. Ass'n of Pa.*, 745 F.2d 248, 260 (3d Cir. 1984).

We must begin by defining the relevant market. *See Dentsply Intern.*, 399 F.3d at 187. The definition of the relevant market "is a question of fact as to which the plaintiff bears the burden of proof." *Mylan Pharm. Inc.*, 838 F.3d at 435 (quoting *Broadcom Corp.*, 501 F.3d at 307). The FTC must prove both the relevant product or products that comprise the market as well as the geographical area for the market. *See Queen City Pizza, Inc.*, 124 F.3d at 442. There is no dispute here that the relevant geographic market encompasses the United States.

To determine whether 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." *Mylan Pharm. Inc.*, 838 F.3d at 435 (internal citation omitted). The term "'[i]nterchangeability' implies that one product is roughly equivalent to another for the use to which it is put." *Id.* at 436 (quoting *Allen-Myland, Inc. v. Int'l Bus. Machs. Corp.*, 33 F.3d 194, 206 (3d Cir. 1994)). It also means that "while there might be some degree of

preference for … one [product] over the other, either would work effectively." *Id.* (quoting *Allen-Myland, Inc.*, 33 F.3d at 206 (alterations in original)). We also look to 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." *Id.* (internal citations omitted). "Cross-elasticity of demand is a measure of the substitutability of products from the point of view of buyers. More technically, it measures the responsiveness of the demand for one product [X] to changes in the price of a different product [Y]." *Id.* at 437 (quoting *Queen City Pizza, Inc.*, 124 F.3d at 438 n.6).

As the Supreme Court has recognized, "in some instances one brand of a product can constitute [the relevant] market." *Eastman Kodak Co.*, 504 U.S. at 482. However, courts generally approve of single-product markets only "in rare circumstances." *Town Sound & Custom Tops, Inc.*, 959 F.2d at 480; *see also Mylan Pharm., Inc. v. Warner Chilcott Pub. Co.*, No. 12-3824, 2015 WL 1736957, at *8 (E.D. Pa. Apr. 16, 2015).

The FTC first proposes what is in essence a single-product market: brand-name AndroGel 1% and brand-name AndroGel 1.62% and their generic equivalents. Within this market, defendants held 100% of sales until entry of Perrigo's generic AndroGel 1% product. After that point, 85% of the AndroGel 1% market converted to generic versions of AndroGel 1% within 24 months, and 90% within 31 months.

In seeking to prove its proposed relevant market, the FTC relies on the expert testimony of Dr. Carl Shapiro, a professor at the Haas School of Business at the University of California at Berkley who previously

served as a member of the President's Council of Economic Advisors. Dr. Shapiro performed the Hypothetical Monopolist Test ("HMT"). That test begins with a narrow set of products, called the candidate market, and asks whether a hypothetical monopolist selling those products could impose a small but significant nontransitory increase in price ("SSNIP"), which would be a 5% increase or more, without losing too many sales to make the price increase unprofitable. If the answer is yes, then the market is correctly defined because products outside the candidate market are not effective price constraints. If not, then the candidate market is too narrow and the relevant market includes other products.

Dr. Shapiro began with a candidate market of brand-name AndroGel and generic versions of AndroGel.[18] He explained that in this situation, the question under the HMT model is whether defendants, as the manufacturers and distributors of brand-name AndroGel, could prevent the price of AndroGel from falling more than 5% by excluding generic competition.

Using data provided by defendants, Dr. Shapiro first calculated the hypothetical monopoly price, which is the price defendants charged for AndroGel prior to generic entry. He then calculated the change in price for AndroGel after generic entry, using a weighted av-

[18] Dr. Shapiro explained that he included brand-name AndroGel 1.62% in his analysis because the delay in generic entry caused by the sham lawsuits provided defendants with additional time to convert AndroGel 1% sales to AndroGel 1.62%. Dr. Shapiro opined that excluding AndroGel 1.62% from the test market could lead to "artificial and misleading" results. This is consistent with AbbVie's own business projections, which predicted that entry of a generic 1% product would impact AndroGel 1.62% sales.

erage price of brand-name and generic AndroGel.[19] Dr. Shapiro performed the test as of the time of the filing of the sham lawsuits in April 2011 and October 2011. He relied on projections of the effect of generic entry created by AbbVie, Teva, and Perrigo. Dr. Shapiro found that entry of an AB-rated generic would cause market prices for AndroGel to decline by at least 41% and that entry of a BX-rated generic would cause a decline of 11%. Based on these calculations, Dr. Shapiro concluded that a hypothetical monopolist of brand-name and generic AndroGel could profitably impose a price increase of more than 5% by excluding competition. Thus, he opines that AndroGel and its generic counterparts constitute the appropriate relevant market for our analysis.

To support Dr. Shapiro's reliance on the HMT, the FTC points to our Court of Appeal's decision in *FTC v. Penn State Hershey Medical Center*, 838 F.3d 327 (3d Cir. 2016). There, the district court applied the HMT to determine the relevant geographic market in evaluating whether a hospital merger violated the antitrust laws. *Id.* at 344-45. On appeal, the Court concluded that the district court failed properly to formulate and apply the test. *Id.* There is no indication that the HMT test is required or even applicable in a monopolization case such as this.

We find that the analysis used by our Court of Appeals in *Mylan* is the appropriate one here. In that case, the Court observed that "the pharmaceutical

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[19] Dr. Shapiro defines average weighted price as "the market price charged by the pharmaceutical companies" and opines that it "is the best way to measure the disparate impact on different customers [i.e., payors, pharmacy benefit managers, and pharmacies] because it measures 'the total payments that are involved.'"

market functions in a unique way." 838 F.3d at 428. Specifically, it stated:

> [I]n a well-functioning market, a consumer selects and pays for a product after evaluating the price and quality of the product. In the prescription drug market, by contrast, the doctor selects the drug, which creates a certain separation between the buyer and the manufacturer. Moreover, in most cases, a third-party, such as a health insurance company, pays for the drug. As a result, consumer buying behavior may have less of an impact on manufacturer pricing than it otherwise would in a traditional open market.

Id. (internal citations and quotation marks omitted).

Due to the vastly different costs associated with launching generic products as compared to brand-name products, generics can be priced considerably lower than brand-name products.[20] AB-rated generics are often priced at a substantial discount far exceeding 5%. This is the result of an intentional regulatory framework promulgated under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., and the Hatch-Waxman Act which provides incentives for innovators that develop brand-name drugs while also encouraging the introduction of low-cost generic drugs to the market. *See Actavis, Inc.*, 570 U.S. at 142. Under this regulatory scheme, application of the HMT would result in a market limited to a brand-name drug

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[20] Generics generally may forgo certain research and development, marketing, and other costs that a brand-name product must incur to launch. *See In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 682 (D.N.J. 2005).

and its AB-rated generic in almost every instance.[21] *See In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 682 (D.N.J. 2005). This approach thus "would render most brand name pharmaceutical companies as per se monopolists prior to generic entry." *See id.* at 683.

The facts of *Mylan* further support our decision. There, the Court of Appeals rejected the plaintiff's contention that the market consisted of only Doryx, a specific brand-name tetracycline approved for the treatment of acne and its generic equivalent. *Mylan Pharm. Inc.*, 838 F.3d at 436. It instead agreed with the district court that "the market was much broader and consisted of all oral tetracyclines prescribed to treat acne." *Id.* In reaching that conclusion, the Court looked to the degree of reasonable interchangeability and cross-elasticity of demand between oral tetracyclines. *Id.* at 435-36. It did not apply the HMT. *See id.* We therefore reject the FTC's proposed single-product market as defined under the HMT.

In the alternative, the FTC proposes a product market consisting of all topical testosterone replacement therapies (as stated above, "TTRTs"). While defendants argue for a broader market including injectables, they do not disagree that TTRTs are part of that market. The TTRTs include the following products:

Patches

- Testoderm (launched in 1994)

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[21] Furthermore, as Dr. Shapiro himself has recognized, the HMT may also lead to relatively narrow markets that would exclude some competing products when gross margins are high, which is the case in the pharmaceutical industry.

- Androderm (launched in 1995)

Gels and Solutions

- AndroGel 1% (launched in 2000)
- Testim (launched in 2002)
- AndroGel 1.62% (launched in 2011)
- Axiron (launched in 2011)
- Fortesta (launched in 2011)
- Vogelxo (launched in 2014, along with an authorized generic of the same product)

Buccal Tablets

- Striant (launched in 2003)[22]

The evidence overwhelmingly demonstrates that all TTRTs, including AndroGel, are reasonably interchangeable. All TTRTs contain the same active ingredient, testosterone. All are approved by the FDA for the treatment of hypogonadism. Furthermore, all TTRTs are consistent with guidelines for the treatment of hypogonadism promulgated by the Endocrine Society, the oldest and largest professional body dedicated to the advancement of clinical care and research in the field of endocrinology.

Defendants presented evidence that some patients have switched between AndroGel and other TTRTs. Defendants' economic expert Dr. Pierre Cremieux presented data from OptumHealth Care Solutions, Inc. showing insurance claims for 18 million patients nationwide, which included 46,000 patients who filed a

[22] Natesto, a testosterone nasal spray, was approved by the FDA in 2014 but was not marketed until 2015, after the time period at issue here.

prescription for AndroGel in the five years preceding generic entry. That dataset demonstrated that 25.8% of all AndroGel patients also used another TTRT product. The OptumHealth data is commonly used in the pharmaceutical industry and has been the basis for hundreds of peer-reviewed publications.

It is true that the various TTRTs may have relative advantages and disadvantages and that an individual patient may prefer one product over another. For instance, some patients may prefer AndroGel over Testim due to Testim's "musky" scent. Certain patients may dislike Fortesta, which is applied to the front and inner thighs, as compared to AndroGel, which is applied to the upper arms, shoulders, and abdomen. However, "[i]nterchangeability is defined by rough equivalence, not perfect correspondence." *Mylan Pharm., Inc.*, 2015 WL 1736957, at *10 (citing *Queen City Pizza, Inc.*, 124 F.3d at 436). Even if more patients prefer AndroGel to other TTRTs, the "test for a relevant market is not commodities reasonably interchangeable by a particular plaintiff, but 'commodities reasonably interchangeable by consumers for the same purposes.'" *Queen City Pizza, Inc.*, 124 F.3d at 438 (quoting *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956)). There is no dispute that, as stated above, all TTRTs contain the same active ingredient and all are approved by the FDA as safe and effective for the treatment of hypogonadism. Accordingly, the fact that certain patients may prefer AndroGel over other TTRTs does not defeat a finding of interchangeability.

Mylan also requires an analysis of cross-elasticity of demand in determining what products are in the relevant market. 838 F.3d at 437. The record demonstrates and no party disputes that there is cross-elasticity of demand between all TTRTs. During the

relevant time period, AndroGel competed on price within the TTRT market by offering rebates to payors to obtain better formulary placement and thereby encourage doctors to prescribe AndroGel. Between 2011 and 2014, AbbVie paid $438 million in rebates to payors, an amount which represented 18.9% of gross sales for AndroGel. Despite these rebates, AndroGel lost several accounts to other TTRTs. Effective July 1, 2011, United Healthcare removed AndroGel from its formulary in favor of Testim, which resulted in a loss of approximately $80 million in sales for AndroGel. When Axiron and Fortesta, two low volume testosterone gels, entered the market in early 2011, rebates on TTRTs increased and AndroGel lost additional business. As of January 1, 2013, CVS Caremark removed AndroGel from its formulary in favor of Fortesta, which resulted in approximately $300 million in lost revenue. And in February 2013, TriCare removed AndroGel from preferred formulary status and replaced it with Fortesta. AbbVie also competed with other TTRTs by developing a copay assistance program. Under that program, AbbVie would bear a portion of a patient's copay, thereby lowering the actual out-of-pocket cost to the patient and encouraging the patient to fill his or her prescription for AndroGel. The other manufacturers of TTRTs also utilized such programs to increase sales. Nonetheless, as will be shown, AndroGel continued to have hundreds of millions of dollars in sales and huge profit margins and retained a high of 71.5% and never lower than in excess of 60% of the TTRT market from 2011 through 2014.

The evidence presented at trial demonstrated that the pharmaceutical companies within the TTRT market spent significant amounts of money on promotional activity to compete for sales. AbbVie employed a sales

force of over 1,000 employees to promote its AndroGel franchise and spent significant money on maintaining that sales force. Sales representatives for AndroGel were compensated based in part on their sales compared to other TTRTs. AbbVie also invested in direct-to-consumer media advertising, including in television, print, and internet.

AbbVie itself viewed other TTRTs as competitors to AndroGel. During trial, several AbbVie employees testified that they considered Testim, Axiron, Fortesta, and other TTRTs to be AndroGel's competitors. In addition, many documents introduced into evidence demonstrate that AbbVie tracked the TTRT market and considered other TTRTs as competitors. In particular, AbbVie reported to its Board of Directors as well as to investors regarding AndroGel's sales within the TTRT market. All of this evidence supports our finding that there is cross-elasticity of demand between AndroGel and other TTRTs.

Defendants counter that the relevant market should be defined to include not only TTRTs but also all testosterone replacement therapies (as stated above, "TRTs"), that is TTRTs plus injectables.[23] We reject this position. It is true that injectables contain testosterone, the same active ingredient as AndroGel. It is also true that injectables, like AndroGel, are approved by the FDA as safe and effective for the treatment of hypogonadism. In addition, defendants introduced evidence of some patient switching between AndroGel and injectables.

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[23] Defendants exclude oral formulations of testosterone, which are distinguishable in efficacy and potential side effects and are generally not recommended within the medical community.

Some patients prefer AndroGel to injectables due to a fear of needles and the associated potential for pain and discomfort. To administer the injection, a 1.5 inch-long needle must be inserted deep into a muscle, typically the buttocks or thigh, until the needle is no longer visible. Yet some prefer injectables to AndroGel because of the peak in testosterone levels that injectables initially provide. On the other hand, some patients dislike the peaks and troughs associated with injectables and thus prefer the steady dosing provided by AndroGel. However, as noted earlier, individual patient preferences will not defeat a finding of interchangeability as long as there is "rough equivalence" between the products. *Mylan Pharm., Inc.*, 2015 WL 1736957, at *10; *see also Queen City Pizza, Inc.*, 124 F.3d at 438. Thus, there is reasonable interchangeability of use between AndroGel and injectables.

But even assuming reasonable interchangeability, there is little cross-elasticity of demand between AndroGel and injectables to include injectables in the relevant market. As noted above, "[c]ross-elasticity of demand is a measure of the substitutability of products from the point of view of buyers. More technically, it measures the responsiveness of the demand for one product [X] to changes in the price of a different product [Y]." *Mylan Pharm. Inc.*, 838 F.3d at 437 (quoting *Queen City Pizza, Inc.*, 124 F.3d at 438 n.6).

Injectables entered the market decades before AndroGel launched in 2000 and the vast majority are generics. As a result, injectables enjoyed the most favorable formulary status with the lowest copay, typically $5-$10 per injection. During the relevant period, the wholesale acquisition cost of injectables was two to three times lower than that of AndroGel. Since launch, AbbVie has consistently raised AndroGel's wholesale

acquisition cost, despite the fact that injectables were available at a fraction of the cost. James Hynd, one of the principal AbbVie executives responsible for the AndroGel franchise, confirmed that AbbVie did not price AndroGel against injectables. For example, AbbVie did not offer rebates to payors in an attempt to match the price of injectables.

Furthermore, AbbVie documents show that while the company tracked injectable sales, it did not consider injectables as direct competition to AndroGel. Hynd believed that injectable patients were "not our [AndroGel] patient type."[24] Similarly, Frank Jaeger, Director of Marketing for AndroGel from 2010 through 2014, testified that AbbVie did not consider injectables as competition and that the company believed based on market research that it could not transition injectable patients to AndroGel. Instead, as stated above, Jaeger and others identified TTRTs such as Axiron, Fortesta and Testim as AndroGel's true competitors. We credit this testimony of Hynd and Jaeger.

Defendants produced an internal AbbVie document stating that a rise in the copay for AndroGel was correlated with an increase in injectables' sales. However, there is no evidence of the underlying analysis supporting the statement and thus no way to evaluate whether there was in fact a causal relationship between the two events. Moreover, this statement focuses on copays, which are patients' out-of-pocket costs, and does not account for the other levels of pricing applicable in the

[24] While Hynd testified that he changed his view and began to recognize injectables as competition, he did not do so until 2014, well after the sham lawsuits were filed and when entry of generic versions of AndroGel was imminent. We do not find credible his change of view.

pharmaceutical industry, such as the amount paid by insurance companies and other payors. In contrast to this statement, the record demonstrates that AbbVie attributed the increase in injectables' sales to a variety of factors, including patient preference, the existence of "Low-T" Centers, and the disproportionate negative publicity testosterone gels received after reports associating TTRTs with heightened cardiovascular risk.

For similar reasons, the patient switching study introduced by Dr. Cremieux is also not evidence of cross-elasticity of demand between AndroGel and injectables. That study does not contain information regarding the reasoning behind the patients' choices. Those patients who moved between injectables and AndroGel may have done so for a variety of reasons, including side effects, personal preferences, and reports of cardiovascular risks from TTRTs, as well as price. Because cross-elasticity of demand focuses on the relationship between pricing for products, evidence of switching for other or unknown reasons is irrelevant to our inquiry on this issue. *See Mylan Pharm. Inc.*, 838 F.3d at 437.

Accordingly, we find that all TTRTs including AndroGel had both interchangeability of use and cross-elasticity of demand during the relevant time period. In contrast, there was not the cross-elasticity of demand between TTRTs and injectables so as to include injectables within the relevant market.[25] We therefore define the relevant market as the market for all

[25] The TRT market would also include subcutaneous pellets such as Testopel, which constitute a de minimis share of the TRT market. There was no evidence presented at trial regarding cross-elasticity of demand between AndroGel and this product. Pellets, like injectables, are not part of the relevant market here.

TTRTs, that is all transdermal testosterone replacement therapies within the United States.

We now turn to the question of whether defendants possessed monopoly power in the defined market. To support a finding of monopoly power, the FTC must prove that defendants had a dominant share in the relevant market and that there were significant barriers to entry into that market. *Broadcom Corp.*, 501 F.3d at 307. Generally, as noted, a market share significantly larger than 55% is required to establish prima facie market power. *See Dentsply Int'l, Inc.*, 399 F.3d at 187. 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.

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.[26] In 2011, AndroGel's annual U.S. net sales exceeded $870 million. By 2012, annual U.S. net sales for the AndroGel franchise grew to $1.152 billion. In 2013, AndroGel's U.S. net sales were approximately $1.035 billion. And in 2014, AndroGel U.S. net sales totaled $934 million. These sales figures are calculated after payment of millions of dollars in rebates and the loss of some accounts.

AndroGel's share of the TTRT market was 71.5% at the time that the first sham lawsuit against Teva was filed in April 2011 and 63.6% at the time that the

[26] The medical experts for both sides testified that they have prescribed AndroGel for hypogonadism more than any other product.

sham lawsuit against Perrigo was filed at the end of October 2011. Thereafter AndroGel's share remained above 60% until the end of 2014, when Perrigo's generic 1% testosterone product entered the market. The closest competitor, Testim, had a share of only approximately 20% of the TTRT market at the time of the filing of the first sham lawsuit, but thereafter its share dropped to approximately 12%. Axiron was launched on March 28, 2011 and had captured approximately 14% of the TTRT market by April 2014. No other TTRT product ever held 10% or more of the market during the period from April 2, 2011 through the end of 2014.

AndroGel's market share was always more than four times larger than the market share of any of its brand-name competitors, except for a short period when its market percentage was slightly smaller, but still over three times the market share of Testim. AbbVie was able to maintain its share of the TTRT market with a profit margin of over 65% during the relevant period, even with huge rebates. It was also able to increase the wholesale acquisition cost for AndroGel throughout this time period. We find based on this data that AndroGel had a dominant share of the TTRT market from April 2011 through December 2014.

The monopoly power of AndroGel is supported by the significant barriers to entry into the TTRT market. *See Mylan Pharm. Inc.*, 838 F.3d at 435. First, any prospective entrant with a brand-name drug must invest large amounts of time and capital in research and development. There are then significant technical and regulatory requirements in the prescription pharmaceutical market that do not exist with respect to ordinary consumer products. Brand-name products must obtain FDA approval through the submission of an NDA. This process may be lengthy. Among other

things, the prospective entrant must demonstrate the capability to manufacture, process, and package the pharmaceutical product in a manner that is adequate "to preserve its identity, strength, quality, and purity." 21 U.S.C. § 355(d); *see also id.* §§ 355(b)(1), (c)(4). During the FDA approval process, third parties including competitors may file citizen petitions to request that the FDA "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action" on the NDA, as happened here. *See* 21 C.F.R. § 10.30. This may further prolong the approval process.

Once approved, the brand-name drug company generally does not attempt to market directly to patients, the ultimate users. Instead, it must convince physicians to prescribe the drug to patients. This requires a significant and knowledgeable sales force that generally meets with physicians individually. The sale and marketing of prescription drugs is highly regulated. *See generally* 21 U.S.C. § 331. For example, the sales force is not permitted to claim that its company's product is better or more effective than a competitor's product, nor is it permitted to promote the drug for uses other than those contained in the drug's labeling. *Id.*; *see also In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239-40 (3d Cir. 2012). The company must also ensure that pharmacies will stock the drug and that third-party payors will reimburse for it. This requires a team of skilled employees who can negotiate contracts with insurance companies and other payors. If the company seeks patent protection, which is not uncommon, it must endure the rigorous patent approval process before the Patent and Trademark Office.

While the Hatch-Waxman Act provides streamlined procedures for the approval of generic products through the filing of an ANDA or section 505(b)(2) NDA, the FDA may ask for additional information and testing as happened here with Perrigo and Teva. The drug once approved must undergo a further process before a different group at the FDA to obtain a therapeutic equivalence ("TE") rating so that the generic drug developer may take advantage of state auto-substitution laws. Again, Teva and Perrigo both confronted this hurdle.

There can be additional obstacles for generic drug companies where, as here, a brand-name drug manufacturer holds a patent for the reference-listed drug. Generic entrants must also consider the possibility of patent infringement litigation by the owner of the referenced brand-name drug and the accompanying delay caused by the automatic thirty-month stay under the Hatch-Waxman Act before entry into the market, as occurred here.

In short, a prospective entrant to the pharmaceutical market whether with a brand-name drug or a generic drug has significant capital, technical, regulatory, and legal barriers to overcome before being able to enter the TTRT market. Again, this is a far cry from entry into a market to sell an ordinary consumer product. As demonstrated by the record, Teva and Perrigo encountered these barriers, and Teva ultimately decided not to launch its generic testosterone 1% product when it did not receive an AB rating from the FDA.

In order to counter the existence of barriers to entry, defendants reference the fact that three brand-name TTRT products entered the market between 2011 and 2014: (1) Fortesta, manufactured by Endo Phar-

maceuticals (February 28, 2011); (2) Axiron, manufactured by Eli Lilly and Co. (March 28, 2011); and (3) Vogelxo, manufactured by Upsher-Smith Laboratories, Inc. (July 2014).[27] These products, however, each maintained a relatively small share of the market compared to AndroGel as discussed in more detail above. Specifically, during the relevant time period Axiron achieved a high of only approximately 14% of the TTRT market, while Fortesta and Volgelxo each held under 10% of the market. Consequently, they did not pose significant competition to defendants' monopolistic conduct.

The barriers enumerated above are sufficiently high to be a factor in our finding of monopoly power. *See Broadcom Corp.*, 501 F.3d at 307. The purpose of the FDCA, of course, is to protect the public from products that are not safe and effective. *See*, *e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 566-67, 574 (2009). The barrier to entry into a prescription drug market is rightly a stringent one to ensure that this salutary goal is achieved.[28]

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[27] An authorized generic of Vogelxo was also launched at the same time as the brand-name product.

[28] Defendants cited *Barr Laboratories, Inc. v. Abbott Laboratories*, 978 F.2d 98 (3d Cir. 1992). This case is inapposite. In that private antitrust action, plaintiff claimed attempted monopolization involving oral erythromycin products, which are prescription antibiotics. 978 F.2d at 102. Unlike the present action, *Barr* did not involve a patent. *Id.* In *Barr*, there were 32 manufacturers and defendant Abbott only held a high of 51.19% of the market in one year. *Id.* at 103. During the relevant time period the number of products competing for sales increased from 111 to 176. *Id.* Under the circumstances, the Court held that barriers to entry remained low and ultimately concluded that no attempted monopolization existed. *Id.* at 113-14. In contrast, the evidence before the court in this pending action demonstrates that the barriers were significant to entry into the TTRT market.

In sum, we find that the FTC has proven that defendants had a dominant share of the TTRT market in the relevant period and that significant barriers existed for entry into that market. The FTC has established the actual market reality that defendants possessed monopoly power and illegally and willfully maintained that monopoly power through the filing of sham litigation. This sham litigation delayed the entry of much less expensive competitive generic products into the TTRT market to the detriment of consumers and protected the defendants against loss of hundreds of millions of dollars in sales and profits.

V

We now move to the issue of the appropriate relief. The FTC seeks equitable relief in the form of disgorgement by defendants of profits which the FTC seeks to return to consumers through the establishment of a fund for this purpose. It also seeks an injunction.

Defendants first contend that section 13(b) of the FTC Act does not permit the FTC to seek equitable monetary relief such as disgorgement. This section provides that the FTC "may bring suit in a district court of the United States to enjoin any such act or practice … [and] in proper cases the [FTC] may seek, and after proper proof, the court may issue, a permanent injunction." 15 U.S.C. § 53(b). Defendants assert that because section 13(b) simply references relief in the form of an "injunction," the court may not order disgorgement.

In support of their position, defendants cite *Kokesh v. SEC*, 137 S. Ct. 1635 (2017). *Kokesh* addressed the narrow question of whether the five-year statute of limitations in 28 U.S.C. § 2462 applied "to claims for

disgorgement imposed as a sanction for violating a federal securities law." 137 S. Ct. at 1639. According to defendants, *Kokesh* stands for the proposition that disgorgement is punitive in nature and thus not included among the equitable remedies authorized under the FTC Act. *Kokesh*, however, did not involve section 13(b) but instead dealt with federal securities law. Moreover, the Supreme Court specifically declined to address whether courts possessed authority to order disgorgement in SEC enforcement proceedings. *See id.* at 1642, n.3. We will not stretch *Kokesh* beyond its holding and will not read it to prevent the court from granting the well-established equitable relief of disgorgement.

The Supreme Court, in *Mitchell v. Robert De Mario Jewelry, Inc.*, held that the provision of the Fair Labor Standards Act, which specifically authorized courts to restrain violations, includes the power to order reimbursement for loss of wages for unlawful discharge or discrimination. 361 U.S. 288, 296 (1960). The Supreme Court aptly stated:

> 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 the light of 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 (quoting *Clark v. Smith*, 38 U.S. 195, 203 (1839)). This language in our view is equally applicable here to the FTC Act. *Id.*; *see also United States v. Lane Labs-USA, Inc.*, 427 F.3d 219, 223 (3d Cir. 2005).

The weight of authority, in accordance with *Mitchell*, 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. *See, e.g.*, *FTC v. Cephalon, Inc.*, 100 F. Supp. 3d 433, 437-39 (E.D. Pa. 2015) (Goldberg, J.). Our Court of Appeals has expressed agreement with this position. *FTC v. Magazine Solns., LLC*, 432 F. App'x 155, 158 n.2 (3d Cir. 2011). This is in line with other appellate precedent in this Circuit, which states that disgorgement "is an equitable remedy meant to prevent the wrongdoer from enriching himself by his wrongs." *Edmonson v. Lincoln Nat. Life Ins. Co.*, 725 F.3d 406, 415 & n.3 (3d Cir. 2013) (quoting *SEC v. Huffman*, 996 F.2d 800, 802 (5th Cir. 1993)).

If the defendants' position about section 13(b) is correct, the monopolist will be able to retain its ill-gotten gains and simply face an injunction against future wrongdoing but even then only if the wrongdoing is continuing or is likely to continue. This interpretation would eviscerate the FTC Act. As our Court of Appeals has stated, "if the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters, then we are obligated to construe [the] statute[] sensibly and [to] avoid constructions which yield absurd or unjust results." *Douglass v. Convergent Outsourcing*, 765 F.3d 299, 302 (3d Cir. 2014) (internal quotation marks and citations omitted). We reject defendants' argument concerning our authority to order disgorgement under section 13(b) of the FTC Act.

Because disgorgement aims to prevent unjust enrichment, a "court may exercise its equitable power only over the property causally related to the wrongdo-

ing." *Commodity Futures Trading Comm'n v. Am. Metals Exch. Corp.*, 991 F.2d 71, 78-79 (3d Cir. 1993) (quoting *SEC v. First City Fin. Corp.*, 890 F.2d 1215, 1231 (D.C. Cir. 1989)). Courts determine the appropriate amount of equitable monetary relief using a two-step burden shifting framework. First, the government must "establish[] a reasonable approximation of the profits tainted by the violation." *SEC v. Teo*, 746 F.3d 90, 107 (3d Cir. 2014). This requires that the FTC meet a "but-for" standard of causation. *Id.* at 105. The burden of going forward then shifts to the defendant to provide "evidence that the [government's] approximation of profits was unreasonable." *Id.* at 107-08. At this point, the defendant may "point[] to intervening events" that break the chain of causation. *Id.* at 105-06 (quoting *First City Fin. Corp.*, 890 F.2d at 1232). Under this standard, "doubts concerning the determination of disgorgements are to be resolved against the defrauding party." *SEC v. Hughes Capital Corp.*, 917 F. Supp. 1080, 1085 (D.N.J. 1996); *see also First City Fin. Corp.*, 890 F.2d at 1231-32.

To determine the appropriate amount of equitable monetary relief to be awarded here, we must make findings about what would have happened absent the sham lawsuits filed by defendants. *See First City Fin. Corp.*, 890 F.2d at 1231-32. The FTC's expert, Dr. Shapiro, constructed a counterfactual world relying on contemporaneous evidence as well as his expert economic analysis. He determined that but for the lawsuits: (1) Teva would have entered the market with a BX-rated product in June 2012; (2) Perrigo would have entered with an AB-rated product in June 2013; and (3) that entry of a generic version of AndroGel 1% would have affected sales of AndroGel 1.62%. He calculated defendants' "incremental revenue," which is the differ-

ence between defendants' actual revenue and their counterfactual revenue from June 2012 through the present. Dr. Shapiro then deducted defendants' incremental costs associated with the excess revenue to determine defendants' financial gain attributable to the sham litigation. He determined that this financial gain was $1.35 billion as of the end of March 2018. He opined that this financial gain will continue to accrue until entry of a generic version of AndroGel 1.62%. The FTC also seeks prejudgment interest on this financial gain, compounded quarterly at interest rates promulgated by the Internal Revenue Service ("IRS"). *See* 26 C.F.R. § 301.6621-1.

Defendants dispute the FTC's assumptions regarding the entry of Teva and Perrigo as well as the FTC's assumption that entry of a generic 1% would have impacted sales of AndroGel 1.62%. Defendants argue that even absent the sham litigation, Teva would not have entered the market. They concede that Perrigo may have entered the market earlier than it did absent any sham lawsuit but assert that the earliest Perrigo would have entered would have been August 2014. Defendants admit, as they must, that delay in entry of generic 1% would have harmed consumers.

We must decide when, if ever, Teva would have entered the market in the "but-for" world. In the real world, Teva submitted to the FDA on January 13, 2011 a section 505(b)(2) NDA for its generic version of AndroGel 1% in pump and packet forms. Shortly thereafter, defendants filed their sham lawsuit against Teva. In December 2011, Teva entered into a settlement agreement with defendants and thereby agreed to a licensed entry date of December 27, 2014. On February 14, 2012, Teva received FDA approval of its section 505(b)(2) NDA for the packet presentation of its prod-

uct only. In July 2014, Teva received from the FDA a BX rating on its product due to discrepancies with the analytical work in Teva's bioequivalence study. Thereafter, Teva decided not to launch its product.

The FTC asserts that, but for the sham lawsuit filed by defendants, Teva would have entered the market with a BX-rated testosterone 1% product in June 2012. The FTC concedes that the filing of the sham lawsuit by defendants did not impact the timing of Teva's FDA approval. Thereafter, the FTC posits that Teva would have continued to move forward with preparations for its launch while waiting for its TE rating. The FTC estimates it would have taken 12-13 months from the time it submitted its section 505(b)(2) NDA to the FDA for Teva to achieve operational readiness.

Defendants dispute whether Teva would have entered the market at all with a BX rating. Teva's generic drug division has never launched a BX-rated retail pharmaceutical product. It has not done so because Teva's generic business model relies on auto-substitution at pharmacies. Without auto-substitution, Teva would have to hire a sales force to promote its BX-rated product. As demonstrated by internal analyses created by Teva, a BX-rated generic without a perceived advantage in the market, such as Teva's product, generally captures only 5% or less of the brand-name product's sales. For this reason, BX-rated generics are rare.

While Tim Crew, Teva's former Commercial Operations Officer, was in particular a strong proponent of a BX-rated launch, Crew left Teva in 2012. Alan Oberman, the Teva executive who replaced Crew, was not a proponent of a BX-rated launch. Maureen Cavanaugh,

Vice President of Customer Operations and Marketing for Teva, testified that she, along with the rest of her team, made the recommendation to Teva management to abandon plans for the launch of the testosterone product. She further stated that she did so not because of defendants' infringement litigation but because of Teva's inability to commercialize the product effectively. We find her testimony to be credible.

In addition to its failure to obtain an AB rating, Teva faced other obstacles to the profitable launch of its product. In July 2011, at the suggestion of the FDA, Teva withdrew the pump presentation of its product from consideration due to packaging issues. As a result, the Teva product was approved in packet form only. The pump was preferred by patients over packets because of ease of use. Teva estimated that this setback cut its potential sales opportunity by over 50%. If it intended to continue to pursue a pump presentation for its product, Teva would need to reformulate and then resubmit its section 505(b)(2) NDA to the FDA for consideration. This would have involved significant additional time and expense, and still may have not been successful.

Teva also faced serious manufacturing issues for its testosterone 1% product. It planned to use Cipla, a contract manufacturer based in India, to manufacture its testosterone 1% gel. Cipla demanded that Teva provide approximately $10 million for construction of manufacturing facilities. Teva had the option of making payment in the form of an up-front capital expenditure or over time as a 35% royalty on sales. Teva never reached an agreement with Cipla regarding this investment. The evidence shows that Teva ultimately refused to make this investment unless the FDA issued an AB rating to its product. Cipla could not move for-

ward with preparations for manufacturing until an agreement was reached.

After considering the evidence presented, the FTC has not established that, but for defendants' sham litigation, Teva would have launched its product in June 2012 or at any time thereafter. We find that Teva's failure to launch was due to other intervening events described above and that the sham litigation against it was not a cause. Accordingly, we will not consider any "but-for" entry date of Teva into the TTRT market when calculating defendants' illegal financial gains.

There remains the question of when Perrigo would have entered the market absent defendants' sham litigation against it. In the real world, Perrigo had a December 27, 2014 licensed entry date for its generic version of AndroGel 1% under its settlement with defendants. The FDA approved Perrigo's section 505(b)(2) NDA on January 31, 2013 and thereafter Perrigo waited for a TE rating for its drug. Nearly eighteen months elapsed before the FDA granted its generic TTRT an AB rating. During this time, Perrigo submitted three letters to the FDA, dated April 18, 2013, September 13, 2013, and February 18, 2014, requesting that the FDA issue an AB rating. The last letter threatened litigation if the FDA failed to act by March 19, 2014 and enclosed a draft complaint. On March 21, 2014, Perrigo filed a lawsuit against the FDA in the United States District Court for the District of Columbia alleging violation of the FDCA and the Administrative Procedures Act based on the FDA's allegedly unreasonable delay in assigning a TE rating to its product. *See Perrigo Israel Pharm. Ltd. v. U.S. Food & Drug Admin.*, No. 14-475 (D.D.C. Mar. 21, 2014).

On April 10, 2014, the FDA filed a response to Perrigo's motion for a speedy hearing. The FDA asserted that "Perrigo itself has obviated the need for a prompt decision by reaching an agreement with the innovator not to market until December 2014." The FDA further stated that it would issue a TE rating for Perrigo's product by July 31, 2014, some five months before Perrigo's planned launch. In the end, the FDA issued an AB rating to Perrigo on July 23, 2014, and thereafter Perrigo voluntarily dismissed its lawsuit. Perrigo launched its product on December 27, 2014.

We acknowledge that there is no statutory, regulatory, or other deadline within which the FDA is mandated to issue a TE rating. The time that the FDA needs to consider a TE rating depends on the specific facts of each situation, including the reason why the application for approval of a generic drug was submitted as a section 505(b)(2) NDA rather than an ANDA.

It is apparent from the lawsuit Perrigo brought against the FDA that the FDA knew of Perrigo's December 27, 2014 licensed entry date under the settlement agreement. As a result, it had no compelling need, as it implied in its court papers, to grant the TE rating long before Perrigo's entry date. We find that the FDA, absent the sham litigation and the resultant settlement agreement, would not have delayed the issuance of an AB rating for Perrigo's generic drug for nearly eighteen months after approval of its section 505(b)(2) NDA. The FDA is presumed to act in the public interest, which includes the mission of benefitting consumers by approving the entry of safe and effective lower-cost generic drugs into the market. Every month that the FDA would have delayed in issuing a TE rating to a generic drug that was otherwise ready

and able to launch would have caused significant financial harm to consumers.

Dr. Kenneth Phelps, the FTC's regulatory expert, testified that in his experience it takes no more than one month for the FDA to assign a TE rating for a section 505(b)(2) drug. The FTC's economic expert, Dr. Shapiro, estimated that, but for the sham litigation, Perrigo would have received its TE rating approximately four months from the date of FDA approval of its section 505(b)(2) NDA. He relied on the approximated four months' time lapse in the real world between Perrigo's filing of the lawsuit against the FDA and the FDA's issuance of the TE rating.

Defendants further point to citizen's petitions filed by AbbVie regarding TE ratings to assert that the FDA would not have issued a TE rating to Perrigo sooner. On August 18, 2011, AbbVie filed a citizen's petition requesting that the FDA conduct notice-and-comment rulemaking to establish procedures for its assignment of TE ratings for drugs approved under section 505(b)(2). That petition did not relate specifically to Perrigo but rather to general procedures for TE ratings. Contrary to defendants' position, there is no indication that the FDA refrained from issuing TE ratings for generic drugs while this petition was pending. Later in a supplement filed on December 11, 2013, AbbVie requested that the FDA assign a BX rating to Perrigo's product. The FDA ultimately responded to this citizen petition in July 2014 at the same time it issued Perrigo's TE rating. However, a June 2013 launch would have been six months before AbbVie filed its supplemental citizen petition, and therefore we find that this supplemental citizen petition would not have delayed Perrigo's launch in the "but-for" world. Thus, the de-

fendants' citizen petition would not have affected Perrigo's "but-for" entry date.

We find that absent the sham lawsuit, Perrigo would have received its AB rating in June 2013 and would have launched its AB-rated generic product at that time. We reject defendants' contention that Perrigo would not have launched its product until August 2014.

The parties next dispute the effect of the sham litigation on sales of AndroGel 1.62%. In his damages model, Dr. Shapiro opines that entry of a generic version of AndroGel 1% would have caused the market share of AndroGel 1.62% to plateau. According to Dr. Shapiro, the delay of generic 1% entrants caused by the sham litigation allowed defendants to transition more patients from brand-name AndroGel 1% to brand-name AndroGel 1.62% and thus avoid auto-substitution for generic versions of AndroGel 1%. We agree. Consequently, Dr. Shapiro properly includes a portion of defendants' profits from AndroGel 1.62% in his calculation of excess profits.

In the real world, AndroGel 1.62% accounted for total AndroGel sales as follows: 57% during the last 7 months of 2012, 67% in 2013, 76% in 2014, 83% in 2015 and 2016, and 82% in 2017. In the "but-for" world, the FTC asserts that AndroGel 1.62%'s share of total AndroGel sales would have frozen at the time that the first generic version of AndroGel 1% entered the market. We have already determined that but for the sham litigation, Perrigo would have entered the market in June 2013. It follows and we find that the share for

AndroGel 1.62% would have frozen at approximately 67%.[29]

In response, defendants contend that AndroGel 1.62% is "superior" to AndroGel 1% and thus prescribers will chose AndroGel 1.62% regardless of the availability of a generic version of AndroGel 1%.[30] In support of their position, they point out that AndroGel 1.62% is not subject to auto-substitution for a generic version of AndroGel 1%. They further maintain that sales of AndroGel 1.62% have come not only from patients who previously used AndroGel 1% but also from patients who used other TRTs or who are new to treatment for hypogonadism. Defendants cite OptumHealth data showing that from the launch of AndroGel 1.62% through March 2016, only 28.1% of AndroGel 1.62% patients had filled an AndroGel 1% prescription within the 12 months preceding their first AndroGel 1.62% prescription. The other sales came from patients who were previously using other TRTs or were new to testosterone replacement therapy. Defendants therefore reason that sales of AndroGel 1.62% would not have been impacted by earlier entry of a generic version of AndroGel 1%. We disagree.

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[29] As discussed above, the FTC initially took the position that Teva would have entered the market in 2012 with a BX-rated generic version of AndroGel 1%. This would freeze AndroGel 1.62%'s share of the AndroGel market at 51%, which is what the FTC asserts the share would have been during the last seven months of 2012.

[30] AndroGel 1.62% has the same active ingredients and effects as AndroGel 1%, but simply requires half the volume of gel. It thus has a quicker drying time and therefore less risk of transference.

We find in favor of the FTC on this issue. The record shows that sales of AndroGel 1.62% grew more slowly after launch than defendants initially anticipated. Around the time of the filing of the sham lawsuits, defendants were concerned about the impact that entry of a generic version of AndroGel 1% would have on sales for AndroGel 1.62%. Contemporaneous forecasts created by AbbVie during the relevant time period predicted that entry of a generic version of AndroGel 1% would not only erode sales for brand-name AndroGel 1% but would also cause sales of brand-name AndroGel 1.62% to plateau or even decline. For example, in the fall of 2011, AbbVie forecast that sales of AndroGel 1.62% would decrease approximately 30-35% after entry of an AB-rated generic version of AndroGel 1%. In 2014, AbbVie similarly predicted that AndroGel 1.62% could lose 20-27% of its sales after entry of a generic version of AndroGel 1%. Again, in the real world, AndroGel 1.62%'s share of AndroGel sales did in fact plateau after Perrigo entered the market in December 2014, although by that time AndroGel 1.62%'s share of the total AndroGel market had reached 83%.

The filing of the sham lawsuits allowed defendants additional time to increase sales for AndroGel 1.62% without any competition from a lower priced generic version of AndroGel 1%. Although AndroGel 1% and AndroGel 1.62% are distinct products, both include the same active ingredient and are indicated for the same purpose, that is, to treat hypogonadism. The only significant difference in the record between the two drugs is that AndroGel 1.62% requires a smaller volume of gel. As stated above, AndroGel 1% and AndroGel 1.62% compete within the TTRT market, both with each other as well as with all other TTRTs. Under these circumstances, we find that the filing of the sham

lawsuits and the resulting delay in generic entry increased defendants' profits on not only AndroGel 1% but also on AndroGel 1.62%.

The parties further dispute the end date for calculation of defendants' profits subject to disgorgement. As stated above, only profits with a causal connection to the wrongdoing are subject to disgorgement. *See Commodity Futures Trading Comm'n*, 991 F.2d at 78-79. This court has discretion to order disgorgement of profits for the time period in which the effects on the market of defendants' wrongful conduct were continuing, even after the entry of Perrigo at the end of 2014. *See id.* On the other hand, we must not award disgorgement of profits where the causal connection to defendants' wrongdoing has become too attenuated or remote. *See Teo*, 746 F.3d at 106; *SEC v. MacDonald*, 699 F.2d 47, 53-55 (1st Cir. 1983).

The FTC takes the position that defendants' financial gain due to the sham lawsuits is ongoing at the rate of $6 million per month until the time in the future when a generic version of AndroGel 1.62% enters the market. We reject this position and instead will award disgorgement of profits through August 2017 only. By that time, Perrigo's generic version of AndroGel 1% had been on the market for 2.5 years and had achieved its maximum penetration rate of approximately 91% of brand-name AndroGel 1% sales. The effect of defendants' wrongful conduct on the TTRT market had largely subsided. We find that any award of disgorgement after that date would be speculative.

Defendants are liable for disgorgement in the amount of $448 million in profits. This amount reflects defendants' financial gain due to the sham lawsuits from June 2013 when Perrigo would have entered the

TTRT market through August 2017. In addition, the FTC is entitled to prejudgment interest calculated at the interest rates set forth by the IRS for underpayments. 26 C.F.R. § 301.6621-1; *see also Teo*, 746 F.3d at 109-10. In reaching this award, we are guided by the Supreme Court's direction that antitrust cases must be resolved according to the "particular facts disclosed by the record" rather than "formalistic distinctions." *Eastman Kodak Co.*, 504 U.S. at 467-68 (internal citations omitted). We also keep in mind the purpose of our equitable power to grant disgorgement, which is not to provide an award of damages at law but instead to deter violations of antitrust law and to prevent the unjust enrichment of defendants. *See Teo*, 746 F.3d at 105-06.

We must also decide how liability for the disgorgement award should be apportioned between defendants AbbVie and Besins. Besins contends that it is immune from equitable monetary relief for its violations of antitrust law because it never received any profits from AndroGel. Instead, royalties on U.S. sales of AndroGel were paid to its European corporate affiliate now known as Laboratoires Besins Iscovesco SAS ("LBI SAS") or to another Besins entity, Besins Healthcare Luxemborg SARL ("BHL SARL"). Here, the FTC has named Besins Healthcare, Inc. (as stated above, "Besins") as a defendant.

Besins is one of the entities that instituted the sham lawsuits against Teva and Perrigo. As co-owner of the '894 patent, the sham lawsuits could not have been filed without Besins. *See Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1468 (Fed. Cir. 1998). We have already determined that Besins, along with AbbVie, filed these objectively baseless lawsuits with actual knowledge that the suits lacked merit with no expectation of prevailing and with the intent to impose

expense and delay on Teva and Perrigo and to impede at least for a time the expected loss by defendants of hundreds of millions of dollars in sales. As we discussed above, counsel for Besins was an experienced patent lawyer who had access to the paragraph IV notices, the patent prosecution history, and the analysis of outside counsel who had full access to the Teva and Perrigo section 505(b)(2) NDAs. He nonetheless made the decision with the requisite subjective intent to join in these objectively baseless lawsuits. Under these circumstances it is appropriate to impose disgorgement on Besins for its role in filing the sham lawsuits.

It is well established that "disgorgement is an equitable obligation to return a sum equal to the amount wrongfully obtained, rather than a requirement to replevy a specific asset". *SEC v. McGee*, 895 F. Supp. 2d 669, 689 (E.D. Pa. 2012) (quoting *SEC v. Banner Fund Int'l*, 211 F.3d 602, 617 (D.C. Cir. 2000)). A wrongdoer such as Besins "may be ordered to disgorge not only the unlawful gains that accrue to the wrongdoer directly, but also the benefit that accrues to third parties whose gains can be attributed to the wrongdoer's conduct." *See SEC v. Contorinis*, 743 F.3d 296, 302 (2d Cir. 2014). This result obtains because the purpose of equitable disgorgement is both to deprive a wrongdoer of its unjust enrichment as well as to deter others from violating the law. *Teo*, 746 F.3d at 105 (citing *SEC v. Hughes Capital Corp.*, 124 F.3d 449, 455 (3d Cir. 1997)).

To accept Besins' position would be tantamount to allowing Besins to enrich unjustly its corporate affiliate through the filing of sham lawsuits. *See Contorinis*, 743 F.3d at 301-04, 307. It would also "perpetuate rather than correct an inequity." *Banner Fund Int'l*, 211 F.3d at 617. The Besins entity named as a defendant here is the party that co-owned the '894 patent and the party

that filed the sham actions. It is of no import that Besins may have chosen to direct profits from its wrongdoing to affiliated corporate entities LBI SAS and BHL SARL.

Joint and several liability for disgorgement is appropriate "when two or more individuals or entities collaborate or have close relationships in engaging in the illegal conduct." *Hughes Capital Corp.*, 124 F.3d at 455. Nonetheless, a court may apportion liability among tortfeasors when it is reasonable and practical to do so, such as when the recipients of ill-gotten profits and the amount each received can be determined from the record. *Id.* at 455. Besins' European affiliates were paid royalties in the amount of 8% of the U.S. net sales of AndroGel through the end of March 2015. As of April 1, 2015, that royalty rate was reduced to 5%. We therefore will apportion liability in those percentages to Besins for the disgorgement award of $448 million plus prejudgment interest according to those percentages.

VI

In addition to disgorgement, the FTC seeks an injunction that in its view would prevent or deter defendants from engaging in similar misconduct in the future. Specifically, the FTC urges 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.

The FTC further contends that an injunction is necessary to restore competitive market conditions. It seeks to compel defendants to license AndroGel 1.62% to one or more generic competitors. It also would command defendants to manufacture and deliver to these generic competitors a supply of generic AndroGel 1.62% until those competitors are independently able to manufacture the drug themselves.

Section 13(b) of the FTC Act allows the FTC to obtain injunctive relief when a defendant "is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission." 15 U.S.C. § 53(b). As our Supreme Court has recognized, "[t]he purpose of an injunction is to prevent future violations." *United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953) (citing *Swift & Co. v. United States*, 276 U.S. 311, 326 (1928)). Accordingly, the FTC must demonstrate that there is a "cognizable danger of recurrent violation." *Id.*; *see also Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 n.3 (1994). As the moving party, the FTC bears the burden to prove that injunctive relief is warranted. *See W. T. Grant Co.*, 345 U.S. at 633.

The FTC has proven that defendants filed two sham infringement lawsuits, one against Teva in April 2011 and another against Perrigo in October 2011. Defendants were able to exclude competition illegally in the TTRT market from June 2013 until the end of December 2014 as a result of sham litigation and the settlement of sham litigation. Nonetheless, the FTC has presented no evidence that defendants are currently violating antitrust laws or about to violate antitrust laws. Generic versions of AndroGel have now been on the market for over three years. AndroGel 1%'s share of the market has shrunk since entry of Perrigo, and the '894 patent expires on January 6, 2020. The FTC

has not alleged that defendants have filed any other sham lawsuits.[31] The fact that defendants filed two such lawsuits, without more, does not establish that defendants have a pattern or practice doing so. On this record there is no basis to conclude that defendants' misconduct is likely to reoccur.

We are also concerned that the injunction sought by the FTC is overbroad and punitive in nature. Because it would implicate defendants' First Amendment right to petition the government, the injunction must "burden no more speech than necessary to serve a significant government interest." *Madsen*, 512 U.S. at 765. The injunction sought by the FTC involves the defendants' ability to file patent infringement suits or otherwise to use the governmental process with respect to any patent. Given the fact that the '894 patent was the only patent at issue here and there is no evidence that defendants filed sham litigation or otherwise abused the government process with regard to other patents, the injunctive relief sought by the FTC does not meet the test set forth in *Madsen*.

We also see no basis to enter an injunction mandating defendants to license to generic competitors its intellectual property rights to AndroGel 1.62%. There is no evidence that sale of AndroGel 1.62% is currently violating, or will violate, section 5 of the FTC Act.

Accordingly, no injunction will be entered.

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[31] The FTC has advised the court that since the filing of the lawsuits against Teva and Perrigo in 2011, defendants have filed numerous other patent infringement suits against competitors, including seven lawsuits related to the '894 patent. The FTC has presented no evidence that these lawsuits were shams, and therefore they do not provide support for the injunctive relief sought here.

VII

Based on defendants' violation of section 5 of the FTC Act, the court awards equitable monetary relief in favor of the FTC and against the defendants in the amount of $448 million, which represents disgorgement of defendants' ill-gotten profits from June 2013, when Perrigo would have entered the TTRT market, through August 2017. The FTC is also entitled to prejudgment interest on this award, calculated at the interest rates set forth by the IRS for underpayments as discussed above. *See* 26 C.F.R. § 301.6621-1. Liability will be apportioned between AbbVie and Besins according to the royalty rates agreed upon by the parties, which were 8% through March 31, 2015 and thereafter 5%.

The parties shall confer and if possible submit to the court for consideration a joint proposed form of judgment and if the parties cannot agree each party shall submit a proposed form of judgment. The court will enter a judgment after conferring with the parties.

BY THE COURT:

/s/ Harvey Bartle III
J.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

NO. 14-5151
CIVIL ACTION

FEDERAL TRADE COMMISSION,

v.

ABBVIE INC., ET AL.,

MEMORANDUM

Bartle, J. September 15, 2017

The Federal Trade Commission ("FTC") has filed this action against defendants AbbVie Inc., Abbott Laboratories, and Unimed Pharmaceuticals LLC (collectively "AbbVie"),[1] as well as against Besins Healthcare Inc. The FTC alleges that the defendants engaged in monopolistic conduct in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a). Section 45(a)(1) states that "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive

[1] AbbVie came into existence in January 2013 when it separated from Abbott Laboratories. Unimed is a wholly-owned, indirect subsidiary of AbbVie. Solvay is a wholly-owned subsidiary of AbbVie.

acts or practices in or affecting commerce, are hereby declared unlawful."

As part of its claim for relief, the FTC asserts that the defendants filed sham patent infringement lawsuits against two competitors, Teva Pharmaceuticals USA, Inc. and Perrigo Company, which were seeking approval from the U.S. Food and Drug Administration ("FDA") for generic versions of AndroGel 1%, the defendants' brand-name product.[2] AndroGel 1% is a transdermal testosterone replacement therapy gel. It has been approved by the FDA for the treatment of conditions in men associated with a deficiency or absence of endogenous testosterone and is protected by U.S. Patent No. 6,503,894 ("the '894 patent"). The FTC further alleges that the defendants possessed monopoly power with respect to AndroGel 1% at the time of the filing of the underlying lawsuits.

The court has before it the motions[3] of the defendants for summary judgment on Count One of the complaint and the motion of the plaintiff FTC for partial summary judgment on the objective baselessness element of the sham litigation prong of their illegal monopolization claim.[4]

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[2] Those lawsuits were *Abbott Products, Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 11-384 (D. Del.), and *Abbott Products, Inc. v. Perrigo Co.*, Civil Action No. 11-6357 (D.N.J.), respectively.

[3] The defendants originally moved for summary judgment in February 2015 before discovery had been conducted in this case. These motions are now ripe for the court's review.

[4] The court previously dismissed Count Two, which was the only other claim for relief, wherein the FTC asserted that AbbVie had entered into an anticompetitive settlement with Teva of their underlying patent infringement litigation against Teva. *See FTC*

I.

We first turn to the undisputed facts from the prosecution history record of the '894 patent, which issued on January 7, 2003 from U.S. Patent Application Serial No. 09/651,777 ("the '777 application").

The patent application process began in August 2000 when AbbVie and Besins filed an application for a "pharmaceutical composition comprising testosterone in a gel formulation, and to methods of using the same." Claim 1 of the '777 application read:

> 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.

(Emphasis added). Claim 1 encompassed all penetration enhancers without limitation.[5] The '777 application explained that "[a] 'penetration enhancer' is an agent known to accelerate the delivery of the drug through the skin." The invention description in the '777 application stated:

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v. AbbVie Inc., 107 F. Supp. 3d 428, 438 (E.D. Pa. 2015). Although Teva was named as a defendant in this action, as result of the dismissal of Count Two, Teva is no longer a party.

[5] On page thirty-three of their brief in support of their motion for summary judgment, the defendants state that there are at least 30,000,000 penetration enhancers. (Doc. # 241).

> *Non-limiting examples of penetration enhancers include* C8-C22 fatty acids such as isostearic acid, octanoic acid, and oleic acid; C8-C22 fatty alcohols such as oleyl alcohol and lauryl alcohol; lower alkyl esters of C8-C22 fatty acids such as ethyl oleate, *isopropyl myristate*, butyl stearate, and methyl laurate; di(lower)alkyl esters of C6-C8 diacids such as diisopropyl adipate; monoglycerides of C8-C22 fatty acids such as glyceryl monolaurate; tetrahydrofurfuryl alcohol polyethylene glycol ether; polyethylene glycol, propylene glycol; 2-(2-ethoxyethoxy)ethanol; diethylene glycol monomethyl ether; alkylaryl ethers of polyethylene oxide; polyethylene oxide monomethyl ethers; polyethylene oxide dimethyl ethers; dimethyl sulfoxide; glycerol; ethyl acetate; acetoacetic ester; N-alkylpyrrolidone; and terpenes.

(Emphasis added). Isopropyl myristate is the penetration enhancer actually used in AndroGel 1%.

In June 2001, the patent examiner at the U.S. Patent and Trademark Office ("PTO") rejected claims 1-9 and 35-36[6] of the '777 application as obvious over prior art references Mak in view of Allen, among others. Allen is an international patent application published in September 1996, which discloses the use of isopropyl myristate, isopropyl palmitate, and three other penetration enhancers in a nitroglycerin cream. Mak is an international patent application published in May 1999, which discloses a transdermal testosterone gel that us-

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[6] Claims 10-34 already had been withdrawn by the applicants by the time that the PTO issued its June 2001 office action.

es the penetration enhancer oleic acid. In rejecting the claims of the '777 application, the examiner stated "[s]ince 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."

In response to the June 2001 office action rejecting the claim of all penetration enhancers, AbbVie and Besins submitted their first amendment to their '777 application in October 2001. Claim 1 of the amended '777 application now read:

> A pharmaceutical composition useful for the percutaneous delivery of an active pharmaceutical ingredient, consisting essentially of:
>
> > (a) *at least one penetration enhancer selected from the group consisting of* isostearic acid, octanoic acid, lauryl alcohol, ethyl oleate, *isopropyl myristate*, butyl stearate, methyl laurate, diisopropyl adipate, glyceryl monolaurate, tetrahydrofurfuryl alcohol, polyethylene glycol ether, polyethylene glycol, propylene glycol, 2-(2-ethoxyethoxy) ethanol, diethylene glycol monomethyl ether, alkylaryl ethers of polyethylene oxide, polyethylene oxide monomethyl ethers, polyethylene oxide dimethyl ethers, dimethyl sulfoxide, glycerol, ethyl acetate, acetoacetic ester, N-alkylpyrrolidone, terpene, and combinations of any of the foregoing; and
> >
> > (b) testosterone.

(Emphasis added). In this amendment, AbbVie and Besins narrowed their claim from one encompassing *all* penetration enhancers to a claim naming only twenty-four penetration enhancers, including isopropyl myristate. They also added several new claims. In new claim 47, AbbVie and Besins claimed "a penetration enhancer selected from the group consisting of isopropyl myristate and lauryl alcohol." In new claims 61 and 62, they identified only isopropyl myristate as the penetration enhancer.

In support of the October 2001 amendment, the defendants argued to the examiner that "[a]pplicants' invention is not obvious because of secondary considerations recognized by the courts as indicia of nonobviousness." They submitted the declaration of Jean-Louis Anspach, the chief executive officer of Unimed Pharmaceuticals, Inc., stating that "Unimed launched AndroGel® in June 2000, and it has met with substantial commercial success as shown below." The AndroGel product used only isopropyl myristate as the penetration enhancer.

On December 6, 2001, attorneys for AbbVie and Besins met with the patent examiner to discuss the October 2001 amendment. In her interview summary, the examiner noted that claims 61 and 62, which identified only isopropyl myristate as the penetration enhancer, "are seen to be allowable over the prior art." The interview summary also stated that "applicants argued claim 47 is novel [and] nonobvious over the prior art because the prior art does not teach the composition with particular concentration." As previously stated, claim 47 identified isopropyl myristate and lauryl alcohol as penetration enhancers.

Two weeks later, on December 21, 2001, AbbVie and Besins submitted a supplemental amendment to their patent application. They cancelled the October 2001 amended claim 1 in its entirety and amended claim 47 to specify only isopropyl myristate as the penetration enhancer. As a result, they reduced the number of penetration enhancers in the '777 application from twenty-four to one. AbbVie and Besins also modified the concentration ranges for isopropyl myristate in claim 61. In support of their amended application, AbbVie and Besins stated:

> With entry of the above amendments and in view of the foregoing remarks, it is respectfully submitted that claims 47, 48, 51, 52, 54-62, 66-96 are in condition for allowance. ... Accordingly, reconsideration and withdrawal of the outstanding rejections and allowance of the present claim is respectfully solicited.

They further asserted that "[t]he prior art does not teach the claimed combination; therefore, it is patentable."

AbbVie and Besins submitted additional amendments in February 2002, July 2002, and August 2002. The February 2002 amendment narrowed the concentration range for isopropyl myristate in claims 47 and 61 and cancelled claim 62. AbbVie and Besins stated in the February 2002 that they sought "reconsideration and withdrawal of the outstanding rejections and allowance of the present claims." The July 2002 and August 2002 amendments contained additional changes not relevant here.

The patent examiner finally issued a Notice of Allowability in August 2002 as to claims 47-48, 51-52, 54-57, 61, 78-81, 83, 87-89, and 97-121. The examiner 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 as discussed below." The examiner then distinguished the most recent version of the '777 application from the previous versions of the application and from the prior art references Mak and Allen, among others, that were the bases for her rejections in her June 2001 office action. The examiner approved the application because "the prior art [including Allen] does not teach or fairly suggest the instant claimed pharmaceutical composition consisting essentially of the specific ingredients herein in the particular amounts."

In January 2003, the '894 patent issued. Isopropyl myristate was now the only claimed penetration enhancer. The '894 patent expires in 2020.

Thereafter, Perrigo and Teva, two competitors of AbbVie and Besins, developed generic versions of AndroGel 1%. In order to be able to market their generic products, Perrigo and Teva sought approval from the FDA. Perrigo's product was similar to AndroGel 1% in most respects, except that it used isostearic acid, rather than isopropyl myristate, as the penetration enhancer. Teva's product used isopropyl palmitate rather than isopropyl myristate as its penetration enhancer.

In April 2011 and October 2011, AbbVie and Besins filed lawsuits against Teva and Perrigo. In those lawsuits, AbbVie and Besins maintained that Teva's and Perrigo's generic products infringed the '894 patent under the doctrine of equivalents. They did not allege literal infringement.

At the time the lawsuits were filed, Teva and Perrigo were still in the process of obtaining approval of

their generic products from the FDA. By filing the lawsuits, AbbVie and Besins automatically triggered a thirty-month stay of FDA approval of those generic products. *See* 21 U.S.C. § 355(c)(3)(C). This step delayed entry of the Teva and Perrigo generic products into the market where they would compete with AndroGel 1%. Perrigo began selling its generic product in December 2014 while Teva has not launched its generic product.

II.

In Count One, the only remaining claim in this action, the FTC asserts that AbbVie and Besins engaged in illegal monopolization by filing sham patent litigation against Perrigo and Teva so as to delay entry of their generic products into the testosterone gel market where those generic products would compete with the defendants' AndroGel 1%. In order to prove a claim of illegal monopolization, the FTC must establish both: "(1) the possession of monopoly power [by the defendants] in the relevant market and (2) the willful acquisition or maintenance [by the defendants] of that power."[7] *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 306-07 (3d Cir. 2007) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)).

As noted above, the defendants have filed a motion for summary judgment, and the FTC has filed a motion for partial summary judgment. Under Rule 56 of the

[7] Although this standard for illegal monopolization comes from cases interpreting the Sherman Act, 15 U.S.C. § 2, it is well-settled that § 45(a) of the FTC Act, the relevant statutory provision here, contemplates a range of conduct that includes, but is not limited to, conduct that violates the Sherman Act. *See, e.g., FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986).

Federal Rules of Civil Procedure, summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). A dispute is genuine if the evidence is such that a reasonable factfinder could return a verdict for the nonmoving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Summary judgment is granted where there is insufficient record evidence for a reasonable factfinder to find for the nonmovant. *See id.* When ruling on a motion for summary judgment, we view the facts and draw all inferences in favor of the nonmoving party. *See In re Flat Glass Antitrust Litig.*, 385 F.3d 350, 357 (3d Cir. 2004).

The FTC seeks partial summary judgment as to only the willful acquisition or maintenance of monopoly power prong of the illegal monopolization claim. In particular, the FTC alleges that the defendants willfully acquired or maintained monopoly power by filing sham patent infringement litigation against Teva and Perrigo. Although parties generally may not be held liable for violating the antitrust laws for petitioning the government for redress, this immunity does not extend to sham litigation. *See Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc. ("PRE")*, 508 U.S. 49, 57 (1993) (citing *United Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965); *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961)); *In re Wellbutrin XL Antitrust Litig.*, ___ F.3d ___, 2017 WL 3531069, at *6 (3d Cir. Aug. 9, 2017).

To prove that the infringement actions filed by AbbVie and Besins against Teva and Perrigo were shams, the FTC must establish that: (1) those lawsuits were objectively baseless; and (2) those filing the law-

suits subjectively intended to interfere directly with a competitor's business interests using government process as an anticompetitive weapon. *See PRE*, 508 U.S. at 60-61. The second element concerning the subjective intent of the defendants is not now before the court.

The defendants argue that they are entitled to summary judgment because the FTC cannot make out as a matter of law either the objective baselessness element of the sham litigation prong or the monopoly power prong of the illegal monopolization claim.

III.

We begin with the objective baselessness element of the sham litigation prong of the monopolization claim. Litigation is objectively baseless if "no reasonable litigant could realistically expect success on the merits." *See PRE*, 508 U.S. at 60. To demonstrate that litigation is objectively baseless, "the plaintiff [must] prove that the defendant lacked probable cause" in filing the underlying lawsuit. *See id.* at 62. Probable cause "requires no more than a 'reasonabl[e] belie[f] that there is a chance that [a] claim may be held valid upon adjudication.'" *Id.* at 62-63 (quoting *Hubbard v. Beatty & Hyde, Inc.*, 178 N.E.2d 485, 488 (Ma. 1961)).

In the two underlying lawsuits at issue here, AbbVie and Besins alleged that Teva's use of the isopropyl palmitate as a penetration enhancer and Perrigo's use of isostearic acid for that same purpose in their respective generic products infringed the '894 patent under the doctrine of equivalents. AbbVie and Besins did not assert that Teva and Perrigo engaged in literal infringement since the '894 patent disclosed the use of only isopropyl myristate, a different penetration enhancer. Instead, AbbVie and Besins claimed that iso-

propyl palmitate and isostearic acid were the equivalents of isopropyl myristate.

The doctrine of equivalents provides that "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. ("Festo VIII")*, 535 U.S. 722, 732 (2002)[8]; *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). "The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." *Festo VIII*, 535 U.S. at 733. An element of the alleged infringing product is equivalent to an element of the patented invention if the alleged equivalent is insubstantially different. *See Dawn Equip. Co. v. Ky. Farms, Inc.*, 140 F.3d 1009, 1015-16 (Fed. Cir. 1998) (citing *Warner-Jenkinson Co.*, 520 U.S. at 40).

The FTC does not dispute that the penetration enhancers used by Perrigo and Teva are insubstantially different from the isopropyl myristate penetration enhancer used in AndroGel 1% and disclosed in the '894 patent. Rather, the FTC maintains that the lawsuits against Teva and Perrigo were objectively baseless under the doctrine of prosecution history estoppel. This doctrine with certain exceptions precludes a patentee from claiming equivalents if the patentee surrendered

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[8] There were numerous opinions written by the Federal Circuit, Supreme Court, and other federal courts during the course of litigation between Festo Corporation and Shoketsu Kinzoku Kogyo Kabushiki Company. Although this Memorandum does not mention many of the related cases, we will refer to the cases that are mentioned by their place in the litigation series, as has been done by other courts.

the equivalents for reasons of patentability during the patent prosecution process. *See Festo VIII*, 535 U.S. at 733-34. The FTC argues that the defendants are estopped from claiming that the isostearic acid used in the Perrigo product or the isopropyl palmitate used in the Teva product are equivalents of the isopropyl myristate claimed in the '894 patent because, in the FTC's view, the defendants clearly and affirmatively surrendered those penetration enhancers during the patent prosecution.

As the Supreme Court has explained, prosecution history estoppel balances the rights of patentees with the interest of the public in understanding the limits of the patent so that the public may "be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights." *See id.* at 731-32. It also "ensures that the doctrine of equivalents remains tied to its underlying purpose" of acknowledging "language's inability to capture the essence of innovation." *Id.* at 734. When the prosecution history record demonstrates 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," the patentee is not entitled to the protections of the doctrine of equivalents as to that subject matter. *Id.* at 734-35. "[T]he purpose of applying the estoppel in the first place [is] to hold the inventor to the representations made during the application process and to the inferences that may reasonably be drawn from the amendment." *Id.* at 737-38. For the patentee to prevail against the defense of prosecution history estoppel, "[t]he 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 equiva-

lent." *See id.* at 741. The Supreme Court has placed the burden on the patentee to establish that any amendment is not for the purpose of patentability. *Id.* at 739.

The Federal Circuit has set forth a well-established three-step inquiry for determining whether prosecution history estoppel bars the defendants from claiming the doctrine of equivalents. First, estoppel applies only if the court determines that "an amendment filed in the Patent and Trademark Office ("PTO") has narrowed the literal scope of a claim." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. ("Festo IX")*, 344 F.3d 1359, 1366 (Fed. Cir. 2003) (citing *Festo VIII*, 535 U.S. at 740; *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1356 (Fed Cir. 2003)).

This first step requires us to identify the relevant amendments in the '777 application. The case law is clear that we must consider the entire prosecution history in determining whether estoppel applies. *See Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 867 (Fed. Cir. 1993); *Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1174 (Fed. Cir. 1993). Yet, with respect to the Teva patent infringement litigation, the defendants argue that only the October 2001 amendment is relevant. In the October 2001 amendment, the defendants narrowed their original claim encompassing *all* penetration enhancers to a claim limited to twenty-four identified penetration enhancers. This amendment did not name and thus excluded isopropyl palmitate, the penetration enhancer in Teva's generic product. The amendment, however, specifically included isostearic acid, the penetration enhancer in Perrigo's generic product, among the twenty-four penetration enhancers that the defendants claimed. Thus, for the patent infringement litigation against Perrigo, the de-

fendants ask us to look only to the December 2001 amendment which eliminated isostearic acid from the scope of the '777 application.

While we agree with the defendants that the prosecution history estoppel inquiry takes into account only the relevant amendments in the prosecution history, we disagree with the defendants' characterization of what is relevant. The examiner, we note, rejected in June 2001 claim 1 which claimed all penetration enhancers. In light of this rejection, over the course of their October 2001, December 2001, and February 2002 amendments, the defendants without question narrowed the claimed penetration enhancers in the '777 application from all penetration enhancers including those used in the Teva and Perrigo products to only isopropyl myristate at a particular concentration.[9] We must focus on the above history in its entirety to obtain an accurate understanding of what occurred.

Having determined that the October 2001, December 2001, and February 2002 amendments narrowed the relevant claims after the examiner's rejection in June 2001, "the second question [for determining prosecution history estoppel] is whether the reason for that amendment was a substantial one relating to patentability." *See Festo IX*, 344 F.3d at 1366-67. Prosecution history estoppel applies to amendments made for a substantial reason relating to patentability—whether to address an earlier rejection or for some other reason that satisfies a requirement of the Patent Act, 35 U.S.C. §§ 101, et seq. *See id.* at 1366 (citing *Festo VIII*, 535 U.S. at 727). As noted above, the patentee "bear[s]

[9] In July 2002 and August 2002, the defendants made additional amendments to other aspects of the claimed invention that are not at issue here.

the burden of showing that the amendment does not surrender the particular equivalent in question." *Festo VIII*, 535 U.S. at 740; *Festo IX*, 344 F.3d at 1368. In doing so, the patentee "is restricted to the evidence in the prosecution history record." *Festo IX*, 344 F.3d at 1367 (citing *Warner-Jenkinson Co.*, 520 U.S. at 33)).

Even if the amendment was for purposes of patentability, the patentee can rebut the presumption of surrender by demonstrating: (1) the alleged equivalent was "unforeseeable at the time of the application;" (2) "the rationale underlying the amendment [ ] bear[s] no more than a *tangential relation* to the equivalent in question;" or (3) there is "some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *See Festo VIII*, 535 U.S. at 740-41 (emphasis added). In this case, the defendants rely only on the tangential relation exception. "The tangential relation criterion for overcoming the *Festo* presumption is very narrow." *Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304, 1315 (Fed. Cir. 2008). It "asks whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Festo IX*, 344 F.3d at 1369. This inquiry "focuses on the patentee's objectively apparent reason for the narrowing amendment." *See id.*

The question whether the patentee demonstrated a tangential relation is a matter of law for the court to decide. The court limits its review to "the prosecution history record without the introduction of additional evidence, except, when necessary, testimony from those skilled in the art as to the interpretation of that record." *Id.* at 1370. This analysis "is an objective one that depends on what a competitor would reasonably conclude from the patent's prosecution history." *See*

Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co., 66 F.3d 285, 291 (Fed. Cir. 1995).

Turning first to the underlying patent infringement litigation filed by AbbVie and Besins against Teva, the defendants concede that they excluded isopropyl palmitate, the penetration enhancer used by Teva, from the scope of the '777 application for purposes of patentability. Nevertheless, they argue that it was objectively reasonable to bring that lawsuit against Teva because the October 2001 amendment excluding isopropyl palmitate was tangential to isopropyl palmitate. Relying on expert testimony,[10] the defendants contend that the sole purpose of the October 2001 amendment was to exclude oleic acid, which is the penetration enhancer disclosed in the Mak prior art reference. Oleic acid, like isopropyl palmitate, was not one of the twenty-four penetration enhancers claimed in the October 2001 amendment.

It is undisputed that the October 2001 amendment did not simply eliminate oleic acid or its components. The examiner, it must be remembered, had rejected the original claim 1 encompassing all penetration enhancers in June 2001. The October 2001 amendment sought to overcome the rejection by narrowing the original claim 1 for all penetration enhancers to only twenty-four. It thereby excluded not only oleic acid but also isopropyl palmitate and countless other pene-

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[10] Testimony from a person skilled in the art is not necessary to interpret the prosecution history record in this case. *See Festo IX*, 344 F.3d at 1370. Yet, even if we were to take into account the rationale offered by the expert witness for the October 2001 amendment, the defendants are nevertheless estopped from asserting the doctrine of equivalents with respect to isopropyl palmitate for the reasons explained below.

tration enhancers previously rejected. If AbbVie and Besins merely sought to relinquish oleic acid and no other penetration enhancer in October 2001, they easily could have said so. The defendants' latter-day explanation for the October 2001 amendment is groundless. It fails the reasonableness test in light of the examiner's June 2001 broad-based rejection to say that the abandonment of isopropyl palmitate and many other penetration enhancers was incidental to abandoning only oleic acid. *See Felix v. Am. Honda Motor Co.*, 562 F.3d 1167, 1184 (Fed. Cir. 2009); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1314-15 (Fed. Cir. 2006).

In addition, the Mak prior art, which disclosed the use of oleic acid, was not the only prior art that AbbVie and Besins had to address to overcome the examiner's rejection. In June 2001, the examiner had found the '777 application obvious in light of the Allen prior art, among others. The Allen prior art listed isopropyl palmitate as one of five penetration enhancers and used isopropyl palmitate in six of its nine composition examples. It cannot be doubted from reading the prosecution history record that the defendants sought to address the examiner's June 2001 obviousness rejection based on the Allen prior art when they relinquished the isopropyl palmitate penetration enhancer in filing their October 2001 amendment. The surrender of isopropyl palmitate in the October 2001 amendment to avoid prior art is "the classic basis for the application of prosecution history estoppel."[11] *See Pioneer Magnetics, Inc. v.*

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[11] Moreover, as the Federal Circuit has explained:

> [T]here is no principle of patent law that the scope of a surrender of subject matter during prosecution is limited to what is absolutely necessary to avoid a prior art refer-

Micro Linear Corp., 330 F.3d 1352, 1357 (Fed Cir. 2003); *Festo IX*, 344 F.3d at 1369.

The defendants further argue that the October 2001 amendment could not have intended to overcome the Allen prior art with its disclosure of isopropyl palmitate because Allen also disclosed isopropyl myristate, which was included in the '894 patent. The defendants' argument is without any merit.

The defendants, during the patent prosecution, cited to evidence of secondary considerations of non-obviousness to support their inclusion of isopropyl myristate at a particular concentration in the October 2001 amendment and to overcome Allen. A patent applicant may rely on secondary considerations of commercial success, long felt but unmet needs, and the failure of others, among other factors, to overcome an obviousness rejection. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 399 (2007) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)). In their remarks in connection with the October 2001 amendment, the defendants argued to the examiner that "[a]pplicants' invention is not obvious because of secondary considerations recognized by the courts as indicia of non-obviousness." In support of their position,

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> ence that was the basis for an examiner's rejection. To the contrary, it frequently happens that patentees surrender more through amendment than may have been absolutely necessary to avoid particular prior art. In such cases, we have held the patentees to the scope of what they ultimately claim, and we have not allowed them to assert that claims should be interpreted as if they had surrendered only what they had to.

Norian Corp. v. Stryker Corp., 432 F.3d 1356, 1361-62 (Fed. Cir. 2005).

they submitted the declaration of Jean-Louis Anspach, the chief executive officer of Unimed Pharmaceuticals, Inc. Anspach stated that "Unimed launched AndroGel® in June 2000, and it has met with substantial commercial success as shown below." Isopropyl myristate, at a concentration within the range disclosed in the '894 patent, is the sole penetration enhancer in AndroGel 1%. The defendants singled out isopropyl myristate on the ground of its commercial success from the other penetration enhancers disclosed in Allen. The defendants made no effort based on commercial success or otherwise to save isopropyl palmitate or the other penetration enhancers disclosed in the Allen prior art and found to be obvious by the examiner in June 2001.

In sum, the defendants have cited no evidence in the prosecution history record to rebut the presumption of surrender of isopropyl palmitate. As the Supreme Court teaches in *Festo VIII*, to avoid prosecution history estoppel, the patentee must establish that it could not reasonably be expected to have drafted the October 2001 amendment to include isopropyl palmitate. See *Festo VIII*, 535 U.S. at 741. There is no way that the defendants can avoid prosecution history estoppel by arguing that it was reasonable for them not to include isopropyl palmitate in the October 2001 amendment. Accordingly, the surrender of isopropyl palmitate in the October 2001 amendment was not tangential or peripheral to the isopropyl palmitate in Teva's generic product. *See Festo IX*, 344 F.3d at 1369.

We next turn to the isostearic acid penetration enhancer at issue in the Perrigo infringement action. The defendants contend that it was objectively reasonable to file infringement litigation against Perrigo because the December 2001 amendment excluding isostearic acid was not for purposes of patentability and was tan-

gential to isostearic acid. In the December 2001 amendment, the defendants disavowed twenty-three of the penetration enhancers listed in the October 2001 amendment, including isostearic acid, when they narrowed the claimed penetration enhancer to isopropyl myristate.

The defendants contend that their exclusion of isostearic acid in December 2001 was not for a substantial reason related to patentability because it was not in response to a rejection by the examiner. They note that the only office action rejecting the '777 application was issued by the examiner in June 2001 and that they had since amended the application in October 2001 to address that office action. According to defendants, none of their pending claims stood rejected by the examiner when they voluntarily submitted another amendment in December 2001. The defendants are incorrect. They would have the court ignore a significant event in the prosecution history, that is the examiner's rejection of all penetration enhancers including isostearic acid in June 2001. This we will not do.

Moreover, in the interview summary from the December 6, 2001 interview, the examiner stated that claim 61, which included *only* isopropyl myristate as the penetration enhancer, is "seen to be allowable over the prior art." The examiner's earlier rejection in June 2001 and her position at the December 6, 2001 interview constituted 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.

The December 2001 amendment also explicitly aimed to overcome the prior art cited by the examiner in her June 2001 office action. The defendants argued

in their December 2001 amendment that "reconsideration and withdrawal of the outstanding rejections and allowance of the present claims is respectfully solicited." They also asserted that "[t]he prior art does not teach the claimed combination; therefore, it is patentable."

The defendants' statements in their various briefs are also telling. On page three of their brief in opposition to the motion of the FTC for partial summary judgment (Doc. # 256), the defendants state that the December 2001 amendment "simplified the pending claims to accord with subject matter that the examiner already indicated was allowable over the prior art at a time when the objective public facts showed that prompt issuance of at least some claims was of pressing concern." The defendants admit at page thirty-nine of their brief filed in support of their summary judgment motion (Doc. # 241) that they dropped their claim to isostearic acid and the other penetration enhancers "immediately follow[ing] an interview in which the examiner stated that a claim reciting isopropyl myristate would be allowable." Thus, as the defendants argued in the prosecution history record and reiterated in their summary judgment briefs, their December 2001 amendment specifically aimed to address in pursuit of patentability the examiner's prior art objections in the June 2001 office action.

The defendants' reliance on a so-called voluntary claim-amendment theory is spurious. A voluntary claim amendment is one that the patent examiner does not require or that is not made based on a specific rejection by the examiner. Such an amendment does not preclude prosecution history estoppel. *Festo IX*, 344 F.3d at 1364, 1366; *Pioneer Magnetics, Inc.*, 330 F.3d at 1357. Otherwise a patent applicant could simply re-

lease its claims to subject matter that it believes the examiner is unlikely to approve before the examiner has issued an office action and then recapture that material under the doctrine of equivalents after the patent issues. If the defendants are correct, they could recapture the twenty-three penetration enhancers that they surrendered in December 2001 or potentially the more than 30,000,000 penetration enhancers that were encompassed in the original claim 1 and relinquished in October 2001.

The defendants further contend that by filing the December 2001 amendment they simply sought to expedite their patent application in anticipation of the end of the three-year FDA marketing exclusivity period for AndroGel 1% in February 2003. An amendment narrowing the scope of the patent application in order to expedite the patent prosecution process is necessarily for the purpose of patentability unless it falls in a narrow exception. *See Regents of the Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1378 (Fed. Cir. 2008); *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1142 (Fed. Cir. 2003). Furthermore, the defendants' extrinsic reasons for seeking expedited approval of their application are not contained in the prosecution history record and therefore are not relevant to vitiate prosecution history estoppel. *See Festo IX*, 344 F.3d at 1367 (citing *Pioneer Magnetics*, 330 F.3d at 1356); *Tex. Instruments, Inc.*, 988 F.2d at 1174; *Wang Labs., Inc.*, 993 F.2d at 867.

As with the isopropyl palmitate in the Teva product, the defendants have no credible argument to rebut the presumption of disavowal of isostearic acid in the Perrigo product. The December 2001 amendment surrendering isostearic acid was not peripheral or tangential to isostearic acid. *See Festo IX*, 344 F.3d at 1369.

Again, the defendants cannot overcome prosecution history estoppel because they cannot establish that it was reasonable for them not to have been expected to draft the December 2001 amendment to include isostearic acid. The clear language of the Supreme Court in *Festo VIII* is decisive. *See Festo VIII*, 535 U.S. at 741.

Finally, "the third question in a prosecution history estoppel analysis addresses the scope of the subject matter surrendered by the narrowing amendment." *Festo IX*, 344 F.3d at 1367. "A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." *Festo VIII*, 535 U.S. at 740. The Supreme Court explained that when a patentee narrows "a prior application describing the precise element at issue … . the prosecution history has established that the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter." *See id.* at 734-35. Consequently, there is a presumption that the patentee has "surrendered all subject matter between the broader and the narrower language." *See id.* at 740; *Pioneer Magnetics, Inc.*, 330 F.3d at 1356 (citing *Warner-Jenkinson*, 520 U.S. at 33).

Again, the defendants originally claimed *all* penetration enhancers in claim 1. The examiner rejected the claim as obvious. Over the course of the patent application process, they narrowed their claim to isopropyl myristate at a particular concentration. In so doing, the defendants relinquished their claims to isopropyl palmitate and isostearic acid. The defendants cannot now "avoid the PTO's gatekeeping role and seek to recapture in an infringement action the very subject matter surrendered as a condition of receiving the patent."

See Festo VIII, 535 U.S. at 740. Prosecution history estoppel without question prevents the defendants from claiming that the doctrine of equivalents encompasses the penetration enhancers that they abandoned during the application process, including isopropyl palmitate and isostearic acid. *See id.* at 736. The defendants clearly surrendered broader language for narrower language. *See id.* at 740. There is no plausible argument to overcome the presumption in favor of the application of prosecution history estoppel.

In sum, the law with respect to sham litigation, the doctrine of equivalents, and prosecution history estoppel was well-settled at the time that defendants filed their lawsuits against Teva and Perrigo in 2011.[12] *See PRE*, 508 U.S. at 60-61; *Festo VIII*, 535 U.S. at 739; *Festo IX*, 344 F.3d at 1369. In the final analysis, it must not be forgotten that the purpose of prosecution history estoppel is to protect the patentees' competitors from patent infringement litigation based on the doctrine of equivalents if the prosecution history demonstrates that an equivalent not specifically disclosed in the patent has been purposefully and not tangentially excluded from its scope. The patentee has the burden to overcome the presumption of surrender. Here, any 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 isopropyl palmitate and isostearic acid as penetration enhancers equivalent to isopropyl myristate.

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[12] The Supreme Court has "made it clear that the doctrine of equivalents and the rule of prosecution history estoppel are settled law. The responsibility for changing them rests with Congress." *See Festo VIII*, 535 U.S. at 739 (citing *Warner-Jenkinson Co.*, 520 U.S. at 28).

The patent lawsuits against Teva and Perrigo were without question objectively baseless. AbbVie and Besins could not realistically have expected success on the merits of this issue or have had a reasonable belief that they had a chance to prevail. *See PRE*, 508 U.S. at 60, 62-63. The FTC is entitled to partial summary judgment on the objective baselessness element of the sham litigation prong of their illegal monopolization claim.[13] To the extent that the defendants move for summary judgment on objective baselessness, their motion will be denied.

IV.

The defendants also seek summary judgment on the monopoly power prong of the FTC's illegal monopolization claim under Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which, as previously noted, provides that "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful." In order to commit illegal monopolization, the defendants must have had "monopoly power in the relevant market." *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 433 (3d Cir. 2016). "[M]onopoly power is 'the ability to control prices and exclude competition in a given market.'" *Id.* at 434 (quoting *Broadcom Corp.*, 501 F.3d at 307). This is a fact-intensive inquiry. *See Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 482 (1992). The plaintiff has the burden of

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[13] The defendants raise a number of other arguments in opposition to the FTC's motion for partial summary judgment and in support of their own motion for summary judgment on the issue of objective baselessness. Those arguments are without merit and do not warrant further discussion.

proof with respect to these questions of fact. *See Mylan Pharm., Inc.*, 838 F.3d at 435.

A plaintiff may prove "[t]he existence of monopoly power … through direct evidence of supracompetitive prices and restricted output." *See Mylan Pharm., Inc.*, 838 F.3d at 434 (quoting *Broadcom Corp.*, 501 F.3d at 307). In demonstrating monopoly power by direct evidence, "a plaintiff must often provide an analysis of the defendant's costs, showing both that the defendant had an 'abnormally high price-cost margin' and that the defendant 'restricted output.'" *See id.*

In addition, a plaintiff may prove monopoly power by indirect evidence. "To support a claim of monopoly power through indirect evidence, [the plaintiff] must show that (1) Defendants had market power in the relevant market and (2) that there were barriers to entry into the market." *Id.* at 435. Products are in the same market if there is reasonable interchangeability of use and cross-elasticity of demand. *See id.* Cross-elasticity of demand is "[a] relationship between two products, usually substitutes for each other, in which a price change for one product affects the price of the other." *Id.* at 435-36 (quoting Black's Law Dictionary 458 (10th ed. 2014)).

Here, there are genuine disputes of material fact concerning defendants' monopoly power. At this stage, the defendants are not entitled to judgment as a matter of law as to the monopoly power prong of the illegal monopolization claim. *See* Fed. R. Civ. P. 56(a). This complex issue will have to await a trial.

V.

Accordingly, we will grant the motion of the plaintiff Federal Trade Commission for partial summary

judgment on the objective baselessness element of the sham litigation prong of its monopolization claim and deny the motions of defendants AbbVie Inc., Abbott Laboratories, Unimed Pharmaceuticals LLC, and Besins Healthcare Inc. for summary judgment.

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 18-2621/18-2748/18-2758

FEDERAL TRADE COMMISSION,
Appellant in No. 18-2621
v.

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

AbbVie Inc; Abbott Laboratories; Unimed Pharmaceuticals, LLC,
Appellants in No. 18-2748

Besins Healthcare, Inc.,
Appellant No. 18-2758

(*Dismissed Pursuant to Court's 3/12/19 Order.)
(E.D. Pa. No. 14-cv-05151)

SUR PETITION FOR REHEARING

Present: SMITH, *Chief Judge*, MCKEE, AMBRO, CHAGARES, JORDAN, HARDIMAN, SHWARTZ, RESTREPO, BIBAS, PORTER, MATEY, and PHIPPS, *Circuit Judges*.

Upon consideration of the petition for rehearing filed by the Federal Trade Commission and the petition

for rehearing filed by AbbVie Inc., Abbott Laboratories, Unimed Pharmaceuticals LLC, and Besins Healthcare, Inc. in the above-entitled cases having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the judges of the circuit in regular service not having voted for rehearing, the petition of the Federal Trade Commission and the petition of AbbVie Inc., Abbott Laboratories, Unimed Pharmaceuticals LLC, and Besins Healthcare, Inc. for rehearing by the panel and the Court en banc, are denied. Judge Ambro would have granted the Federal Trade Commission's petition.

BY THE COURT,

s/ *Thomas M. Hardiman*
Circuit Judge

Dated: December 4, 2020
CJG/cc: All Counsel of Record

APPENDIX E

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.

JUDGMENT

This cause came on to be heard on the record from the United States District Court for the Eastern District of Pennsylvania and was argued on January 15, 2020. On consideration whereof, it is now hereby

ORDERED and ADJUDGED that the order of the United States District Court for the Eastern District of Pennsylvania entered on May 6, 2015 is hereby reversed and the judgment entered on July 18, 2018 is hereby AFFIRMED in part, REVERSED in part, VACATED in part and the matter REMANDED to the District Court. All of the above in accordance with the Opinion of this Court.

No costs shall be taxed.

ATTEST:

s/ Patricia S. Dodszuweit
Clerk

Dated: September 30, 2020

APPENDIX F

RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS

U.S. CONSTITUTION AMENDMENT I

Amendment I. Establishment of Religion; Free Exercise of Religion; Freedom of Speech and the Press; Peaceful Assembly; Petition for Redress of Grievances

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

21 U.S.C. § 355

§ 355. New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the

composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 355c of this title. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by

or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) Notice of opinion that patent is invalid or will not be infringed

(A) Agreement to give notice

An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in

the application a statement that the applicant will give notice as required by this paragraph.

(B) Timing of notice

An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) Recipients of notice

An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative

of the holder designated to receive such a notice).

(D) Contents of notice

A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 262 of Title 42, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and

which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 262 of Title 42 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size—

> **(i)(I)** of clinical trials intended to form the primary basis of an effectiveness claim; or
>
> **(II)** in the case where human efficacy studies are not ethical or feasible, of animal and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim; or
>
> **(ii)** with respect to an application for approval of a biological product under section 262(k) of Title 42, of any necessary clinical study or studies.

The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

> **(i)** with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 262 of Title 42 (including all scientific and medical matters, chemistry, manufacturing, and controls).

(6) An application submitted under this subsection shall be accompanied by the certification required under section 282(j)(5)(B) of Title 42. Such certification shall not be considered an element of such application.

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) Not later than 30 days after the date of approval of an application submitted under subsection (b), the holder of the approved application shall file with the Secretary the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii), except that a patent that is identified as claiming a method of using such drug shall be filed only if the patent claims a method of use approved in the application. If a patent described in

subsection (b)(1)(A)(viii) is issued after the date of approval of an application submitted under subsection (b), the holder of the approved application shall, not later than 30 days after the date of issuance of the patent, file the patent number and the expiration date of the patent, except that a patent that claims a method of using such drug shall be filed only if approval for such use has been granted in the application. If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii). If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information under subsection (b) because no patent of the type for which information is required to be submitted in subsection (b)(1)(A)(viii) had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it. Patent information that is not the type of patent information required by subsection

(b)(1)(A)(viii) shall not be submitted under this paragraph.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

> **(A)** If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.
>
> **(B)** If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).
>
> **(C)** If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period

as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed—

(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stat-

ing that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28 by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that

civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer

of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an

order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of another application for a drug for which the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not ob-

tained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the

subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailabilty [1] studies) essential to the approval of the supplement and conducted or spon-

sored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from September 24, 1984.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and

effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(5)(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

(B) A supplemental application is eligible for review as described in subparagraph (A) only if—

(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

(ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

(C) The Secretary shall post on the Internet website of the Food and Drug Administration and update annually—

(i) the number of applications reviewed solely under subparagraph (A) or section 262(a)(2)(E) of title 42;

(ii) the average time for completion of review under subparagraph (A) or section 262(a)(2)(E) of title 42;

(iii) the average time for review of supplemental applications where the Secretary did not use review flexibility under subparagraph (A) or section 262(a)(2)(E) of title 42; and

(iv) the number of applications reviewed under subparagraph (A) or section 262(a)(2)(E) of title 42 for which the Secretary made use of full data sets in addition to the qualified data summary.

(D) In this paragraph—

(i) the term "qualified indication" means an indication for a drug that the Secretary determines to be appropriate for summary level review under this paragraph; and

(ii) the term "qualified data summary" means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.

* * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to

show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug re-

ferred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

> **(I)** that such patent information has not been filed,
>
> **(II)** that such patent has expired,
>
> **(III)** of the date on which such patent will expire, or
>
> **(IV)** that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection

(b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) Notice of opinion that patent is invalid or will not be infringed

(i) Agreement to give notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) Timing of notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an

amendment or supplement to the application.

(iii) Recipients of notice

An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) Contents of notice

A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

> **(i)** that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or
>
> **(ii)** that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

* * *

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

> **(i)** If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.
>
> **(ii)** If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).
>
> **(iii)** If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under

paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the

patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-day exclusivity period

(I) Effectiveness of application

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug

for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions

In this paragraph:

(aa) 180-day exclusivity period

The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant

As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application

As used in this subsection, the term "substantially complete application"

means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(v) 180-day exclusivity period for competitive generic therapies

(I) Effectiveness of application

Subject to subparagraph (D)(iv), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

(II) Limitation

The exclusivity period under subclause (I) shall not apply with respect to a competitive generic therapy that has previously received an exclusivity period under subclause (I).

(III) Definitions

In this clause and subparagraph (D)(iv):

(aa) The term "competitive generic therapy" means a drug—

(AA) that is designated as a competitive generic therapy under section 356h of this title; and

(BB) for which there are no unexpired patents or exclusivities on the list of products described in section 355(j)(7)(A) of this title at the time of submission.

(bb) The term "first approved applicant" means any applicant that has submitted an application that—

(AA) is for a competitive generic therapy that is approved on the first day on which any application for such competitive generic therapy is approved;

(BB) is not eligible for a 180-day exclusivity period under clause (iv) for the drug that is the subject of the application for the competitive generic therapy; and

(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D).

* * *