Nos. 18-2621, -2748, -2758

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff/Appellant,

v.

ABBVIE INC.; ABBOTT LABORATORIES; UNIMED PHARMACEUTICALS LLC; BESINS HEALTHCARE, INC.; *TEVA PHARMACEUTICALS USA, INC.,
Defendants/Cross-Appellants.

(*Dismissed Pursuant To Court's 3/12/2019 Order)

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

OPENING/RESPONSE BRIEF FOR APPELLEES/CROSS-APPELLANTS ABBVIE INC., ABBOTT LABORATORIES, AND UNIMED PHARMACEUTICALS LLC

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CORPORATE DISCLOSURE STATEMENT

AbbVie Inc. has no parent corporation, and no publicly held company owns 10% or more of its stock.

Abbott Laboratories has no parent corporation, and no publicly held company owns 10% or more of its stock.

Unimed Pharmaceuticals LLC is an indirect, wholly owned subsidiary of AbbVie Inc., a publicly traded company.

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INTRODUCTION

This Court recently warned that the Federal Trade Commission's "improper use of Section 13(b)" of the FTC Act, 15 U.S.C. §53(b), threatens to "discourage lawful petitioning activity by interested citizens—activity that is protected by the First Amendment." *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147, 161 (3d Cir. 2019). This appeal directly implicates that concern.

In 2011, AbbVie and Besins brought suits under the Hatch-Waxman Act to enforce an undisputedly valid patent, asserting infringement claims against two companies (Teva and Perrigo) based on theories that have prevailed in other cases on similar facts. The patent-infringement suits ended in settlements in which Teva and Perrigo made significant concessions. Years later, the FTC brought this action against AbbVie and Besins under §13(b), challenging the infringement suits as "shams" and AbbVie's settlement with Teva as an anticompetitive "reverse payment." The district court correctly dismissed the FTC's claim challenging the Teva settlement. Yet the court ordered nearly half a billion dollars in disgorgement for alleged "sham" litigation based on the court's conclusion that it would have sided with Teva and Perrigo on the merits of the infringement suits. That misapplication of the sham-litigation standard, which will chill legitimate litigation conduct encouraged by the Hatch-Waxman Act and protected by the First Amendment, should be reversed.

As this Court has emphasized, the sham-litigation standard is stringent. *See In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 147-148 (3d Cir. 2017). It requires a showing that no objectively reasonable litigant "could have believed that it had some chance of winning." *Professional Real Estate Inv'rs, v. Columbia Pictures Indus.*, 508 U.S. 49, 65 (1993) ("*PRE*"). And antitrust liability can attach only if the lawsuit subjectively was brought not to seek relief, but to use the judicial process itself to suppress competition. *Id.* at 60-61. Courts must police these requirements vigorously, both to protect First Amendment interests and to avoid "punish[ing] behavior that Congress sought to encourage" through the Hatch-Waxman Act. *Wellbutrin*, 868 F.3d at 158.

The FTC does not dispute that AbbVie and Besins's patent is valid. It claims instead, and the district court concluded, that the infringement claims were precluded by "prosecution-history estoppel"—a technical doctrine involving elaborate presumptions and exceptions that defy predictable rules. Substantial authority suggests the court's conclusion was wrong as a matter of patent law. But regardless of the correct answer to that patent-law question—which was not the issue in this antitrust case—the court made several errors in imposing liability for sham litigation, any of which alone requires reversal.

First, the court found the suits objectively baseless solely because it disagreed with AbbVie and Besins on the merits of complex patent issues, without

making any genuine determination—under the objective element of the sham-litigation standard—that no reasonable litigant could have believed it had some chance of prevailing. Second, the court collapsed the objective and subjective elements of the sham standard. Rather than assessing AbbVie's and Besins's subjective purposes in bringing the infringement actions, it simply ascribed to their decisionmakers the court's own views under the objective element.

Third, the court erroneously found monopoly power based solely on market share in what the FTC's expert conceded was *not* the proper market. And even in that market, the court disregarded overwhelming real-world evidence that AbbVie lacked power to control prices or exclude competition; instead, AbbVie lost substantial business even as it competed vigorously to keep pace with rivals. Finally, the court ordered disgorgement where it had no authority to do so. Section 13(b) does not authorize disgorgement, and even if it did, the award here rests on unfounded speculation and contravenes the record evidence.

The FTC brings its own appeal, which disregards these flaws in the judgment below and the limits on the FTC's authority under §13(b). The FTC contends the district court should have ordered even greater disgorgement and enjoined AbbVie and Besins from asserting patent rights in the future. But there was no basis to find liability or award relief here in the first place, much less the punitive remedies the FTC urged. And the FTC's challenges to the remedy distort

the record and assign error where there was none. As to the reverse-payment count, the FTC failed to state a plausible claim. But even if it had, reinstating the claim would serve no purpose: Teva would never have entered the market even absent the settlement (as the court found), and relief under §13(b) is unavailable.

If the judgment against AbbVie and Besins were upheld, patent holders would face the threat of punitive disgorgement (and treble damages in private litigation) for asserting colorable patent claims in exactly the manner the Hatch-Waxman Act encourages and the First Amendment protects—chilling effects that the stringent antitrust standards were meant to prevent. This Court should reject the FTC's appeal and reverse the judgment against AbbVie and Besins.

JURISDICTIONAL STATEMENT

The FTC sued under §13(b) of the FTC Act, 15 U.S.C. §53(b). The district court had jurisdiction under 28 U.S.C. §§1331, 1337(a), and 1345, and entered final judgment on July 18, 2018 (JA171). AbbVie timely appealed on August 6, 2018 (JA177). This Court has jurisdiction under 28 U.S.C. §1291.

STATEMENT OF ISSUES

ABBVIE AND BESINS APPEAL

1. Whether AbbVie and Besins's infringement suits were objectively baseless. (Raised: ECF Nos. 241, 256, 272, 411, 416. Decided: ECF Nos. 300, 301, 438 (JA33-68).)

2. Whether the suits were subjectively baseless. (Raised: ECF Nos. 324 at 7-19, 49-56; 412 at 2-12; 413 at 3-41, 114-124. Decided: ECF No. 439 at 30-53 (JA98-121).)

3. Whether AbbVie and Besins had monopoly power. (Raised: ECF Nos. 324 at 19-26, 57-58; 412 at 12-26; 413 at 42-75, 124-129. Decided: ECF No. 439 at 53-78 (JA 121-146).)

4. Whether §13(b) authorizes disgorgement and, if so, whether the district court abused its discretion in awarding disgorgement here. (Raised: ECF Nos. 324 at 27-31, 38-46; 412 at 26-36; 413 at 75-113, 130-138. Decided: ECF No. 439 at 78-98 (JA146-166).)

FTC APPEAL

5. Whether the FTC's challenge to an alleged "reverse payment" settlement failed to state a claim. (Raised: ECF Nos. 38, 55, 113. Decided: ECF Nos. 81, 82, 118, 119 (JA2-30).)

6. Whether the district court abused its discretion in denying the FTC additional disgorgement. (Raised and decided as noted at Issue 4.)

7. Whether the district court abused its discretion in denying the FTC's request for injunctive relief. (Raised: ECF Nos. 324 at 26-27; 412 at 2 n.1; 413 at 75 n.7. Decided: ECF No. 439 at 98-101 (JA166-169).)

STATEMENT OF RELATED CASES

This case has not previously been before this Court. One related case is pending in the U.S. District Court for the Eastern District of Pennsylvania: *Value Drug Co. v. AbbVie Inc.*, No. 2:18-cv-2804. Two others recently concluded there. *Walgreen Co. v. AbbVie Inc.*, No. 2:18-cv-3494; *CVS Pharmacy, Inc. v. AbbVie Inc.*, No 2:18-cv-3495. Another antitrust case involving AndroGel, but involving different settlements, plaintiffs, and claims, is pending in the U.S. District Court for the Northern District of Georgia: *In re AndroGel Antitrust Litig. (No. II)*, No. 09-md-02084. A second recently concluded there. *FTC v. Actavis, Inc.*, No. 1:09-cv-00955.

STATEMENT OF THE CASE

A. AndroGel And The Testosterone Replacement Therapy Market

This case arises from AbbVie and Besins's assertion in 2011 of their patent rights in AndroGel, the first FDA-approved testosterone replacement therapy (TRT) in a topical gel. Physicians prescribe AndroGel to treat hypogonadism (insufficient testosterone). JA75 (Op.).[1] AndroGel contains testosterone and other ingredients, including isopropyl myristate—a "penetration enhancer" that accelerates drug delivery through the skin. JA1210 (PLX061) (patent). Defendant Unimed Pharmaceuticals LLC and affiliates of defendant Besins Healthcare, Inc.

[1] This brief applies the FTC's citation conventions. *See* FTC Br. 8 n.4.

collaborated to develop AndroGel 1%—a gel containing one-percent testosterone—which Unimed's parent company, Solvay Pharmaceuticals, brought to market in 2000 following FDA approval. JA77-78 (Op.). Defendant Abbott Laboratories acquired Solvay and Unimed in 2010, and in 2013, defendant AbbVie Inc. assumed Abbott's proprietary pharmaceutical business, including AndroGel. *Id.* (Here, "AbbVie" refers to AbbVie Inc., Abbott Laboratories, and/or Unimed.)

When it launched, AndroGel 1% joined a competitive and growing market for TRTs. Injectable TRTs, introduced in the 1950s, had been available in generic form for decades. JA75-76 (Op.). In the 1990s, transdermal TRT patches were introduced. JA77. Several competing TRT gels entered the market after AndroGel 1%. JA79. AbbVie also launched a more concentrated gel, AndroGel 1.62%, in 2011. JA77.[2] All these TRTs contain the same active ingredient (testosterone), work by raising testosterone levels in the blood, have been FDA-approved, and are considered appropriate for treating hypogonadism in most patients. JA135 (Op.); JA3798 (Tr. 6:45-48) (Hayes); JA4259-4260 (Tr. 14:6-12) (Ritenour).

AndroGel's launch was successful. U.S. net sales (including 1% and 1.62%) were approximately $874 million in 2011 and $1.15 billion in 2012. JA78 (Op.). But AndroGel faced increasing competition. JA4330-4333 (Tr. 15:33-47)

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[2] Other FDA-approved TRTs include a buccal tablet introduced in 2003, a surgically insertable pellet introduced in 2008, and a nasal solution introduced in 2014. JA80 (Op.).

(Cremieux); *see also* JA3862 (Tr. 7:108) (Shapiro). Four new branded TRTs entered the market between 2011 and 2014. JA79 (Op.); JA3783-3785 (Tr. 5:269-280) (Hynd); JA3798 (Tr. 6:45-48) (Hayes). Patients routinely switched among TRTs, including injectables. JA135 (Op.); JA4326-4332 (Tr. 15:17-41) (Cremieux). Nearly half of AndroGel patients also received prescriptions for other TRTs, including 21.8% who were prescribed injectables. JA2184 (DX111). As patients' out-of-pocket co-pays for AndroGel rose, patients increasingly turned to less costly injectables. JA137-138 (Op.); JA2473 (DX201).

AbbVie undertook various measures to compete, including offering rebates to insurers and pharmacy benefit managers and covering portions of patient co-pays. JA133 (Op.). Between 2011 and 2014, AbbVie paid $438 million in rebates—about 19% of AndroGel gross sales. *Id.* Nonetheless, AbbVie lost substantial business to competitors, JA78, 133-134, and AndroGel's market share fell. U.S. net sales declined to $1.035 billion in 2013 and $934 million in 2014. JA78. AndroGel's share of topical TRTs—*i.e.*, TRTs applied to the skin—fell from 71.5% in April 2011 to 63.6% by October 2011 and hovered around 60% through the end of 2014. JA140. Considering all TRTs—including injectables—AndroGel's market share fell from approximately 50% in January 2011 to 32% in December 2014. JA2190 (DX122); *see also* JA2077 (DX098); JA2188-2189 (DX119, DX121); JA4148-4149 (Tr. 11:245-250) (Gautsch).

B. The Patent-Infringement Suits

1. The ’894 patent

AndroGel is protected by U.S. Patent No. 6,503,894 (“the ’894 patent”), co-owned by AbbVie and Besins. JA1155 (PLX061). As filed in August 2000, claim 1 of the original patent application recited “[a] pharmaceutical composition … comprising: (a) a C1-C4 alcohol; (b) a penetration enhancer; (c) the active pharmaceutical ingredient; and (d) water.” JA909 (PLX051). Dependent claim 5 specified a composition in which “the active pharmaceutical ingredient is testosterone, and the [penetration] enhancer is isopropyl myristate.” *Id.*

In June 2001, the patent examiner rejected the claims, concluding that prior art rendered it obvious to combine testosterone with isopropyl myristate. JA1014-1016 (PLX052). The examiner emphasized one prior-art reference, Mak, that combined testosterone with the penetration enhancer oleic acid. The examiner acknowledged that Mak did not “expressly disclose the employment of … isopropyl myristate,” but cited other prior art—Allen—that used isopropyl myristate as a penetration enhancer in a product unrelated to testosterone therapy. JA1015. The examiner concluded that it would have been obvious to combine isopropyl myristate (as taught by Allen) with the testosterone composition in Mak. JA1015-1016. The examiner did not cite any other claimed penetration enhancer as obvious. JA1014-1016.

In October 2001, AbbVie and Besins amended their patent application. JA1018-1048 (PLX053). Amended claim 1 eliminated the open-ended reference to any penetration enhancer and instead recited a composition comprising testosterone and one of 24 enumerated penetration enhancers, including isopropyl myristate. JA1020. A new claim 61 specifically recited only isopropyl myristate. JA1024. Challenging the examiner's rejection of isopropyl myristate as obvious, AbbVie and Besins argued that the amended claims were not obvious because the prior art did not suggest combining isopropyl myristate, nor any of the other claimed penetration enhancers, with testosterone. JA1031. They emphasized that the penetration enhancer used with testosterone in Mak—oleic acid—was chemically and physically distinguishable from isopropyl myristate and the other enhancers recited in the amended claims and argued that it would not have been obvious to combine testosterone with isopropyl myristate or the other enhancers used in Allen. JA1029-1039.

Following that amendment, without commenting on any other claims, the examiner indicated on December 6, 2001, that claim 61—the claim specifying isopropyl myristate—was "seen to be allowable over the prior art." JA1084 (PLX056). By that time, nearly two years had passed since the FDA had approved AndroGel 1%. While approval had triggered a three-year period of statutory marketing exclusivity, there would have been no protection for AndroGel beyond

that period unless the patent issued. JA3725 (Tr. 5:40) (Hynd). On December 21, 2001, before the examiner took any other action, AbbVie and Besins voluntarily amended all of the pending claims to specify only isopropyl myristate. JA1086-1092 (PLX057). With that change, AbbVie and Besins submitted that the claims were "in condition for allowance" and "urged" the examiner to "expedite prosecution." JA1095. The '894 patent issued on January 7, 2003, reciting isopropyl myristate as the penetration enhancer. JA1155, 1229 (PLX061).

2. The Hatch-Waxman Act

Issuance of the '894 patent prohibited others from "mak[ing], us[ing] [or] sell[ing]" copies of AndroGel 1% without authorization during the patent term, which was set to expire in 2020. 35 U.S.C. §271(a). In the pharmaceutical context, that prohibition serves "the significant 'public interest in encouraging investment in drug development'" by providing "'an incentive to inventors to risk the often enormous costs in terms of time, research, and development'" necessary to bring new medicines to market. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1362-1363 (Fed. Cir. 2008). At the same time, the Hatch-Waxman Act facilitates competition between patented drugs and less-expensive generic copies by allowing generic manufacturers to obtain FDA approval through streamlined procedures and providing a framework for resolving patent disputes. *See Eli Lilly & Co. v.*

Medtronic, Inc., 496 U.S. 661, 670-671 (1990); *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 143-144 (3d Cir. 2017).

In particular, while a manufacturer seeking to market a new branded drug must submit a New Drug Application (NDA) to the FDA and undertake a lengthy testing process, Hatch-Waxman permits generic manufacturers to pursue abbreviated approval pathways—an Abbreviated New Drug Application (ANDA) or a "section 505(b)(2) NDA"—that "allow[] the generic to piggy-back on the pioneer's approval efforts." *Wellbutrin*, 868 F.3d at 143; *see* FTC Br. 5-6. On both pathways, the generic manufacturer must certify either that the branded drug is not covered by an existing patent or that any applicable patent "is invalid or will not be infringed" by the manufacture, use, or sale of the generic drug. 21 U.S.C. §355(b)(2)(A)(iv), (j)(2)(A)(vii)(IV). The latter is known as a "paragraph IV certification."

"To facilitate the filing of infringement suits," the Hatch-Waxman Act provides that submitting a paragraph IV certification constitutes an act of patent infringement, allowing the patent holder to sue for injunctive relief without waiting for the generic product's actual manufacture or sale. *Wellbutrin*, 868 F.3d at 144. The statute also "encourages brand-name manufacturers to file patent infringement suits quickly," providing that if the patentee commences an infringement suit within 45 days after receiving a paragraph IV certification, the FDA must withhold

approval of the generic drug for 30 months or until the infringement suit ends, whichever comes first. *Id.* During that period, FDA review of the generic drug continues unabated. JA3572 (Tr. 2:113-114) (Phelps). By design, these provisions incentivize early dispute resolution to remove the uncertainty and risk of liability that could otherwise deter generic manufacturers from entering the market. *Wellbutrin*, 868 F.3d at 144.

3. Teva's and Perrigo's products and the ensuing lawsuits

Beginning in 2008, Teva Pharmaceuticals USA and Perrigo Company each sought FDA approval for 1% testosterone gels. JA81-82, 85 (Op.). Their applications referenced AndroGel 1% and the '894 patent, seeking to piggy-back on AndroGel's FDA approval while using different penetration enhancers that are chemically and functionally similar to isopropyl myristate: Teva's gel contained isopropyl palmitate; Perrigo's contained isostearic acid. *Id.* Both manufacturers initially sought approval through the ANDA process, but the FDA mandated safety testing using §505(b)(2) NDAs. JA84-85.

a. Teva

In January 2011, Teva filed a §505(b)(2) NDA seeking approval for a testosterone gel containing isopropyl palmitate. In March 2011, Teva sent a paragraph IV certification that its gel would not infringe the '894 patent because the gel did not contain isopropyl myristate. JA1663, 1678-1679 (PLX303). Under

Hatch-Waxman, that certification constituted an act of infringement, and AbbVie and Besins had 45 days to decide whether to sue and invoke the statutory stay. AbbVie's counsel had confidential access to Teva's NDA, and after investigating the issues and consulting an analysis from outside counsel, AbbVie's in-house lawyers made the decision to sue for AbbVie. JA4083-4084 (Tr. 10:235-237) (Hynd); JA4217-4218, 4243-4247 (Tr. 13:112-115, 215-229) (Siatis).

In April 2011, AbbVie and Besins sued, alleging infringement of the '894 patent under the doctrine of equivalents. JA1247-1253 (PLX133) (complaint). Under that doctrine, "[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.*, 535 U.S. 722, 732 (2002); *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). The doctrine recognizes that "[i]f patents were always interpreted by their literal terms, their value would be greatly diminished," as "[u]nimportant and insubstantial substitutes for certain elements could defeat the patent." *Festo*, 535 U.S. at 731. AbbVie and Besins argued that any differences between Teva's penetration enhancer (isopropyl palmitate) and the one claimed in the '894 patent (isopropyl myristate) were insubstantial and that Teva's gel therefore infringed the patent. JA398-405 (interrogatory response). The filing of the complaint triggered the Hatch-Waxman stay. JA87 (Op.).

In August 2011, Teva moved for summary judgment. Teva did not dispute the validity of the '894 patent and did not deny that isopropyl palmitate was substantially equivalent to isopropyl myristate. JA409-440 (motion). Teva argued instead that "prosecution-history estoppel" barred AbbVie and Besins from claiming infringement based on that equivalence. JA429-440. Under that doctrine, a patent applicant's "decision to narrow his [patent] claims through amendment" in response to a patent examiner's rejection may be "presumed to be a general disclaimer of the territory between the original claim and the amended claim." *Festo*, 535 U.S. at 740. Teva contended that AbbVie and Besins surrendered patent protection for a 1% testosterone gel using isopropyl palmitate by narrowing their patent application in October 2001 from the original claim of any penetration enhancer to a group of 24 penetration enhancers that did not include isopropyl palmitate. JA429-440; *supra* p. 10.

AbbVie and Besins opposed Teva's motion and sought discovery. JA447-470 (opposition). Citing the "tangentiality" exception to prosecution-history estoppel recognized in *Festo*, 535 U.S. at 737-741, they argued that no estoppel arose because the rationale for the October 2001 amendment was to overcome the prior art's use of oleic acid and was only "tangentially related" to Teva's penetration enhancer, isopropyl palmitate. JA454-470. In October 2011, noting that *Festo* approved of expert testimony bearing on tangentiality and that any

disagreement between the experts would likely preclude summary judgment, the trial court ordered limited discovery and set trial for May 2012. JA89 (Op.); JA508-511, 550-551, 557 (hearing); JA1866-1867 (DX012) (order).

Shortly thereafter, AbbVie and Teva discussed a settlement allowing Teva to enter the market before expiration of the '894 patent, JA91-92 (Op.)—a common form of settlement the Supreme Court and the FTC have specifically approved, *see FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013); JA15 (MTD Op.). Teva initially proposed to launch its product in September 2013, notwithstanding the May 2012 trial date. JA92 (Op.). AbbVie countered, proposing that Teva not enter the market until January 1, 2015. *Id.* The parties agreed to an entry date of December 27, 2014—more than two years after Teva could have launched upon a victory at the May 2012 trial. *Id.* The parties executed the agreement on December 20, 2011. *Id.*; *see* JA4219-4222 (Tr. 13:118-132) (Siatis describing negotiations).

Around the same time, AbbVie and Teva were separately negotiating agreements relating to two other drugs, Simcor and TriCor, and executed those agreements on the same day as the AndroGel settlement. JA92 (Op.). Under one of those agreements, Teva agreed to pay AbbVie for a four-year option to buy a supply of TriCor, a popular cholesterol drug, for resale to consumers. Years before, AbbVie had granted Teva a license to market a generic version of TriCor, and the new agreement allowed Teva to use the AbbVie supply for this purpose in

exchange for payments from Teva to AbbVie that covered AbbVie's costs for TriCor, plus an additional percentage above those costs, plus a royalty on Teva's profits. JA10-11, 17 (MTD Op.). There was "no evidence that these negotiations were linked to the AndroGel settlement." JA92 (Op.); *see* JA4223-4224 (Tr. 13:133-140) (Siatis).

Meanwhile, the FDA had continued to review Teva's §505(b)(2) NDA. In February 2012, the FDA approved Teva's testosterone gel, but only for distribution in the form of single-dose foil packets; Teva had to withdraw its application for distribution in the more popular pump form in July 2011 after the FDA identified a safety concern with Teva's dispenser. JA93, 153 (Op.). As Teva executive Maureen Cavanaugh testified and the district court found, loss of the pump cut Teva's potential sales roughly in half. *Id.*; JA3612-3613, 3632-3633 (Tr. 3:43-45, 121-125). In 2011, Teva also encountered obstacles with its manufacturer, Cipla, which demanded a $10 million upfront payment or a 35% royalty to fund construction of manufacturing facilities. JA154 (Op.); JA3633-3634 (Tr. 3:126-131) (Cavanaugh); JA621-626 (PLX018) (Cipla-Teva correspondence). Teva viewed these demands as "very significant" and understood that Cipla would not begin preparing for production—preparations expected to take two years—until the parties reached agreement on the capital investments. JA3633-3634 (Tr. 3:128-131). Teva and Cipla never resolved the dispute. *Id.*; JA154 (Op.).

Teva also faced financial risk based on the therapeutic equivalence (TE) rating for its testosterone gel. A TE rating reflects the degree of similarity, determined by the FDA, between a generic and a branded drug. JA73 (Op.). An "A" or "AB" rating—reflecting a determination that the products are therapeutically equivalent—is desirable because state laws generally provide for pharmacists to automatically substitute therapeutically equivalent, lower-cost generic drugs for prescribed branded drugs. JA73-74. Thus, generic manufacturers can sell their products without investing in the marketing infrastructure that brand-name manufacturers require. A "B" or "BX" rating, however, indicates that therapeutic equivalence was not established and precludes automatic substitution. JA73.

By June 2011, Teva knew its product was unlikely to receive an AB rating. JA3608, 3628-3629 (Tr. 3:26-28, 108-109) (Cavanaugh). Ultimately, in July 2014, the FDA issued a BX rating, as expected, "due to discrepancies with the analytical work in Teva's bioequivalence study." JA151-152 (Op.). Teva's generic division, which relies on automatic substitution, has never launched a BX-rated retail pharmaceutical and did not employ a sales force that could have marketed the gel. JA152; JA3630 (Tr. 3:113-115) (Cavanaugh). In 2012, Teva decided not to launch its testosterone gel. JA3634 (Tr. 3:132) (Cavanaugh).

b. Perrigo

Perrigo submitted its §505(b)(2) NDA in July 2011, seeking approval for a 1% testosterone gel containing the penetration enhancer isostearic acid. JA89-90 (Op.). In September 2011, Perrigo served a paragraph IV certification contending that its gel would not infringe the '894 patent either literally, because it did not contain isopropyl myristate, or under the doctrine of equivalents, in light of the patent's prosecution history. JA90; JA1509-1570 (PLX264) (certification). Perrigo claimed AbbVie and Besins had surrendered isostearic acid by narrowing their patent application in December 2001 from 24 claimed penetration enhancers (including isostearic acid) to only one (isopropyl myristate). JA1532-1551.

In October 2011, AbbVie and Besins sued Perrigo for infringement, triggering the Hatch-Waxman stay. JA90-91 (Op.). AbbVie's in-house attorneys made the decision to sue for AbbVie after examining the issues and conferring with outside counsel. JA91. That decision differed from the judgment Solvay had made when Perrigo served a paragraph IV certification with a prior ANDA in 2009. JA609 (PLX009); JA82-83 (Op.). Solvay stated in 2009 that Perrigo's assertion of noninfringement based on the formulation of its testosterone gel "played a role" in Solvay's decision not to sue "at th[at] time," but underscored that Solvay "d[id] not waive its right" to sue "at a later stage." JA609 (PLX009). By the time of Perrigo's 2011 paragraph IV certification, AbbVie had acquired

Solvay, and none of the AbbVie attorneys who made the decision to sue in 2011 had been employed by Solvay or involved in the 2009 decision. JA108 (Op.). They made their own decision, following counsel's confidential review of Perrigo's 2011 NDA. JA91.

Shortly after filing the complaint, AbbVie approached Perrigo to discuss settlement, proposing that Perrigo launch on January 1, 2015. JA92 (Op.). Although Perrigo initially sought an earlier date, it ultimately accepted AbbVie's offer. JA92-93. The final agreement, executed on December 8, 2011, licensed Perrigo to market its gel beginning January 1, 2015, but included an acceleration clause allowing Perrigo to launch earlier if another product referencing AndroGel was licensed to launch before then. JA93. As a result of the Teva settlement, Perrigo's license date moved up to match Teva's: December 27, 2014. *Id.*

The FDA approved Perrigo's NDA on January 31, 2013. JA155 (Op.). The FDA took longer, however, to act on Perrigo's request for a TE rating. Drugs approved under §505(b)(2) NDAs do not automatically receive TE ratings. Rather, the manufacturer may request a TE rating only after the FDA has approved the NDA. JA3561 (Tr. 2:71-72) (Phelps); JA4289 (Tr. 14:125-126) (Mathers). No statute or regulation entitles the applicant to a TE rating, and no deadline governs the FDA's decision to grant one. JA3578-3579 (Tr. 2:140-141) (Phelps); JA4288-4289 (Tr. 14:124-125) (Mathers).

While Perrigo was seeking a TE rating, the FDA was considering whether to conduct a rulemaking to establish procedures for assigning TE ratings to §505(b)(2) drugs. AbbVie had submitted a citizen petition in 2011 asking the FDA to withhold TE ratings for new §505(b)(2) drugs referencing AndroGel until the FDA had conducted such a rulemaking. JA2211-2236 (DX169); JA3583-3585 (Tr. 2:159-168) (Phelps); JA4292 (Tr. 14:137-138) (Mathers); *see also* JA1409-1424 (PLX221). The FDA considered these issues "significant [and] complex" and decided that it should resolve Perrigo's request for a TE rating together with the citizen petition. JA1933 (DX021); JA3578 (Tr. 2:137-138) (Phelps).

In April 2013, September 2013, and February 2014, Perrigo sent letters to the FDA requesting prompt issuance of an AB rating; the last letter threatened litigation if the FDA failed to act by March 19, 2014. JA155 (Op.). On March 21, 2014, Perrigo sued the FDA, alleging unreasonable delay. *Id.* In that litigation, the FDA learned for the first time that Perrigo had agreed to a licensed entry date in December 2014. JA3815-3816 (Tr. 6:116-118) (Solomon). The FDA responded to Perrigo's suit by explaining that the FDA had no obligation to issue TE ratings, much less to do so by any particular time. JA1939-1945 (DX021). The FDA further noted that a prompt decision was unnecessary given Perrigo's revelation of the December 2014 entry date, but that in any event the FDA expected to issue a rating by July 31, 2014. JA155 (Op.); JA1593-1610 (PLX288); JA1945-1946

(DX021). On July 23, 2014, the FDA granted Perrigo an AB rating. JA155-156 (Op.). Perrigo launched its gel on December 27, 2014. JA156.

C. The FTC's Complaint And Proceedings Below

On September 8, 2014—three years after the patent-infringement suits—the FTC filed the complaint in this case against AbbVie, Besins, and Teva, invoking the authority under §13(b) of the FTC Act "to enjoin" any person that "is violating, or is about to violate" antitrust laws. JA4415-4416 (sealed complaint); *see* 15 U.S.C. §53(b). The FTC alleged that AbbVie and Besins's infringement suits and AbbVie's settlement with Teva violated §5(a) of the FTC Act, 15 U.S.C. §45(a), by denying consumers the opportunity to buy generic versions of AndroGel.

Count 1 alleged that AbbVie and Besins illegally maintained a monopoly by filing sham patent litigation. JA4453. According to the FTC, the prosecution history of the '894 patent estopped AbbVie and Besins from asserting infringement under the doctrine of equivalents, and the suits against Teva and Perrigo were therefore baseless. JA4417-4418. Count 2 alleged that the settlement agreement between AbbVie and Teva constituted an illegal restraint of trade. The FTC did not challenge the terms of the AndroGel settlement itself, but contended that the separately negotiated TriCor agreement, *supra* pp. 16-17, involved a large and unjustified "reverse payment" from AbbVie to Teva in exchange for Teva's agreement to delay launch of its testosterone gel. JA4442-4447, 4453-4454. The

FTC did not allege any impropriety in the Simcor agreement that AbbVie and Teva executed on the same day. The FTC also did not challenge the Perrigo settlement.

The FTC requested an order granting "equitable relief … including restitution or disgorgement" in the amount of $1.472 billion. JA4454. The FTC also sought an injunction prohibiting AbbVie and Besins from filing "any claims of patent infringement" based on the '894 patent against products not containing isopropyl myristate—regardless of the claim's validity—as well as orders prohibiting any other sham litigation or "any action that misuses governmental processes"; mandating that AbbVie and Besins license generic AndroGel 1.62% products; and requiring AbbVie and Besins to certify the validity of "any and all patent litigations" to the FTC. ECF No. 321 at 18-21 (Pretrial Mem.); *see also* ECF No. 403 at 35 (Post-Trial Brief, advocating the injunction "set forth … in" the pretrial memorandum); ECF No. 403-1 at 3-8 (Proposed Order).

1. Dismissal of Count 2

In May 2015, the district court dismissed Count 2 (and Count 1 to the extent it rested on the Teva settlement) for failure to state a claim. JA2-22. The court applied *Actavis*, in which the Supreme Court held that a large and unjustified payment by a patentee to an accused infringer in exchange for the infringer's agreement to delay entering the market can constitute an illegal restraint of trade. 570 U.S. at 140-141. To avoid undermining public policy favoring settlements, the

Supreme Court rejected the FTC's argument that such payments are presumptively unlawful, but allowed the suit to proceed under the rule of reason. *Id.* at 158-159.

The district court here found the Teva settlement "materially different" from *Actavis*, in which the accused infringers allegedly agreed to delay marketing their generic drugs for nine years in exchange for large annual payments from the patentee. JA15 (MTD Op.). The settlement here, in contrast, would have allowed Teva to enter the TRT market (had it been in position to do so) well before expiration of the '894 patent, without any payments to Teva. JA15-16. *Actavis* approved such arrangements, which "promote[] competition," and "the FTC concede[d] that by itself this settlement agreement is legal." *Id.* (citing *Actavis*, 570 U.S. at 158). The court further rejected the FTC's theory that the TriCor supply agreement, *supra* pp. 16-17, amounted to a reverse payment. The TriCor payments were not "reverse": they flowed from Teva to AbbVie, not the other way around. JA16-17. And while the FTC contended that the TriCor agreement entailed "a good deal for Teva," the complaint made no allegation that AbbVie "agreed to sell TriCor to Teva for less than its cost," and the TriCor agreement included no anticompetitive terms. JA17. The TriCor agreement was, "[i]n a word, … procompetitive" because whatever benefit Teva reaped was "also a benefit flowing to consumers who w[ould] now be able to purchase the generic form of TriCor at a reduced price." *Id.* Therefore, the court found that the

AndroGel and TriCor agreements were each "clearly in the best interests of the consumer" and that the FTC could not combine them to construct an antitrust violation: "'[t]wo wrong claims do not make one that is right.'" JA18 (quoting *Pacific Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 457 (2009)).

The FTC moved for reconsideration after this Court decided *King Drug Co. v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015). The district court distinguished *King Drug* and denied reconsideration. JA28 (MTD Recon. Op.).

2. Summary judgment on objective baselessness

To prevail on the remaining count, the FTC had to demonstrate that AbbVie and Besins willfully maintained monopoly power by filing sham litigation against Teva and Perrigo. Under the *Noerr-Pennington* doctrine, litigants "'who petition [the] government for redress are generally immune from antitrust liability.'" *Wellbutrin*, 868 F.3d at 147-148 (alteration in original). A lawsuit qualifies as a "sham" exempt from that protection only where (1) the suit is "'objectively baseless'"—that is, so baseless that no reasonable litigant could believe "'there is a chance that [the] claim may be held valid'"—and (2) the litigant subjectively used the litigation process itself, as opposed to the outcome of that process, as an "'anticompetitive weapon'" to "'interfere *directly* with the business relationships of a competitor.'" *Id.* at 148 (quoting *PRE*, 508 U.S. 49, 60-63 (1993)).

After discovery, the parties filed cross-motions for summary judgment on objective baselessness, and on September 15, 2017, the district court entered summary judgment for the FTC on that issue. JA33-66 (MSJ Op.). As the court acknowledged, the FTC did "not dispute that the penetration enhancers used by Perrigo and Teva are insubstantially different from the isopropyl myristate penetration enhancer" recited in the '894 patent. JA46. But the court concluded that the prosecution history estopped AbbVie and Besins from claiming infringement, reasoning that AbbVie and Besins had "surrendered broader language for narrower language" during prosecution and therefore could not allege infringement by any penetration enhancer beyond isopropyl myristate. JA61-62.

As to the suit against Teva, the court concluded that "surrender of isopropyl palmitate in the October 2001 [patent] amendment was not tangential or peripheral to the isopropyl palmitate in Teva's generic product." JA56. AbbVie and Besins had cited evidence, expert testimony, and case law supporting the argument that estoppel did not apply because the October 2001 amendment was directed at distinguishing prior art using oleic acid and had nothing to do with isopropyl palmitate. But the court asserted, without discussing those authorities, that if AbbVie and Besins had "merely sought to relinquish oleic acid," they "easily could have said so." JA53. The court inferred that AbbVie and Besins omitted isopropyl palmitate from the amended claims to avoid the Allen prior art, *id.*—even though

the examiner had cited Allen only in connection with isopropyl myristate (not isopropyl palmitate) and had allowed claims reciting isopropyl myristate despite Allen's disclosure of that enhancer. *Supra* pp. 9-10. In the court's view, AbbVie and Besins's position was therefore "without any merit." JA54.

Turning to the Perrigo suit, the district court concluded—again without discussing authorities cited by AbbVie and Besins—that "[t]he December 2001 amendment surrendering isostearic acid was not peripheral or tangential to isostearic acid." JA60. The court also rejected as "incorrect" AbbVie and Besins's argument that, because none of the claims stood rejected when the amendment was made, the amendment did not relate to patentability. JA57. The court identified no authority foreclosing that argument, however. JA59.

The court then stated that the suits against Teva and Perrigo "were without question objectively baseless." JA63. The court conducted no analysis under the *Noerr-Pennington* standard and did not explain why it believed the arguments against estoppel were not merely, in its assessment, "incorrect" as a matter of patent law, but so lacking in merit that no reasonable litigant could perceive any chance of success. *Id.* AbbVie and Besins moved for reconsideration in light of additional case law accepting tangentiality arguments on facts similar to this case, but the court summarily rejected the intervening decisions as "inapposite." JA67-68 (MSJ Recon. Op.).

3. Trial

The court held a bench trial on the remaining issues. On June 29, 2018, the court issued findings of fact and conclusions of law ruling that AbbVie and Besins had subjectively intended to file sham lawsuits and that, by doing so, they maintained monopoly power in a market for topical TRTs. JA69-146 (Op.). The court denied injunctive relief but ordered AbbVie and Besins to pay disgorgement plus interest totaling more than $493 million. JA146-172.

Regarding the subjective component of the sham-litigation standard, the court acknowledged that the FTC bore the burden to prove by clear and convincing evidence that AbbVie and Besins had actual knowledge that the suits were baseless. JA104-108. The court found that standard satisfied based on its view that the in-house lawyers who decided to pursue the suits were "experienced patent attorneys" who knew the law and the prosecution history and "knew the extensive financial benefits" that would follow if generic competition was delayed. JA120-121. Because the court deemed the suits objectively baseless, the court found it "reasonable to conclude" that the in-house patent lawyers' "subjective intent" must have been "to file sham lawsuits." JA120.

As to monopoly power, the court acknowledged that the FTC had "presented no direct evidence of monopoly power" in the form of supra-competitive pricing or restricted output. JA123. The FTC attempted instead to establish monopoly power

through indirect evidence, contending that (1) AndroGel had high market share in a relevant market—which the FTC's economist said consisted only of AndroGel and its generic equivalents, ECF No. 405 at 69-79—and (2) barriers to entry existed in that market. JA123 (citing *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd.*, 838 F.3d 421, 434 (3d Cir. 2016); *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 445 n.2 (3d Cir. 1997)).

The court rejected the FTC's narrow proposed market, finding that the evidence showed reasonable interchangeability and cross-elasticity of demand among all topical TRTs. JA125-135. Over AbbVie and Besins's objections, however, the court excluded injectable TRTs from the market, finding "little cross-elasticity of demand" between injectables and topical TRTs. JA135-139. The court thus defined the relevant antitrust market in terms no expert had endorsed: all topical TRTs, but not injectable TRTs. JA139. Within that market, the court found that AndroGel had market power based solely on its market share, which declined from 71.5% when AbbVie and Besins sued Teva in April 2011, to 63.6% when they sued Perrigo, to approximately 60% when Perrigo entered the market in December 2014. JA139-141. And despite the entry of several new TRTs during the relevant period, the court found that the FDA approval regime created barriers to entry supporting a finding of monopoly power. JA141-145.

Turning to remedy, the court denied injunctive relief because "the FTC ha[d] presented no evidence" that AbbVie and Besins were "currently violating … or about to violate antitrust laws," as §13(b) of the FTC Act requires. JA166-169. But the court held that disgorgement is an equitable remedy implicitly authorized by §13(b), even without any ongoing or imminent violation. JA146-149.

To determine disgorgement, the court considered "what would have happened absent the sham lawsuits." JA150. Based on documentary evidence and the testimony of the sole Teva witness, whom the court found credible, the court concluded that Teva would not have launched a BX-rated gel in light of the many obstacles it had encountered, *see supra* pp. 17-18, and that Teva's failure to launch should therefore not be considered in calculating AbbVie's and Besins's gains from monopolization. JA151-154. The court concluded, however, that but for the infringement suit, Perrigo would have received an AB rating in June 2013 and launched immediately thereafter. JA158. The court acknowledged that the FDA in fact did not issue Perrigo's AB rating until July 2014 and that Perrigo would not have launched without it, *supra* pp. 20-22, but speculated that the FDA would have acted sooner absent the infringement litigation. JA155-158. The court surmised that the FDA felt "no compelling need" to issue a rating more quickly once it became "apparent from the lawsuit Perrigo brought against the FDA" that Perrigo had agreed to a license date in December 2014. JA156. The court made no

attempt to reconcile that theory—which attributed nearly all of the FDA's delay to its supposed awareness of Perrigo's license date—with the uncontroverted evidence that the FDA did not learn of Perrigo's confidential license date until March 2014, *supra* p. 21. JA155-158.

The court further held that, absent the litigation, AbbVie's and Besins's profits from sales of AndroGel 1.62% would have "plateau[ed]" upon Perrigo's hypothetical launch in June 2013, such that the lawsuits allowed AbbVie and Besins to reap boosted profits from AndroGel 1.62% sales in addition to AndroGel 1% sales. JA158-161. Taking those profits into account, the court calculated AbbVie and Besins's total financial gain from the lawsuits through August 2017 to be $448 million. JA162. After adding prejudgment interest and apportioning liability, the court entered judgment in the amount of $462 million against AbbVie and $31.5 million against Besins. JA171-172.

SUMMARY OF ARGUMENT

The judgment that AbbVie and Besins brought sham litigation in violation of the FTC Act should be reversed. To sustain that claim in the face of *Noerr-Pennington*'s First Amendment protections, the FTC had to show that AbbVie and Besins's patent-infringement suits were both objectively and subjectively baseless. It showed neither, and the district court's contrary analysis misapplied the stringent antitrust standards under *PRE*, 508 U.S. 49 (1993).

To survive antitrust challenge on the objective element, the infringement suits merely had to be sufficiently colorable that a reasonable litigant could have perceived a chance of prevailing. AbbVie and Besins's suits to enforce an undisputedly valid patent drew strong support from the prosecution history, expert testimony, and case law. And they resulted in favorable settlements evidencing the parties' views that the infringement claims had merit. The district court disagreed with AbbVie and Besins's arguments on prosecution-history estoppel, but the court cited no authority foreclosing those arguments and never explained why it found the infringement suits so lacking in merit as to be objectively baseless.

As to subjective baselessness, the FTC adduced no evidence that AbbVie and Besins subjectively lacked any intention to win and instead intended to use the litigation process as an anticompetitive weapon. The court found the suits to be shams only by reading the subjective element out of the sham-litigation standard: It found subjective baselessness based solely on an inference from its own conclusion on the objective element—collapsing the two elements into one and discounting evidence that AbbVie and Besins in fact believed their claims had merit and pursued them with the aim of obtaining favorable outcomes.

The FTC likewise failed to establish the other element of its claim—that AbbVie and Besins held monopoly power. In concluding otherwise, the court again committed errors of antitrust law. In defining the relevant antitrust market to

exclude injectable TRTs, the court disregarded real-world evidence of injectables' market strength and constructed an unsupported market definition that neither party's expert endorsed. And in finding monopoly power within that market, the court rigidly assigned dispositive weight to AndroGel's market share in the face of market realities showing that robust competition constrained AbbVie's behavior and took substantial business from AndroGel.

Even if the liability judgment were sustainable, the disgorgement award must be reversed. Section 13(b) of the FTC Act authorizes only injunctions, not other equitable remedies. And even if other equitable remedies were authorized, *Kokesh v. SEC*, 137 S. Ct. 1635 (2017), dictates that the disgorgement here is not an equitable remedy but an impermissible penalty. Moreover, the district court found that the statutory prerequisites to equitable relief were not met because the FTC failed to show an imminent or ongoing violation—a finding that forecloses both injunctive relief and any other equitable relief that §13(b) might impliedly authorize. *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147, 160 & n.19 (3d Cir. 2019). In any event, even if the court had authority to order disgorgement, it abused its discretion in doing so based on unsupportable speculation, contradicted by the record, about what would have happened absent the infringement suits.

Given the many defects in the judgment below, the liability finding and disgorgement award should be reversed, and this Court need not even consider the

FTC's demands for injunctive relief and even greater disgorgement. Those arguments lack merit in any event. The FTC presented no evidence establishing the statutory requirements for injunctive relief in any form—much less the broad prohibitions it urged—and its insistence on a greater monetary award depends on a counterfactual theory that defies the record and common sense.

The FTC's effort to revive its challenge to AbbVie's settlement with Teva also fails. As the district court found, that challenge failed to state a claim for an unlawful reverse payment in any form. But even if it did state a claim, remanding would be useless because no relief—injunctive or monetary—would be available given that Teva would never have launched even absent the alleged reverse payment and given the limitations of §13(b). *Shire*, 917 F.3d at 161.

ARGUMENT

ABBVIE AND BESINS APPEAL

I. THE INFRINGEMENT SUITS WERE NOT OBJECTIVELY BASELESS

The *Noerr-Pennington* doctrine protects the First Amendment right to "'petition the Government for a redress of grievances'"—"one of 'the most precious of the liberties safeguarded by the Bill of Rights.'" *BE&K Constr. Co. v. NLRB*, 536 U.S. 516, 524-525 (2002). Under that doctrine, "'[t]hose who petition [the] government for redress are generally immune from antitrust liability,'" and "[a] plaintiff claiming that a lawsuit is, by its very existence, anticompetitive and

unlawful faces an uphill battle." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 147-148 (3d Cir. 2017) (alterations in original) (quoting *PRE*, 508 U.S. 49, 56 (1993)). So long as a reasonable litigant "could have believed that it had some chance of winning," the suit is not objectively baseless and cannot give rise to antitrust liability. *PRE*, 508 U.S. at 65.

Here, the infringement claims against Teva and Perrigo turned on whether the prosecution history of the '894 patent estopped AbbVie and Besins from asserting infringement based on the substantial equivalence between the penetration enhancer claimed in their patent (isopropyl myristate) and the enhancers used in Teva's and Perrigo's products (isopropyl palmitate and isostearic acid). Under *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 724 (2002), that is a "flexible," multifactor inquiry. It asks first whether the patent applicant made an amendment that narrowed the patent's literal scope to exclude the accused equivalent and did so for a "'substantial reason related to patentability.'" *Id.* at 735 (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33 (1997)). If so, the patentee can still rebut the presumption that it surrendered the subject matter between the original and amended claims, including by showing that "the rationale underlying the amendment [bore] no more than a tangential relation to the equivalent in question." *Id.* at 740-741; *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1367 (Fed.

Cir. 2003) (en banc). "[T]here is no hard-and-fast test for what is and what is not a tangential relation." *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010). A "case-by-case" determination, *Festo*, 344 F.3d at 1370, focused on "the specifics of the amendment and the rejection that provoked the amendment," is required. *Intervet*, 617 F.3d at 1291; *see also Festo*, 344 F.3d at 1368 (courts "cannot anticipate all of the circumstances in which a patentee might rebut the presumption of surrender").

When these standards are properly applied, the FTC cannot succeed in its "uphill battle" to establish objective baselessness. *Wellbutrin*, 868 F.3d at 147. The infringement claims against Teva and Perrigo were not merely reasonable, but strong—strong enough to elicit highly favorable settlements. The district court concluded otherwise by failing to apply the correct antitrust standard, instead substituting its own debatable view of the ultimate merit of the estoppel arguments.

A. Standard Of Review

This Court "'exercise[s] plenary review'" over the order granting summary judgment. *Wellbutrin*, 868 F.3d at 147 n.15. Where, as here, there is no dispute as to the predicate facts, the question whether litigation was objectively baseless is a question of law. *PRE*, 508 U.S. at 63.

B. The Teva Suit Was Not A Sham

While specifically claiming isopropyl myristate, AbbVie and Besins's original patent application also broadly claimed any "penetration enhancer." The October 2001 amendment narrowed the broad claims to recite 24 penetration enhancers, not including isopropyl palmitate—the one used in Teva's product. *Supra* p. 10. Teva argued that AbbVie and Besins thereby surrendered isopropyl palmitate. But AbbVie and Besins had ample basis to argue that the rationale underlying the October 2001 amendment was aimed at avoiding the prior art's use of oleic acid, a substantially different penetration enhancer, and "[bore] no more than a tangential relation" to isopropyl palmitate. *Festo*, 535 U.S. at 740-741.

A reasonable litigant could have believed that argument had a chance of prevailing. First, the examiner's and applicants' statements during prosecution supported that position. In June 2001, the examiner rejected the original claims, both broad and narrow, on the ground that it would have been obvious to a skilled artisan to combine Mak (prior art that paired testosterone with the penetration enhancer oleic acid) with isopropyl myristate, one of the penetration enhancers used in the non-testosterone composition in Allen. JA1014-1016 (PLX052); *supra* p. 9. The applicants did not yield to that analysis. They maintained the specific isopropyl myristate claim and kept isopropyl myristate in the claimed group of 24 penetration enhancers included in the October 2001 amendment. *Supra* p. 10.

Instead, the applicants challenged the examiner's analysis of isopropyl myristate as obvious, arguing that nothing in the prior art suggested combining testosterone with isopropyl myristate or any of the other claimed penetration enhancers in the group of 24. JA1030-1031 (PLX053). The applicants emphasized that Mak used oleic acid and that the amended claims avoided Mak by omitting oleic acid. JA1031. They further explained that a skilled artisan would not have found it obvious to replace oleic acid with isopropyl myristate or the other penetration enhancers recited in Allen or the amended group of 24. JA1031-1039. The "prior art recognize[d] the chemical and physiologic/functional differences … between oleic acid and the claimed enhancers, such as isopropyl myristate," in terms of their chemical structural features and the physiological significance of those features. JA1037-1038. And those differences were not unique to isopropyl myristate, but extended to many penetration enhancers with characteristics similar to isopropyl myristate but different from oleic acid, *id.*—a conclusion that applied equally to isopropyl palmitate. *See* JA1031-1039.

That prosecution history supports a strong—certainly reasonable—argument that the rationale for the October 2001 amendment was to avoid oleic acid and was thus only "tangential" to isopropyl palmitate. *Festo*, 535 U.S. at 740-741. Indeed, the amendment had nothing to do with isopropyl palmitate. Neither the examiner nor the applicants even mentioned isopropyl palmitate during prosecution. The

district court dismissed AbbVie and Besins's tangentiality argument as a "latter-day explanation," JA53 (MSJ Op.), but as shown, the rationale of omitting oleic acid while arguing for patentability based on the "chemical and physiologic/functional differences" between the claimed enhancers and oleic acid was explicitly stated in the October 2001 amendment. JA1030-1039 (PLX053).

Expert testimony supported AbbVie and Besins's analysis. In assessing tangentiality, courts may consider "testimony from those skilled in the art as to the interpretation of th[e] [prosecution history] record." *Festo*, 344 F.3d at 1370. AbbVie and Besins presented evidence in the district court from Dr. Jonathan Hadgraft, Professor Emeritus of Biophysical Chemistry at University College London, who was undisputedly skilled in the art. JA4482-4522 (sealed Hadgraft declarations). He explained that "the chemical and functional differences identified by the patent applicants" in distinguishing isopropyl myristate and the other penetration enhancers retained in the October 2001 amended claims from the penetration enhancer used in the prior art (oleic acid) "would apply equally to isopropyl palmitate." JA4511; *see* JA4492-4499 (analyzing similarities between isopropyl palmitate and isopropyl myristate and distinguishing both from oleic acid); JA4499-4503 (analyzing prosecution-history record). In other words, the same rationale that the applicants presented during prosecution to distinguish oleic acid from isopropyl myristate applied equally to distinguish oleic acid from

isopropyl palmitate. JA4492-4503, 4511-4512. Although Dr. Hadgraft's testimony clearly bore on the reasonableness of AbbVie and Besins's position, the district court disregarded it. JA52 (MSJ Op.).

AbbVie and Besins's position was also strongly supported by Federal Circuit authority the district court failed to address. For example, in *Insituform Technologies, Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004), the Federal Circuit affirmed a judgment of infringement under the doctrine of equivalents of a patent claiming a method for repairing pipes by installing pipe liners and filling them with resin using "vacuum cups." *Id.* at 1362-1363. The original patent application did not specify the position or number of vacuum cups. *Id.* at 1369. During prosecution, to distinguish prior art that disclosed a single vacuum cup at the far end of the liner, the applicant narrowed the claims to specify a single cup positioned near the front of the liner. *Id.* at 1368-1369. The accused products in the infringement suit used multiple cups, thus falling within the territory that had arguably been surrendered by the narrowing amendment. *Id.* at 1363, 1368. Based on the prosecution history, however, the Federal Circuit concluded that the purpose of the amendment was to distinguish the prior art based on the positioning of the cups, not their number. *Id.* at 1370. Therefore, although the applicant had narrowed the claims so they would not literally cover multiple

cups, the amendment "[bore] 'only a tangential relation'" to the multiple-cup equivalent, and there was no estoppel. *Id.* at 1370-1371.

In *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841 (Fed. Cir. 2006), the Federal Circuit accepted a similar tangentiality argument concerning a patent directed to "diaphragm mouth calls," which hunters use to simulate animal sounds. An amendment to the patent application had narrowed the claims to recite a "plate being 'differentially spaced' above" a membrane, while the accused product in the infringement suit used a dome spaced above the membrane. *Id.* at 849. The dome was substantially equivalent to the plate, *id.* at 850, and based on the prosecution history, the court found that the narrowing amendment was merely tangential to that equivalent because the amendment's purpose was to distinguish prior art consisting of a "structure positioned on top of the membrane *without any spacing*," not to distinguish between plates and other structures, *id.* at 849. The court therefore affirmed the judgment of infringement under the doctrine of equivalents. *Id.* at 849-850; *see also, e.g.*, *Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1378 (Fed. Cir. 2008) (finding amendments tangential where record showed that "in narrowing the claim to overcome the prior art rejections, the focus of the patentees' arguments centered on the method of blocking—not on the particular type of nucleic acid that could be used for blocking").

At a minimum, this case law gave AbbVie and Besins a reasonable basis to believe their argument might have prevailed. The claims in the October 2001 amendment did not literally cover isopropyl palmitate, just as the amended claims did not literally cover multiple vacuum cups in *Insituform* or domes in *Primos*. But the prosecution history demonstrates that the rationale for that amendment was not to avoid isopropyl palmitate, but to avoid prior art teaching the use of oleic acid, just as the amendments concerned the positioning of the cups in *Insituform* and plate spacing in *Primos*. The tangentiality arguments advanced in those analogous cases were not merely reasonable, but successful in the Federal Circuit. Under *PRE*, a claim is not objectively baseless where it "was arguably 'warranted by existing law' or at the very least was based on an objectively 'good faith argument for the extension, modification, or reversal of existing law.'" 508 U.S. at 65. Yet the district court completely ignored these decisions. JA51-56 (MSJ Op.).

After the court ruled, AbbVie and Besins brought to its attention a subsequent decision of another district court rejecting a claim of prosecution-history estoppel on facts materially indistinguishable from those here. In *Eli Lilly & Co. v. Dr. Reddy's Laboratories*, No. 16-cv-00308, 2017 WL 6387316 (S.D. Ind. Dec. 14, 2017), *appeal docketed*, No. 2018-2128 (Fed. Cir. July 6, 2018), the district court considered Lilly's patent describing a method of administering a chemotherapy drug following a particular pretreatment regimen. *Id.* at *1. The

drug—pemetrexed disodium—is a type of antifolate, and Lilly's original patent application claimed the entire category of antifolates. *Id.* The examiner rejected the claim in light of prior art (Arsenyan) teaching administration of a different antifolate—methotrexate—following a different pretreatment regimen. *Id.* at *1, *7. In response, Lilly amended the claim to specify pemetrexed disodium instead of the broad category of antifolates. *Id.* at *1. Dr. Reddy's sought to market a similar product that avoided infringement by using pemetrexed ditromethamine instead of pemetrexed disodium—*i.e.*, a pemetrexed compound in a different salt form. *Id.* at *1-2. Lilly claimed infringement under the doctrine of equivalents. It was undisputed that Dr. Reddy's product would have fallen within the scope of the original claim and that Lilly had narrowed that broad claim to specify only pemetrexed disodium. *Id.* at *6. As the FTC argues here, Dr. Reddy's argued that Lilly had presumptively surrendered other antifolates, including other salt forms of pemetrexed, and could not overcome the presumption because the purpose of the amendment was to specify one antifolate rather than a broad group. *Id.* The district court rejected that argument and ruled for Lilly. *Id.* at *6-7. The court found the rationale for the narrowing amendment was to distinguish the Arsenyan prior art on grounds that had nothing to do with the particular salt forms of pemetrexed. *Id.* at *7. Lilly had therefore "met its burden of showing that it did

not surrender the equivalent in question because the choice of pemetrexed salt [wa]s tangential to the reasons for the amendment." *Id.*

The facts here are the same in all relevant respects. Just as Lilly initially claimed a broad category of antifolates, AbbVie and Besins initially claimed a broad category of penetration enhancers. And just as Lilly then amended its category to specify a particular antifolate, AbbVie and Besins amended their category to specify certain penetration enhancers. But like Lilly, they did so to distinguish prior art that had nothing to do with the accused equivalent. The court in *Dr. Reddy's* found that argument not merely reasonable, but strong enough to prevail. Other district courts considering similar cases have reached the same result. *See, e.g.*, *Bio-Rad Labs., Inc. v. 10X Genomics, Inc.*, 322 F. Supp. 3d 537, 543 (D. Del. 2018); *Integra LifeSciences Corp. v. HyperBranch Med. Tech., Inc.*, No. 15-CV-819, 2018 WL 1737781, at *3 (D. Del. Apr. 10, 2018). AbbVie and Besins moved for reconsideration of the objective-baselessness ruling in light of *Dr. Reddy's*, arguing that their claim against Teva could not be considered objectively baseless when a similar claim was accepted as meritorious on similar facts by another court. But the district court dismissed *Dr. Reddy's* as irrelevant, even though neither the court nor the FTC cited any precedent foreclosing AbbVie and Besins's argument. JA67-68 (MSJ Recon. Op.).

Other than bookending its analysis with citations to *PRE*, the district court utterly failed to apply the proper antitrust standard. Instead of asking whether a reasonable litigant could have believed "there [wa]s a chance" that AbbVie and Besins's suit might prevail in light of the prosecution record, expert testimony, and favorable case law, *Wellbutrin*, 868 F.3d at 148, the court analyzed whether they had a *winning* position—*i.e.*, whether they had conclusively established an exception to prosecution-history estoppel. In finding that they had not, the district court limited its analysis to determining on the merits that "the surrender of isopropyl palmitate … was not tangential" to isopropyl palmitate, JA56 (MSJ Op.), simply "disagree[ing]" with AbbVie and Besins's arguments as a matter of patent law, JA49; *see* JA54. And having concluded that AbbVie and Besins's arguments failed, the court leapt—without discussion—to the conclusion that "any reasonable person" reviewing the prosecution history would necessarily reach the same conclusion. JA62-63.

In this antitrust action, however, it is the Court's duty to assess the objective reasonableness of the suit against Teva—not its ultimate merit. Given the constitutional interests protected by the *Noerr-Pennington* doctrine, the sham-litigation standard is intentionally rigorous and poses a distinct inquiry from whether the challenged claims would actually have prevailed. "[T]he essential question" in identifying objectively baseless litigation "is not whether the suit

succeeds, but whether the suit was a sham at the time it was filed." *Wellbutrin*, 868 F.3d at 148; *see also BE&K*, 536 U.S. at 532. Merely showing that "the law or the facts appear[ed] questionable or unfavorable at the outset," *PRE*, 508 U.S. at 61 n.5, or that the infringement claim "would have been subject to a serious defense," *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Novartis Pharm. Corp.*, 902 F.3d 1, 15 (1st Cir. 2018), does not suffice. The district court's decision here was doubtful even as a matter of patent law; as a matter of antitrust law, it failed to apply the governing standard and must be rejected.

C. The Perrigo Suit Was Not A Sham

AbbVie and Besins's suit against Perrigo was similarly reasonable, and the district court again misapplied the sham-litigation standard in holding otherwise. Perrigo's penetration enhancer—isostearic acid—was never mentioned during prosecution and remained within the literal scope of the '894 patent claims even after the October 2001 amendment. JA1021 (PLX053). It was not until December 2001—without any further rejection by the examiner—that AbbVie and Besins amended the claims to specifically recite isopropyl myristate and asked the examiner to "expedite" issuance of the patent. JA1086-1092, 1095 (PLX057); *supra* pp. 10-11. Two reasonable (and independent) arguments supported the contention that no estoppel applied in those circumstances.

First, AbbVie and Besins had a reasonable basis to contend that the December 2001 amendment was not made for a "substantial reason related to patentability" and did not give rise to a presumption of surrender in the first place. *Festo*, 535 U.S. at 735. Under *Festo*, "estoppel does not arise in every instance when a patent application is amended." *Id.* It arises only when a narrowing amendment is "made to satisfy any requirement of the Patent Act," *id.* at 736—*e.g.*, "'to avoid the prior art, or otherwise to address a specific concern—such as obviousness—that arguably would have rendered the claimed subject matter unpatentable,'" *id.* at 735 (quoting *Warner-Jenkinson*, 520 U.S. at 30-31). Here, the claims pending at the time of the December 2001 amendment, including the claims reciting isostearic acid, were never rejected or threatened with rejection. While the examiner had indicated after the October 2001 amendment that the claims specifically directed to isopropyl myristate were "seen to be allowable over the prior art," JA1084 (PLX056), the examiner never commented on the broader claims, never cited any prior art using isostearic acid, and never suggested that a claim with isostearic acid might be rejected.

"[W]here the prosecution history is silent or unclear" as to the reasons for a narrowing amendment, "the district court should give a patentee the opportunity to establish the reason, if any, for a claim change." *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 114 F.3d 1161, 1163 (Fed. Cir. 1997) (en banc). AbbVie

and Besins explained to the district court the context surrounding the December 2001 amendment: Only a year of statutory marketing exclusivity remained for AndroGel 1%, and no patent protected AndroGel yet. *Supra* pp. 10-11; JA3725 (Tr. 5:40) (Hynd). It was reasonable to have contended in the Perrigo suit that AbbVie and Besins amended the claims in December 2001 to expedite the timing of patent protection for AndroGel 1%—not to avoid any rejection by the patent examiner or to overcome any obstacle to patentability.[3]

The district court rejected that argument on the ground that a voluntary amendment does not "preclude" prosecution-history estoppel, JA59-60 (MSJ Op.), but the argument was not foreclosed by any case law cited by the district court. The court cited *Dakocytomation*, 517 F.3d at 1378, but the cited passage merely notes that amendments made to "facilitate prosecution" were "clearly nonsubstantive" and did not aid a tangentiality analysis. And in the cited passage of *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1142 (Fed. Cir. 2003), the Federal Circuit considered only an issue of claim construction relevant to literal infringement; a related doctrine-of-equivalents issue "[wa]s not appealed" or considered by the Federal Circuit. *Id.* The district court thus cited no basis to find

[3] The district court asserted that this rationale did not appear in the prosecution history, JA60 (MSJ Op.), but the statutory-exclusivity period was clear as a matter of law, and the December 2001 amendment "urge[d]" the examiner to "expedite prosecution." JA1095 (PLX057).

AbbVie and Besins's position here objectively unreasonable. It simply rejected the argument as "incorrect." JA57.

Second, even viewing the December 2001 amendment as a further effort to overcome the June 2001 rejection, as the district court did, JA57-58, AbbVie and Besins had a strong argument that—just as in the Teva case—the rationale for that amendment "[bore] no more than a tangential relation" to isostearic acid, *Festo*, 535 U.S. at 740-741. The prosecution history makes clear that the amendments made in response to the June 2001 rejection were designed to distinguish oleic acid, the penetration enhancer in Mak. *Supra* pp. 37-39. The record was uncontroverted that the amendments had nothing to do with isostearic acid. Isostearic acid was not the basis of the obviousness rejection—which focused solely on isopropyl myristate—and the examiner never mentioned isostearic acid.

Moreover, Dr. Hadgraft explained in the district court that "[t]he important chemical and functional differences identified by the patent applicants" to distinguish isopropyl myristate and the other claimed enhancers from oleic acid "would apply equally to isostearic acid." JA4521 (sealed Hadgraft declaration); *see also id.* ("[O]leic acid has different structural properties … and employs a different mechanism of action from isopropyl myristate and isostearic acid."); JA4517-4522 (Hadgraft describing chemical and functional differences between oleic acid and isostearic acid). Isostearic acid was not disclosed in any relevant

prior art or ever discussed during prosecution. Like Lilly's amendment narrowing the broad category of antifolates in *Dr. Reddy's*, the amendments narrowing the claims here from a broad category of penetration enhancers to isopropyl myristate had nothing to do with avoiding isostearic acid. *Supra* pp. 9-11, 42-44. If a tangentiality argument could succeed on the merits in *Dr. Reddy's* under circumstances so analogous to this case, then that argument cannot have lacked any realistic chance of success.

As in its analysis of the Teva suit, the district court assessed only whether AbbVie and Besins had a winning case against Perrigo. In concluding they did not, the district court cited no authority requiring application of prosecution-history estoppel on this factual record. Instead, it rejected AbbVie and Besins's position as not "correct" based on vague considerations including policy arguments and what the court deemed "telling signal[s]" in the prosecution history. JA57, 59. The court never explained why AbbVie and Besins's positions were not merely, in its view, "[in]correct," but "so baseless that no reasonable litigant could realistically expect to secure favorable relief." *PRE*, 508 U.S. at 62. The court simply found the FTC's arguments more compelling. That is not the standard.

D. The Settlement Agreements Flatly Refute The District Court's Conclusion

The favorable settlements AbbVie and Besins obtained in both suits foreclose the proposition that no reasonable person could have perceived a chance

of success for the infringement claims. The lawsuits ended not in victories for Teva and Perrigo, but in settlements under which Teva and Perrigo each agreed to continued market exclusivity for AndroGel until late 2014—"far beyond the maximum 30-month Hatch-Waxman stays" that would have applied had the lawsuits continued. JA111 (Op.).

Those terms reflected significant concessions by Teva and Perrigo. At the time of the settlements in December 2011, the Teva trial had already been scheduled for May 2012. If the infringement claims against Teva were truly objectively baseless, Teva would have expected to prevail—ending the Hatch-Waxman stay—at that time. And given the overlap between the two cases, Perrigo could also have expected to prevail quickly following Teva's trial. It defies common sense to suggest that Teva and Perrigo would have agreed to settle truly baseless claims on terms so favorable to AbbVie and Besins merely as "'[t]ribute,'" as the district court asserted. JA112-113 (Op.). Far more plausible is that the settlements reflected Teva's and Perrigo's understandings that they faced meaningful risk of losing and being kept off the market as a result until the '894 patent expired in 2020. The sole Perrigo witness to testify, for example, explained that Perrigo based its decision to settle in part on an estimated 25% chance of losing. JA3812 (Tr. 6:102) (Solomon).

Courts have recognized that a patent settlement under which the alleged infringer provides substantial consideration to the patentee belies a finding of objective baselessness. *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); *In re Lantus Direct Purchaser Antitrust Litig.*, 284 F. Supp. 3d 91, 110 (D. Mass. 2018), *appeal filed*, No. 18-2086 (1st Cir. Nov. 2, 2018). The FTC itself has recognized that such settlements show that the infringement claim has strength. *See* FTC Petition for Certiorari 9, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (hypothetical settlement "compromis[ing] on a time of entry without cash payments" reflects the "strength of the patent as viewed by the parties"); FTC Amicus Br. 23, *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (Nos. 10-2078, 10-2077, 10-2079) (similar). The FTC's observation applies equally here. AbbVie and Besins's infringement claims were amply supported by the prosecution history and case law. Far from objectively baseless, they were strong enough to elicit indisputably substantial concessions from indisputably sophisticated litigants.

The district court's misapplication of the objective-baselessness standard is especially problematic under the Hatch-Waxman Act, which embodies "congressionally designed pressures to file suit quickly" upon receipt of a paragraph IV certification so that uncertainty and the risk of infringement liability

will not deter market entry by generic competitors. *Wellbutrin*, 868 F.3d at 151 n.22; *see supra* pp. 12-13. Under the district court's approach, patent holders would face a serious disincentive to bring suit whenever the outcome was uncertain, even if there were a chance of prevailing. This Court has admonished against "penaliz[ing] a brand-name manufacturer whose litigiousness was a product of Hatch-Waxman," recognizing that "[d]oing so would punish behavior that Congress sought to encourage." *Wellbutrin*, 868 F.3d at 158 (quotation marks omitted). The Court should reject that approach again here.

II. THE INFRINGEMENT SUITS WERE NOT SUBJECTIVELY BASELESS

Even where litigation is objectively baseless, *Noerr-Pennington* immunity applies unless the litigant's "subjective motivation" for suing was "to interfere *directly* with the business relationships of a competitor" by using "the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *PRE*, 508 U.S. at 60-61 (quotation marks omitted). The FTC had to prove, by clear and convincing evidence, that AbbVie and Besins sued not because they genuinely perceived a chance to prevail and wished to procure a favorable outcome, but because they sought to use the litigation process itself to disable potential competitors. *City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380-381 (1991); *see also Armstrong Surgical Ctr., Inc. v. Armstrong County Memorial Hosp.*, 185 F.3d 154, 158 & n.2 (3d Cir. 1999) (sham exception

"does not apply" where purpose of petitioning conduct "was to secure the *outcome* of the process").[4] While objective baselessness focuses on a suit's legal viability, the subjective component considers its "*economic* viability," *PRE*, 508 U.S. at 61—*i.e.*, whether the suit was economically irrational because any relief would be inadequate "to justify [the] investment in the suit," evidencing that the litigant was "indifferent to the outcome" and suing merely to use the litigation process to forestall competition, *id.* at 60-61, 65.

The FTC failed to meet its burden. The FTC adduced "no direct evidence of the subjective intent of the decision-makers" at AbbVie and Besins. JA118 (Op.). And the court identified no credible evidence—much less clear and convincing evidence—that the suits were subjectively baseless, which should have been dispositive. As discussed below, the court instead erred as a matter of law by inferring subjective baselessness from its finding of objective baselessness and failing to assess subjective baselessness as an independent element of the sham-litigation analysis. JA118-121. In fact, evidence the district court erroneously discounted showed that the lawsuits were not subjectively baseless.

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[4] Although this Court has not addressed the quantum of evidence required to prove sham litigation, *see Wellbutrin*, 868 F.3d at 148 n.18, the district court correctly required the FTC to prove subjective baselessness by "clear and convincing evidence," citing decisions of other courts and the importance of the First Amendment right at issue. JA106-107 (Op.). In any event, as discussed in text, the FTC failed to prove subjective baselessness under any standard, and the district court committed legal error in holding otherwise.

A. Standard Of Review

On appeal from a bench trial, the Court reviews the district court's findings of fact for clear error, but reviews its conclusions of law de novo. *VICI Racing, LLC v. T-Mobile USA, Inc.*, 763 F.3d 273, 282-283 (3d Cir. 2014). For mixed questions of fact and law, the district court's "'choice and interpretation of legal precepts remain subject to plenary review.'" *Id.* at 283.

B. The District Court Improperly Collapsed The Objective And Subjective Elements And Identified No Evidence Of Subjective Baselessness

The district court committed legal error by merging the subjective and objective elements of the sham-litigation test. In purporting to assess the AbbVie and Besins decisionmakers' subjective intent, the court reiterated its determination that "'any reasonable person who reads the prosecution history of the '894 patent' would know that all penetration enhancers other than isopropyl myristate … were surrendered." JA119 (Op.). And it emphasized that AbbVie's and Besins's decisionmakers were "experienced patent attorneys" who had access to all of the relevant facts on which the court relied to make that determination—and knew that keeping generic versions of AndroGel off the market was important to AbbVie's and Besins's finances. JA120. From there, the court inferred—solely because the court deemed the suits baseless—that the decisionmakers must also have had "actual knowledge" that the suits were baseless and "had no expectation of

prevailing," but sued anyway for no reason but to "impose expense and delay on Teva and Perrigo so as to block their entry." JA120-121.

By simply ascribing to the AbbVie and Besins decisionmakers the court's own determination under the objective element, the district court failed to conduct the relevant inquiry under the subjective element: whether those decisionmakers actually believed the lawsuits had no possibility of success and thus made no economic sense to prosecute but for the opportunity to impose delay and expense on competitors. *See Armstrong*, 185 F.3d at 158 & n.2. Had the court conducted that inquiry, it would have had to reject the FTC's assertion of subjective baselessness. The FTC presented, and the court cited, no affirmative evidence—circumstantial or otherwise—that AbbVie or Besins subjectively believed their arguments lacked sufficient promise to make the infringement actions economically viable based on the prospects of winning. *PRE*, 508 U.S. at 61. That should have been dispositive. Courts "presum[e] that the assertion of a duly granted patent is made in good faith," and that "presumption [can be] overcome"—and the sham standard satisfied—"only by affirmative evidence of bad faith." *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1369 (Fed. Cir. 1998). The court cited none.

That AbbVie and Besins had financial interests in AndroGel's position in the market—a fact that will be present in virtually every Hatch-Waxman suit—does

not establish that they sued to use the litigation process as an anticompetitive weapon. If anything, the financial stakes—hundreds of millions of dollars in AndroGel sales, JA119-120 (Op.)—underscored the rationality of pursuing a favorable outcome in the suit. *See PRE*, 508 U.S. at 61, 65. The decisionmakers' awareness of the financial consequences of generic entry simply means that AbbVie and Besins had ample reason to sue with the aim of *winning*. And litigation aimed at procuring a favorable outcome is not a sham. *City of Columbia*, 499 U.S. at 380.

By relying on an inference from its finding of objective baselessness, the district court not only flouted the clear requirements of *PRE* and its progeny, but endorsed an impractical approach that contradicts the policies animating *PRE* and the Hatch-Waxman Act. The vast majority of suits brought under Hatch-Waxman will involve decisions made or influenced by "experienced patent attorneys." JA120 (Op.). 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. *Cf. Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1047 (9th Cir. 2009) ("insufficient evidence" of sham litigation where antitrust defendant was acting to "preserve its rights under Hatch-Waxman" and "to some degree its litigiousness was a product of Hatch-Waxman"). But the *PRE* standards are intended to ensure that litigants are not

chilled from asserting their rights by the possibility that a court might not only disagree with them, but also penalize them for having sued. The court's approach here results in precisely that chilling effect.

C. The District Court Disregarded Substantial Evidence That AbbVie And Besins Sued To Procure A Favorable Outcome

The FTC's failure to adduce any evidence of subjective baselessness—much less clear and convincing evidence—and the district court's legal errors in finding otherwise warrant reversal of the judgment. But there is more: Substantial evidence showed that AbbVie and Besins brought their infringement actions with the aim and expectation of prevailing, not to use the litigation process itself as an anticompetitive weapon.

First, in negotiations with Teva and Perrigo, AbbVie and Besins held out for substantial concessions before agreeing to settle. *Supra* pp. 16, 20. If AbbVie and Besins had believed their claims had no chance of prevailing, they would have been willing to settle on much less favorable terms. According to the district court, at the time of the settlements in December 2011, AbbVie and Besins would have known they were in for an imminent, definitive loss at the Teva trial in May 2012 that would have ended the Hatch-Waxman stay and eliminated any prospect of valuable settlements. They nonetheless held firm to their demands. *Supra* pp. 16, 20. The district court gave this evidence no weight, based on its own speculation as to Teva's and Perrigo's motivations for settling. JA112-113 (Op.). But the

subjective motivations that matter under *PRE* are those of AbbVie and Besins, not Teva and Perrigo; and AbbVie and Besins's conduct of the settlement negotiations reflected subjective confidence in their claims.

Second, the court erroneously gave no weight to significant strategic business planning documents AbbVie created in 2011 that reflected an expectation of maintaining exclusivity for AndroGel until August 31, 2015—the date two other generics were licensed to enter the market. JA110-111. For example, as of April 2011, AbbVie's Long Range Plan reflected the "key assumption for the business" that AndroGel would have exclusivity through August 2015. JA3966 (Tr. 9:46-48) (Hynd); *see also* JA1827-1865 (DX005), JA3378-3401 (DX301), and JA3403-3470 (DX302) (plan documents). By the time that plan was prepared, AbbVie had already received Teva's paragraph IV certification, and the plan accordingly acknowledged a "risk" to AndroGel from earlier entry of a product like Teva's. JA3971 (Tr. 9:67-69) (Hynd). But that risk did not alter the bottom-line expectation of continued exclusivity, which held steady throughout 2011 as AbbVie developed its annual plan for 2012. Even after receiving Perrigo's paragraph IV certification, even after both lawsuits began, even after Teva moved for summary judgment, and even after the Teva trial was scheduled for May 2012, AbbVie's annual plan for 2012 continued to reflect the expectation that AndroGel would not only retain exclusivity, but also experience growing sales. JA3977-3982

(Tr. 9:91-95, 98-100, 103-109) (Hynd); *see also* JA2016-2070 (DX066), JA2538-2598 (DX223), and JA2599-2663 (DX224) (annual plan documents).

If AbbVie had believed that its infringement claims were bound to lose, these crucial planning documents surely would have reflected an expectation that entry by Teva or Perrigo was imminent or likely. *See* JA3977 (Tr. 9:91) (Hynd: loss of exclusivity is reflected in planning documents because of its significant effects on margins, expenses, and investment strategy). Effectively penalizing AbbVie for asserting the attorney-client privilege, the court thought these documents immaterial because they were created by businesspeople, not the lawyers who made the decision to sue, and there was no "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 litigation." JA111 (Op.). *But see* JA4119 (Tr. 11:130) (Stewart: dates used in planning documents "universally c[a]me from … our legal teams"). But it was the FTC's burden to prove subjective baselessness by clear and convincing evidence. Instead, the evidence showed that AbbVie and Besins sued to protect their patent rights in an important product, exactly as Hatch-Waxman seeks to encourage; that their conduct and settlement of that litigation reflected confidence in their position; and that they harbored no expectations of certain defeat. These suits were not shams, and the judgment should be reversed.

III. THE FTC FAILED TO PROVE MONOPOLY POWER

Even if the FTC had proven the suits were shams, its claim would fail unless it also proved that AbbVie and Besins held monopoly power—*i.e.*, the ability to control prices and exclude competition in a given market. *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007). But many TRTs were already on the market when AndroGel launched in 2000, and competition only increased as new TRTs in many forms entered the market before, during, and after the patent-infringement suits at issue. *Supra* pp. 7-8. These included the competing brand-name TRT gels Testim in 2002, Fortesta in 2011, Axiron in 2011, and Vogelxo in 2014. JA79 (Op.).

The FTC made no attempt to establish monopoly power through direct evidence—*i.e.*, evidence of "supra competitive prices and restricted output." JA123 (Op.); *see Mylan Pharm. Inc. v. Warner Chilcott PLC*, 838 F.3d 421, 435 (3d Cir. 2016). Instead, the district court found monopoly power based on "indirect evidence" of AndroGel's market share in an antitrust market limited to topical TRTs. JA123; *see also* JA139-146; *Mylan*, 838 F.3d at 435. That holding rests on two independently reversible errors.

First, the court erred in defining an antitrust market limited to topical TRTs and excluding injectable TRTs. The FTC introduced no econometric analysis supporting an antitrust market of all topical TRTs but excluding injectables, and its

expert conceded that a topicals-only TRT market was *not* the appropriate market. By omitting injectables, the district court disregarded evidence that AndroGel's share of the total TRT market was only 50.3% in January 2011 and fell to 32.2% by December 2014, while injectables grew from 30.4% to 47.9% over the same period—taking market share away from AndroGel and other topical TRTs. JA2190 (DX122); *see also* JA2189 (DX121); JA2191 (DX123).

Second, even if the court had correctly defined a market limited to topical TRTs, it erred in finding monopoly power by placing conclusive reliance on AndroGel's share within that market—a market share that created, at most, a marginal inference of monopoly power. In fact, overwhelming real-world evidence showed that AbbVie had no ability to control prices and exclude competition and that barriers to entry were insufficient to prevent several competitors from launching their own topical TRTs.

A. Standard Of Review

This Court reviews the district court's conclusions of law de novo and its findings of fact for clear error. *Supra* p. 55; *see also United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 186 (3d Cir. 2005). The scope of the relevant antitrust market is a question of fact. *Broadcom*, 501 F.3d at 307. Review of the district court's formulation or application of legal principles in finding monopoly power is plenary. *Allen-Myland, Inc. v. IBM Corp.*, 33 F.3d 194, 201 (3d Cir. 1994).

B. The District Court Clearly Erred By Excluding Injectables From The Relevant Market

It was the FTC's burden to prove a relevant market. *Mylan*, 838 F.3d at 435; *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 442 (3d Cir. 1997). Two products are in the same market if they are "readily substitutable for one another"—*i.e.*, if they have "reasonable interchangeability" of use and there is "cross-elasticity of demand," meaning that a price change for one product affects demand for the other. *Mylan*, 838 F.3d at 435-438. The FTC presented an economic expert who opined that the relevant market consisted only of AndroGel and its generic equivalents. JA3844 (Tr. 7:34-35) (Shapiro). The district court correctly rejected that proposed market. JA125-130 (Op.). But instead of adopting in its place the market for all TRTs, as proposed by AbbVie and Besins's expert, the court defined a market that no party had advocated and no expert endorsed: a market including all topical TRTs, but excluding injectables. JA131-139.

In reaching that result, the court acknowledged—and the FTC did not dispute—that "there is reasonable interchangeability of use between AndroGel and injectables." JA136. Both contain the same active ingredient and are approved as safe and effective for the treatment of hypogonadism, and patients regularly switch between them. JA135-136. Nonetheless, the district court found "little cross-elasticity of demand" between topical TRTs and injectables. JA136. But it was the FTC's burden to prove a market that excluded injectables, *Mylan*, 838 F.3d at

435, 437, and it presented no cross-elasticity study to support the district court's conclusion. The FTC's economist conceded that he was not "putting forward" a market of topical TRTs excluding injectables, that he "ha[d] not done [an] econometric analysis" supporting such a market, and that it was "not [his] opinion" that a topical TRT market excluding injectables was the proper market. JA3931 (Tr. 8:152) (Shapiro). Under *Mylan*, the FTC's failure to introduce evidence supporting a market limited to topical TRTs—let alone the required "quantitative analysis" showing lack of cross-elasticity between topical TRTs and injectables, 838 F.3d at 437—is fatal to the district court's finding.

In contrast, although they had no obligation to do so given the FTC's failure to carry its burden, AbbVie and Besins presented voluminous evidence, including expert testimony, showing substantial cross-elasticity between topical TRTs and injectables. That evidence showed that large numbers of patients switched from AndroGel to injectables and that they did so based on price. JA4263, 4265 (Tr. 14:21, 30) (Ritenour). For example, one study found that "[p]hysicians and patients report[ed] cost as the primary driver of injection use," with market share for injectables increasing as patients' out-of-pocket costs for AndroGel increased. JA2461, 2471, 2473 (DX201); *see also* JA2184 (DX111); JA2185 (DX112); JA2186 (DX113); JA2411-2412 (DX197); JA2458-2510 (DX201); JA3781 (Tr. 5:262-264) (Hynd); JA3958 (Tr. 9:14-16) (Hynd); JA4318-4320 (Tr. 14:243-249)

(Cremieux); JA4325-4332 (Tr. 15:15-41) (Cremieux). To avoid losing more business to injectables, AbbVie had to develop a co-pay assistance program to keep patient costs for AndroGel competitive with those for injectables. JA4203 (Tr. 13:53-55) (Hernandez).

Even the FTC's expert acknowledged some price competition and cross-elasticity of demand between topical TRTs and injectables:

> I want to be very clear for the court that … some patients are switching between an injectable and a gel. They try one; they may like one or the other. There is also some degree of price competition we see. There is some cross-elasticity, I have seen documents about that, between AndroGel and injectables. I'm not saying it's zero …. So I'm not disputing a bunch of that evidence about injectables.

JA3862 (Tr. 7:108) (Shapiro). Even putting aside the FTC's failure to meet its burden, the court thus erred in discounting the compelling evidence that injectables belonged in the relevant market. *See SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1059, 1065 (3d Cir. 1978) (finding a relevant market consisting of both oral and injectable cephalosporin antibiotics).

When injectables are included, AbbVie and Besins clearly lacked monopoly power. *See* JA4314 (Tr. 14:225) (Cremieux); JA4334-4338 (Tr. 15:52-66) (Cremieux). AndroGel's share in the market consisting of all TRTs peaked at about 50% during the relevant period and declined from there. *Supra* p. 8. That share is well below the level that is consistent with monopoly power. *See Mylan*,

838 F.3d at 437 (share substantially above 55% required for monopoly power in absence of other factors).

C. The District Court Committed Legal Error In Finding Monopoly Power Within The Defined Market

Even accepting the district court's market definition, its finding of monopoly power must be reversed because the court misapplied the legal standard as to both market power and barriers to entry. *See Mylan*, 838 F.3d at 435.

1. The court erred in giving dispositive weight to market share data while ignoring real-world evidence

A firm has monopoly power—*i.e.*, the ability to control prices and exclude competition—if it "'can profitably raise prices without causing competing firms to expand output and drive down prices.'" *Mylan*, 838 F.3d at 434 (quoting *Broadcom*, 501 F.3d at 307). A high market share can indicate monopoly power within a defined market. *Dentsply*, 399 F.3d at 187. But "market share alone is not sufficient" to prove the ultimate issue—whether the defendant can actually control prices and exclude competition. *Crossroads Cogenerations Corp. v. Orange & Rockland Utils., Inc.*, 159 F.3d 129, 141 (3d Cir. 1998); *see also Weiss v. York Hosp.*, 745 F.2d 786, 827 n.72 (3d Cir. 1984). Proving monopoly power "requires something more" than high market share, rooted in market realities. *Crossroads*, 159 F.3d at 141 (citing *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 112 (3d Cir. 1992)).

The district court therefore erred as a matter of law in giving conclusive weight to AndroGel's market share without meaningfully considering the plentiful real-world evidence rebutting any inference that could be drawn from that share. JA139-141 (Op.). Doing so was particularly inappropriate because AndroGel's market share was, at most, at the low end of what courts have found can support a finding of monopoly power. Considering monopoly power at the time of the alleged anticompetitive conduct, *see* JA122 (citing *Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 472-473, 481 (3d Cir. 1992)), the district court found that AndroGel's market share among topical TRTs was 63.6% when AbbVie and Besins sued Perrigo in October 2011 and hovered around 60% through 2014. JA140; *see also* JA3861 (Tr. 7:103-104) (Shapiro).[5] As Judge Hand explained, however, "it is doubtful whether sixty or sixty-four percent would be enough" to establish monopoly power, *United States v. Aluminum Co. of America*, 148 F.2d 416, 424 (2d Cir. 1945); rather, "[a] significantly larger market share than 55 percent has been required," *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 202 (3d Cir. 1992); *see also Mylan*, 838 F.3d at 437; *Weiss*, 745 F.2d at 827 n.72.

[5] AndroGel's share when AbbVie and Besins sued Teva in April 2011 is irrelevant given the court's well-supported finding that Teva would not have launched its testosterone gel regardless of the lawsuit. JA151 (Op.); *infra* pp. 93-101.

Against that weak inference, abundant evidence showed the "market realit[y]" that AbbVie in fact could not "'raise prices [for AndroGel] without causing competing firms to expand output and drive down prices.'" *Mylan*, 838 F.3d at 434; *see also Dentsply*, 399 F.3d at 188-191 (considering not only market share, but also evidence of actual pricing power and exclusion of rivals). Rivals were demonstrably able to expand their output, take business from AndroGel, and constrain AndroGel's pricing.

As the district court found, AbbVie lost substantial business to competing topical TRTs during the relevant period. These losses arose in part from lost placements on the formularies of leading insurers and pharmacy benefit managers:

- In 2011, after Testim's manufacturer offered aggressive rebating, insurer United Healthcare removed AndroGel from its formulary in favor of Testim, resulting in $80 million of lost AndroGel sales in a year when AndroGel's sales totaled $874 million. JA120, 133 (Op.).

- In 2011, AndroGel lost its formulary placement with insurer Coventry Healthy Care due to rebate competition. JA3958 (Tr. 9:14) (Hynd).

- In 2013, pharmacy benefit manager CVS/Caremark removed AndroGel from its formulary in favor of Fortesta, costing AbbVie about $300 million in sales—nearly 30 percent of U.S. net AndroGel sales in 2013. JA78, 133 (Op.).

- In 2013, insurer TriCare removed AndroGel from preferred formulary status and replaced it with Fortesta. JA133-134 (Op.).

To compete, AbbVie was forced to provide large rebates to insurers and pharmacy benefit managers. JA133 (Op.). Between 2011 and 2014, AbbVie paid $438

million in rebates—roughly 19 percent of AndroGel's gross sales over that period. *Id.* When Fortesta and Axiron entered the market in 2011, "rebates on [topical TRTs] increased and AndroGel lost additional business." *Id.* The competitive pressure also forced AbbVie to develop a co-pay assistance program to avoid losing more sales to injectables. JA134; *see* JA4134-4136 (Tr. 11:192-198) (Gautsch); JA4203 (Tr. 13:53-55) (Hernandez).

In basing its finding of market power almost exclusively on AndroGel's bare market share among topical TRTs, the district court discounted this evidence that competing testosterone treatments were winning significant business from AndroGel and constraining AbbVie's competitive behavior. JA139-141 (Op.). But courts "cannot be blinded by market share figures and ignore marketplace realities." *Tops Markets, Inc. v. Quality Markets, Inc.*, 142 F.3d 90, 99 (2d Cir. 1998). The market realities here demonstrated that this was anything but a case where rivals could not constrain a market leader.

Notably, the FTC presented no evidence that AbbVie enjoyed "abnormally high price-cost margins on AndroGel" or was able to restrict output. JA123 (Op.). Absent such evidence, the evidence that AbbVie continuously lost AndroGel sales to rivals and was forced to offer significant rebates and other concessions to avoid losing more business, JA133-134, conclusively demonstrates that AbbVie and Besins lacked monopoly power. *Mylan*, 838 F.3d at 434.

2. The district court erred in finding high barriers to entry

To prove monopoly power by indirect evidence, the FTC had to prove not only that AbbVie and Besins had market power within a defined market, but that "significant 'entry barriers' protect[ed] th[e] [relevant] market." *Broadcom*, 501 F.3d at 307; *see also Handicomp, Inc. v. U.S. Golf Ass'n*, No. 99-5372, 2000 WL 426245, at *3 (3d Cir. Mar. 22, 2000) (unpublished) (72% market share insufficient to establish monopoly power where new entrants could enter with ease); *Tops Markets*, 142 F.3d at 99 (over 70% market share insufficient without high barriers to entry). The district court discerned high barriers to entry based on "technical and regulatory requirements in the prescription pharmaceutical market that do not exist with respect to ordinary consumer products," including the FDA approval process—factors that will be present in every antitrust case in the pharmaceutical context. JA141-144 (Op.).

Once again, the court committed legal error by discounting actual market performance. During the relevant period, three new competing brand-name topical TRTs entered the market: Fortesta in February 2011; Axiron in March 2011; and Vogelxo in July 2014. JA144. The district court gave no weight to these new entrants because, individually, they maintained relatively small shares of the market compared to AndroGel. *Id.* But collectively, these three products quickly took over roughly one-third of the topical TRT market. *Id.* And as discussed,

supra pp. 68-69, these competitors were able not only to enter the market, but also to constrain competitive behavior by taking substantial business from AndroGel.

In a similar case, this Court has held that the FDA approval process does not constitute a high barrier to entry. In *Barr Laboratories*, the Court affirmed summary judgment for the defense based on the plaintiffs' failure to prove high barriers to entry where "six new products [had] received FDA approval" over a six-year period. 978 F.2d at 114. As the Court explained, "whatever barrier to entry FDA approval for new products poses, that barrier is not insurmountable." *Id.* Here, three new products received approval in three years. *Supra* p. 61.

Moreover, Hatch-Waxman's abbreviated FDA approval process significantly reduces regulatory barriers to entry for generic competitors. *Supra* p. 12. If the FDA framework standing alone could constitute a high barrier to entry, a finding of monopoly power would likely follow in almost all pharmaceutical cases involving incumbent branded drugs, regardless of real-world activity in the market. But a wooden approach that ignores "actual market realities" is "generally disfavored in antitrust law." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466-467 (1992). The district court took that disfavored approach here, and its erroneous finding of monopoly power requires reversal.

IV. THE DISGORGEMENT AWARD IS UNLAWFUL

Independent of the defects in the district court's finding of liability, the disgorgement award was unauthorized by law and unsupported by the record and should be reversed. The court held that its remedial authority under §13(b) of the FTC Act "includes the full range of equitable remedies, including the power to order a defendant to disgorge illegally obtained funds." JA148 (Op.). Invoking that statute, the court awarded the FTC nearly half a billion dollars as "disgorgement of defendants' ill-gotten profits from June 2013"—when the court concluded that Perrigo would have entered the market but for AbbVie and Besins's patent-infringement suit—"through August 2017." JA169. But §13(b) of the FTC Act does not authorize disgorgement—particularly where, as here, the FTC failed to prove that AbbVie and Besins were currently violating or about to violate antitrust laws. And even if the court had authority to award disgorgement, it erred in basing the award on unsupported and illogical speculation as to when Perrigo would have entered the market absent the infringement suits.

A. Standard Of Review

Whether authority to order disgorgement exists "'is a question of statutory interpretation that requires de novo review.'" *In re Unisys Corp. Retiree Med. Benefits ERISA Litig.*, 579 F.3d 220, 227 (3d Cir. 2009). If the district court had

such authority, its award is reviewed for abuse of discretion. *SEC v. Teo*, 746 F.3d 90, 100-101 (3d Cir. 2014).

B. The Court Had No Authority To Order Disgorgement

Section 13(b) was added to the FTC Act to supplement the FTC's traditional administrative remedies under §5(b) by "allow[ing] the FTC to obtain a temporary restraining order or preliminary injunction" when it "'has reason to believe' that violations of the FTC Act are occurring or are about to occur." *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147, 155 (3d Cir. 2019). As discussed below, that provision does not authorize the disgorgement award here, for three reasons. First, §13(b) does not expressly provide for disgorgement, and that remedy cannot properly be inferred. Second, even if §13(b) implicitly authorizes equitable remedies, the disgorgement award is not an equitable remedy. The Supreme Court's holding in *Kokesh v. SEC*, 137 S. Ct. 1635, 1639 (2017), that "disgorgement imposed as a sanction for violating a federal securities law" is a "penalty" for statute-of-limitation purposes dictates that disgorgement is also a penalty here. *See FTC v. AMG Capital Mgmt., LLC*, 910 F.3d 417, 429 (9th Cir. 2018) (O'Scannlain, J., concurring). Finally, even if disgorgement were available, the FTC could not obtain it without showing that a defendant "'is' or 'is about to'" violate antitrust laws. *Shire*, 917 F.3d at 160 n.19 (quoting §13(b)). The district court's finding that the FTC did not establish the imminent or ongoing violation

necessary to authorize an injunction should therefore also have foreclosed any disgorgement award.

1. Section 13(b) does not authorize disgorgement

Section 13(b) authorizes the FTC to bring suit "to enjoin" imminent or ongoing violations of antitrust laws. 15 U.S.C. §53(b). The remedies available in a suit "to enjoin" violations are specifically enumerated: the FTC may seek a "temporary restraining order," a "preliminary injunction," or a "permanent injunction." *Id*. Section 13(b) nowhere expressly authorizes disgorgement or other monetary relief.

That delineation of precisely chosen remedies reflects the history and purpose of §13(b). The FTC's "traditional enforcement tool" under the FTC Act is the administrative remedy in §5, under which the FTC can adjudicate and remedy violations of the antitrust laws within its jurisdiction, including by imposing monetary penalties. *Shire*, 917 F.3d at 155. Section 13(b) was "added later" to address a specific gap in the "slow-moving" administrative regime under §5: "the need to quickly enjoin ongoing or imminent illegal conduct" without "wait[ing] for an administrative proceeding to conclude." *Id.* Section 13(b) was thus "expected to be used for obtaining injunctions against illegal conduct pending completion of FTC administrative hearings," not to "duplicate Section 5, which already

prohibit[ed] past conduct" and afforded the FTC a range of monetary and other remedies. *Id.* at 156.

Consistent with that history, §13(b)—unlike other provisions of the FTC Act—contains no general authorization for "appropriate" or "necessary" relief apart from injunctions. Section 5 empowers courts to grant injunctions "and such other and further equitable relief as they deem appropriate" in enforcing FTC orders. 15 U.S.C. §45(*l*). And §19, authorizing actions to address violations of certain FTC rules or orders, empowers courts to grant "such relief as the court finds necessary to redress injury to consumers," which "may include, but shall not be limited to, rescission or reformation of contracts, the refund of money or return of property, [or] the payment of damages." 15 U.S.C. §57b(b). Section 13(b) contains no comparable language. Where Congress "expressly provide[d]" injunctive remedies in §13(b), "'courts must be especially reluctant to provide additional remedies.'" *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1675 (2017).

The district court nonetheless determined that §13(b) impliedly authorizes courts to order "the full range of equitable remedies, including the power to order a defendant to disgorge illegally obtained funds." JA148 (Op.). Quoting *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 291-292 (1960), which concerned the Fair Labor Standards Act, the court reasoned that "'[w]hen 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.'" JA147; *see also United States v. Lane Labs-USA Inc.*, 427 F.3d 219 (3d Cir. 2005) (applying *Mitchell* in interpreting Federal Food, Drug, and Cosmetic Act). But §13(b) does not broadly "entrust[] to an equity court the enforcement of prohibitions" in the FTC Act. Unlike the statutes in *Mitchell* and *Lane Labs*, §13(b) authorizes only a single equitable remedy—injunctive relief—to be awarded only under specific conditions. *Cf. Lane Labs*, 427 F.3d at 225 ("a district court sitting in equity may order restitution *unless there is a clear statutory limitation on the district court's equitable jurisdiction*" (emphasis added)). And "injunctive relief" is "not an umbrella term that encompasses restitution or disgorgement." *Owner-Operator Indep. Drivers Ass'n v. Landstar Sys., Inc.*, 622 F.3d 1307, 1324 (11th Cir. 2010).

Moreover, since *Mitchell*, the Supreme Court has "adopted a far more cautious course" before recognizing implied remedies. *Ziglar v. Abbasi*, 137 S. Ct. 1843, 1855-1857 (2017). "[A]ffirmative evidence of congressional intent must be provided *for* an implied remedy." *Alexander v. Sandoval*, 532 U.S. 275, 293 n.8 (2001) (quotation marks omitted). Section 13(b) manifests no such "'affirmative' evidence of congressional intent" to create remedies beyond injunctive relief. *Id.* Where, as here, a statute explicitly provides for "injunctive relief," and not other equitable remedies, there is no basis to infer that Congress also intended to

authorize disgorgement—particularly given §13(b)'s narrow and targeted purposes. *Id.*; *see also AMG Capital*, 910 F.3d at 431 (O'Scannlain, J., concurring) ("Such sensible interpretation—that 'injunction' means only 'injunction'—makes good sense in the context of the overall statutory scheme." (quotation marks omitted)).

2. The disgorgement order is a penalty, not an equitable remedy

Even if §13(b) impliedly authorized equitable remedies beyond the injunction it expressly mentions, the disgorgement order here would be impermissible because it is not an equitable remedy. As the Supreme Court's decision in *Kokesh* makes clear, a disgorgement award like the one here is a penalty. And courts' equitable remedial powers do not encompass the imposition of penalties. *E.g.*, *Marshall v. City of Vicksburg*, 82 U.S. 146, 149 (1872) ("Equity never … lends its aid to enforce a forfeiture or penalty, or anything in the nature of either."); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 434-435 (1945) ("relief in equity is remedial, not penal"), *supplemented*, 324 U.S. 570.

In *Kokesh*, the Court held that "[d]isgorgement in the securities-enforcement context is a 'penalty'" within the meaning of the statute of limitations in 28 U.S.C. §2462. 137 S. Ct. at 1639. The Court explained that determining whether a remedy is equitable or penal turns on two inquiries: (1) "whether the wrong sought to be redressed is a wrong to the public, or a wrong to the individual," and

(2) whether the sanction is sought "for the purpose of punishment, and to deter others from offending in like manner—as opposed to compensating a victim for his loss." *Id.* at 1642 (quotation marks omitted).

Under *Kokesh*, the disgorgement order here is plainly a penalty. First, it was ordered to address a violation of a public law, the FTC Act, that protects competition and consumers generally, not private interests. There is no private right of action under the FTC Act. *See Holloway v. Bristol-Myers Corp.*, 485 F.2d 986, 997 (D.C. Cir. 1973). The FTC acknowledged here that, like the SEC in *Kokesh*, the alleged wrong it seeks to vindicate is public, not private. ECF No. 403 at 28 n.19 ("[l]ike the SEC," the FTC "as government enforcer stand[s] in different shoes from private plaintiffs" (quotation marks omitted)).

Second, the disgorgement award was "imposed for punitive purposes" because it aims to deter future violations. *Kokesh*, 137 S. Ct. at 1643. As the district court stated, the award's purpose was to "deter violations of antitrust law and to prevent the unjust enrichment of defendants." JA163 (Op.); *see Kokesh*, 137 S. Ct. at 1645 (giving weight to justification for disgorgement provided by the court below). The FTC agreed, admitting that it sought disgorgement in part to "deprive Defendants of their ill-gotten gains, and deter future similar conduct." ECF No. 403 at 26; *see also* ECF No. 404 at 1, 9. But as the Supreme Court explained, "[s]anctions imposed for the purpose of deterring infractions of public

laws are inherently punitive because deterrence is not a legitimate nonpunitive governmental objective." *Kokesh*, 137 S. Ct. at 1643 (quotation marks omitted). Even a disgorgement award that serves both compensatory and deterrent goals remains a punishment. *Id.* at 1645.[6]

Contrary to the district court's conclusory dismissal of *Kokesh*, JA147, the Supreme Court's analysis of SEC disgorgement thus applies with equal force to the FTC. And while courts in other circuits have considered themselves bound by their own pre-*Kokesh* precedent permitting disgorgement under §13(b), *see FTC v. Dantuma*, 748 F. App'x 735, 737 (9th Cir. 2018); *FTC v. J. William Enters., LLC*, 283 F. Supp. 3d 1259, 1262 (M.D. Fla. 2017), this Court has no such binding precedent. *Kokesh* therefore points the way, confirming that the disgorgement award is unlawful. *See AMG Capital*, 910 F.3d at 433-437 (O'Scannlain, J., concurring).[7]

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[6] The possibility that the FTC might choose to disburse some disgorged monies to consumers does not negate the award's punitive nature. *See Kokesh*, 137 S. Ct. at 1644-1645; *see also* ECF No. 403 at 28 n.19 (FTC arguing that "[l]ike the SEC," the FTC "need not identify specific victims to whom payment is due because it seeks to deter violations of the laws" (quotation marks omitted)).

[7] In a footnote in an unpublished pre-*Kokesh* decision, a panel of this Court disagreed that the district court "lacked authority to order restitution as ancillary equitable relief under §13(b) of the FTCA." *FTC v. Magazine Sols., LLC*, 432 F. App'x 155, 158 n.2 (3d Cir. 2011). That footnote is "not binding." *United States v. Kluger*, 722 F.3d 549, 559 n.15 (3d Cir. 2013).

3. The FTC's failure to prove the preconditions for injunctive relief also forecloses disgorgement

Finally, even if disgorgement were available, it would only be by implication from §13(b)'s authorization of injunctive relief, and the statutory preconditions for injunctive relief would also be preconditions for disgorgement. *See Shire*, 917 F.3d at 160 n.19. The district court held that the FTC failed to prove the statutory prerequisites for an injunction. JA167-168 (Op.). That holding invalidates the disgorgement award as well.

The FTC may obtain injunctive relief under §13(b) only where 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)(1). In *Shire*, this Court held that the "'is' or 'is about to'" requirement applies equally to any equitable monetary relief that §13(b) might authorize. 917 F.3d at 160 n.19. There, because the FTC had not met that requirement, this Court not only affirmed the dismissal of the FTC's complaint for injunctive relief, but also "reject[ed] the FTC's standalone claim for equitable monetary relief"—even "[a]ssuming" such relief were available. *Id.*

The same result follows here. In denying the FTC's request for an injunction, the district court found that the FTC "presented no evidence that defendants are currently violating antitrust laws or about to violate antitrust laws." JA167. As discussed below, that finding was amply supported by the record. *Infra* pp. 102-106. The court's determination means that the FTC also failed to establish

the prerequisites for any other form of equitable remedy that §13(b) might impliedly authorize. Because AbbVie and Besins were not "currently violating" or "about to violate" antitrust laws, the statutory conditions for the FTC to seek relief under §13(b)—including disgorgement—were not met.

C. The District Court Abused Its Discretion In Awarding Disgorgement

Even if it had authority to award disgorgement, the district court abused its discretion in ordering disgorgement here. The court purported to order disgorgement of profits that were "causally related" to AbbVie and Besins's alleged anticompetitive conduct. JA149 (Op.) (requiring FTC to satisfy a "but-for" standard). In light of the many obstacles Teva faced—and as discussed further below—the court correctly found that Teva's failure to launch its testosterone gel was not caused by the supposedly sham litigation and thus warranted no disgorgement. JA151-154; *infra* pp. 93-101. But the court erroneously found that, absent the infringement suit, Perrigo would have launched its product in June 2013—18 months before it actually did. JA154-158.

That flawed conclusion, which was the basis for virtually the entire disgorgement award, rested on unsupportable assumptions about one crucial prerequisite to Perrigo's market entry: the FDA's issuance of a therapeutic equivalence rating. *See supra* pp. 20-22. As the FTC conceded below, Perrigo would not have entered the market before receiving a rating. *See* ECF No. 405 at

156. In the real world, the FDA did not issue Perrigo's AB rating until July 2014, after the FTC resolved complex citizen petitions regarding the regulatory process for issuing ratings. JA155-156 (Op.); *supra* pp. 20-22. It was sheer speculation to conclude that the FDA would have issued Perrigo's rating any earlier, even without AbbVie and Besins's litigation against Perrigo.

Two of the district court's errors are particularly clear: (1) the court's erroneous finding regarding the FDA's knowledge of Perrigo's licensed entry date, and (2) the court's unreasonable assumption that Perrigo would have sued the FDA for unreasonable delay before any delay had occurred.

1. The court misconstrued the record regarding the FDA's knowledge of Perrigo's license date

The district court posited that the FDA felt "no compelling need" to issue a TE rating more quickly because it knew that Perrigo had agreed to a licensed entry date in December 2014. JA156 (Op.). The court thus attributed all 18 months that passed between the FDA's approval of Perrigo's drug application in January 2013 and its issuance of the TE rating in July 2014 to FDA's supposed knowledge of the license date.

But there is no evidence that the FDA knew about Perrigo's license date before March 2014, when Perrigo sued the FDA and disclosed that confidential fact for the first time in a declaration under seal accompanying its preliminary-injunction motion. JA3815-3816 (Tr. 6:115-118) (Solomon). The sole Perrigo

witness confirmed that Perrigo had decided "not to provide the settlement agreement license date to the FDA as long as there wasn't some legal requirement that it do so." JA3816 (Tr. 6:117) (Solomon). The FDA was thus unaware of Perrigo's license date for at least the first 14 months after it approved Perrigo's drug in January 2013, and its failure to issue a rating during that time indisputably could not have been caused by AbbVie and Besins's suit against Perrigo or the resulting settlement.

2. The court unreasonably assumed that Perrigo would have sued the FDA for undue delay before any delay occurred

The district court's finding that Perrigo would have launched its testosterone gel in June 2013 absent the alleged sham litigation also rested on the improbable premise—borrowed from the FTC's economist, Dr. Shapiro—that Perrigo would have sued the FDA for undue delay in issuing the TE rating before any delay had actually occurred. JA157 (Op.). Shapiro "assum[ed]" that Perrigo would have sued the FDA in February 2013, only a month after the FDA approved Perrigo's NDA, and that the suit would have prompted the FDA to issue Perrigo's AB rating four months later, in June 2013. JA3877-3878 (Tr. 7:168-171) (Shapiro). But Shapiro's assumptions were unsupported by the evidence.

Shapiro admitted he had no expertise in FDA regulatory matters. JA3888 (Tr. 7:209); JA3909 (Tr. 8:62-63). He said he relied on the testimony of the FTC's regulatory expert, Kenneth Phelps, and Perrigo executive Andrew Solomon, but

neither testified that Perrigo would have sued the FDA any earlier than March 2014, even absent the alleged sham litigation. JA3909-3910 (Tr. 8:64-68) (Shapiro); JA3579-3581 (Tr. 2:141-143, 147-151) (Phelps). To the contrary, Solomon—the sole Perrigo witness—testified that it was Perrigo's practice to sue the FDA only as a "tactic of last resort," and that it did so here only after it had submitted three letters to the FDA over a span of ten months requesting a rating, to no avail. JA3711 (Tr. 4:206-207); *see id.* ("[A] decision to sue a governmental agency with whom you rely upon heavily for approval of your products is something we don't take lightly and we don't do very often."). Solomon dismissed as "all speculation" the possibility that that Perrigo might have sued the FDA earlier. JA3711-3712 (Tr. 4:208-209).

Moreover, even if Perrigo had sued the FDA earlier, no evidence suggests that the FDA would or could have completed its review and issued Perrigo's rating any earlier than July 2014—let alone by June 2013. The FDA had made clear that it would not issue any TE rating without first resolving pending citizen petitions that raised "significant, complex, and evolving scientific and legal issues" concerning the procedures for determining TE ratings. JA1933 (DX021); *see supra* p. 21. As late as May 2014, the FDA was still considering the petitions and believed "it [was] critical to resolve them in order to make a decision regarding Perrigo's TE rating." JA1933 (DX021). When Perrigo sued the FDA in March

2014, the FDA accordingly denied that it had engaged in any undue delay. JA1598-1605 (PLX288); *see also* JA1939-1945 (DX021). Even accepting the district court's assumption—contrary to the uncontradicted evidence—that Perrigo would have sued the FDA earlier, there was no basis to think such a suit would have accelerated the FDA's issuance of Perrigo's rating.

The court's speculation as to when Perrigo would have entered the market absent the alleged sham litigation was the crucial assumption underlying the vast majority of its disgorgement calculation. The court abused its discretion in ordering disgorgement on that basis. Once the court's unfounded assumption falls, as the evidence demands, the disgorgement award must fall with it.[8]

RESPONSE TO FTC APPEAL

For the foregoing reasons, the FTC failed to establish a violation of the FTC Act and would not have been entitled to disgorgement even if it had. Because the judgment was wrong—and for further reasons discussed below—the Court need not even consider the FTC's grounds for appeal. If it does, it should reject them.

[8] Even accepting liability and the availability of disgorgement under §13(b), expert testimony showed that correcting for the unfounded assumptions underlying the disgorgement award—*i.e.*, assuming instead that Perrigo would have launched in August 2014 after receiving an AB rating in July 2014 and correcting for the associated effects on AndroGel 1.62% sales—would have supported disgorgement of no more than $39.8 million. JA4314-4315 (Tr. 14:225-230) (Cremieux); JA4352-4360 (Tr. 15:123-156) (Cremieux).

V. THE COURT CORRECTLY DISMISSED THE "REVERSE PAYMENT" CLAIM

The district court correctly determined that the FTC's challenge to AbbVie's settlement with Teva failed to state a claim. Even if it had stated a claim, however, remand would be futile because Teva would not have launched its product anyway, and the FTC cannot obtain relief under §13(b).

A. Standard Of Review

This Court "exercise[s] plenary review" over an order granting dismissal for failure to state a claim. *Shire*, 917 F.3d at 154 n.12. To survive dismissal, a complaint must allege enough facts to "'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

B. The FTC Failed To State A Reverse-Payment Claim

As the district court found, the agreement settling AbbVie and Besins's infringement suit against Teva "simply allow[ed] Teva to enter the AndroGel market almost six years prior to the expiration of the '894 Patent." JA15 (MTD Op.). "*Actavis* specifically states that such an agreement does not run afoul of the antitrust laws." *Id.* (citing *Actavis*, 570 U.S. at 158). The "FTC concede[d] that by itself this settlement agreement [wa]s legal," *id.*, and never challenged the similar settlement with Perrigo. That makes sense: Those agreements "promote[d] competition" by enabling Teva and Perrigo to compete with AndroGel before the '894 patent expired. JA15-16.

The FTC instead sought to construct an illegal reverse payment by linking the settlement of the infringement suit to one of two separate agreements AbbVie and Teva signed on the same day concerning different products. *Supra* pp. 16-17. Under the separate agreement, Teva agreed to pay AbbVie for an option to buy (for resale to consumers) a supply of the drug TriCor at a price that reflected AbbVie's cost of production, an additional percentage of that cost, and a substantial royalty on Teva's profits. JA16 (MTD Op.). As the district court observed, "there is no evidence that the[] [TriCor] negotiations were linked to the AndroGel settlement." JA92 (Op.). The FTC nevertheless posited that the TriCor agreement effectuated a large and unjustified transfer of value to compensate Teva for agreeing in the AndroGel settlement not to launch its testosterone gel until December 2014.

The district court correctly rejected that claim. JA17-21 (MTD Op.). Unlike the allegations in *Actavis*, the court explained, the allegations here show that the TriCor agreement enhanced competition by allowing Teva to sell TriCor in competition with AbbVie, accelerating consumers' opportunity to "purchase the generic form of TriCor at a reduced price." JA17. The TriCor and AndroGel agreements were therefore both "procompetitive" and "in the best interests of the consumer." JA17-18.

Those facts distinguish this case from *King Drug Co. v. Smithkline Beecham Corp.*, 791 F.3d 388, 393-396 (3d Cir. 2015), where this Court found that the

manufacturer of a branded drug effectively paid a generic manufacturer to drop a patent challenge and delay entering the market. The alleged payment took the form of an agreement by the brand manufacturer not to launch its own "authorized generic," which could have competed against the generic manufacturer's product during a 180-day statutory exclusivity period. As this Court stated, that "no-AG" agreement had potential to harm consumers by precluding competition between the generic manufacturer and an authorized generic that otherwise would have occurred during the exclusivity period. *Id.* at 403. Here, in contrast, the TriCor agreement had no such potential. The FTC's allegations instead made clear that the TriCor agreement enhanced competition by facilitating entry of a generic competitor to TriCor earlier than would have occurred absent the agreement. As the district court explained, "[t]he anticompetitive effects that the court dealt with in *King Drug* are simply absent here." JA28 (MTD Recon. Op.).

In re Lipitor Antitrust Litigation, 868 F.3d 231 (3d Cir. 2017), is distinguishable for the same reason. There, the Court considered two reverse-payment claims. One involved a "no-AG" agreement like the one in *King Drug*. *Id.* at 258-259. The other concerned an agreement in which the branded manufacturer gave up a strong infringement claim involving one drug—a claim with "large expected damages" and a "high likelihood of success"—in exchange for the accused infringer's agreement to delay generic sales of a second drug for 20

months beyond the expiration of patent protection for that drug. *Id.* at 243-245, 253-254. Neither agreement enhanced competition by facilitating early generic entry, and neither reverse-payment claim sought to predicate liability on a combination of otherwise lawful and pro-competitive agreements.

The FTC does not dispute that—viewed independently—the AndroGel and TriCor agreements both benefited consumers by promoting competition in their respective markets. *See* FTC Br. 33.[9] The district court did not err in dismissing the claim on that basis. "Antitrust law is designed to protect consumers from arrangements that *prevent* competition[.]" *King Drug*, 791 F.3d at 405 (emphasis added). None of the cases the FTC cites supports the proposition that two independently lawful, procompetitive agreements can become unlawful when considered together. Neither *King Drug* nor *Lipitor* presented that scenario, *supra* pp. 87-89, and the other authorities cited by the FTC are even further afield. *See, e.g.*, *Continental Ore v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962) (considering sufficiency of evidence that plaintiff made timely demands for supplies and exhausted other sources); *Dentsply*, 399 F.3d at 189 (considering monopoly power).

[9] This case thus does not present the question whether "procompetitive effects in one market can justify anticompetitive harm in another" or how a court would make that comparison. FTC Br. 34 n.8 (citing *King Drug*, 791 F.3d at 410 n.34).

Moreover, the FTC did not plead facts supporting a plausible inference that the TriCor agreement constituted a large and unjustified benefit to Teva "in exchange" for Teva's accepting a 2014 license date for Teva's testosterone product. As the district court observed, "this is not a situation where the FTC has alleged that [AbbVie] agreed to sell TriCor to Teva for less than its cost." JA17 (MTD Op.). And the FTC did not plausibly allege any reason why any compensation would have been necessary for Teva to accept the AndroGel agreement, which already conferred an important benefit: licensing Teva to launch its testosterone product approximately six years before patent expiration (had Teva been capable of doing so). The FTC's sole allegation on that point was that Teva was unwilling to accept AbbVie and Besins's proposed license date "absent significant compensation" because Teva believed the patent-infringement suit "was a sham" that was bound to lose. JA4442 (sealed complaint). But the district court rejected that allegation as implausible, and the FTC has not challenged that finding. JA19-20 (MTD Op.) (at time of settlement, "Teva did not and could not plausibly know … whether the lawsuit was a sham"). Indeed, Perrigo agreed to the same entry date, and the FTC did not allege that any reverse payment was required as an inducement.

Nor did the complaint plausibly allege that the TriCor agreement made no economic sense for AbbVie. *See* FTC Br. 30-31. As the complaint acknowledges,

Teva had already secured a license to market a generic version of TriCor, JA4442, and it makes perfect sense for AbbVie to have entered into a supply agreement to mitigate expected losses from generic entry. The FTC cited Teva's difficulty obtaining FDA approval for its own TriCor tablets, JA4446, but the complaint nowhere alleges that AbbVie knew at the time of the settlement that Teva would be unable to secure approval or other supply by its license date six months later. JA4440-4447. In short, even if two independently lawful and procompetitive agreements could be linked to form an unlawful reverse payment, the complaint fails to allege facts plausibly supporting such a link here.

C. Remand On The Reverse-Payment Claim Would Be Futile

Even if the FTC had stated a reverse-payment claim, reinstating that claim would be pointless for several reasons. First, the FTC would not be entitled to any form of relief because it did not, and cannot, allege that AbbVie "is violating, or is about to violate any provision of law enforced by the [FTC]." 15 U.S.C. §53(b). As discussed, this Court made clear in *Shire* that such a showing is required for the FTC to obtain an injunction or any other form of equitable relief that §13(b) might allow, 917 F.3d at 160 & n.19:

> Simply put, Section 13(b) does not permit the FTC to bring a claim based on long-past conduct without some evidence that the defendant "is" committing or "is about to" commit another violation.

Id. at 156.

Here, the complaint contains no allegation that AbbVie is continuing to violate or about to violate the antitrust laws by entering into illegal reverse payments. The only purportedly unlawful settlement alleged occurred in December 2011, more than seven years ago. Under the AndroGel agreement, Teva was free to launch its testosterone gel in late December 2014, more than four years ago. Any continuing effects of the alleged reverse payment have thus long ceased. In these circumstances, the FTC cannot proceed under §13(b) in the first place and cannot obtain any injunction nor other remedy. *Shire*, 917 F.3d at 155-159.

Second, for the reasons discussed, §13(b) does not authorize disgorgement. *Supra* pp. 73-79. And third, even if it did, disgorgement is appropriate only where the defendant obtained ill-gotten gains causally connected to its unlawful conduct. JA149 (Op.). Here, AbbVie obtained no ill-gotten gains from the alleged reverse-payment agreement with Teva (even assuming it was unlawful). As the district court found, Teva would not have launched its testosterone product regardless of the infringement litigation, for reasons having nothing to do with any AbbVie conduct. JA154. The overwhelming evidence showed that Teva would not and could not have launched a BX-rated product, particularly in light of the many other obstacles it faced. *Supra* pp. 17-18; *infra* pp. 93-101. Accordingly, even if disgorgement were available, there is nothing to disgorge.

The Court thus need not decide whether the reverse-payment count stated a claim. Even if the FTC had stated a plausible claim for relief—and it did not—it cannot proceed or obtain relief under §13(b). Any remand would be futile.

VI. THE FTC'S CHALLENGES TO THE REMEDIAL ORDERS FAIL

The FTC's remaining grounds for appeal concern the relief it obtained on the sham-litigation claim. Because there was no basis to find liability on that claim, these arguments need not be addressed. In any event, the arguments fail.

A. Standard Of Review

The FTC's challenge to the disgorgement award is reviewed for abuse of discretion. *Supra* pp. 72-73. This Court "review[s] the denial of [a] request for injunctive relief for abuse of discretion." *A&H Sportswear, Inc. v. Victoria's Secret Stores, Inc.*, 237 F.3d 198, 210 (3d Cir. 2000). The district court's findings of fact are reviewed for clear error. *Supra* p. 55.

B. The FTC's Challenge To The Disgorgement Award Fails Because Teva Would Not Have Entered The Market Regardless Of The Infringement Suit

Even where a court has authority to order disgorgement, it may exercise that power only over property that is "'causally related to the wrongdoing.'" JA149 (Op.) (quoting *CFTC v. American Metals Exch. Corp.*, 991 F.2d 71, 78-79 (3d Cir. 1993)). The FTC therefore concedes (at 36) it had to prove "'but-for'" causation—*i.e.*, that the profits to be disgorged would not have accrued but for the alleged

sham litigation. *Teo*, 746 F.3d at 107; *see also* JA149 (Op.). Where the FTC meets that initial burden, the defense "may 'point[] to intervening events' that break the chain of causation." JA149 (Op.) (alteration in original) (quoting *Teo*, 746 F.3d at 105-106). Applying that standard after trial, the district court found that "Teva's failure to launch was due to other intervening events" and that "the sham litigation against it was not a cause." JA154 (Op.). Among other things, the court cited Teva's "inability to commercialize" a BX-rated product, the loss of "over 50%" of potential sales due to Teva's forced withdrawal of the pump presentation, and the "serious manufacturing issues" Teva faced as a result of its disputes with Cipla. JA153-154; *supra* pp. 17-18.

That finding was supported by overwhelming evidence that the FTC all but ignores. Maureen Cavanaugh—the Teva executive responsible for making a launch recommendation, and the only Teva witness to testify—described Teva's various obstacles at length. *Supra* pp. 17-18; JA3603-3643 (Tr. 3:8-166) (Cavanaugh). She explained that Teva's generic business model relies on automatic substitution and that, because a BX rating would preclude automatic substitution, Teva could not "create demand" for its product without hiring a sales force and undertaking other marketing efforts—steps Teva was not equipped to take. JA3629-3631 (Tr. 3:109-120). Indeed, Teva's generic division has never launched a BX-rated product. JA3630 (Tr. 3:115).

Cavanaugh further explained how other obstacles confirmed that Teva could not effectively commercialize a BX-rated product: Loss of the pump presentation cut Teva's sales prospects considerably and put Teva at a competitive disadvantage, JA3632 (Tr. 3:121-124), while Cipla's capital demands would have required substantially higher-than-typical upfront costs to launch, JA3633-3634 (Tr. 3:127-129); *see also, e.g.*, JA621-626 (PLX018) (Cipla-Teva correspondence). Cavanaugh explained how these factors led Teva to conclude that it could not launch its product effectively, JA3634 (Tr. 3:132), and that even without AbbVie and Besins's patent suit and settlement, her recommendation not to launch "would not have been any different," JA3635 (Tr. 3:134).[10]

Although the district court found Cavanaugh's testimony credible and relied heavily on it, JA153, the FTC proceeds as if it did not exist. Instead, the FTC offers a series of purported errors by the district court, but none establishes an abuse of discretion.

The FTC first faults the district court for supposedly requiring the FTC to "establish" whether Teva would have launched absent the alleged sham litigation. FTC Br. 36-37. But the FTC concedes (at 36) it had to prove but-for causation.

[10] AbbVie and Besins's expert thus opined, based on Cavanaugh's testimony, Teva's contemporaneous financial forecasts, and related evidence, that Teva would not have launched a BX-rated product. JA4352-4354 (Tr. 15:124-130) (Cremieux).

The "reasonable approximation" and "reasonable inference" standards it invokes apply in measuring the amount of ill-gotten profits, not in determining whether profits were ill-gotten in the first place. *See, e.g.*, *id.* at 37 (citing *Behrend v. Comcast Corp.*, 633 F.3d 182, 203 (3d Cir. 2011), for the proposition that damages need not be "*measured* with certainty"). Here, the district court had no need to "reasonabl[y] approximat[e]" AbbVie's and Besins's profits from Teva's failure to launch in the but-for world because it determined that there was no causal relationship at all between the alleged sham litigation and Teva's decision not to launch. JA154 (Op.); *see Teo*, 746 F.3d at 111 (Jordan, J., dissenting in part) ("[i]mplicit in" the reasonable-approximation standard is a "recognition that the SEC must have satisfied its initial burden of showing causation by producing evidence that a violation occurred and that some plausible relationship exists between that violation and the profits gained"). In making that determination, the court applied the precise legal framework the FTC advocates, *compare* JA149-150 (Op.), *with* FTC Br. 37, and concluded that the evidence at trial conclusively demonstrated that Teva's failure to launch was "due to other intervening events" and that the litigation against it "was not a cause," JA154.

The court by no means erred in giving weight to the independent developments that influenced Teva's decision not to launch. *Cf.* FTC Br. 41-47. There is simply no causal connection between the infringement litigation and

Teva's institutional inability to effectively commercialize a BX-rated product, the FDA's refusal in mid-2011 to approve Teva's testosterone pump, the capital demands Cipla made before the litigation, and the other factors the district court cited. As Cavanaugh testified—credibly, without contradiction—Teva's decision not to launch had nothing to do with the patent litigation or the settlement of that litigation. JA3635 (Tr. 3:134). Far from tainted consequences of the patent suits, these considerations were common reasons for Teva to terminate a project—even after sinking substantial costs into it—and represented a clear break in causation between the alleged sham litigation and Teva's launch decision. *Id.* (Tr. 3:133).

In response, the FTC offers a logical fallacy. According to the FTC, all developments occurring after the litigation commenced in April 2011 must have been caused by the litigation, no matter how attenuated the connection, and should therefore have been disregarded. FTC Br. 41-42. That assertion contradicts the record. *Supra* pp. 17-18; *infra* pp. 98-100. And neither *Teo* nor the FTC's other cases support the FTC's position. To the contrary, they make clear that reconstructing the but-for world and factoring out the consequences of illegal conduct requires "sound economic proof of the nature of the market and likely outcome," lest "the hypothetical … laps[e] into pure speculation." *Grain Processing Corp. v. American Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999); *see also National Farmers Org., Inc. v. Associated Milk Producers, Inc.*,

850 F.2d 1286, 1292-1293, 1306 (8th Cir. 1989) (distinguishing between plaintiff's burden to prove causation of injury and "lesser standard" applicable to proving amount of damages). The FTC's speculation that the intervening causes of Teva's decision not to launch resulted from the alleged sham litigation—rather than, for example, the FDA's independent decision not to approve Teva's pump or Cipla's independent decision to demand what Teva deemed exorbitant capital expenditures—fall far short of that mark. *See* FTC Br. 44-47.

In any event, even freezing time before patent-infringement suit, the FTC's proposed but-for world finds no support. Citing supposedly "undisputed evidence," the FTC contends (at 37-38) that, as of spring 2011, Teva was "full speed ahead" to launch a BX-rated product "by June 2012." The cited documents support no such inference. The first cited document states: "[W]e expect to launch the product in 2013." JA627 (PLX021).[11] And it recognizes that the actual date would depend on "complete operational readiness with Cipla," *id.*—an issue that

[11] The email was written in August 2011 by Teva executive Tim Crew, *id.*, for whom the TRT gel was a "pet project" and whose departure from Teva the following year sealed the project's fate. JA3634 (Tr. 3:132) (Cavanaugh); JA153 (Op.). The district court did not abuse its discretion in citing Crew's departure as yet another reason to find that Teva never would have launched, JA153, and the FTC offers no basis for its suggestion that Crew's departure was somehow a "product[] of the lawsuit," FTC Br. 44. The FTC further suggests that, absent the lawsuit, all necessary decisions would have been made "no later than the spring of 2011," before Crew's departure. *Id.* at 44-45. The FTC cites no evidence for that assertion because there is none.

was already in doubt by early 2011 given the disagreement over Cipla's capital demands, *see* JA621-626 (PLX018) (early 2011 Cipla-Teva correspondence). A second cited document predicts operational readiness in March or August 2013. JA796 (PLX042). The FTC's other citations similarly fail.[12] Cleared of the FTC's mischaracterizations, these documents are instead consistent with other Teva documents showing that, even in 2011 before the infringement suit—and even in 2010 before the problem with Teva's pump arose—Teva did not expect to launch, if at all, until sometime in 2013 at the earliest. *See* JA714-745 (PLX035) (analyzing scenarios with launch dates of October 2013 or March 2014); JA1745-1750 (PLX318) (pre-lawsuit projections of 2013 launch); JA3621-3623, 3635-3637 (Tr. 3:78-86, 134-142) (Cavanaugh explaining projections and work plans).

The FTC posits (at 47) that the absence of approval for Teva's pump "was a consequence of the delay created by the settlement." That too is wrong. The FDA raised concerns about the pump in June 2011, and Teva withdrew it in July 2011—before the settlement. JA1988 (DX047); JA3635 (Tr. 3:136) (Cavanaugh). Obtaining approval for the pump after that point, as the FTC blithely suggests Teva could have done before June 2012, would have required reformulating the pump,

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[12] *See* JA1618-1639 (PLX296) (financial projections for several different launch scenarios, with most projected sales beginning in 2014); JA1740 (PLX317) (February 2012 notes of trade names discussion with no reference to launch dates); JA1648 (PLX301) (financial projections with no predicted launch date); JA635 (PLX026) (not a Teva document); JA686-690 (PLX032) (not a Teva document).

testing it, and resubmitting it for FDA review—time-consuming steps that Cavanaugh estimated to be successful only "half of the time[]." JA3632 (Tr. 3:124). Contrary to the FTC's assertion (at 47), the FTC's expert did not testify that Teva "could have gotten pump approval within six months"; he testified that Teva would first have to redesign the pump, conduct additional studies, gather more data, and resubmit it for approval, and only then would FDA review begin and take an estimated six months. JA3586 (Tr. 2:171-172) (Phelps).

In the face of this evidence, the FTC insists that without the lawsuit, Teva would have had strong "incentive[s]" to overcome the obstacles and launch even a BX-rated product as soon as possible, given the size of the TRT market and the investment it had already sunk into its §505(b)(2) NDA. FTC Br. 38-39. *But see, e.g.*, JA2203 (DX153) ("[T]here will be no agreement [with Cipla] until we have an AB rating."). But as Cavanaugh testified, Teva "terminate[s] projects all the time" despite substantial initial investments. JA3634-3635 (Tr. 3:132-133); *id.* (Cavanaugh: out of 130 pending projects, Teva was focused on 60 and hoped to launch 40). The district court did not abuse its discretion in finding that the testosterone gel project would have met the same fate.

Ultimately, the FTC seeks only another bite at the apple, suggesting that the district court's dismissal of the reverse-payment claim somehow tainted its analysis of Teva's launch decision. But the FTC articulates no possible reason

why or how the court's conclusion and factual findings would have been different. Cavanaugh testified that her recommendation would not have changed even without the "agreement settling the patent litigation." JA3635 (Tr. 3:133-134). The district court found that Teva's decision was "due to other intervening events," including the disagreement with Cipla, the failure to obtain approval for the pump, and Teva's inability to market a BX-rated product. JA152-154 (Op.). There is no conceivable scenario in which the "impact of the TriCor deal on Teva's incentives" would have changed that mix of independent, intervening events, and the FTC does not suggest otherwise. Nor does the FTC explain how additional discovery could possibly have altered the court's analysis. *See Massachusetts Sch. of Law at Andover v. American Bar Ass'n*, 107 F.3d 1026, 1033 (3d Cir. 1997).[13] The district court acted well within its discretion in denying disgorgement related to Teva's failure to launch.

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[13] The FTC complains about the district court's discovery order, *see* FTC Br. 41 (citing ECF No. 79), but the FTC did not appeal that order, *see* JA175 (FTC notice of appeal), and the "passing reference" to it in the FTC's brief "will not suffice to bring that issue before this [C]ourt," *United States v. Jackson*, 849 F.3d 540, 555 n.13 (3d Cir. 2017) (quotation marks omitted). Nor did the FTC ask the district court to modify that order after Count II was dismissed—though it did move to modify other aspects of the order. *See* ECF No. 91. (The court granted that motion. ECF Nos. 111, 112.) As to the supposed limitations on testimony at trial, *see* FTC Br. 41, the cited passage has nothing to do with Teva's launch plans but instead concerns a dispute over the relevance of testimony the FTC sought from Cavanaugh—despite her lack of "knowledge of anything on that subject matter"—as to whether the patent-infringement claims had a "realistic possibility of success." JA3623-3624 (Tr. 3:86-90).

C. The Court Did Not Abuse Its Discretion In Denying Injunctive Relief

As the FTC concedes (at 48), injunctive relief is appropriate only to address a "'cognizable danger of recurrent violation.'" JA167 (Op.) (quoting *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953)); *see* 15 U.S.C. §53(b). The district court properly exercised its discretion to deny an injunction based on its finding that the FTC presented "no evidence" to meet that standard. JA167 (Op.). As the court explained, the FTC did not allege that AbbVie and Besins "filed any other sham lawsuits" and offered "no basis to conclude" that any misconduct was "likely to reoccur." JA168.

The FTC claims (at 48-52) the court failed to apply the proper test for determining the likelihood of recurrence because it did not mechanically recite five factors discussed in *SEC v. Bonastia*, 614 F.2d 908, 912 (3d Cir. 1980). But the FTC cites no authority suggesting the court was required to do so. A party seeking injunctive relief "must satisfy the court that relief is needed." *Shire*, 917 F.3d at 157 (quoting *W.T. Grant Co.*, 345 U.S. at 633). "The necessary determination is that there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive." *Id.* Here, the district court had ample basis to find no such cognizable danger, and the FTC fails to make the "strong showing of abuse" required to disturb that finding. *W.T. Grant*, 345 U.S. at 633.

Even considering the *Bonastia* factors, the FTC's argument fails. The FTC contends (at 50) that "this is not an isolated case of misconduct." But other than the lawsuits against Teva and Perrigo—both resolved nearly three years before the FTC sued and more than seven years before the court denied an injunction—the FTC makes only general reference to other infringement cases (some more than a decade old) that it admits were never found to be shams. *See* JA168 (FTC "presented no evidence that these lawsuits were shams"). In the one antitrust case the FTC cites, *see* FTC Br. 50, it was AbbVie that won summary judgment on two of three allegations of anticompetitive conduct, while issues of fact precluded summary judgment as to the third. *See Teva Pharm. USA, Inc. v. Abbott Labs.*, 580 F. Supp. 2d 345, 356-358 (D. Del. 2008).

The FTC claims (at 51) it is "beside the point" whether these suits were shams because the suits show that AbbVie and Besins have "opportunities to engage in … misconduct." But "a permanent injunction will issue only where a threat of harm exists, not just where potential harm exists." *McLendon v. Continental Can Co.*, 908 F.2d 1171, 1182-1183 (3d Cir. 1990); *see also Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 250-251 (3d Cir. 2010) (injunctive relief unjustified, despite opportunities for continued wrongdoing, absent "evidence that [defendants] are now injuring [plaintiffs] or will soon do so").

The FTC also argues (at 51) an injunction is warranted because AbbVie and Besins "continue to insist their sham litigation was justified." But "[t]he antitrust laws … afford no [injunctive] relief on that basis alone." *Howard Hess*, 602 F.3d at 251 (citing *Bonastia*, 614 F.2d at 912). Moreover, AbbVie and Besins's suits against Teva and Perrigo were not shams under a proper application of the antitrust laws, *supra* pp. 34-60, and defending themselves against the FTC's contrary allegation is hardly wrongful. The FTC's assertion that AbbVie and Besins engaged in "intentional" misconduct fails for the same reasons.

Lacking the evidentiary record necessary to support injunctive relief, the FTC seeks remand on the ground that the district court mischaracterized the scope of relief the FTC sought and failed to consider the requests it actually made. FTC Br. 52-55. But demonstrating a "cognizable danger of recurrent violation" is a prerequisite for injunctive relief in any form. *W.T. Grant*, 345 U.S. at 633. The FTC's failure to satisfy that standard foreclosed every form of relief it sought.

In any event, the FTC's argument misrepresents both its own submissions and the district court's opinion. The FTC acknowledges (at 52 n.13) that "its pretrial brief" requested precisely the relief the district court described, *see* ECF No. 319 at 17-21 (FTC Pretrial Mem.), but the FTC fails to disclose that it adhered to that request after trial, urging the court to adopt the broad injunction "set forth … in the FTC's Pretrial Memorandum." ECF No. 403 at 35 (FTC Post-Trial

Brief). Moreover, in portions of the opinion the FTC omits to mention, the court acknowledged each of the supposedly "narrow[er]" forms of relief the FTC requested. The court stated:

> [T]he FTC urge[d] 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.

JA166; *see* ECF No. 403-1 at 3 (FTC Proposed Order); *cf.* FTC Br. 52 (acknowledging only the court's reference to (3) above).

The court specifically considered an order prohibiting future assertions of the '894 patent against any product that does not contain isopropyl myristate. JA168 (Op.). But it found such an injunction unnecessary given that "[g]eneric versions of AndroGel have now been on the market" for more than four years, AndroGel's share of the market has declined even further since Perrigo's entry, and the '894 patent expires in 2020. *Id.*

The court also considered and rejected the FTC's request for an injunction involving AbbVie and Besins's ability to file infringement suits "with respect to any patent," ruling that such an order would undermine AbbVie's and Besins's First Amendment rights. *Id.* As the FTC acknowledges, there must be "a reasonable relation" between the injunction and "the unlawful practices found to

exist," FTC Br. 53 (quotation marks omitted), and in describing its well-founded First Amendment concerns, the district court correctly concluded there was no such relation: "[T]he '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." JA168-169. While the FTC claims (at 53) that "[a]ny overbreadth concerns can be mitigated through appropriate tailoring," it proposed no such "tailoring" below. *See* ECF No. 403 at 34-35. The FTC's proposed certification requirement, *see* FTC Br. 53-54, was similarly overbroad.

In short, the district court rightly found the FTC's requested relief "overbroad and punitive." JA168. The FTC confirms that conclusion by asserting entitlement to an injunction "with respect to *any* patent," *id.* (emphasis added), based solely on the fact that AbbVie and Besins regularly assert infringement claims, including perfectly meritorious ones. FTC Br. 51 ("whether these suits are shams is beside the point"). This Court should affirm the denial of that punitive remedy, and in doing so should again reject the "FTC's improper use of Section 13(b) to pursue long-past petitioning" and its disregard of First Amendment protections under the *Noerr-Pennington* doctrine. *Shire*, 917 F.3d at 161.

CONCLUSION

The Court should affirm the dismissal of the reverse-payment count, reverse the judgment of liability, and reverse the disgorgement award.

Respectfully submitted,

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June 5, 2019

CERTIFICATE OF BAR MEMBERSHIP (LAR 46.1)

Pursuant to Third Circuit Local Appellate Rule 46.1, I, Seth P. Waxman, hereby certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

/s/ Seth P. Waxman
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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 28.1(e)(2)(B)(i) as modified by this Court's May 22, 2019 Order.

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(f), the brief contains 24,683 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

3. In addition, pursuant to Third Circuit Local Appellate Rule 31.1(c), I certify that the text of the brief filed with the Court via CM/ECF is identical to the text of the paper copies. I further certify that the electronic version of the brief has been scanned for viruses by Cylance Protect version 2.0.1530.5 (updated continuously) and is, according to that program, free of viruses.

/s/ Seth P. Waxman
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June 5, 2019

CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of June, 2019, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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