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

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellant,

v.

ABBVIE INC. *et al.*,
Defendants-Appellees.

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

THIRD-STEP (REPLY/RESPONSE) BRIEF OF THE FEDERAL TRADE COMMISSION

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INTRODUCTION AND SUMMARY

The district court's improper dismissal of the FTC's reverse-payment allegations was a fundamental error that reverberated throughout this case. The district court did not just wrongly dismiss the FTC's *Actavis* claim. It also dismissed the FTC's sham litigation claim to the extent it involved the reverse-payment agreement between AbbVie and Teva, thereby shaping how the parties and the court approached the remaining count.

For example, after the court took the reverse-payment issue off the table, it forbade the FTC from questioning Teva executive Maureen Cavanaugh about the $175 million payoff the FTC alleged Teva received from AbbVie via the TriCor deal. It defies reason to believe the payment did not influence Teva's decision not to launch a generic AndroGel product, yet the court assessed a "but-for" world without considering the payoff. The court similarly did not consider the reverse-payment settlement (one of many AbbVie has entered into) in deciding that a behavioral injunction was unwarranted. The error even infected questions presented in AbbVie's appeal, such as whether Teva's decision to settle the patent lawsuit reflected its merit.

The dismissal of the reverse-payment claim was legal error. As shown in our opening brief, the complaint alleged that the settlement of the AndroGel

litigation and the TriCor agreements were two sides of a single *quid-pro-quo* transaction, with AbbVie effectively paying Teva $175 million in exchange for Teva's agreement to drop its patent challenge and refrain from competing with AndroGel for several years. The district court wrongly failed to accept these well-pleaded and plausible allegations as true. It compounded the error by considering whether the litigation settlement and the TriCor deal individually furthered competition—an inquiry not properly conducted at the motion to dismiss stage.

AbbVie's arguments largely recapitulate the district court's errors, claiming simply that the settlement and the TriCor deal were unrelated agreements that were independently procompetitive. AbbVie also urges a new ground for dismissal that it did not properly raise before the district court: that the complaint did not adequately allege that the FTC had reason to believe AbbVie was violating or about to violate the law as required by Section 13(b) of the FTC Act, 15 U.S.C. §53(b). AbbVie waived this argument by failing to raise it in its motion-to-dismiss briefing. It is meritless in any event because unlike the situation in *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147 (3d Cir. 2019), the FTC filed this case while the illegal conduct was still occurring, and the complaint alleged ongoing misconduct.

AbbVie is wrong that there would be no point in remanding even if the FTC prevailed. The district court plainly has authority to award monetary relief under the settled law of this Circuit. And even if monetary relief were unavailable, the

court could still award injunctive relief on remand, particularly given AbbVie's demonstrated history of entering into reverse-payment agreements.

The district court's determination that Teva would not have launched its product even if it had never been sued, and thus had never entered into the reverse-payment agreement, was also erroneous. Remand is required for the court to consider the effect of the reverse payment. Furthermore, in holding that Teva would not have entered the market under any circumstances, the district court erred as by considering matters that arose only *after* the lawsuit had fundamentally changed the business landscape. The district court should have examined what Teva *would have done* had there been no litigation in the first place.

AbbVie's response brief largely sidesteps the question of how the dismissal of the reverse-payment allegations affected the court's analysis of the but-for world. Instead, it argues that the district court reasonably concluded that Teva would never have decided to launch under any circumstances. But that conclusion cannot be squared with Teva's internal planning documents, which clearly show that before the lawsuit Teva was planning to launch a generic version of AndroGel with or without an AB-rating. The district court did not take account of this evidence because it improperly focused on what Teva actually decided to do after the lawsuit settled and Teva had agreed to defer launching its product, not what Teva would have done if there had been no lawsuit at all.

Whether or not this Court reinstates the reverse-payment allegations, it should also remand for reconsideration of injunctive relief. AbbVie concedes that the district court did not apply the test set forth in *SEC v. Bonastia*, 614 F.2d 908 (3d Cir. 1980). Moreover, the district court did not properly consider the specific relief that the FTC requested in its post-trial proposed judgment. Each of these errors necessitates a remand.

ARGUMENT

I. THE DISTRICT COURT WRONGLY DISMISSED THE REVERSE-PAYMENT CLAIM, AND THE ERROR REQUIRES A REMAND.

Our opening brief showed that the complaint plausibly alleges a reverse-payment claim under *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). AbbVie offers two responses, both of which are meritless. First, AbbVie contradicts the complaint by arguing that the AndroGel settlement and the TriCor deal were completely separate and independent agreements. But the complaint's extensive factual allegations, which must be taken as true on a motion to dismiss, plausibly show that although the contracts were physically separate, they were inextricably linked, with the TriCor deal amounting to a large and unjustified payment to induce AbbVie to settle. Nothing more was required to state a claim. Second, AbbVie argues that the district court could not award any relief and that a remand would therefore be futile. AbbVie is wrong; if the district court finds on the merits that AbbVie restrained trade through an unlawful settlement agreement, it could

properly award both injunctive relief to prevent similar violations and equitable monetary relief to redress consumer injury.

A. The Complaint Plausibly Alleges an Unlawful Reverse-Payment Agreement.

AbbVie's first argument suffers from the same errors as the district court's analysis and cannot be reconciled with well-settled principles governing motions to dismiss for failure to state a claim.[1] AbbVie argues that the AndroGel settlement and the TriCor deal were completely separate, and that "viewed independently" both agreements were procompetitive. AbbVie Br. 89. But as our opening brief shows, the complaint includes numerous factual allegations supporting the inference that these agreements, negotiated at the same time and executed on the same day, were in fact two halves of a single *quid pro quo* arrangement. In effect, AbbVie agreed to confer a $175 million benefit on Teva via the TriCor deal in exchange for Teva's agreement to settle the AndroGel lawsuit and defer market entry. *See* Compl. ¶¶115, 119, 119-25, 132 (JA4442-45, 4447).

These allegations fit squarely within the framework this Court has laid out in reverse-payment cases. In *King Drug Co. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015), the Court held that any "unexplained large transfer of value from the patent holder to the alleged infringer" that is "likely to present the same

[1] AbbVie does not defend the district court's mistaken reliance on *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*, 555 U.S. 438 (2009).

types of problems" as a cash payment constitutes a reverse payment and may be unlawful under *Actavis*. *Id.* at 403-04. And *In re Lipitor Antitrust Litigation*, 868 F.3d 231 (3d Cir. 2017), makes clear that the payoff may involve a lucrative arrangement for a different product. *Id.* at 253-58. Applying these principles, the FTC adequately alleged a large and unjustified reverse payment.

AbbVie again repeats the district court's errors by asserting that the TriCor agreement and the AndroGel settlement were each independently procompetitive. But the complaint alleges that *taken together*, the two deals amounted to an anticompetitive reverse-payment scheme. And as *Lipitor* makes clear, the motion-to-dismiss stage is not the proper time to evaluate any potential procompetitive justifications for the arrangement. 868 F.3d at 257. Like the *Lipitor* plaintiffs, the FTC "sufficiently alleged the absence of a convincing justification for the reverse payment and w[as] not required to plead more than that." *Id*.

Unable to explain why the extensive factual allegations in the FTC's complaint do not plausibly allege a reverse payment, AbbVie points to the district court's statement in its trial opinion that "there is no evidence that [the TriCor] negotiations were linked to the AndroGel settlement." AbbVie Br. 87 (quoting Op. 24 n.7 (JA92)). But the FTC never had an opportunity to take discovery or present

evidence on that question due to the dismissal.[2] The question here is whether the reverse-payment claim was properly dismissed, and for that purpose the FTC's allegation that the two agreements were linked must be taken as true.

Finally, as discussed in our opening brief, *Continental Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690 (1962), and *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181 (3d Cir. 2005), broadly stand for the principles that an antitrust conspiracy consisting of multiple parts cannot simply be picked apart and analyzed piece-by-piece, but must be assessed as a whole based on its economic substance. *See Cont'l Ore*, 370 U.S. at 699; *Dentsply*, 399 F.3d at 189. AbbVie attempts to distinguish these cases on their facts, but does not dispute these fundamental principles. The district court's failure to properly apply these principles as part of the motion-to-dismiss analysis mandates reversal.

B. The District Court May Award an Injunction or Equitable Monetary Relief on Remand.

AbbVie argues that a remand of the reverse-payment claim would be futile because (in its view) the complaint did not allege reason to believe AbbVie "is violating, or is about to violate" the law, as required by Section 13(b) of the FTC Act, 15 U.S.C. §53(b). AbbVie Br. 91. AbbVie did not raise this argument in its

[2] Although the FTC did not appeal the order limiting discovery (ECF No. 79 (JA1)), it appealed the substantive order dismissing the reverse-payment claim. Absent the dismissal, the FTC would have been entitled to full discovery on the reverse-payment issues.

motion to dismiss, and it therefore is waived. *See, e.g.*, *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 335-36 (3d Cir. 2009). In any event, the argument is meritless.

AbbVie relies on this court's recent decision in *Shire*, but ignores the fundamental differences between that case and this. *Shire* held that Section 13(b) requires the FTC to plead that a defendant "is violating, or is about to violate" the law at the time of suit, a standard stricter than the one applied at the relief stage. *Shire*, 917 F.3d at 157-58. In *Shire*, the FTC's complaint did not allege an ongoing violation; the sole question was whether the FTC had adequately alleged that the defendant was "about to violate" the law. The court found the complaint inadequate on this score because the FTC did not file suit until five years after the illegal conduct ceased. *Id.* at 159-60.

This case, by contrast, involves misconduct that was *ongoing* at the time of suit. When the complaint was filed in September 2014, AbbVie and Teva were continuing to restrain trade through their anticompetitive reverse-payment agreement, which kept generics off the market through December 27, 2014. Unlike the situation in *Shire*, AbbVie was continuing to sell AndroGel (as it still does today). The complaint thus alleged that the defendants' "exclusionary conduct has denied, and *continues to deny*, patients the opportunity to purchase lower-cost versions of AndroGel, forcing patients and other purchasers to pay

hundreds of millions of dollars more for AndroGel." Compl. ¶143 (JA4451) (emphasis added).

AbbVie tries to make this case look like *Shire* by arguing that it has *now* been more than seven years since the reverse-payment agreement was signed. AbbVie Br. 92. But *Shir*e makes clear that courts must assess whether the pleading requirements of Section 13(b) are met "at the time [the FTC] files suit"—not years later while on appeal. *Shire*, 917 F.3d at 158.

AbbVie further asserts that (a) Section 13(b) does not authorize equitable monetary relief and (b) the reverse-payment agreement caused no monetary injury to consumers because the district court found that Teva would not have launched its product anyway. AbbVie Br. 92. The first argument is simply incorrect. As discussed below (at 87-94), every court of appeals to address this issue has held that Section 13(b) authorizes equitable monetary relief, and this result is compelled by binding decisions of the Supreme Court and this Court. As to the second, the error in dismissing the reverse-payment claim by itself calls for reconsideration of whether Teva would have entered the market, as we showed in our opening brief and discuss further immediately below. In any case, even if monetary relief were ultimately deemed unwarranted, the district court could still grant injunctive relief to prevent similar violations in the future. The question of injunctive relief is particularly pressing here because AbbVie is a serial violator, having previously

entered into reverse-payment settlement agreements with three other companies regarding generic AndroGel. Those were the very agreements at issue in *Actavis*, *see* 570 U.S. at 144-45. On remand, the court may properly take this evidence into account in deciding whether injunctive relief is warranted.

II. REMAND IS REQUIRED TO RECONSIDER WHETHER TEVA WOULD HAVE ENTERED THE MARKET ABSENT THE SHAM LAWSUIT AND REVERSE-PAYMENT SETTLEMENT.

Our opening brief showed that the district court's determination that Teva would not have launched an AndroGel generic in the "but-for world" must be reconsidered for two reasons. First, the district court's error in dismissing the FTC's reverse-payment allegations by itself requires reconsideration of the entire issue. The court could not properly assess whether Teva would have launched a non-AB rated generic absent the sham lawsuit without recognizing that AbbVie effectively paid Teva $175 million to delay its launch. Take away that payment, and Teva's incentives would have looked very different. Second, the district court erred by focusing on the factors that led Teva to abandon the AndroGel project in 2012—after the sham lawsuit and settlement had delayed any launch until the end of 2014. This was a legal error. The "but-for" analysis required the court to reconstruct the world as it *would have* existed absent the antitrust violation—not the world as it the world as it *actually* existed after the lawsuit and settlement had locked in the launch delay.

1. Effect of the Reverse-Payment Agreement. AbbVie asserts that the FTC "articulates no possible reason why or how the court's conclusion and factual findings would have been different" if the reverse-payment agreement were taken into consideration. AbbVie Br. 100-01. But it defies economic logic and common sense to suggest that a gigantic payment to stay out of the AndroGel market for three years had no effect on Teva's decision not to enter that market. The whole point of the agreement was to keep Teva from launching generic AndroGel. Again, the district court's dismissal prevented the FTC from taking discovery or presenting evidence on this issue.

AbbVie also points to testimony from Teva employee Maureen Cavanaugh that her recommendation to cancel the AndroGel generic in 2012 would have been the same if there been no patent litigation settlement. AbbVie Br. 101. As a starting point, Cavanaugh was no neutral third-party witness. She works for Teva, which participated in a conspiracy to restrain trade by entering into the reverse-payment agreement and had been named as a defendant on the reverse-payment claim. She therefore had an obvious incentive to downplay the effect of the payoff on her employer's conduct. A witness's potential bias bears directly "on the accuracy and truth of [her] testimony." *United States v. Abel*, 469 U.S. 45, 52 (1984). The district court's refusal to consider the reverse-payment agreement prevented it from hearing evidence that would have uncovered this source of bias.

Compounding that error, the district court prevented the FTC from asking Cavanaugh about the effect of the reverse-payment agreement. The FTC sought to establish through Cavanaugh "that Teva got more than just a license entry date. Teva got access to generic sales of a product that they would not otherwise have been able to sell [*i.e.*, TriCor]." Tr. 3:89 (JA3624). But the court did not allow this line of inquiry. Tr. 3:90 (JA3624).

2. Failure to Properly Reconstruct the But-For World. AbbVie does not dispute that the relevant question before the district court was what Teva *would have done* if it had not been sued in 2011. But AbbVie identifies nothing showing that the district court ever attempted to answer that question. Instead, AbbVie (like the district court), relies almost entirely on Cavanaugh's testimony about why she recommended killing the AndroGel project in 2012, *after* the settlement had blocked Teva from launching before December 2014. That testimony says nothing about what Teva would have done in 2011 if it had never been sued.

Rather than addressing the district court's failure to conduct the proper legal inquiry, AbbVie quibbles about the standard of proof the FTC was required to meet. It argues that the "reasonable approximation" standard set forth in *SEC v. Teo*, 746 F.3d 90 (3d Cir. 2014), applies only to measuring the amount of unlawful profits and not to determining whether any such profits exist. AbbVie Br. 96. *Teo* itself refutes this argument. Like AbbVie, the defendant in *Teo* argued that there

were no illegal profits because intervening events broke the chain of causation. *Teo*, 746 F.3d at 101, 107. But the Court explained that "intervening causation is not an element of the [government's] evidentiary burden in setting out an amount to be disgorged that reasonably approximates illegal profits"; it is part of the defendant's burden. *Id.* at 105-06. And it held that the SEC's evidence "presumptively demonstrated a reasonable approximation" of the tainted profits. *Id.* at 107. Thus, *Teo* makes clear that reasonable approximation is the correct standard, even where (as here) the defendant argues there were no illegal profits. This makes sense because it is impossible to definitively establish what would have happened in the "but-for world" (which by its nature is a hypothetical construct). A "just and reasonable inference" is the best any litigant can do. *Behrend v. Comcast Corp.*, 655 F.3d 182, 203 (3d Cir. 2011), *rev'd on other grounds*, 569 U.S. 27 (2013).

AbbVie also argues that the monetary relief calculation may not be based on "pure speculation." AbbVie Br. 97. The FTC is relying not on speculation, but on reasonable inferences drawn from Teva's business documents (as well as internal AbbVie documents showing it was thinking along the same lines). As discussed in our opening brief, before the lawsuit Teva was in discussions with its manufacturing partner, Cipla, for production of its AndroGel generic, and it worked out a schedule that called for shipment of the finished drugs by "May/June

2012." PLX018-006 (JA626). Based on that schedule, the FTC's economic expert reasonably opined that absent a lawsuit Teva would have launched by June 2012. The reasonableness of this assessment is confirmed by an AbbVie internal document stating that a Teva launch by April 2012 was the "most likely scenario." PLX030-001 (JA682).

AbbVie tries to muddy the waters by pointing to a different document from Teva executive Tim Crew stating that Teva expected to launch the product in 2013. PLX021-001 (JA627). But that document was prepared in August 2011—*after* Teva was sued and the Hatch-Waxman stay kicked in, forcing the projected launch back to October 2013. Even then, Crew was confident that Teva would eventually launch its product despite the fact that "we do not expect a generic 'AB' rating." *Id.* The fact that Teva still expected a launch—despite the reduction in anticipated sales resulting from the delay—is further evidenced by the inclusion of a non-AB rated AndroGel substitute in the company's formal "work plan." PLX318-004; Tr. 3:73-76, 86 (JA1746, 3620, 3623).[3] AbbVie does not cite a single document created before the settlement in which anyone at Teva expressed any doubt that the company would launch an AndroGel generic.

[3] AbbVie erroneously asserts that the work plan represents a "pre-lawsuit projection." AbbVie Br. 99. The figures for the 2012 work plan came from projections dated May 26, 2011, after the lawsuit was filed. PLX035 (JA714-45).

Instead, AbbVie simply repeats the district court's analytical error. It assumes that absent the sham lawsuit, Teva would have made its decision on the same timeline that it did in the real world, and that the same "intervening" management and business factors would have led to the same decision. The basic flaw in that approach is that the sham litigation and resulting settlement put the project on a later timeline, allowed AbbVie to shift the market to the 1.62% product, slashed Teva's generic AndroGel sales projections, and fundamentally altered its financial incentives.

For example, AbbVie asserts Teva—one of the world's largest and most sophisticated generic manufacturers—could never have obtained approval for a pump form of AndroGel or reached a final manufacturing agreement with Cipla because it did not do those things in the real world.[4] Aside from their implausibility, these arguments ignore the fact that Teva had no immediate need to proceed with seeking approval for a pump or finalizing arrangements with Cipla once the lawsuit and settlement delayed the launch date.

[4] Contrary to AbbVie's assertion, Teva was not "forced" to withdraw the pump, nor did the FDA make a "decision not to approve" the pump. AbbVie Br. 94, 98. Teva voluntarily withdrew the pump to expedite processing of its NDA, on the understanding that it would resubmit the pump as a post-approval supplement. DX047-001 (JA1988). Teva accounted for the delay in pump approval in its financial projections. PLX035-020 (JA732).

The same analytical error demonstrates why Cavanaugh's testimony is not a reliable basis for assessing what Teva would have done if it had never been sued. While Cavanaugh testified that she recommended against continuing with the AndroGel project in late 2012 after Alan Oberman became CEO of Teva, there is no evidence that she (or anyone else at Teva) ever expressed any reservations about the project before the lawsuit or the settlement. To the contrary, the evidence showed that Teva senior executive Tim Crew, who was Cavanaugh's superior, was strongly committed to the project. Op. 85 (JA153). AbbVie acknowledges as much, noting that Cavanaugh described generic AndroGel as Crew's "pet project" and asserting that it was his departure in late 2012 that "sealed the project's fate." AbbVie Br. 98 n.11. Between April 2011 and the settlement, however, Crew was still in charge, and nothing indicates that his support for the AndroGel project ever wavered. Had the court properly focused on what Teva would have done in that time frame rather than what it actually did post-settlement, it could not have reached the conclusion it did.

III. REMAND IS REQUIRED FOR RECONSIDERATION OF INJUNCTIVE RELIEF UNDER THE PROPER STANDARD.

Our opening brief showed that the district court abused its discretion in denying injunctive relief by failing to apply the correct legal standard for assessing likelihood of recurrence, mischaracterizing the relief that the FTC requested, and

failing to address the specific relief that the FTC actually requested. AbbVie's arguments to the contrary are unavailing.

A. Failure To Apply the Proper Legal Standard Is an Abuse of Discretion.

The parties agree that the proper test for issuance of an injunction is whether there is a "cognizable danger of recurrent violation" (also referred to as the "likelihood-of-recurrence test"). *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *Shire*, 917 F.3d at 158. In *SEC v. Bonastia*, 614 F.2d 908 (3d Cir. 1980), this Court explained that this test requires a court to "make[] a prediction of the likelihood of future violations based on an assessment of the totality of the circumstances surrounding the particular defendant and the past violations that were committed." *Id.* at 912. It identified five specific factors to look at as part of this test. *Id.*; *see also FTC v. Accusearch Inc.*, 570 F.3d 1187, 1201 (10th Cir. 2009) (considering similar factors). The Court reversed the district court's denial of an injunction because it "failed to evaluate" all of these factors, which were "essential to a proper determination." *Bonastia*, 614 F.2d at 913.

AbbVie concedes that the district court did not apply the *Bonastia* factors, but argues that it was not "required to do so." AbbVie Br. 102. But the failure to apply the proper legal framework for making a decision is a classic abuse of discretion. For example, in *In re Cendant Corp. PRIDES Litigation*, 235 F.3d 176 (3d Cir. 2000), the district court did not consider the factors relevant to a totality-

of-the-circumstances inquiry in connection with an "excusable neglect" determination. This Court held that "the District Court should properly have entertained an analysis of [these] factors" and that its failure to do so was an abuse of discretion. *Id.* at 182; *see also Bonastia*, 614 F.2d at 913 ("When a district court refuses to apply well-settled legal precepts to a conceded set of facts, it acts outside its allowable discretion.").

AbbVie also asserts that an injunction is not warranted under the *Bonastia* factors. AbbVie Br. 103. Application of the factors is a job for the district court in the first instance, not this Court. In any event, AbbVie's arguments lack merit. AbbVie simply ignores the first *Bonastia* factor ("the degree of scienter involved on the part of the defendant"), even though, as the Supreme Court has emphasized, "the degree of intentional wrongdoing evident in a defendant's past conduct" is an "important factor" in assessing likelihood of recurrence. *Aaron v. SEC*, 446 U.S. 680, 701 (1980). AbbVie and Besins's intentional disregard for antitrust laws strongly weighs in favor of injunctive relief.

As to the second factor ("the isolated or recurrent nature of the violation"), AbbVie cannot and does not dispute that this case involves two separate sham lawsuits. Moreover, in another sham litigation case arising out of Hatch-Waxman litigation, the district court held that AbbVie's arguments in the underlying infringement case were "nonsensical" and "exceeded all reasonable interpretations

of the major tenets of claim construction." *Teva Pharm. USA, Inc. v. Abbott Labs.*, 580 F. Supp. 2d 345, 364-65 (D. Del. 2008). AbbVie tries to downplay this case, but ignores the relevant holdings, which show that AbbVie's misconduct here is part of a larger pattern.

As to the third and fourth factors, AbbVie does not dispute that defendants have neither "recogni[zed] the wrongful nature of [their] conduct" nor given any "assurances"—sincere or otherwise—"against future violations." *Bonastia*, 614 F.2d at 912. AbbVie argues that those two factors alone do not warrant injunctive relief (AbbVie Br. 104), but they are part of the *Bonastia* calculus, and the district court could not simply ignore them.

AbbVie ignores the fifth *Bonastia* factor, which is "the likelihood, because of defendant[s'] professional occupation, that future violations might occur." *Bonastia*, 614 F.2d at 912. As shown in our opening brief, both defendants are still in the pharmaceutical business and continue to regularly engage in Hatch-Waxman litigation. All told, the *Bonastia* factors demonstrate a cognizable danger of recurrence justifying an injunction.

B. The Court Did Not Address the Specific Relief the FTC Requested.

The district court also mischaracterized the relief that the FTC was seeking when it stated that the FTC sought "to prohibit defendants from engaging in any action that misuses the government process for anticompetitive purposes." Op. 98

(JA166). That language appeared in the FTC's pretrial brief but was dropped from its final proposed post-trial order. ECF No. 403-1, at 3. The district court erred by failing to consider the requests the FTC made in its post-trial submissions.[5]

In that proposed order, the FTC requested (1) a prohibition on suing under the '894 patent against products that do not contain isopropyl myristate, (2) a broader prohibition on filing any objectively baseless patent litigation to interfere with a generic product, and (3) a requirement that a corporate executive certify that patent infringement lawsuits against generic products are objectively reasonable. ECF No. 403-1, at 3. AbbVie argues that the district court "specifically considered" these requests. AbbVie Br. 105. It did not. The court simply stated generally that it was "concerned that the injunction sought by the FTC is overbroad and punitive in nature," without discussing whether any specific aspect of the relief could be imposed. Op. 100 (JA168). Moreover, the court's concern was almost certainly tainted by its mistaken belief that the FTC was seeking a sweeping injunction against *any* misuse of government processes.

And as explained in our opening brief, the district court's generalized First Amendment concerns are not germane to the specific requests the FTC actually made. The First Amendment does not protect sham litigation, which is the only

[5] Contrary to AbbVie's assertion, the FTC did not "adhere to" the pretrial request in its post-trial brief. It merely referenced the prior discussion of legal standards.

type of conduct the proposed order would prohibit. *See, e.g.*, *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 148 (3d Cir. 2017). Nor does AbbVie assert that a certification requirement poses any First Amendment issue. Instead, it simply asserts that the relief is "overbroad" because the FTC did not prove that AbbVie and Besins have engaged in sham litigation with respect to any other patent. AbbVie Br. 106. But the FTC "is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past"; a defendant who has been "caught violating the [FTC] Act … must expect some fencing in." *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 395 (1965). Here the proposed relief is narrowly tailored to the precise type of conduct at issue: sham patent litigation to block generic competition in pharmaceutical markets, which is well within the type of fencing-in relief courts have historically allowed. Because the district court did not adequately explain its decision to deny the FTC any injunctive relief, a remand is required.

CONCLUSION

The dismissal of the reverse-payment claim should be reversed and the case remanded for further proceedings as set forth above.

RESPONSE TO CROSS-APPEALS

ISSUES PRESENTED

The cross-appeals raise the following issues:

1. Did the district court properly determine on summary judgment that the underlying patent infringement suits against Teva and Perrigo were objectively baseless?

2. Did the district court properly find at trial that both AbbVie and Besins acted with the intent to use the legal process to interfere with competition?

3. Did the district court properly find at trial that AbbVie possessed monopoly power in the market for transdermal testosterone products?

4. Did the district court properly award equitable monetary relief against AbbVie and Besins?

COUNTERSTATEMENT OF THE CASE

The FTC incorporates by reference its Statement of the Case from its opening brief. Additional facts relevant to particular issues are set forth as necessary in the Argument.

SUMMARY OF ARGUMENT

AbbVie and Besins take a kitchen-sink approach to their appeals, contesting virtually every aspect of the district court's decision (and raising a few issues they did not present below). Many of their arguments involve not legal issues but

factual challenges, asking this Court to reweigh the evidence and reach a different conclusion than the lower court did after trial. AbbVie and Besins provide no basis for disturbing the district court's careful factual findings, rendered in a 102-page opinion after a complex 16-day trial with numerous fact and expert witnesses on both sides and more than 300 exhibits. Nor have they identified any legal error that would warrant reversal of the judgment.

1. The district court correctly applied the two-part test of *Professional Real Estate Investors v. Columbia Pictures Industries*, 508 U.S. 49 (1993) ("*PRE*"), to determine that the patent infringement lawsuits against Teva and Perrigo were shams beyond the protection of the First Amendment. The court properly ruled on summary judgment that the first part of this test was satisfied because the lawsuits were objectively baseless—no reasonable litigant could have realistically expected to succeed on the merits.

Any reasonable litigant would have understood that Teva's and Perrigo's products did not infringe the AndroGel patent. By its terms, the patent only covered testosterone gel formulation containing specified amounts of isopropyl myristate—a "penetration enhancer" that facilitates absorption of testosterone through the skin. Teva and Perrigo used different penetration enhancers. AbbVie and Besins's original patent application had claimed formulations using any penetration enhancer, but after the examiner rejected that broad claim, they

abandoned it in favor of much narrower claims limited to formulations containing isopropyl myristate in specific amounts. Under the well-established doctrine of "prosecution history estoppel," by narrowing their claims in this manner, AbbVie and Besins surrendered any claim to formulations using different penetration enhancers, like Teva's and Perrigo's products. As the district court held, on this record there is no reasonable basis for escaping the application of prosecution history estoppel.

AbbVie argues that if the infringement lawsuits were meritless, Teva and Perrigo would not have agreed to settle. But the settlements have no bearing on the question of objective baselessness under *PRE*. As the district court recognized, parties routinely settle litigation for reasons unrelated to the merits. Here, both companies had financial incentives to settle. Teva got paid $175 million through the TriCor deal to settle, while Perrigo got the right to launch generic AndroGel at the same time as Teva.

2. After hearing the evidence at the 16-day trial, the district court properly found that the FTC had also proven the second part of the *PRE* test, which asks whether the baseless lawsuit was filed with the intent to use the litigation process itself—as opposed to the outcome of that process—as an anticompetitive weapon. *PRE*, 508 U.S. at 60-61. The court found that the "only reason for filing the infringement suits was to impose expense and delay on Teva and Perrigo so as

to block their entry into the market with lower price generics and to delay defendants' impending loss of hundreds of millions of dollars in AndroGel sales and profits." Op. 52-53 (JA120-21).

That finding was not clearly erroneous. Because the Hatch-Waxman Act allows a patent holder to block competitors from the market for up to 30 months, win or lose, filing a baseless Hatch-Waxman case gives rise to an inference of anticompetitive intent. The 30-month stay makes an infringement lawsuit *economically* viable, even if it is not *legally* viable. And that inference was bolstered here by record evidence showing that the in-house lawyers who made the decision to sue were experienced patent attorneys who were well aware of the relevant facts and law (and had been explicitly warned that a suit against Perrigo would be a sham), as well as the huge financial success of AndroGel and the devastating impact that generics would have on its sales. The district court reasonably concluded that they filed a Hatch-Waxman lawsuit simply to preserve this lucrative franchise.

3. The district court found that from 2011 to 2014, AbbVie had monopoly power in the market consisting of transdermal testosterone replacement therapies. That finding was not clearly erroneous. The court properly defined the market to include transdermal testosterone products but not injectable forms of testosterone. The distinctions between injectables and transdermals are obvious

and suggest on their face that the two products belong in different markets. Injectables require a painful shot in the thigh or buttocks, which is typically administered in a doctor's office or clinic, while transdermals are painlessly applied at home. The evidence showed little cross-elasticity of demand between the transdermal and injectable products, meaning that a change in the price of one did not significantly affect demand for the other. That conclusion is reinforced by AbbVie's business documents and the testimony of its executives showing that they did not consider injectables to be significant competitors to AndroGel.

The district court also properly found as fact that AbbVie had monopoly power within the transdermal market. Its market share consistently remained over 60% from 2011 through generic entry at the end of 2014, which by itself raises a strong inference of market power. Although new competitors entered the market, none of them came close to AbbVie's market share, and AbbVie was able to maintain its profit margin and increase prices despite the new entrants. The court also correctly concluded that there were significant barriers to entry, including the difficult process of developing a pharmaceutical product, gaining regulatory approval for it, and marketing it to doctors. The fact that a few products entered the market and made minor inroads does not disprove AbbVie's market power.

4. The district court properly awarded equitable monetary relief. Every court of appeals to have considered the issue has held that Section 13(b) of the

FTC Act, 15 U.S.C. §53(b), authorizes such relief. This Court ruled as much in an unpublished decision under the FTC Act, and it similarly ruled that equitable monetary relief is available under a statute directly analogous to Section 13(b). *United States v. Lane Labs-USA, Inc.*, 427 F.3d 219 (3d Cir. 2005). As the Court recognized there, its decision was effectively compelled by the Supreme Court's rulings in *Porter v. Warner Holding Co.*, 328 U.S. 395 (1946), and *Mitchell v. Robert DeMario Jewelry, Inc*., 361 U.S. 288 (1960).

AbbVie is wrong that *Kokesh v. SEC*, 137 S. Ct. 1635 (2017), a case that dealt with the application of a statute of limitations, silently upended this decades-old body of settled law. Indeed, the Court expressly disclaimed any such intention. AbbVie is also wrong that this Court's ruling in *Shire* precludes monetary relief. *Shire* deals with the standard for pleading a claim, and AbbVie and Besins waived any challenged to the adequacy of the FTC's pleadings by failing to raise the argument below. In any event *Shire* involved unlawful conduct that had stopped years before the FTC filed suit, whereas here AbbVie and Besins were still illegally restraining trade and maintaining their monopoly at the time the FTC filed suit.

Nor does the district court's denial of injunctive relief preclude an award of monetary relief. For one thing, the district court should not have denied an injunction, but even so the law is clear that once the door of equity is open, the

district court retains the power to afford whatever relief is appropriate. The district court did not abuse its discretion in determining that, absent the sham litigation, Perrigo would have launched its product by June 2013. AbbVie has provided no basis to second-guess the court's assessment of the evidence on that issue. Finally, the district court properly held Besins liable for monetary relief. Besins acted jointly with AbbVie in filing the sham lawsuits and caused an indivisible harm that made the two companies jointly and severally liable. The court properly attributed a portion of the financial judgment to Besins.

ARGUMENT

I. THE DISTRICT COURT PROPERLY DETERMINED THAT THE PATENT INFRINGEMENT LAWSUITS AGAINST TEVA AND PERRIGO WERE OBJECTIVELY BASELESS.

A major theme of AbbVie's brief is that the First Amendment protected the lawsuits against Teva and Perrigo. But as this Court has made clear, "[a]ctivity ostensibly directed toward influencing governmental action does not qualify for first amendment immunity if it is a mere sham to cover an attempt to interfere directly with the business relationships of a competitor." *Wellbutrin*, 868 F.3d at 148 (cleaned up). The district court properly held that the patent lawsuits were beyond the protection of the First Amendment because they were shams.

The Supreme Court has established a two-part test for determining whether litigation is a sham. First, the lawsuit must be "objectively baseless in the sense

that no reasonable litigant could realistically expect success on the merits." *PRE*, 508 U.S. at 60. Second, the baseless lawsuit must "conceal[] an attempt to interfere *directly* with the business relationships of a competitor through the use of the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *Id.* at 60-61 (cleaned up). We address the first *PRE* inquiry in this section and the second in Part II below.

The district court determined on summary judgment that the patent infringement lawsuits against both Teva and Perrigo were objectively baseless. It concluded that "without question" the prosecution history of the '894 patent showed that AbbVie and Besins "could not realistically have expected success on the merits" of their claims against Teva and Perrigo or "have had a reasonable belief that they had a chance to prevail." MSJ Op. 31 (JA63).

That conclusion was correct and should be affirmed. By its terms, the '894 patent covers only testosterone gel formulations containing specified amounts of isopropyl myristate—a "penetration enhancer" that facilitates drug delivery through the skin. Neither Teva's product nor Perrigo's product contained that ingredient; Teva used isopropyl palmitate and Perrigo used isostearic acid. To prevail on their infringement claims, AbbVie and Besins had to show that these substances were "equivalent" to isopropyl myristate under patent law. But the public prosecution history of the patent unambiguously shows that AbbVie and

Besins surrendered any claim to formulations using isopropyl palmitate or isostearic acid. The well-established doctrine of "prosecution history estoppel" thus barred AbbVie and Besins from claiming that these substances were equivalent to isopropyl myristate. The principles governing this doctrine were set forth in detail by the Supreme Court in its 2002 *Festo* decision and by the Federal Circuit in its *en banc* decision on remand, *see Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), *on remand*, 344 F.3d 1359 (Fed. Cir. 2003) (en banc), and have consistently been applied in dozens of cases since then. In light of this case law, no reasonable litigant could have believed there was a viable infringement claim against Teva or Perrigo.

A. Standard of Review

The grant of partial summary judgment is reviewed *de novo*. *See, e.g.*, *Morgan v. Covington Twp.*, 648 F.3d 172, 177 (3d Cir. 2011).

B. The Prosecution History

AbbVie omits many key details from the prosecution history of the '894 patent. AbbVie Br. 9-11. We provide the full history below.

1. The original application

A patent application contains both a written description, which explains the invention, and claims, which define the precise scope of what is being patented. *See* 35 U.S.C. §112. Claim 1 of the original patent application broadly covered transdermal pharmaceutical products containing *any* "penetration enhancer."

PLX051-078 (JA909). The accompanying written description listed various classes of substances that could serve as penetration enhancers and several specific examples within each class—including "lower alkyl esters of C8-C22 fatty acids such as ethyl oleate, isopropyl myristate, butyl stearate, and methyl laurate" and "C8-C22 fatty acids such as isostearic acid, octanoic acid, and oleic acid." PLX051-030 (JA861).[6] This description encompassed both Teva's and Perrigo's enhancers: isostearic acid (Perrigo's) was listed explicitly, and isopropyl palmitate (Teva's) is a lower alkyl ester of a C8-C22 fatty acid. *See* ECF No. 262 at 41.

2. Obviousness rejection

The patent examiner rejected all the original claims as obvious, meaning that the various elements of the invention were already known in the "prior art" and that the idea of combining them would have been obvious to a person of ordinary skill in the art. PLX052-006 to -008 (JA1014-16); *see generally* 35 U.S.C. §103; *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 415-18 (2007). Among other things, the examiner cited two international patent applications known as "Mak" and "Allen" (after the inventors' names). PLX052-006 to -007 (JA1014-15). Mak disclosed a pharmaceutical composition for the transdermal delivery of testosterone using oleic acid as a penetration enhancer; Allen disclosed a

[6] An ester is an organic compound usually derived from a carboxylic acid and an alcohol. The "C" refers to the number of carbon atoms in the molecular backbone of the acid.

pharmaceutical cream using a penetration enhancer and identified both isopropyl myristate and isopropyl palmitate as "preferred" penetration enhancers. ECF No. 241-13 at 20; ECF No. 241-14, at 9 (JA309, 328). The examiner explained that "since all composition components herein are known to be useful for the percutaneous delivery of pharmaceuticals, it is considered prima facie obvious to combine them into a single composition useful for the very same purpose." PLX052-008 (JA1016).

3. October 2001 amendment

AbbVie and Besins responded to the rejection by substantially narrowing the scope of Claim 1, requiring that the penetration enhancer be selected from a group of 24 specific compounds or classes of compounds. PLX053-003 (JA1020). The 24-member group did not include *all* "lower alkyl esters of C8-C22 fatty acids." Instead, it included only the four specific members of this class identified in the written description: ethyl oleate, isopropyl myristate, butyl stearate, and methyl laurate. This had the effect of excluding isopropyl palmitate, which was one of the enhancers disclosed in Allen. Similarly, the 24-member group did not include *all* "C8-C22" fatty acids. Instead, it listed two specific members of this class: isostearic acid and octanoic acid (but not oleic acid, which was disclosed in Mak). In short, as a result of these changes, the amended claim still covered formulations

using isopropyl myristate and isostearic acid as penetration enhancers, but not formulations using isopropyl palmitate or oleic acid.

As part of the same October 2001 amendment, AbbVie and Besins also added two new claims (Claims 61 and 62) that were even narrower. These claims required the use of one specific enhancer—isopropyl myristate—in specified amounts. PLX053-007 (JA1024). Thus they did not literally cover any products like Teva's and Perrigo's, which used different penetration enhancers in lieu of isopropyl myristate.

In accompanying remarks, AbbVie and Besins argued that the amendments and new claims were sufficient to overcome the obviousness rejection. PLX053-012 to -022 (JA1029-39). Additionally, they argued that the commercial success of AndroGel was a "secondary consideration" supporting a finding of non-obviousness. PLX053-020 to -022 (JA1037-39); *see generally KSR*, 550 U.S. at 406. In support of that argument, they submitted a declaration showing that the sales growth of AndroGel greatly exceeded other testosterone products. PLX053-028 to -031 (JA1045-48).

4. Interview with examiner

After meeting with the applicants' patent prosecution lawyer, the patent examiner concluded that Claims 61 and 62—which required isopropyl myristate in specific amounts—were "allowable over the prior art." PLX056-001 (JA1084).

The lawyer explained in a contemporaneous e-mail that the examiner was willing to "allow composition claims directed to the AndroGel composition, i.e., focused on isopropyl myristate." PLX001-001 (JA587). But the examiner did not withdraw the objection to the broader claims that permitted use of other enhancers.

5. Supplemental amendments and patent issuance

Following the interview, AbbVie and Besins filed supplemental amendments in December 2001 and February 2002 cancelling Claim 1 entirely and narrowing the remaining claims to require the use of isopropyl myristate in specific amounts, consistent with the examiner's advice as to what was allowable. PLX057; PLX059 (JA1087-92, 1117-26). With each amendment, AbbVie and Besins requested "reconsideration and withdrawal of the outstanding rejections." PLX057-010; PLX059-028 (JA1095, 1129).

With the claims thus limited, the examiner eventually allowed the patent to issue. PLX060-001 (JA1150). She explained that "[t]he claimed pharmaceutical composition consisting essentially of the particular ingredients herein in the specific amounts, is not seen to be taught or fairly suggested by the prior art." PLX060-003 (JA1152). The amendments "all together" were "sufficient to remove the prior art rejection." *Id.*

C. Under the Well-Established Legal Principles Governing Prosecution History Estoppel, the Infringement Lawsuits Were Objectively Baseless.

The question before the district court was whether, based on the undisputed prosecution history, AbbVie and Besins had an objectively reasonable basis for their infringement lawsuits. It is undisputed that Teva's and Perrigo's products did not *literally* infringe the '894 patent because they did not contain isopropyl myristate. *See, e.g.*, *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995) ("To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly."). Instead, AbbVie and Besins relied on the "doctrine of equivalents," which extends a patent's scope to cover "insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." *Festo*, 535 U.S. at 733.

But the doctrine of equivalents is limited by a rule known as "prosecution history estoppel." Where a patent application originally claimed a broad subject matter, but the applicant later narrowed the claims for "a substantial reason related to patentability," the patentee "may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent." *Festo*, 535 U.S. at 733-34, 735 (cleaned up). This

ensures that the patentee cannot "recapture in an infringement action the very subject matter surrendered as a condition of receiving the patent." *Id.* at 734.

That is exactly what AbbVie and Besins sought to do in their infringement action. They originally filed a very broad claim that would have covered testosterone gels using isopropyl palmitate or isostearic acid (or millions of other substances) as penetration enhancers, but after that claim was rejected, they adopted a series of narrowing amendments, ultimately limiting their claims to formulations containing isopropyl myristate in specified amounts. Based on well-established legal rules set forth by the Supreme Court and the Federal Circuit, the district court correctly held that prosecution history estoppel barred the infringement claims and that no reasonable litigant could have believed otherwise. MSJ Op. 30-31 (JA62-63).

1. The Court properly held that the Teva lawsuit was objectively baseless.

As the district court held, determining whether prosecution history estoppel applies is a three-step inquiry. MSJ Op. 16 (JA48). First, a court asks whether an amendment "narrowed the literal scope of a claim." *Festo*, 344 F.3d at 1366. That is not in dispute here; AbbVie concedes that the October 2001 amendment narrowed the literal scope of the claims and in so doing excluded isopropyl palmitate. AbbVie Br. 37; *see also* ECF No. 256 at 10 (conceding that

"[i]sopropyl palmitate was … part of the 'territory' implicated by the October 2001 amendment").

The second question is whether "the reason for [the] amendment was a substantial one relating to patentability." *Festo*, 344 F.3d at 1366. AbbVie does not dispute that the October 2001 amendment, which responded to the examiner's rejection, meets this test.

The third question is the scope of the subject matter surrendered. *Id.* at 1367. The Supreme Court has instructed courts to "presume that the patentee surrendered all subject matter between the broader and the narrower language," unless the patentee rebuts that presumption by showing, *inter alia*, that the rationale for the amendment "bear[s] no more than a tangential relation to the equivalent in question." *Festo*, 535 U.S. at 740. The patentee bears the burden of showing that the "the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Festo*, 344 F.3d at 1369.

AbbVie's only argument that the Teva lawsuit was not objectively baseless is premised on this tangentiality exception, which is "very narrow." *Cross Med. Prods. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1342 (Fed. Cir. 2007). Specifically, AbbVie contends that there was a reasonable basis to argue that the sole purpose of the October 2001 amendment was to distinguish oleic acid—the specific penetration enhancer disclosed in Mak—and that the exclusion of

isopropyl palmitate was merely peripheral to that goal. As the district court correctly held, no reasonable litigant in AbbVie and Besins's shoes realistically could have expected to succeed on this argument. MSJ Op. 21-24 (JA53-56).

AbbVie's tangentiality argument fails for several independent reasons.

a. The fact that Allen disclosed isopropyl palmitate precludes a tangentiality finding. As the district court correctly noted, Mak was not the only prior art reference AbbVie and Besins needed to overcome. MSJ Op. 21 (JA53). The examiner also cited Allen, which specifically identified isopropyl palmitate as a "preferred penetration enhancer[]" in a pharmaceutical cream. ECF No. 241-14, at 9 (JA328). That fact, by itself, is fatal to AbbVie's argument.

In *Festo*, the Federal Circuit held *en banc* that "an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim." 344 F.3d at 1369. It has reiterated this fundamental principle many times.[7] Since Allen was cited by both the examiner and the applicants (PLX052-006 to -007; PLX053-017 (JA1014-15, 1034)), and it

[7] *See, e.g., Felix v. Am. Honda Motor Co.*, 562 F.3d 1167, 1184 (Fed. Cir. 2009); *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1383 (Fed. Cir. 2005); *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1357 (Fed. Cir. 2003).

specifically discloses isopropyl palmitate, as a matter of law isopropyl palmitate was not tangential. No reasonable litigant could have believed otherwise.[8]

AbbVie argues that the exclusion of isopropyl palmitate was tangential because the examiner and the applicants did not specifically discuss it, focusing instead on the differences between isopropyl myristate and oleic acid. AbbVie Br. 38. But AbbVie and Besins had no reason to discuss isopropyl palmitate; they focused on isopropyl myristate because that was the enhancer used in AndroGel. AbbVie is trying to flip the *Festo* presumption and escape its burden, arguing that since the examiner and applicants did not specifically mention isopropyl palmitate they could not have meant to exclude it. But the law is just the reverse: the applicants are presumed to have surrendered "all subject matter" between the original and amended claim, regardless of whether the subject matter was specifically discussed. *Festo*, 535 U.S. at 740. The patent owner must prove tangentiality—and AbbVie and Besins could not meet that burden here because Allen specifically disclosed isopropyl palmitate.

b. The oleic acid rationale does not explain the entire amendment. Even if the prior art did not specifically identify isopropyl palmitate, AbbVie's

[8] While Allen also disclosed isopropyl myristate as a preferred enhancer, AbbVie and Besins avoided that problem by limiting their claim to isopropyl myristate in a particular concentration and pointing to the commercial success of AndroGel as evidence of nonobviousness.

tangentiality argument would not pass the reasonableness test. To meet the patentee's burden for the tangentiality exception, the asserted rationale must "explain the entire amendment." *Felix v. Am. Honda Motor Co.*, 562 F.3d 1167, 1184 (Fed. Cir. 2009). Here, AbbVie's oleic acid rationale does not explain the entire amendment, which did much more than simply exclude oleic acid. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293 (Fed. Cir. 2006), rejected an argument nearly identical to AbbVie's. That case involved a patent on a synthetic version of the hormone erythropoietin (EPO). The claims had been amended during prosecution to require the product to have a particular sequence of 166 amino acids found in humans. The patentee argued that the purpose of the amendment was simply to limit the claims to human (as opposed to monkey) EPO and that the amendment therefore was tangential to an alleged equivalent containing only 165 amino acids. The Federal Circuit disagreed, holding that "if the patentee had wished only to limit the claims to human EPO, the patentee could have done so by continuing to use the adjective 'human'" in the amendment, but instead "chose to further narrow the claims … by making reference to [a] specific sequence." *Id.* at 1315.

The same reasoning applies here. As the district court correctly noted, "[i]f AbbVie and Besins merely sought to relinquish oleic acid and no other penetration enhancer in October 2001, they easily could have said so." MSJ Op. 21 (JA53).

For example, they could easily have kept the entire class of "lower alkyl esters of C8-C22 fatty acids" in the group of 24 potential penetration enhancers, thereby keeping isopropyl palmitate within the claim scope The fact that they further limited the group of permitted penetration enhancers shows that the intent of the amendment was *not* simply to distinguish oleic acid.

c. Viewing the prosecution history as a whole, it is clear that the applicants intended to do more than distinguish oleic acid. The October 2001 amendment to Claim 1 cannot be viewed in isolation. As the district court held, the law is clear that "[t]he prosecution history must be examined as a whole in determining whether estoppel applies." *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 867 (Fed. Cir. 1993); MSJ Op. 16 (JA48). AbbVie and Besins progressively narrowed the scope of the claims through a series of amendments, going from formulations containing *any* penetration enhancer to those containing an enhancer selected from the 24-member group, and then to just formulations containing isopropyl myristate in specified amounts. Even if the October 2001 amendment had not excluded isopropyl palmitate, the later amendments would have.

Viewing the prosecution history as a whole rather than as a series of discrete and unrelated steps, it is clear that the purpose of these serial amendments cannot have been simply to distinguish oleic acid. If that had been AbbVie's sole goal,

there would have been no reason to add Claims 61 and 62 in the first place. Furthermore, the December 2001 and February 2002 amendments plainly could not have been intended to distinguish oleic acid, which (as AbbVie concedes) had already been excluded by the October 2001 amendment. The only possible inference that can be drawn from the full history is that in order to obtain a patent, AbbVie and Besins limited their claims to the specific kind of formulation used in AndroGel—*i.e.*, formulations containing specified amounts of isopropyl myristate—because that is all the examiner was willing to allow.[9] The exclusion of isopropyl palmitate was not tangential to that goal.

d. The expert declaration could not change the written prosecution history record. AbbVie also argues that the district court erred by not considering its expert chemist's declaration. AbbVie Br. 39-40. As the Federal Circuit has made clear, tangentiality is to be determined based "solely on the public record of the patent's prosecution" because allowing the patent owner to rely on evidence beyond the public record would undermine "the public notice function of the patent record." *Festo*, 344 F.3d at 1369-70. But "when necessary" to understand the prosecution history, a court may consider "testimony from those skilled in the

[9] Although not part of the public prosecution history, the contemporaneous e-mail from AbbVie and Besins's patent lawyer explaining that the examiner would "allow composition claims directed to the AndroGel composition, i.e., focused on isopropyl myristate" makes the point utterly clear. PLX001-001 (JA587).

art as to the interpretation of that record." *Id.* at 1370. Here, the district court held that expert testimony was "not necessary" to interpret the prosecution history, but that even taking the expert's opinion into account, the defendants would still be estopped. MSJ Op. 20 n.10 (JA52). AbbVie has shown no error in those determinations.

"[E]xtrinsic evidence consisting of expert reports and testimony" must be viewed with caution when construing patents because it is "generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) (en banc). Courts therefore "discount any expert testimony that is clearly at odds with … the written record of the patent." *Id.* (internal quotation marks omitted). That principle also applies here. As shown above, the reason for amending Claim 1 cannot have been tangential to the exclusion of isopropyl palmitate because Allen explicitly discloses isopropyl palmitate as a preferred penetration enhancer. *See Festo*, 344 F.3d at 1369. Defendants' expert declaration, generated for litigation purposes, cannot change that fact. And though the expert asserted that AbbVie narrowed Claim 1 to distinguish oleic acid, he failed to explain why the applicants also excluded all other "lower alkyl esters of C8-C22 fatty acids," or why they subsequently filed supplemental amendments limiting the claim to formulations containing specified amounts of isopropyl myristate. The district

court did not err in concluding that the expert declaration was neither necessary to interpret the prosecution history nor persuasive on the issue of tangentiality.

e. AbbVie's cases are inapposite. AbbVie's cases applying the tangentiality exception in specific patent disputes also do not establish a reasonable basis for suing Teva. AbbVie seemingly cites the decisions to show that tangentiality is such a complex issue that it can never form the basis for a finding of objective baselessness. But while some tangentiality matters may present close questions, *this* one does not.

AbbVie relies primarily on *Insituform Technologies, Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004), and *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841 (Fed. Cir. 2006). Those cases are inapposite because they involve situations where "the reason for the amendment and the alleged equivalent involved different aspects of the invention." *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1306 (Fed. Cir. 2005); *accord Cross Med.*, 480 F.3d at 1342; *Amgen*, 457 F.3d at 1314. Here, by contrast, the narrowing amendment and the alleged equivalent relate to the *same* aspect of the invention: the selection of a penetration enhancer.

Insituform involved a patent on a method of pipe repair using a vacuum cup to impregnate a lining with resin; the allegedly infringing product used multiple cups rather than a single cup. An amendment to the claim specifying a single cup

at a particular location was deemed tangential because the claim was amended to distinguish prior art relating to the location of the cup, not the number of cups. 385 F.3d at 1370. As the Federal Circuit later explained, "an amendment distinguishing prior art based on *where* the vacuum source was located was only tangentially related to an equivalent directed at the *number* of vacuum sources." *Cross Med.*, 480 F.3d at 1342. Similarly, *Primos* involved a patent on a device used to mimic animal sounds that involved a plate "differentially spaced" above a membrane; the alleged equivalent used a dome instead of a plate. 451 F.3d at 843-44. The narrowing amendment added the "differentially spaced" limitation to distinguish prior art with no spacing; the use of a plate as opposed to a dome was held tangential to that purpose. *Id.* at 848-49.[10]

Eli Lilly & Co. v. Dr. Reddy's Laboratories, No. 16-cv-00308, 2017 WL 6387316 (S.D. Ind. Dec. 14, 2017), *appeal pending*, No. 2018-2128 (Fed. Cir.), likewise presented a situation where the rationale for the amendment and the alleged equivalent involved different aspects of the invention. The patent in *Eli Lilly* claimed a method of administering a chemotherapy drug, pemetrexed disodium, using a pretreatment regime to reduce toxicity. *Id* at *1. Pemetrexed

[10] Likewise, in *Regents of the University of California v. Dakocytomation California, Inc.*, 517 F.3d 1364 (Fed. Cir. 2008), the amendment at issue "centered on the method of blocking—not on the particular type of nucleic acid that could be used for blocking." *Id.* at 1378.

disodium is a salt of pemetrexed, which is part of a class of drugs known as antifolates. The original application referred broadly to "antifolates," but the applicant narrowed the claim to avoid prior art disclosing a pretreatment regime for a different antifolate, methotrexate, arguing that the claim was new and nonobvious because it was directed toward reducing the toxicity of pemetrexed disodium. *Id*. at *1-2, 7. The alleged equivalent was a different salt of pemetrexed—the same antifolate, which presented the same toxicity problem. The amendment in Eli Lilly was at least arguably tangential because its purpose was to distinguish pemetrexed from other antifolates, not to distinguish between pemetrexed salts.

This case also involves a number of dispositive facts that were not present in *Insituform*, *Primos* and *Eli Lilly*. None of those involved a situation where the application was amended to avoid prior art that specifically disclosed the alleged equivalent, the way Allen disclosed isopropyl palmitate. As discussed above, that fact by itself is fatal to a tangentiality argument. Furthermore, in all those cases, the patentee offered a facially plausible explanation for the exclusion of the alleged equivalent. Here, for the reasons discussed above, AbbVie's assertion that the sole purpose of the amendments was to distinguish oleic acid does not even begin to hold water, since it does not explain the entire October 2001 amendment, and the applicants continued to whittle the claims down further even after oleic acid was

excluded. Nor is there any indication in any of AbbVie's cases that the applicants relied on commercial success to demonstrate nonobviousness or that the examiner was only willing to allow claims narrowly directed to an existing product. In light of these critical differences, no reasonable litigant would have thought this case was close enough to *Eli Lilly*, *Insituform*, or *Primos* to give a tangentiality argument a reasonable chance of success.

2. The court properly held that the Perrigo lawsuit was objectively baseless.

Perrigo's penetration enhancer, isostearic acid, was specifically identified in the written description and was one of the 24 potential penetration enhancers listed in amended Claim 1 (as modified by the October 2001 amendment). The December 2001 amendment limited the claims to formulations containing isopropyl myristate, thereby excluding isostearic acid. AbbVie does not dispute that this was a narrowing amendment—*i.e.*, that the first step in the prosecution history estoppel analysis is satisfied. But it argues that a court could reasonably have found in its favor as to the second and third steps. Neither argument withstands scrutiny.

As discussed above, the second step asks whether the narrowing amendment was for a substantial reason related to patentability. The Supreme Court has held that the patent owner has the burden to show the reason for an amendment, and instructed that "[w]here no explanation is established … the court should presume

that the patent applicant had a substantial reason related to patentability." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33 (1997). Here, AbbVie claims there was a reasonable basis to contend that the December 2001 amendment was not related to patentability because amended Claim 1 was "never rejected or threatened with rejection." AbbVie Br. 47.

This is not a reasonable argument because it is contrary to controlling case law and the clear record of the prosecution history. To begin with, the Federal Circuit squarely held in its *en banc Festo* decision that it does not matter whether the amendments were made in response to a rejection or threat of rejection; even "a 'voluntary' amendment may give rise to prosecution history estoppel." *Festo*, 344 F.3d at 1366.[11] As the district court noted, a contrary rule would have the absurd consequence of allowing an applicant to strategically abandon questionable subject matter before a rejection has issued and then recapture it through the doctrine of equivalents. MSJ Op. 27 (JA59).

In any case, the prosecution history clearly shows that both the December 2001 and February 2002 amendments *were* made to overcome the examiner's June 2001 obviousness rejection. That is why AbbVie and Besins requested "reconsideration and withdrawal of the outstanding rejections" with each

[11] *See also Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1357 (Fed. Cir. 2003); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1345 (Fed. Cir. 2003).

amendment. PLX057-010; PLX059-028 (JA1095, 1129). It is also why the examiner stated in issuing the patent that the amendments "all together" were "sufficient to remove the prior art rejection." PLX060-003 (JA1152).

AbbVie argues that the examiner never specifically mentioned isostearic acid. AbbVie Br. 47. This is another improper effort to flip the burden. Under *Warner-Jenkinson*, courts must presume that an amendment was for a substantial reason relating to patentability, and the burden is on the patentee to prove otherwise. *Warner-Jenkinson*, 520 U.S. at 33; *Festo*, 344 F.3d at 1366-67.

AbbVie offers no reasonable argument to meet that burden. It argues simply that the purpose of the December 2001 amendment was "to expedite the timing of patent prosecution." AbbVie Br. 48. As the district court held, this argument fails for two reasons. MSJ Op. 27-28 (JA59-60). First, "a patentee's rebuttal of the *Warner-Jenkinson* presumption is restricted to the evidence in the prosecution history record." *Festo*, 344 F.3d at 1367. AbbVie's argument is based not on the prosecution history, but on its own after-the-fact justification for the amendment. AbbVie argues that it "explained to the *district court*" that in December 2001 "[o]nly a year of statutory marketing exclusivity remained for AndroGel 1% and no patent protected AndroGel yet." AbbVie Br. 48 (emphasis added). But this

appears nowhere in the public prosecution history record, which is what matters.[12] AbbVie points to a boilerplate statement in its amendment remarks which urged the examiner "to call the undersigned [patent prosecution counsel] with any questions or to otherwise expedite prosecution." PLX057-010 (JA1095). This hardly demonstrates that the purpose of the amendment was not to overcome the outstanding rejections—especially since the applicants expressly requested reconsideration and withdrawal of the rejections in the immediately preceding paragraph.

But in any case, even if AbbVie could show that the purpose of the amendment was solely to "expedite prosecution," it would not matter. AbbVie is arguing that it made the amendment so that it could obtain a patent more quickly by narrowing the claims to those which the examiner had found patentable. As the district court held, that is a clearly a "substantial reason related to patentability." MSJ Op. 27 (JA59) (citing *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132 (Fed. Cir. 2003) and *Regents of the Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1378 (Fed. Cir. 2008)). AbbVie asserts that the cases cited by the district court are not directly controlling, AbbVie Br. 48, but cites no authority for the proposition that a desire to expedite prosecution is unrelated to patentability. The

[12] The evidence AbbVie cites is *trial testimony* from an AbbVie executive, which was not even part of the summary judgment record before the district court.

district court properly held that AbbVie and Besins had "no credible argument" to overcome the *Warner-Jenkins* presumption. MSJ Op. 28 (JA60).

AbbVie argues in the alternative that even if the December 2001 amendment was made for a substantial reason related to patentability—which it plainly was—a reasonable litigant could have argued that the purpose of the amendment was to distinguish oleic acid, and that the exclusion of isostearic acid was tangential to that goal. AbbVie Br. 49-50. This argument makes even less sense than AbbVie's tangentiality argument involving Teva. As noted above, the October 2001 amendment had already excluded oleic acid; the later amendments must have had a different purpose. No reasonable litigant could realistically have expected to win on this argument. Once again, viewing the prosecution history as a whole, the only reasonable conclusion is that AbbVie and Besins sought to limit their claims to formulations containing specific amounts of isopropyl myristate—the specific enhancer used in AndroGel—because those were the only claims that the examiner deemed allowable over the prior art.

3. The district court applied the correct standard.

AbbVie argues that the district court improperly focused on whether it had a winning position in the underlying litigation, as opposed to whether its arguments were objectively baseless. AbbVie Br. 45, 50. This argument is groundless. The district court correctly recited and applied the objective baselessness standard

under *PRE*, holding that "AbbVie and Besins could not realistically have expected success on the merits … or have had a reasonable belief that they had a chance to prevail." MSJ Op. 31 (JA63).[13] AbbVie and Besins's arguments were not merely weak; they were squarely contrary to long-established controlling precedents and disregarded key parts of the prosecution history. No reasonable litigant could have expected to prevail.

D. The Settlement Agreements Do Not Show That the Infringement Lawsuits Had Merit.

AbbVie argues that infringement lawsuits could not have been meritless because Teva and Perrigo agreed to settlements that kept them out of the market until December 27, 2014. AbbVie waived this argument with respect to the Teva settlement by failing to raise it before the district court.[14] *See, e.g.*, *Morgan*, 648 F.3d at 179. In any case, the argument is meritless as to both Teva and Perrigo. As the district court explained in its post-trial opinion, "[p]arties often settle

[13] *See also* MSJ Op. 30 ("There is no plausible argument to overcome the presumption in favor of the application of prosecution history estoppel."); MSJ Op. 30-31 ("[A]ny reasonable person who reads the prosecution history of the '894 patent can reach no other conclusion ….") (JA62-63).

[14] In their summary judgment briefings, defendants argued that the Perrigo settlement showed that the Perrigo litigation was not objectively baseless, but made no such argument about Teva. Defendants referenced the Teva settlement in their reconsideration motion, but "raising an argument for the first time in a motion for reconsideration results in waiver of that argument for purposes of appeal." *United States v. Franz*, 772 F.3d 134, 150 (3d Cir. 2014). They also raised the Teva settlement at trial with respect to the second prong of *PRE*, but that was long after the ruling on objective baselessness and relates to a separate issue.

litigation for a variety of reasons independent of the merits of the claims…. Even frivolous lawsuits can be very costly to defend and to take to trial, especially when the plaintiffs, such as the defendants here, have extensive resources." Op. 44 (JA112).

The district court's reasoning is correct. The fact that a party settles does not necessarily prove the underlying claim was meritorious—and certainly not where, as here, the law and the undisputed prosecution history record show the lawsuit was baseless. Under these circumstances, the FTC did not have to probe why Teva and Perrigo settled. But as the complaint explains, Teva had a strong incentive to settle because AbbVie was essentially *paying* it $175 million through the TriCor deal, and this was more than Teva expected to earn from selling generic AndroGel. AbbVie's argument merely confirms the district court's fundamental error in dismissing the FTC's reverse-payment claim.

Perrigo also had good reason to settle without regard to the merits. As a starting point, AbbVie ignores the fact that the settlement allowed Perrigo to enter the market nearly six years before patent expiration, and also provided for payment to Perrigo of $2 million in reasonable litigation expenses. Op. 24 (JA92). But even more importantly, Perrigo received something of great value that it could not have gotten through litigation: an acceleration clause permitting it to launch its product at the same time as Teva. Perrigo was at a significant competitive

disadvantage vis-à-vis Teva because it had filed its NDA six months later. Perrigo's assistant general counsel, Andrew Solomon, testified that given the 30-month Hatch-Waxman stay, Perrigo did not expect to launch before April 2014. Tr. 6:98 (JA3811). But it believed there was "a very good probability that Teva could prevail" in its lawsuit by late 2012 or early 2013 and launch its product soon afterwards. Tr. 4:185, 187 (JA3706). Accordingly, Perrigo insisted that the settlement include an acceleration clause, so that it would have parity with Teva. Tr. 4:191 (JA3707). Perrigo did not know at the time that Teva was also negotiating a settlement that would delay its launch until December 27, 2014. *Id.*

Clearly, Perrigo did not agree to settle because it lacked confidence in its case. Perrigo notified AbbVie and Besins in its Paragraph IV certification that any infringement lawsuit would be objectively baseless, and Solomon testified that it did not learn anything during the pendency of the lawsuit to change its assessment of the merits. Tr. 4: 166-67. 174-75 (JA3701, 3703); PLX264-061 (JA1569). Solomon told his client it had a 75% chance of victory. Tr. 6:102, 10:187-88 (JA3812, 4071). As he explained, no reasonable attorney would ever tell a client it had a 100% chance of victory because there is "inherent uncertainty that goes any time a case gets in front of an arbiter," but his assessment reflected a "high level of confidence," showing that "we fe[lt] very, very strongly about [Perrigo's] chances for success." Tr. 10: 187-88 (JA4071). Solomon's estimate thus reflects an

understanding that the lawsuit was objectively baseless but settlement nonetheless made sense for good business reasons.

AbbVie cites a few cases in which courts have relied on settlements as evidence that litigation was not objectively baseless, but none involve situations where a party had reasons to settle unrelated to the merits of the case. The settlements in those cases involved very different circumstances. For example, in *In re Lantus Direct Purchaser Antitrust Litigation*, 284 F. Supp. 3d 91 (D. Mass. 2018), *appeal pending*, No. 18-2086 (1st Cir.), the parties settled on the eve of trial after a year-and-a-half of hard-fought litigation, and even there, the court recognized that the settlement was "not dispositive." *Id.* at 109-10. By contrast, here AbbVie settled with Teva after an early trial date was set on the dispositive prosecution history estoppel issue and reached out to settle with Perrigo immediately after filing its complaint.

AbbVie also points to the FTC's statement in a petition for certiorari to the Supreme Court (prior to *Actavis*) that "a hypothetical settlement in which the parties compromised on a time of entry without cash payments would reflect the strength of the patent as viewed by the parties." Petition for Writ of Certiorari, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), at 9. But that is not the situation here: as discussed above, both Teva and Perrigo received extremely valuable rights they could not have gotten through litigation. Such

settlement agreements cannot override the clear evidence in the patent prosecution history showing the lawsuits to be objectively baseless.

Finally, AbbVie argues that the district court's application of the objective baselessness test is somehow "problematic" under the Hatch-Waxman Act. AbbVie Br. 52-53. Quite the reverse. The structure of the Hatch-Waxman Act creates a strong incentive for sham litigation, because merely filing even a baseless lawsuit enables a patent holder to block competition for up to 30 months. For the law to function properly, pharmaceutical patent owners must act scrupulously and in good faith. AbbVie and Besins did not meet that standard when they filed objectively baseless infringement claims. Antitrust law properly provides a remedy for their misconduct.

II. THE DISTRICT COURT PROPERLY FOUND THAT ABBVIE AND BESINS INTENDED TO USE THE LITIGATION PROCESS FOR ANTICOMPETITIVE PURPOSES.

The second prong of *PRE* asks whether a baseless lawsuit "conceals an attempt to interfere *directly* with the business relationships of a competitor through the use of the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *PRE*, 508 U.S. at 60-61 (cleaned up). "In other words, the plaintiff must have brought baseless claims in an attempt to thwart competition (*i.e.*, in bad faith)." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 556 (2014). The test focuses on a party's "economic

motivations in bringing suit," *i.e.* whether it "decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process." *PRE*, 508 U.S. at 65-66.

The district court held that the FTC was required to prove "not merely the intent to thwart competition," but also that AbbVie and Besins had "actual knowledge that the patent infringement suits were baseless. Op. 36-37 (JA104-05). In doing so, it required the FTC to prove more than was necessary. *Octane Fitness* makes clear that what matters is the intent to "thwart competition." 572 U.S. at 556. The subjective inquiry "has nothing to do with what a litigant knew or should have known regarding the merits of its claims." *Kilopass Tech., Inc. v. Sidense Corp.*, 738 F.3d 1302, 1313 (Fed. Cir. 2013). But the court's holding the FTC to the higher burden of proof is of no import because it found by clear and convincing evidence that the AbbVie and Besins lawyers who made the decisions to sue acted with the intent to thwart competition by blocking Teva's and Perrigo's market entry—exactly what *PRE* requires. Op. 53 (JA121).[15]

[15] This Court has not decided what standard of proof applies to sham litigation claims. *See Wellbutrin*, 868 F.3d at 148 n.18. Although the district court's findings are not clearly erroneous under any standard, it should have applied the preponderance standard, which is "generally applicable in civil actions," including antitrust cases. *Octane Fitness*, 572 U.S. at 558; *Herman & MacLean v. Huddleston*, 459 U.S. 375, 390 (1983).

A. Standard of Review

The district court's determination of intent is a finding of fact that "must not be set aside unless clearly erroneous." Fed. R. Civ. P. 52(a)(6). If the court's determination "is plausible in light of the record viewed in its entirety," it must be affirmed. *Anderson v. Bessemer City*, 470 U.S. 564, 573-74 (1985). "Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." *Id*. at 574.

B. The District Court Properly Found That AbbVie and Besins Sued for the Purpose of Interfering With Competition.

The district court found that at both AbbVie and Besins, the decisions to sue were made by in-house lawyers and that their "only reason for filing the infringement suits was to impose expense and delay on Teva and Perrigo so as to block their entry into the [transdermal] market with lower price generics and to delay defendants' impending loss of hundreds of millions of dollars in AndroGel sales and profits." Op. 52-53 (JA120-21). In other words, the court found as fact that AbbVie and Besins filed their baseless lawsuits intending to use the litigation process itself to thwart competition—exactly meeting *PRE*'s second prong. *See PRE*, 508 U.S. at 60-61; *Octane Fitness*, 572 U.S. at 556. That finding was not clearly erroneous and by itself justifies affirmance.

AbbVie and Besins both asserted privilege, so the FTC could not ask the in-house lawyers why they filed the baseless lawsuits.[16] In the absence of direct testimony, the district court properly drew an inference of intent. As this Court has explained, "[a] person's state of mind is a narrative or historical fact" that "often must be determined by drawing inferences from evidence of his conduct and the surrounding circumstances." *Universal Minerals, Inc. v. C. A. Hughes & Co.*, 669 F.2d 98, 104 (3d Cir. 1981).

Especially in the antitrust context, where direct evidence of anticompetitive intent is often unavailable, "[s]pecific intent … may be inferred from a defendant's unlawful conduct." *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 257 (3d Cir. 2010); *see also Apex Hosiery Co. v. Leader*, 310 U.S. 469, 485 (1940) (jury could reasonably find that antitrust defendants intended to interfere with commerce where that was the "natural and probable consequence[]" of their actions); *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 106 (3d Cir. 1992) ("[A] plaintiff may show predatory intent either by express evidence or by inference from below-cost pricing."). Consistent with these holdings, the leading antitrust law treatise advises that *PRE*'s second prong "should not be read to require an inquiry into the infringement plaintiff's actual state of mind. Here, like

[16] Besins's in-house lawyer, Thomas MacAllister, testified regarding documents produced in discovery, but Besins asserted privilege as to questions going beyond that scope. Tr. 4:74-75, 78-80, 86-87 (JA3678-79, 3681).

anywhere else, intent can be inferred from sufficiently unambiguous conduct." 3 Phillip E. Areeda & Herbert Hovencamp, *Antitrust Law* ¶706, at 334 (4th ed. 2015). The district court relied on these principles, citing the well-established rule that a trier of fact may reasonably infer that a party intends the natural and probable consequences of its actions as well as numerous cases in which courts have inferred intent from other evidence in the record. Op. 48 (JA116).

The facts here support a compelling inference that the in-house AbbVie and Besins lawyers intended to use the litigation process itself to thwart competition. To begin with, they must have had *some* reason for filing a lawsuit that no reasonable attorney could believe had merit. The Hatch-Waxman Act's automatic stay provision suggests the motivation. Because even a baseless suit blocks a would-be competitor from entering the market for up to 30 months, the Act creates a powerful incentive for patent holders to use the litigation *process*, without regard to the *outcome* of that process, as an anticompetitive weapon. The filing of an objectively baseless Hatch-Waxman lawsuit thus by itself supports a strong inference that the suit was intended "primarily for the benefit of collateral injuries inflicted through the use of the legal process." *PRE*, 508 U.S. at 65.

As the district court found, that inference is bolstered by substantial evidence in the record. The in-house attorneys who filed the lawsuits were all "very experienced patent attorneys" who would have known the law of prosecution

history estoppel and understood that it barred the lawsuits against Teva and Perrigo. Op. 52 (JA120).[17] Furthermore, Teva's and Perrigo's Paragraph IV notices explained the legal and factual basis for the prosecution history estoppel defense in detail. Op. 50 (JA118).[18] Perrigo went so far as to assert that an infringement lawsuit would be "objectively baseless and a sham brought in bad faith for the improper purpose of … delaying Perrigo's NDA approval." PLX264-061 (JA1569). The in-house lawyers also knew that Teva's and Perrigo's products did not contain isopropyl myristate—and thus did not infringe—because they had outside counsel who were given confidential access to the generic companies FDA submissions. Op. 50 (JA118).

Additionally, the district court noted that several of the lawyers were "long-time employees" of AbbVie and Besins who would certainly have known of AndroGel's "extensive financial success." Op. 51 (JA119).[19] The evidence at trial showed that AndroGel was "a blockbuster product" that was "bringing in hundreds

[17] AbbVie's lawyers had decades of combined experience (Tr. 11:40-44, 13:160-63 (JA4096-97, 4229-30)), while Besins's in-house lawyer, Thomas MacAllister, is not only a longtime patent lawyer but a former patent examiner who testified that he was "certainly familiar" with the prosecution history case law. Tr. 4:53, 55, 90, 127-28 (JA3673, 3682, 3691). He also testified that he "worked with the Hatch-Waxman Act all the time" and "certainly" understood a lawsuit would trigger a 30-month stay of FDA approval. Tr. 4:69 (JA3677).

[18] *See* PLX264-009, -012 to -043; PLX303-005 to -017 (JA1517, 1520-51, 1667-79).

[19] AbbVie's lead lawyer had worked there since 2005, while MacAllister had worked for Besins since 2003. Tr. 4:49-52, 13:151, 161 (JA3672, 4227, 4230).

of millions of dollars annually"—$874 million in 2011—"with a very high profit margin," and based on their experience, the lawyers would have understood that "the entry of generic versions of AndroGel with their much lower prices would quickly and significantly erode this ideal financial picture." Op. 51-52 (JA119-20).

Taking all of this evidence into account, the district court properly found that "[s]ince these experienced patent attorneys filed objectively baseless infringement lawsuits, it is reasonable to conclude that they intended the natural and probable consequences of acts they knowingly did." Op. 52 (JA120). And as noted above, it concluded that the lawyers had "no expectation of prevailing in the lawsuits" and that the "only reason" for filing them was to block Teva's and Perrigo's entry into the transdermal market. Op. 53 (JA121).

Before this Court, AbbVie does not contend that the district court got any of the underlying facts wrong. Nor does AbbVie seriously dispute that it and Besins filed the lawsuits with the intent to take advantage of the automatic 30-month Hatch-Waxman stay to keep generic competition off the market. To the contrary, AbbVie concedes that defendants "had financial interests in AndroGel's position in the market"—in other words, that they had a powerful motive to use the Hatch-Waxman process to stave off competition, win or lose. AbbVie Br. 56.

AbbVie makes two main arguments, neither of which has merit. First, it argues that the FTC was required to show that the lawyers "actually believed the lawsuits had no possibility of success." AbbVie Br. 56. As discussed above, this is not the correct standard: the FTC was required only to show that defendants intended to use the litigation process to thwart competition. *Octane Fitness*, 572 U.S. at 556; *see also Kilopass*, 738 F.3d at 1313. But in any case, the district court found that the experienced in-house lawyers *did* have "actual knowledge" that the infringement lawsuits were baseless. Op. 52-53 (JA120-21). All of the evidence cited above also supports the district court's finding of actual knowledge. In particular, the lawyers here were highly experienced; they were specifically notified of the prosecution history estoppel defense and the relevant facts and law (and even warned that a suit against Perrigo would be a sham); and they had outside counsel who could verify that Teva's and Perrigo's products did not infringe. While the district court was not required to find actual knowledge, that finding was not clearly erroneous.

Second, AbbVie argues that the district court's analysis effectively merged the two prongs of *PRE*, allowing the court to find anticompetitive intent based "solely" on the finding of objective baselessness. AbbVie Br. 55. Whatever merit that argument might have outside the context of Hatch-Waxman litigation, it has none here. As discussed above, given the unique structure of the Hatch-Waxman

Act, which allows a plaintiff to thwart competition merely by filing suit, an objectively baseless Hatch-Waxman lawsuit gives rise to a strong inference that the suit was filed with the intent to interfere with competition. But in any case, contrary to AbbVie's argument, the district court did not rely solely on that inference. It considered a substantial body of other record evidence that, taken together, led to the "ineluctabl[e]" conclusion that the sole reason for filing the lawsuits was to block competition. Op. 52 (JA120).[20]

AbbVie complains that "in virtually every Hatch-Waxman suit," plaintiffs will have an economic incentive to block competition. AbbVie Br. 56. But most Hatch-Waxman suits are not objectively baseless. Under *PRE*, a patent holder can lawfully use the litigation process, including Hatch-Waxman's automatic stay, to gain a competitive advantage so long as there is an objectively reasonable basis for suing. But where the patent holder seeks to use the litigation process to gain a competitive advantage without an objectively reasonable basis for suing, it may properly be subject to antitrust liability. In light of all of the evidence presented

[20] AbbVie argues that under *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340 (Fed. Cir. 1998), a patent holder's assertion of a duly granted patent should be presumed to be in good faith, but any such presumption is overcome here by the evidence the district court cited. Nor is this case anything like *Kaiser Foundation Health Plan, Inc. v. Abbott Laboratories, Inc.*, 552 F.3d 1033 (9th Cir. 2009), where Abbott presented "plausible argument[s]" and "did not persist in litigating when it became obvious that the suits were baseless." *Id.* at 1046-47.

over the course of the 16-day trial, the district court properly concluded that AbbVie and Besins acted with the necessary anticompetitive intent.

C. Solvay's Decision Not To Sue Perrigo in 2009 Reinforces the District Court's Subjective Intent Finding.

Other evidence not relied on by the district court strongly reinforces its finding that the in-house lawyers who made the decision to sue acted in bad faith with the goal of thwarting competition. In 2009, when Perrigo first sought approval for a generic version of AndroGel using isostearic acid, Solvay Pharmaceuticals (AbbVie's predecessor) publicly announced that it would not sue Perrigo for infringement. Op. 14-15; PLX009-002 (JA82-83, 609). Solvay concluded that because of the differences between Perrigo's formulation and AndroGel, "there was not a sufficient basis for filing patent infringement litigation." PLX009-006 (JA613).

The district court chose not to rely on this evidence because the AbbVie lawyers who made the decision to sue in 2011 never worked for Solvay and were not involved in the 2009 decision. Op. 40-41 (JA108-09). But it is inconceivable that the AbbVie lawyers would not have known of Solvay's decision not to sue just two years earlier or that they were unfamiliar with the analysis underlying that decision. The record shows that in 2009, the outside law firm jointly retained by Solvay and Besins e-mailed both companies attaching "a summary of the legal test for amendment-based prosecution history estoppel" and "excerpts from the

prosecution history of the '894 patent." PLX004-001 (JA595). A later e-mail to both companies with the subject line "[t]angentialness case law and comment" attached many of the key prosecution history estoppel cases, including the Supreme Court and Federal Circuit *Festo* decisions. PLX005-001 (SA1).[21] Solvay's general counsel communicated the legal advice and work product it had created to AbbVie shortly after AbbVie agreed to purchase Solvay, and AbbVie also consulted with the outside counsel Solvay and Besins had retained. Tr. 13:182-84, 191-94 (JA4235, 4237-38). Thus, Solvay's analysis was available to AbbVie.

Furthermore, Besins's lawyer, MacAllister, was directly involved in the analysis of Perrigo's 2009 application. He received the e-mails from outside counsel discussing the prosecution history estoppel issue, and he personally discussed the issue with Solvay's lawyers and the companies' joint outside counsel.[22] He also personally reviewed and commented on Solvay's draft press release announcing its decision not to sue before it was issued. Tr. 4:101 (JA3685). Even though Besins never issued its own public statement, MacAllister certainly knew that Solvay had determined there was no reasonable basis for a suit against Perrigo. Since MacAllister "routinely conferred with counsel at AbbVie as

[21] "SA" page numbers refer to the FTC's Supplemental Appendix.

[22] *See* PLX004; PLX005-001; PLX006; PLX007-001; DX256 (JA595-600, 2708-09, SA1, 6).

[he] did with Solvay previously on all matters concerning this" (Tr. 4:113 (JA3688)), the AbbVie lawyers would have known as well.

D. Defendants' Remaining Arguments Are Meritless.

AbbVie and Besins raise a series of meritless legal and evidentiary arguments challenging the district court's finding of subjective intent. None provides any basis for second-guessing the court's factual findings.

1. The court properly gave no weight to the settlement agreements.

AbbVie contends that the Teva and Perrigo settlements show defendants believed they had a reasonable chance of prevailing. AbbVie Br. 58. As discussed above (at 52-56), the district court found that the settlements supported no inferences about belief of success because "[p]arties often settle for a variety of reasons independent of the merits of the claims." Op. 44 (JA112). The court thus properly declined to view the settlement agreements as showing that AbbVie and Besins acted in subjective good faith. Op. 45 (JA113). Furthermore, for the reasons discussed above, the terms of these settlements do not remotely suggest that AbbVie and Besins had an "expectation of prevailing." AbbVie Br. 58. To the contrary, AbbVie was able to induce Teva to settle only by offering it a payoff via the TriCor deal, which was worth $175 million to Teva but cost AbbVie $100 million. *See* discussion above at 5-7.

2. The court properly declined to rely on AbbVie's business planning documents.

AbbVie next faults the district court for not relying on certain business projections purportedly showing that the company expected to retain market exclusivity through August 2015, when other generics were slated to enter. AbbVie Br. 59-60. The district court declined to consider either these or other business documents cited by the FTC showing that AbbVie expected to lose the lawsuits and face generic competition well before 2015.[23] The court found the business documents were not probative because they were not created by the in-house lawyers and there was no evidence of communications between the lawyers and the business people. Op. 43 (JA111). AbbVie does not contest the district court's determination that its lawyers made the decision to sue without any input from the business people. Accordingly, the court's decision not to rely on documents created by the business people—regardless of which side was relying on them—does not amount to clear error.

[23] The documents cited by the FTC include: a chart drawn by a senior AbbVie executive showing a steep decline in AndroGel sales beginning in April 2012 (PLX025 (JA629)); an email describing Teva entry in April 2012 as "[t]he most likely scenario" (PLX030-001 (JA682)); projections showing lost sales of AndroGel based on generic entry scenarios before 2015 (PLX026-005 to -006; PLX029-033 (JA634-35, 657)); and an e-mail after the settlement stating that "[n]o one thought" AndroGel would not have a loss of exclusivity in 2012 (PLX041-001 (JA793)).

AbbVie argues that the district court "[e]ffectively penaliz[ed]" it for asserting privilege. AbbVie Br. 60. In fact, the court made very clear that "[w]e do not and will not draw any negative inference as to subjective intent based on defendants' decision to invoke the attorney-client privilege and the attorney work product doctrine and thereby to shroud certain information from view." Op. 49 (JA117). If anything, AbbVie is improperly trying to use privilege as both a shield and sword. It prevented the FTC from asking the in-house attorneys their view of the merits of the case, but suggests that the district court should have inferred that statements in business planning documents reflected advice from the attorneys. AbbVie cannot have it both ways.

3. The court did not clearly err in finding that Besins's general counsel made the decision to sue.

Besins also invites this Court to reweigh the evidence, arguing that the district court clearly erred when it found that MacAllister made the decisions to sue. Besins Br. 13-17. Whether MacAllister was Besins's final decisionmaker does not matter; he certainly knew all the relevant facts and law and that knowledge is imputed to the company. *Buchanan v. Reliance Ins. Co.*, 475 F.3d 508, 513 (3d Cir. 2007); *Restatement (Third) of Agency* §5.03 (2006).

In any event, the district court did not clearly err in finding that MacAllister made the decision. MacAllister testified that he was the head of Besins's global intellectual property group, that he served as either general counsel or special

counsel for the U.S. entity that co-owned the '894 patent, and that he was the only attorney in Besins's U.S. organization for most of the period from 2009 to 2011. Tr. 4:49-52 (JA3672). MacAllister also testified that he had responsibility for legal matters relating to AndroGel, including patent litigation and FDA regulatory matters. Tr. 4:53 (JA3673). He further testified that he was "involved" in the decision to file the Teva and Perrigo suits, and that he routinely conferred with AbbVie's in-house counsel and received analyses from outside counsel relating to AndroGel. Tr. 4:112-14, 122 (JA367-88, 3690). Furthermore, Besins was asked in discovery to identify the persons with knowledge of the basis for the Teva litigation, and MacAllister was the only employee it identified. PLX368-011 (SA46). No one else could have made the decision to sue.

III. THE DISTRICT COURT PROPERLY FOUND THAT ABBVIE HAD MONOPOLY POWER.

In addition to proving that the infringement suits against Teva and Perrigo were shams, the FTC also had to prove that AbbVie possessed monopoly power in a relevant market. *See, e.g.*, *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 433 (3d Cir. 2016). Monopoly power may be "inferred from the structure and composition of the relevant market." *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 307 (3d Cir. 2007). "To support an inference of monopoly power, a plaintiff typically must plead and prove that a firm has a dominant share in a relevant market, and that significant 'entry barriers' protect that market." *Id.*

Following the 16-day trial, the district court found that "[t]he FTC has established the actual market reality that defendants possessed monopoly power and illegally and willfully maintained that monopoly power through the filing of sham litigation." Op. 77 (JA145). The court defined the relevant product market as transdermal (or topical) testosterone replacement therapy products, which allow for absorption of testosterone through the skin, rather than by injection. Op. 9-11, 62-63, 71 (JA77-79, 130-31, 139).[24] Like AndroGel, these are products that the user can apply painlessly at home. Op. 9-11 (JA77-79). The court found that injectable testosterone products were not properly included in the market. Op. 68-71 (JA136-39). It further found that AbbVie had maintained a dominant share of the transdermal market for many years and that there were significant barriers to entry. Op. 73, 75-77 (JA141, 143-45). AbbVie attacks each of these findings, but they are all well supported by the evidence and none is clearly erroneous.

A. Standard of Review

The existence of monopoly power is a question of fact reviewed for clear error. *E.g.*, *Weiss v. York Hosp.*, 745 F.2d 786, 827 (3d Cir. 1984).

B. The District Court Properly Found That the Relevant Product Market Did Not Include Injectables.

AbbVie first argues that the district court erred by excluding injectables from the relevant product market. AbbVie Br. 63-66. But the distinctions between

[24] There is no dispute that the geographic market is the United States as a whole.

injectables and transdermals are obvious and suggest on their face that they belong in different markets. Even though it cost much more than injectables, AndroGel was a runaway commercial success precisely because it offered substantial advantages over the older class of products. The '894 patent itself explains the serious drawbacks of injectables (PLX061-052 to -053 (JA1206-07)), and the district court summarized them as well. Injections typically require a trip to a doctor's office or specialized clinic every one to three weeks. Op. 7-8 (JA75-76). They require injection with a 1.5-inch needle, which must be "inserted deep into a muscle, typically the buttocks or thigh, until the needle is no longer visible." Op. 8 (JA76). This can be quite painful. *Id.* Additionally, injectables "generally provide an initial peak in testosterone level at the time of injection followed by troughs or valleys as the injection wears off," which may cause "swings in mood, libido, and energy." *Id.*

As both sides' medical experts testified at trial, transdermal products like AndroGel offer clear advantages.[25] Patients administer the products in the privacy of their own homes, they are painless, and they deliver a steady dose of testosterone without peaks or valleys. Op. 8-9 (JA76-77). While transdermals and injectables both deliver the same active ingredient—testosterone—transdermal products are thus vastly more convenient and comfortable for most users.

[25] Tr. 6:16-17, 25-28, 14:18, 54-57, 61-62 (JA3790-91, 3793, 4262, 4271-73).

In finding that injectables do not belong in the same market as transdermal products, the district court conducted the precise analysis laid out by this Court in *Mylan* and similar cases. It carefully examined the economic evidence, focusing on the question of whether there was cross-elasticity of demand between transdermals and injectables. Cross-elasticity of demand measures the responsiveness of the demand for one product to changes in the price of a different product. *See, e.g.*, *Mylan*, 838 F.3d at 435-36. High cross-elasticity means that a modest price increase for one product will cause many consumers to switch to another product, and vice versa. This indicates that the two products constrain each other's prices and are part of the same market. Conversely, low cross-elasticity means that a small but significant price increase for one product will not cause sales to shift to the other product. Products may be reasonably interchangeable with each other and serve similar functions, but they do not belong in the same product market unless there is "significant positive cross-elasticity of demand." *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1063-64 (3d Cir. 1978).

Because it is often not possible to calculate cross-elasticity with precision, courts frequently rely on qualitative factors rather than numerical data. The Supreme Court has identified such "practical indicia" as "industry or public recognition of the submarket as a separate economic entity, the product's peculiar

characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). Only some of these factors are needed to define a market. *Gen. Foods Corp. v. FTC*, 386 F.2d 936, 941 (3d Cir. 1967).

The district court concluded that AndroGel and other transdermals have significant cross-elasticity of demand and thus belong in the same product market. Op. 65-67 (JA133-35). AbbVie does not dispute that finding. But the court did not include injectables in the market because it found "little cross-elasticity of demand between AndroGel and injectables." Op. 68 (JA136).

The court first noted the significant price difference between AndroGel and injectables. Most injectables are generic, which means they have favorable status on prescription drug formularies and hence the lowest copay, typically $5 to $10 per injection. Op. 68 (JA136). During the relevant time period, injections were available "at a fraction of the cost" of AndroGel, yet AbbVie was consistently able to raise AndroGel's prices and sales soared. Op. 10, 69 (JA78, 137). This shows that injectables did not constrain AndroGel's price. These findings are amply supported by the record and by themselves disprove significant cross-elasticity of demand.[26]

[26] *See*, *e.g.*, DX280; Tr. 3:205, 4:43, 5:225-27, 12:77-78) (JA2735, 3653, 3670, 3772, 4174).

Evidence of AbbVie's own understanding is equally dispositive. The court considered testimony from senior AbbVie business executives James Hynd and Frank Jaeger. Op. 69 (JA137). Hynd confirmed that AbbVie did not price AndroGel against injectables.[27] Jaeger, AbbVie's director of marketing, testified that AbbVie did not consider injectables to be competitors and did not think the company could transition injectable patients to AndroGel.[28] The court also relied on AbbVie's internal business documents showing that the company did not consider injectables direct competitors to AndroGel. Op. 69 (JA137). AbbVie's reports to its Board of Directors and investors refer exclusively to AndroGel's growth, sales, and market shares in a transdermal market, with no reference to injectables.[29]

In the face of this extensive evidence, AbbVie's main argument is that the district court "defined a market that no party had advocated and no expert endorsed." AbbVie Br. 63. This argument is rooted in the fact that the FTC's economic expert, Dr. Carl Shapiro, opined that the relevant market should be defined more narrowly to include only AndroGel and its generic equivalents, and much of his economic analysis was directed toward explaining why that market

[27] *See* Tr. 5:225-27, 251, 275-76, 9:172-75, 211-12 (JA3772, 3778, 3784, 3997-98, 4007).

[28] Tr. 1:159-165, 169-170 (JA3524-26, 3527).

[29] *See* PLX044-003; PLX124-005; PLX205-007; Tr. 5:237-40, 11:116-118, 12:89-94, (JA800, 1239, 1401, 3775, 4115-16, 4177-78).

definition was proper. Defendants' expert, Dr. Pierre Cremieux, opined that the market should include both transdermals and injectables. After hearing both sides and considering the evidence and this Court's legal framework, the district court chose a middle ground, defining the market to include all transdermals but not injectables. There was nothing improper about that approach.

Furthermore, AbbVie's assertion that the FTC never advocated for an all-transdermals market is wrong. The complaint alleged "a relevant market … no broader than testosterone drugs delivered transdermally," but not including injectables. Compl. ¶139 (JA4449-50). At summary judgment, trial, and post-trial briefing, the FTC advocated that either an AndroGel-only or an all-transdermals market was appropriate.[30] That is why Dr. Shapiro also provided market share calculations for that broader market. Tr. 7:103-04 (JA3681).

AbbVie is flat-out wrong when it says that the FTC "presented no cross-elasticity study" to support the exclusion of injectables. AbbVie Br. 64. In fact, Dr. Shapiro testified that he conducted a cross-elasticity analysis that examined how entry of lower-priced generic equivalents to AndroGel and Testim affected injectable sales. PLX425; Tr. 7:104-07, 8:223-24 (JA1803, 3949, 3861-62, 3949). If injectables had any meaningful cross-elasticity with transdermals, a price drop

[30] *See* ECF No. 263 at 34-39 (summary judgment brief); Tr. 1:27-28 (JA3491) (opening argument); ECF No. 403 at 18-25 (post-trial brief); ECF No. 405 at 91-111 (post-trial findings).

for gel products would have caused a corresponding drop in sales of injectables as consumers switched to the now-more-affordable alternative. But Dr. Shapiro found low cross-elasticity between injectables and gels. Tr. 7:107 (JA3862). That analysis shows that injectables do not belong in the relevant market.

In any event, while expert testimony is commonly presented in antitrust cases and is often helpful to the court, econometric analysis is not essential to proving a relevant market. AbbVie suggests that *Mylan* imposed such a requirement, but that case simply held that an expert's "theoretical views on cross-elasticity" did not create a genuine issue of material fact where the defendants had offered unrebutted econometric analysis to support their market definition. *Mylan*, 838 F.3d at 437. *Mylan* does not hold that courts cannot define relevant antitrust markets without econometric analysis. To the contrary, *Brown Shoe* makes clear that a court may determine cross-elasticity through "practical indicia," 370 U.S. at 325, and this Court has often followed that approach. *See, e.g.*, *Tunis Bros. Co. v. Ford Motor Co.*, 952 F.2d 715, 723-25 (3d Cir. 1991) (analyzing cross-elasticity "primarily through the testimony of [company executives] … several local mushroom farmers and … a tractor dealer"); *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 199-201 (3d Cir. 1992) (considering evidence of "product information, sales training and techniques, and interviews with industry experts"). As the Eleventh Circuit has noted, there is "no support in the caselaw for [the]

claim that [econometric] analysis is always required." *McWane Inc. v. FTC*, 783 F.3d 814, 829 (11th Cir. 2015).

AbbVie's remaining arguments also lack merit. It points to Dr. Shapiro's testimony that there is "some degree of price competition" between injectables and gels (Tr. 7:108 (JA3862)) and posits that it disproves the court's market definition. AbbVie. Br. 65. The legal test is not whether there is no cross-elasticity of demand whatsoever, but whether there is "significant" positive cross-elasticity. *SmithKline*, 575 F.2d at 1063-64. As Dr. Shapiro explained, the fact that there may be some modest price competition between two groups of products does not necessarily mean they belong in the same market. Tr. 7:109-11 (JA3863).

AbbVie also invites this Court to reweigh the evidence. It cites a patient-switching study conducted by its expert, Dr. Cremieux, and a business document stating that a rise in AndroGel copays was correlated with an increase in injectable sales. AbbVie Br. 64 (citing DX201, DX111, DX112, and DX113). The district court considered this evidence but found it unpersuasive because it did not establish that patients were switching between AndroGel and injectables because of price. Op. 69-71 (JA137-39). AbbVie also claims it developed copay assistance program to compete with injectables. AbbVie Br. 65. The court considered that evidence and found the program was adopted to compete with other transdermal products that had similar programs. Op. 66 (JA134). Finally,

AbbVie cites testimony from its medical expert (AbbVie Br. 64), who testified that some patients switched to injectables due *either* to their lower cost or the convenience of a less frequent dosing schedule.[31] But the fact that some patients may have switched from AndroGel to injectables does not mean that there is sufficient cross-elasticity that they belong in the same market. Moreover, the FTC's medical expert testified that she had not switched a patient between testosterone formulations due to cost in more than 20 years of practice.[32] Even if another judge might find some of AbbVie's evidence persuasive—which is doubtful—the district court was entitled to weigh the evidence for itself, and its decision not to accord particular pieces of evidence the weight AbbVie would like does not amount to clear error.

C. The District Court Properly Determined That AbbVie Had Monopoly Power in the Transdermal Market.

Having found that the relevant product market consisted of all transdermal products, the district court found that AbbVie had monopoly power because it had a dominant market share in the relevant time period and there were significant barriers to entry. Op. 71-77 (JA139-45). AbbVie argues that these findings rested on a legal error, arguing that the court gave "conclusive weight" to AndroGel's market share alone and ignored other evidence about actual market performance.

[31] Tr. 14:21, 30 (JA4263, 4265).

[32] Tr. 6:9-10, 43 (JA3789, 3797).

AbbVie Br. 67. But the court carefully followed this Court's guidance on monopoly power, and AbbVie identifies no proposition of law that the district court got wrong or misapplied. AbbVie is simply making a factual challenge to the weighing of evidence, which is subject to the clearly erroneous standard.

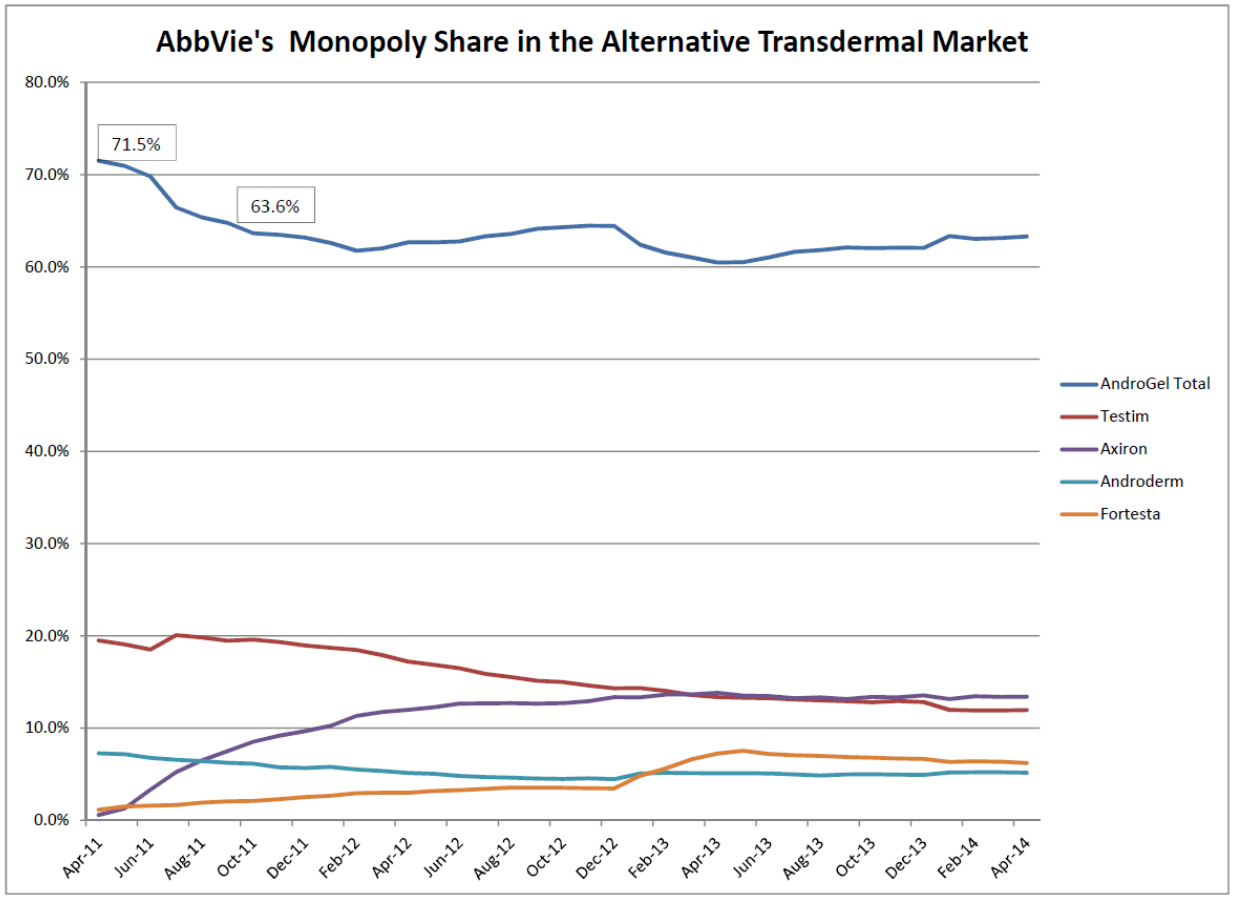
1. The district court properly found that AbbVie maintained a dominant share of the transdermal market.

As the district court properly held, a market share "significantly larger than 55%" generally establishes an inference of monopoly power. *Mylan*, 838 F.3d at 437 (quoting *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005)). AndroGel's market share was 71.5% when Defendants sued Teva in April 2011 and never dropped below 60% until generic entry at the end of 2014.[33] Op. 72 (JA140). AbbVie asserts that these numbers are "at the low end" of what courts have found sufficient (AbbVie Br. 67), but it does not dispute that a market share above 60% for years on end, despite both existing and new competitors, is sufficient to support an inference of market power under this Court's precedent. A company's "ability to *maintain* market share" over time is an itself an important indicator of market power. *Dentsply*, 399 F.3d at 189 (cleaned up).

[33] AbbVie ignores the 71.5% figure, arguing that AndroGel's market share at the time of the Teva lawsuit is irrelevant because at the remedy stage the court decided Teva would not have entered the market. That argument improperly conflates issues of violation and remedy.

Because AndroGel consistently maintained such a high market share, the district court did not need to go any further. *See Dentsply*, 399 F.3d at 187, 189; *Mylan*, 838 F.3d at 437 n.72. But contrary to AbbVie's assertion, the district court did not limit its inquiry to AbbVie's absolute market share; it considered other evidence supporting an inference of market power. *See Dentsply*, 399 F.3d at 187, 189 (listing "other factors" that can support an inference of monopoly power absent a dominant share). The court first considered consumer demand. The court found that AndroGel was "by far the most-prescribed product and was widely-recognized as the 'market leader,'" and that both sides' medical experts testified that "they have prescribed AndroGel for hypogonadism more than any other product." Op. 72 & n.26 (JA140). The court then looked at the size and strength of AndroGel's competitors. AndroGel's closest competitor, Testim, had a roughly 20% market share in April 2011, but its share dropped to about 12% by the end of 2014. Op. 72 (JA140). Axiron and Fortesta entered the entered the market in 2011 and Vogelxo entered in July 2014, but the most successful of these new entrants, Axiron, only captured 14% of the market by April 2014, and the others fell far short of that.[34] Op. 63, 72-73 (JA131, 140-41). As the following chart illustrates, none of these products made a significant dent in AbbVie's market share:

[34] AbbVie asserts that Axiron, Fortesta, and Vogelxo "took over roughly one-third" of the market. AbbVie Br. 70. In fact, their combined share was never more than about 20% from 2011 to 2014. PLX124-005; PLX205-007; PLX238-003;



Source: NPA_CHANNEL_TOTALS_2014_28NOV16.xlsx (PLX335), NPA_CURRENT_REPORT_03JAN17.xlsx (PLX333)

PLX445-001

The court also considered AbbVie's pricing and profits. It found that AbbVie was able to maintain its high market share while also maintaining a very high profit margin—over 65%—and consistently increasing its prices for AndroGel. (Op. 72-73 (JA140-41)).[35] Taking all of this evidence together, the court reasonably concluded that AbbVie had a dominant share of the market.

PLX445 **(**JA1239, 1401, SA10, 80). AbbVie also offers no legal basis for treating competing entrants as if they possessed the size and strength of a single firm.

[35] When generic AndroGel 1% entered the market in late 2014, it sold at a substantially lower price than branded AndroGel and captured significant sales,

AbbVie cherry-picks some anecdotes that supposedly call its market dominance into question. It describes a handful of incidents in 2011 and 2013 in which AndroGel lost preferred status on a few insurance company formularies. AbbVie Br. 68. But AbbVie's business plans show that in 2011 AndroGel gained a more favorable formulary position for 86% of managed-care-covered lives. DX282-244 (JA3153). AbbVie has shown nothing more than some give-and-take in the market, and AndroGel took far more than it gave. AbbVie also argues that competition from other transdermals forced it to pay large rebates and offer other incentives like copay assistance. AbbVie Br. 68-69. But at the same time that AbbVie was offering rebates, it was also raising the wholesale prices that it was rebating. Op. 73 (JA141). At most, rebate competition between AbbVie and other transdermals simply supports the district court's conclusion that all transdermals belonged in the same market. Within a relevant market, even a dominant player can expect to face some price competition. Indeed, "[e]ven a complete monopolist can seldom raise his price without losing some sales; many buyers will cease to buy the product, or buy less, as the price rises." *Fortner Enters., Inc. v. U.S. Steel Corp.*, 394 U.S. 495, 503 (1969). While the district court considered this anecdotal

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showing that the pre-generic price was well above the competitive level. Op. 10; PLX418; PLX433; Tr. 5:216, 219, 7:101, 12:134 (JA78, 3769-70, 3861, 4188, SA78-79,).

evidence in connection with market definition, it had no bearing on the issue of AbbVie's market dominance.

2. The district court properly found significant barriers to entry.

The district court found that "a prospective entrant to the [transdermal] pharmaceutical market whether a brand-name drug or a generic drug has significant capital, technical, regulatory, and legal barriers to overcome." Op. 75-76 (JA143-44). First, developing a new brand-name drug requires significant investments of time and capital for research and development. Op. 73 (JA141). There are then "significant technical and regulatory requirements … that do not exist with respect to ordinary consumer products." *Id.* The drug must be approved by the FDA—a lengthy process that requires both clinical data showing that the drug is safe and effective and compliance with a host of other regulations relating to manufacturing, packaging, and labeling. Op. 73-74 (JA141-42); *see generally* 21 C.F.R. §314.50 (NDA requirements). Once a drug is approved, a company must make another significant investment in sales and marketing to convince doctors to prescribe it. Op. 74 (JA142). These are all significant barriers to entry. *See, e.g.*, *SmithKline*, 575 F.2d at 1056 (affirming district court finding that "the high costs of research and market development … made competition from a new entrant to the market unlikely").

AbbVie argues that the entry of three new branded transdermal products from 2011 to 2014 shows that the district court erred in finding significant entry barriers. But this argument, which the district court considered and rejected (Op. 76 (JA144)), misconceives the nature of entry barriers. Barriers to entry need not foreclose new entry entirely; they are simply "factors (such as certain regulatory requirements) that prevent new rivals from timely responding to an increase in price above the competitive level." *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001). In this case, no new transdermals were introduced between 2003 and 2011 (Op. 62-63 (JA130-31))—even though AndroGel was enjoying huge sales and profits during that period, which would naturally encourage competition. This supports the court's conclusion that the various obstacles to launching a new drug product were significant.

AbbVie next argues that "Hatch-Waxman's abbreviated FDA approval process significantly reduces regulatory barriers to entry for generic competitors." AbbVie Br. 71. But as the district court found, while Hatch-Waxman provides streamlined procedures for generic approval, a would-be competitor still faces formidable barriers—many of which are illustrated by this case. Op. 75 (JA143).

AbbVie's reliance on *Barr Laboratories, Inc. v. Abbott Laboratories*, 978 F.2d 98 (3d Cir. 1992), is misplaced. As the district court correctly held, *Barr* is "inapposite" because it involved a very different market. Op. 77 n.28 (JA145).

The drug in that case (oral erythromycin) was off-patent and fully genericized. *Barr*, 978 F.2d at 102. During the relevant time period, the number of manufacturers increased from 26 to 32 and the number of oral erythromycin products increased from 111 to 176. *Id.* at 103. That market bears no resemblance to the one at issue here.

Finally, AbbVie argues that "[i]f 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." AbbVie Br. 71. Not so. The barriers posed by the FDA regulatory process are simply one of the "actual market realities" that a court must consider. *Eastman Kodak Co. v. Image Tech Servs., Inc.*, 504 U.S. 451, 466-67 (1992). The district court did not clearly err by taking them into account in this case.

IV. THE DISTRICT COURT PROPERLY AWARDED EQUITABLE MONETARY RELIEF AGAINST BOTH DEFENDANTS.

AbbVie and Besins launch several different attacks on the court's equitable monetary relief award. First, AbbVie argues that the district court had no authority to award equitable monetary relief under Section 13(b) of the FTC Act—ignoring controlling precedent from this Court and the Supreme Court and decisions from eight other circuits that have squarely held to the contrary. Second, it argues that the district court overstated the amount of defendants' illegal profits because it erred in its determination of when Perrigo would have launched its product absent

the sham litigation. Finally, Besins argues that it could not be required to pay equitable monetary relief because revenue from the sale of AndroGel did not flow directly to the U.S. entity that was named as a defendant here, but instead went to a different company in the same corporate family. All of these arguments fail.

A. Standard of Review

The district court's authority to award equitable monetary relief is a question of law reviewed *de novo*. *Lane Labs*, 427 F.3d at 223. The court's determination of equitable monetary relief and the apportionment of that relief between AbbVie and Besins are reviewed for abuse of discretion. *Teo*, 746 F.3d at 101; *SEC v. Hughes Capital Corp.*, 124 F.3d 449, 455-56 (3d Cir. 1997).

B. The District Court Had Authority To Award Equitable Monetary Relief.

AbbVie challenges the district court's authority to award equitable monetary relief on three different grounds. All of them lack merit.

1. Section 13(b) authorizes equitable monetary relief.

Section 13(b) authorizes the FTC to sue in federal court for either (1) a preliminary injunction to preserve the status quo during the pendency of an administrative case before the Commission or (2) a "permanent injunction" when the Commission has not chosen to file an administrative case. 15 U.S.C. §53(b); *FTC v. H.N. Singer, Inc.*, 668 F.2d 1107, 1111 (9th Cir. 1982). This case falls in the latter category. AbbVie argues that since the statute refers only to a

"permanent injunction," it does not permit any form of monetary relief. AbbVie Br. 74-77.

AbbVie neglects to mention that every court of appeals to have considered the issue—eight so far—has squarely held that Section 13(b)'s grant of authority to issue a "permanent injunction" includes the authority to award equitable monetary relief, such as restitution or disgorgement. *See FTC v. Commerce Planet, Inc.*, 815 F.3d 593, 598-99 (9th Cir. 2016); *FTC v. Ross*, 743 F.3d 886, 890-92 (4th Cir. 2014); *FTC v. Bronson Partners, LLC*, 654 F.3d 359, 365 (2d Cir. 2011); *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 15 (1st Cir. 2010); *FTC v. Freecom Commc'ns, Inc.*, 401 F.3d 1192, 1202 n.6 (10th Cir. 2005); *FTC v. Gem Merch. Corp.*, 87 F.3d 466, 468-70 (11th Cir. 1996); *FTC v. Sec. Rare Coin & Bullion Corp.*, 931 F.2d 1312, 1316 (8th Cir. 1991); *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 571-72 (7th Cir. 1989). And this Court agreed (in a non-precedential decision) "that district courts have discretion to grant monetary equitable relief under section 13(b)." *FTC v. Magazine Sols., LLC*, 432 F. App'x 155, 158 n.2 (3d Cir. 2011). AbbVie may disagree with those decisions, but it may not simply ignore them.[36]

[36] Instead of addressing precedential opinions, AbbVie relies on a special concurrence from a Ninth Circuit judge expressing a different view. *FTC v. AMG Capital Mgmt. LLC*, 910 F.3d 417, 429 (9th Cir. 2018) (O'Scannlain, J. concurring), *reh'g denied*, 2019 U.S. App. LEXIS 18551 (9th Cir. June 20, 2019). That same judge wrote the panel opinion recognizing that the controlling law of the

These decisions flow directly from Supreme Court precedent holding that when a statute confers an unqualified grant of authority to enter a permanent injunction, "all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction," including the power to award monetary relief. *Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946). Where, as here, the public interest is involved, the court's "equitable powers assume an even broader and more flexible character." *Id.* The Court reaffirmed the general applicability of these principles in *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288 (1960), holding 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 light of the statutory purposes." *Id*. at 291-92. Thus, "[u]nless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied." *Id.* at 291.

In *Lane Labs*, this Court analyzed *Porter* and *Mitchell* in detail and concluded that they remain controlling precedents. *Lane Labs*, 427 F.3d at 236. It held that these cases set a course that is "fairly easy to follow" in determining

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circuit was to the contrary, 910 F.3d at 426-427, and the full court denied rehearing *en banc* without any judge requesting a vote.

whether a statute authorizing an injunction also authorizes equitable monetary relief. *Id.* at 225. First, "a district court sitting in equity may order restitution unless there is a clear statutory limitation on the district court's equitable jurisdiction and powers." *Id.* Second, "restitution is permitted only where it furthers the purposes of the statute." *Id.* Applying these principles, the Court held that a statute authorizing district courts to "restrain violations" of the Food, Drug, and Cosmetics Act also conferred the authority to award equitable restitution. *Id.* at 235-36. The Court's reasoning compels the conclusion that Section 13(b) also authorizes equitable monetary relief.

AbbVie pays brief lip service to *Mitchell* and *Lane Labs* (while ignoring *Porter*) but fails to acknowledge their core holding. It argues that Section 13(b) is different from the statutes in *Mitchell* and *Lane Labs* because it "authorizes only a single equitable remedy—injunctive relief—to be awarded only under specific conditions." AbbVie Br. 75-76. This is a distinction without a difference. The statutes at issue in *Mitchell* and *Lane Labs* did not, on their face, authorize anything other than an injunction, but the courts still held that the authority to award equitable monetary relief was encompassed in that grant. Furthermore, in *Lane Labs*, this Court noted that "[n]umerous courts have followed this approach in opining about a court's power to order restitution or disgorgement under several different statutes." 427 F.3d at 225. The very first example it gave was the

Eleventh Circuit's decision in *Gem Merchandising*, which held that disgorgement was appropriate under Section 13(b). *Id.* (citing *Gem Merch.*, 87 F.3d at 470).[37] The Court thus clearly found no meaningful distinction between Section 13(b) and the statute at issue in *Lane Labs*.

AbbVie also suggests that Section 13(b) contains a "clear statutory limitation" on the court's equitable jurisdiction (AbbVie Br. 76), but points to nothing in the statute that imposes such a limitation. Again, Congress's intent to limit the court's equitable jurisdiction must be expressed "in so many words" or "by a necessary and inescapable inference." *Mitchell*, 361 U.S. at 291. As the Ninth Circuit has held, "nothing in the [FTC] Act" restricts the court's equitable authority. *Commerce Planet*, 815 F.3d at 599.

AbbVie next argues that since *Mitchell* was decided, "the Supreme Court has 'adopted a far more cautious course' before recognizing implied remedies." AbbVie Br. 76 (quoting *Ziglar v. Abbasi*, 137 S. Ct. 1843 (2017)). Again, *Lane Labs* held that *Porter* and *Mitchell* are controlling precedent, and this Court has no authority to depart from them. *Lane Labs*, 427 F.3d at 236. *Ziglar* and *Alexander*

[37] AbbVie cites an Eleventh Circuit case holding that a provision of the Motor Carrier Act authorizing a *private* party to sue for "injunctive relief" did not authorize restitution or disgorgement. AbbVie Br. 76 (citing *Owner-Operator Indep. Drivers Ass'n v. Landstar Sys.*, 622 F.3d 1307, 1324 (11th Cir. 2010)). But the Eleventh Circuit has repeatedly held that Section 13(b) *does* authorize the FTC to recover equitable monetary relief. *See FTC v. Wash. Data Res., Inc.*, 704 F.3d 1323, 1326 (11th Cir. 2013); *Gem Merch.*, 87 F.3d at 469.

v. Sandoval, 532 U.S. 275 (2001), deal with a different issue: whether a private right of action can be implied to redress constitutional or statutory violations. Here, there is no question that the FTC has a right of action because Congress expressly conferred one in Section 13(b). The question is simply the scope of the equitable relief authority that Congress granted. As this Court held in *Lane Labs*, it is a "fundamental error" to view the availability of monetary relief under a statute like Section 13(b) as a question of implied remedies. 427 F.3d at 235. It explained that in awarding monetary relief, "[t]he District Court did not 'discover' an implied remedy, but rather exercised the equitable power that Congress explicitly granted to it." *Id.* The same is true here.

Rather than addressing the controlling precedents, AbbVie makes a vague appeal to "the history and purpose of §13(b)." AbbVie Br. 74. In fact, history confirms the unanimous view of the federal courts that Section 13(b) authorizes monetary relief. When Congress enacted Section 13(b) in 1973, *Porter* and *Mitchell* were well-established precedents, and numerous courts had relied on them to hold that similarly worded provisions of the securities laws authorizing courts to issue injunctions also authorized other forms of equitable relief, including monetary relief. *See SEC v. Tex. Gulf Sulphur Co.*, 446 F.2d 1301, 1307-08 (2d Cir. 1971) (collecting cases). Congress would have expected the new statute to be

construed the same way as previous statutes authorizing issuance of an injunction. *See Lorillard v. Pons*, 434 U.S. 575, 580-81 (1978).

Congress has twice ratified the consistent understanding of the courts of appeals. In 1994, Congress expanded the venue and service of process provisions of Section 13(b). *See* FTC Act Amendments of 1994, Pub. L. No. 103-312, §10, 108 Stat. 1691 (Aug. 26, 1994). Not only did Congress let the judicial decisions stand, but the Senate Report accompanying the act recognized that Section 13(b) authorizes the FTC to "go into court … to obtain consumer redress." S. Rep. No. 103-130, at 15-16 (1993). Twelve years later, after scores of additional cases awarding monetary relief under Section 13(b), Congress expressly codified the judicial understanding of the remedies allowed under that statute when it made "[a]ll remedies available to the Commission … *including restitution to domestic or foreign victims*" available for certain unfair practices abroad. U.S. Safe Web Act of 2006, Pub. L. 109-455, §3, 120 Stat. 3372 (Dec. 22, 2006) (amending 15 U.S.C. §45(a)(4)(B)) (emphasis added). Congress thus expected that courts would continue their existing practice of awarding equitable monetary relief under Section 13(b).

Finally, AbbVie argues that Section 13(b) cannot be read to authorize equitable monetary relief because Section 19 of the FTC Act authorizes the FTC to sue in court to enforce its administrative orders and obtain "such relief as the court

finds necessary to redress injury to consumers," including "rescission or reformation of contracts, the refund of money or return of property, [and] the payment of damages." AbbVie Br. 75 (quoting 15 U.S.C. §57b(b)). Every court to consider this argument has rejected it. *See, e.g.*, *Commerce Planet*, 815 F.3d at 599; *Bronson Partners*, 654 F.3d at 367; *Sec. Rare Coin*, 931 F.2d at 1315; *Singer*, 668 F.2d at 1113. And for good reason: the argument is foreclosed by the text of the statute. Section 19 was enacted two years after Section 13(b), and it states that the "[r]emedies provided in this section are in addition to, and not in lieu of, any other remedy or right of action provided by State or Federal law," and that "[n]othing in this section shall be construed to affect any authority of the Commission under any other provision of law." 15 U.S.C. §57b(e). We can be sure that Section 19 does not limit monetary relief under Section 13(b) because Congress said so directly.

2. *Kokesh* does not change the court's authority to order monetary relief.

AbbVie next argues that the particular form of remedy ordered by the district court—which required defendants to disgorge their illegal profits into a fund to be paid out to injured consumers—is a "penalty" that is beyond the scope of a district court's equitable authority. AbbVie Br. 77-78. Again, this argument ignores Supreme Court precedent. In *Porter*, the Court held that "a decree compelling one to disgorge profits … may properly be entered by a District Court

once its equity jurisdiction has been invoked." 328 U.S. at 398-99. And the Court applied that principle just three years ago in a dispute between two states—a proceeding that is "basically equitable in nature." *Kansas v. Nebraska*, 135 S. Ct. 1042, 1051 (2015) (cleaned up). It cited *Porter* and held that a disgorgement order was "a fair and equitable remedy." *Id.* at 1053, 1057.

AbbVie contends that *Kokesh v. SEC*, 137 S. Ct. 1635 (2017), silently upended the entire regime of equitable monetary relief. It did no such thing. In *Kokesh*, the Supreme Court addressed a 14-year course of conduct for which the SEC obtained penalties for the most recent five years and disgorgement for the older acts. The "sole question presented" was whether the disgorgement portion of the order functioned as a "penalty" for purposes of the five-year statute of limitations in 28 U.S.C. §2462. 137 S. Ct. at 1641-42 & n.3. The Court held that it was a penalty for that purpose. *Id.* at 1642. But it specifically instructed that "[n]othing in this opinion should be interpreted as an opinion on whether courts possess authority to order disgorgement in SEC enforcement proceedings or on whether courts have properly applied disgorgement principles in this context." *Id.* at 1642 n.3. As the Ninth Circuit recently held, addressing this very question, this language "expressly limits the implications" of *Kokesh*, and the decision therefore does not undermine the well-established case law recognizing the availability of equitable monetary relief under Section 13(b). *FTC v. AMG Capital Mgmt., LLC*,

910 F.3d 417, 427 (9th Cir. 2018); *see also United States v. Dyer*, 908 F.3d 995, 1003 (6th Cir. 2018) ("The holding in *Kokesh* was narrow and limited solely to the statute of limitations in 28 U.S.C. §2462.").

The fact that something may be a "penalty" for statute-of-limitations purposes does not necessarily mean that it is a penalty for all purposes. The Supreme Court recognized long ago that "penalty" is "a term of varying and uncertain meaning." *Life & Cas. Ins. Co. of Tenn. v. McCray*, 291 U.S. 566, 574 (1934). This principle is illustrated by the Supreme Court's decision in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012), which addressed the constitutionality of the Affordable Care Act mandate requiring individuals to maintain health insurance or pay a tax penalty. The Court held that the payment was a "penalty"—not a tax—for purposes of the Anti-Injunction Act, which prohibits litigation to enjoin the collection of a tax. *Id.* at 543-46. But that did not mean the payment was a non-tax "penalty" for all purposes. To the contrary, the Court held that Congress had authority to require the payment because "the shared responsibility payment may for constitutional purposes be considered a tax, not a penalty." *Id.* at 566.

Similar reasoning applies here. The purpose of statutes of limitations is to allow a defendant to "legitimately have peace of mind; it also recognizes that after a certain period of time it is unfair to require the defendant to attempt to piece

together his defense to an old claim." *Walker v. Armco Steel Corp.*, 446 U.S. 740, 751 (1980). These considerations may apply to some claims for equitable monetary relief as they do to claims for purely legal relief. But there is no reason to think that Congress intended that imposing a time limit on monetary relief would completely deprive an equity court of its traditional power to effectuate complete justice. Like the statutes in *Sebelius*, the statute of limitations considered in *Kokesh* and Section 13(b) both "are creatures of Congress's own creation," and "[h]ow they relate to each other is up to Congress." *Sebelius*, 567 U.S. at 544. As explained above, Congress would have understood that Section 13(b) granted the power to award equitable monetary relief when it passed the statute and it ratified that authority in two later legislative enactments. The idea that Congress had already removed the authority to award monetary relief by enacting a general statute of limitations is nonsensical.

Finally, even if "penalty" necessarily meant the same thing for purposes of determining a court's equitable jurisdiction as it does for statute-of-limitations purposes, the remedy awarded by the district court here would not be a penalty under *Kokesh* because it is purely compensatory. *Kokesh* held that "a pecuniary sanction operates as a penalty *only* if it 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." 137 S. Ct. at 1642 (cleaned up) (emphasis added). In *Kokesh*,

the punitive purpose of the remedy was plain because the SEC had attempted to divide the same course of conduct into two parts, labeling the monetary relief for one part as a "penalty" and the other half, calculated the same way, as "disgorgement." *Id.* at 1641. Moreover, the Court expressed concern as a general matter that in SEC cases, some disgorged funds are often paid to the Treasury rather than used to compensate victims. *Id.* at 1644. The judgment simply provided for disgorgement to the SEC without further elaboration. *SEC v. Kokesh*, No. 09-cv-1021, 2015 WL 11142470 (D.N.M. Mar. 30, 2015). This case does not involve the kind of remedy splitting at issue in *Kokesh*, and the district court's judgment provides that the defendants' illegal profits are to be paid into a trust fund for equitable relief and used for "consumer and other purchaser redress and any attendant expenses for the administration of the fund." ECF No. 448 at 2 (JA172).[38] Nothing will go to the Treasury. AbbVie is thus wrong to suggest that the FTC can "choose" whether to compensate consumers. AbbVie Br. 79 n.6.

AbbVie's argument that the district court's monetary award is necessarily punitive because "it aims to deter future violations" (AbbVie Br. 78) likewise misreads *Kokesh*. All remedies serve some deterrent purposes. The problem the Supreme Court identified in *Kokesh* was that as courts had employed the

[38] The district court must approve the FTC's distribution plan, after getting input from the defendants, and if any money remains in the trust fund after five years, the court will decide how to dispose of it, again after input from the defendants.

disgorgement remedy in SEC cases, deterrence was the "primary purpose" of the remedy and not "simply an incidental effect of disgorgement." 137 S. Ct. at 1643. Here, although the district court referenced the deterrent effect of its monetary relief order, the judgment makes clear that the overriding purpose of the remedy is to compensate injured consumers. Insofar as that has the incidental effect of deterring future illegal conduct, that beneficial outcome does not transform the relief into "a noncompensatory sanction." *Id*. at 1644.

3. Denial of injunctive relief does not preclude equitable monetary relief.

AbbVie's third swing likewise fails to connect. AbbVie argues that the district court's denial of injunctive relief invalidates the equitable monetary relief award. AbbVie Br. 80-81. As a preliminary matter, we have shown above and in our opening brief that the district court erred in denying the FTC's request for an injunction. If the Court agrees, it need not consider this argument at all.

In any event, the argument is meritless. Once a district court's equitable jurisdiction is invoked, it has power to award equitable monetary relief even where an injunction is not warranted. *See United States v. Moore*, 340 U.S. 616, 619-20 (1951) (affirming order requiring restitution of rent overcharges, even though injunction was not possible because underlying rent control law had terminated); *CFTC v. Am. Metals Exch. Corp.*, 991 F.2d 71, 74, 76 (3d Cir. 1993) (district court "did not err in imposing" disgorgement remedy even though plaintiffs had not

shown likelihood of recurrence as required for injunction); *SEC v. Commonwealth Chem. Sec., Inc.*, 574 F.2d 90, 103 n.13 (2d Cir. 1978) (when a violation has been established, "failure … to show the likelihood of recurrence required to justify an injunction" will not "relieve a defendant … from the obligation to disgorge"). The Ninth Circuit, sitting *en banc*, recently applied this principle in an FTC case, explaining that even if the agency could not obtain an injunction it could "still potentially achieve monetary relief for [the defendant's] past violations." *FTC v. AT&T Mobility, LLC*, 883 F.3d 848, 864 (9th Cir. 2018) (en banc).

AbbVie disregards these cases, instead citing this Court's recent holding in *Shire* that if the FTC has not adequately pled in the complaint that it has reason to believe a defendant "is violating, or is about to violate" the law, it cannot state a claim for either injunctive or monetary relief. *See Shire*, 917 F.3d at 160 n.19. That principle does not help AbbVie here because, as discussed above (at 7), *Shire* only concerns the *pleading* standard in FTC cases, *see id.* at 158, and AbbVie and Besins never challenged the adequacy of the FTC's complaint on this ground. In any case, as discussed above (at 7-9), the complaint here alleged ongoing misconduct. At the time suit was filed, generics had not yet entered the market, the reverse-payment agreement was still in effect, and AbbVie and Besins were continuing to maintain their unlawful AndroGel monopoly.

C. The District Court Reasonably Found That Perrigo Would Have Launched in June 2013 Absent the Delayed Launch Date Resulting From the Sham Lawsuit.

One of the key inputs in determining the amount of defendants' illegal profits is Perrigo's but-for entry date. AbbVie argues that the district court overstated the amount of illegal profits by finding that absent the sham litigation, Perrigo would have launched its AB-rated generic in June 2013. AbbVie Br. 81. The district court's finding was reasonable and supported by the evidence. AbbVie has shown no abuse of discretion.

The relevant facts are as follows. The FDA approved Perrigo's generic in January 2013 but did not issue a therapeutic equivalence rating at that time. Op. 26 (JA94). By then, Perrigo had settled the lawsuit and could not launch before December 27, 2014. In March 2014, with the launch date approaching, Perrigo sued the FDA to compel the issuance of a rating. *Id.* In response, the FDA stated that in light of the December 2014 launch date there was no need for a prompt decision, but it committed to issuing a rating by July 2014. Op. 26-27 (JA94-95). Perrigo received an AB rating on July 23, 2014. Op. 27 (JA95).

Before the district court, AbbVie agreed that in the but-for world, Perrigo would have launched before December 2014, but argued that the earliest it would have done so was August 2014—the month after receiving the AB rating. Op. 83 (JA151). The district court found, however, that if Perrigo had not been sued and

thus had been free to launch, FDA would have moved more quickly and issued a therapeutic equivalence rating by June 2013. Op. 88-90 (JA156-58).

That finding was supported by testimony from both Perrigo's assistant general counsel, Andrew Solomon, and the FTC's expert in FDA regulatory procedures, Kenneth Phelps, a 40-year veteran of the pharmaceutical industry who has worked on more than 450 505(b)(2) drug applications. Tr. 2:5, 15; Tr. 4:150 (JA3545, 3547, 3679). Solomon testified that the timing of the lawsuit was dictated by the agreed-upon launch date. Tr. 4:198, 206-07 (JA3709, 3711). To maximize profits, Perrigo made "a business decision to launch as early as possible." Tr. 4:208 (JA3711). If not for the launch delay resulting from settlement, Perrigo "probably would have pushed harder back in 2013 to get a decision [from the FDA]," and might have filed suit earlier if the agency failed to respond. Tr. 4:208-09 (JA3711-12).

Similarly, Phelps testified that Perrigo had "great incentive to get a TE-rating" and that there were numerous things it could have done to expedite the process—including but not limited to filing a lawsuit. Tr. 2:61, 83-84, 177-78 (JA3559, 3564, 3588). He testified that in his experience, the FDA typically issues equivalence ratings for 505(b)(2) products in less than a month. Tr. 2:75 (JA3562). And he further testified that the FDA would have "had every desire to get a generic approved for these products" because part of its mission is "to deliver

cheaper drugs to the American public." Tr. 2:177-78 (JA3588). In light of this evidence, the court's conclusion that Perrigo would have received an equivalence rating by June 2013—five months after approval—is reasonable and consistent with the record.

AbbVie's challenges need not detain the Court long. AbbVie first argues that there was no evidence that the FDA knew before March 2014 (when Perrigo filed its lawsuit) that Perrigo had agreed to delay its launch until December 2014. AbbVie Br. 82-83. AbbVie offers no reason why, if there had been no settlement, Perrigo would not have immediately told the FDA that it planned to launch as soon as it received an equivalence rating. The evidence showed that if Perrigo had not agreed to delay its launch, it likely would have pushed the FDA to act faster, and the agency would likely have responded.

AbbVie also argues that the district court improperly assumed that in the but-for world Perrigo would have sued the FDA in February 2013. AbbVie Br. 83. The court said nothing of the kind. It simply relied on the fact that the FDA "is presumed to act in the public interest, which includes the mission of benefitting consumers by approving the entry of safe and effective lower-cost generic drugs into the market." Op. 88 (JA156). In other words, the court reasonably assumed—consistent with the testimony cited above—that the FDA would act promptly if it knew that its delay was keeping a lower-priced generic off the market.

Finally, AbbVie argues that the FDA would not have issued its rating earlier because it needed to consider two citizen petitions that AbbVie filed. AbbVie Br. 84-85. The district court properly rejected this argument, finding that "there is no indication that the FDA refrained from issuing TE ratings for generic drugs while this [first] petition was pending" and "a June 2013 launch would have been six months before AbbVie filed its supplemental citizen petition." Op. 89-90 (JA157-58).[39] These findings are supported by the record and not clearly erroneous.

D. The Court Properly Awarded Monetary Relief Against Besins.

Besins contends that the district court abused its discretion by holding it liable for a portion of the monetary relief award.[40] Besins Br. 17-25. Briefly, the district court held that defendants' illegal profits from the sale of AndroGel totaled $448 million. Op. 94 (JA162). It held that because AbbVie and Besins acted jointly in filing the sham lawsuits, they could properly be held jointly and severally liable for this entire amount. Op. 97 (JA165) (citing *Hughes Capital*, 124 F.3d at 455). But Besins argued that it should not be required to pay anything because it did not actually receive any money from the sale of AndroGel; rather, the money went to sister companies in the Besins corporate family located in Europe. In the

[39] The data on which AbbVie based its supplemental petition was not even available until five months after Perrigo's product was approved. PLX221-005; Tr. 14:141-42 (JA1413, 4293).

[40] In this section "Besins" refers solely to the named defendant.

alternative, it urged the district court to apportion liability between the defendants based on the contractual arrangements between AbbVie and the Besins affiliates. ECF No. 414 at 14-17. The district court agreed that apportionment was proper and held AbbVie liable for $419 million and Besins liable for $28 million (not counting prejudgment interest). Op. 97-98; ECF No. 448 at 1 (JA162-63, 171).

Besins now renews its argument that it should not have been required to pay anything. The argument fails because it is based on a misunderstanding of the legal principles governing liability of joint wrongdoers. The district court did not abuse its discretion in holding Besins liable for a portion of the illegal profits.

Besins, an American company, is a subsidiary of a privately held global pharmaceutical business headquartered in Belgium. DX304-001 (JA3471). Besins and AbbVie co-own the '894 patent. Op. 1 (JA69). Thus, as a matter of patent law, neither could sue for infringement without the other's consent. *See Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1468 (Fed. Cir. 1998). Besins and AbbVie cooperated in filing the sham lawsuits and caused a single, indivisible harm to consumers by keeping the price of AndroGel artificially elevated.

Besins is essentially a holding company with no operations of its own. Tr. 4:56-57, 130-31 (JA3673-74, 3692). AndroGel is manufactured in France by a different Besins entity, which sells the drug to AbbVie. DX304-002 (JA3472). AbbVie in turn sells the drug to its U.S. customers and pays the European Besins

entities a royalty on its sales. *Id.* While Besins itself does not earn revenue from the sale of AndroGel, its corporate siblings do. *Id.*

On these facts, the district court properly held that Besins could be subject to joint-and-several liability with AbbVie. Op. 97 (JA165). The law of this Circuit is clear that "joint-and-several liability is appropriate … when two or more individuals or entities collaborate or have close relationships in engaging in the illegal conduct." *Hughes Capital*, 124 F.3d at 455. Under that rule, each wrongdoer "is subject to liability for the entire harm." *United States v. Alcan Aluminum Corp.*, 964 F.2d 252, 268-69 (3d Cir. 1992); *accord Honeycutt v. United States*, 137 S. Ct. 1626, 1631 (2017). This necessarily means that an equitable monetary relief award against defendants who are jointly liable is not "limited to the unjust gains each defendant personally received." *Commerce Planet*, 815 F.3d at 601; *see also FTC v. WV Univ. Mgmt.*, 877 F.3d 1234, 1243 (11th Cir. 2017) (disgorgement not limited to funds defendant personally retained). Besins therefore cannot escape monetary liability simply because it did not directly receive money. It jointly caused the harms and therefore could properly be held liable for the entire amount of the unjust gains.

But the district court did not hold Besins liable for the entire amount. Rather, it agreed with Besins that even though the *harm* here was indivisible, there was a reasonable basis for apportionment of the monetary relief award, based on

the contractual allocation of revenue between AbbVie and the Besins affiliates. Op. 97-98 (JA165-66). The court had discretion to apportion relief in this manner. *See Hughes Capital*, 124 F.3d at 455. The net result is that even though Besins and AbbVie are equally culpable for the harm they caused to consumers, Besins was required to pay only a small fraction of the monetary judgment intended to compensate consumers for that harm. Equity surely permits such a result, which ensures that consumers are fully compensated but that neither defendant is forced to pay more than its fair share.[41]

Besins's argument based on *Kokesh* is simply a variation on AbbVie's and fails for the same reasons. The "sole question" in *Kokesh* was whether SEC disgorgement was subject to the five-year statute of limitations, and the Court expressly declined to address the propriety of equitable monetary relief. 137 S. Ct. at 1642 n.3. Nothing in *Kokesh* suggests that the Court intended to silently overturn decades of precedent on joint and several liability in the context of equitable remedies.

Besins faults the district court for its reliance on *SEC v. Contorinis*, 743 F.3d 296 (2d Cir. 2014), arguing that that case is "neither controlling nor persuasive."

[41] There is no dispute that AbbVie, the party that sold AndroGel, received all of the sales revenue in the first instance. Accordingly, if the Court were to reverse the award against Besins, it should remand with instructions to hold AbbVie liable for the full amount of illegal profits, so that consumers are not shortchanged.

Besins Br. 21. But as discussed, the principles the district court relied upon to impose monetary liability on a joint wrongdoer are well established in this Circuit. *See Hughes Capital*, 124 F.3d at 455; *Alcan*, 964 F.2d at 268-69. In any event, *Contorinis*, while supportive of the district court's decision, involves a distinctly different (and more difficult) set of facts. The defendant there was a broker who engaged in insider trading for the benefit of a client, without the client's participation. The question was whether he could be required to disgorge the benefits his client received. *Contorinis*, 743 F.3d at 299. The Second Circuit held that he could. *Id.*[42] The case presented no issue of joint-and-several liability.

Finally, Besins faults the FTC for not having named its European sister companies that received payments from AbbVie as relief defendants. Besins Br. 23-24. The FTC did not need to do so here because Besins's financial liability rests on its joint unlawful conduct with AbbVie.

CONCLUSION

The district court's determination that AbbVie and Besins willfully maintained a monopoly through sham litigation should be affirmed. The court's decision to award equitable monetary relief, its determination of Perrigo's but-for

[42] It was this aspect of the case that troubled the Supreme Court in *Kokesh*. *See* 137 S. Ct. at 1644. But in any case, the Court never suggested that an award like the one in *Contorinis* was beyond the power of an equity court—simply that it was subject to the five-year statute of limitations.

entry date, and its apportionment of liability between AbbVie and Besins should also be affirmed.

Respectfully submitted,

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COMBINED CERTIFICATIONS

COMPLIANCE WITH TYPE-VOLUME LIMIT, TYPEFACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENTS

1. This brief complies with the type-volume limit of Fed. R. App. P. 37(a)(7)(B), as modified by the Court's order of May 22, 2019, because it contains 25,660 words (excluding the parts of the brief exempted by Fed. R. App. P. 32(f)).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010, in 14 point Times New Roman.

BAR MEMBERSHIP

All signatories to this brief are attorneys who work for a federal government agency.

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I certify that the text of the electronically filed brief is identical to the text of the original copies that were sent on July 19, 2019, to the Clerk of the Court of the United States Court of Appeals for the Third Circuit.

PERFORMANCE OF VIRUS CHECK

I certify that on July 19, 2019, I performed a virus check on the electronically filed copy of this brief using Symantec Endpoint Protection Version 14 (14.2) build 1031 (14.2.1031.0100) (last updated July 19, 2019). No virus was detected.

SERVICE

I certify that on July 19, 2019, I filed the foregoing brief via the Court's electronic filing system. All parties will be served by the CM/ECF system.

July 19, 2019 /s/Matthew M. Hoffman
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