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

OPENING BRIEF OF THE FEDERAL TRADE COMMISSION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

In

STATUTES

RULES AND REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

This antitrust case involves the unlawful efforts of defendants AbbVie Inc. and Besins Healthcare Inc. to protect their monopoly profits on AndroGel, a multibillion-dollar "blockbuster" testosterone replacement drug sold by AbbVie under a patent it jointly owns with Besins.[1] In 2011, AbbVie and Besins faced significant competitive threats when two other drugmakers, Teva Pharmaceuticals USA, Inc. and Perrigo Company, applied to the Food and Drug Administration for permission to market lower-priced generic versions of AndroGel. That spurred a course of unlawful conduct with two principal parts.

First, AbbVie and Besins filed sham patent infringement lawsuits to block competition. They had no viable infringement claim because Teva and Perrigo had designed their products so they did not infringe the AndroGel patent. But AbbVie and Besins knew that merely filing the lawsuits would trigger a statutory block on FDA approval of the generic products (and hence any sales) for 30 months, unless the lawsuit ended earlier.

Second, when the Teva litigation moved more quickly than expected, AbbVie resorted to another strategy: it paid Teva to defer launch of its generic

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[1] "AbbVie" refers collectively to AbbVie Inc. and its affiliates and predecessors-in-interest, including Abbott Laboratories, Solvay Pharmaceuticals, Inc., and Unimed Pharmaceuticals, LLC. "Besins" refers collectively to Besins Healthcare, Inc. and its affiliates.

product. The payment took the form of AbbVie's agreement to supply Teva with a generic version of another drug, TriCor—a deal worth $175 million to Teva. While extremely lucrative for Teva, the TriCor deal made no economic sense for AbbVie except as a means to obtain Teva's agreement not to compete with AndroGel for three years. AbbVie expected to lose $100 million in TriCor sales, but that sum was dwarfed by the billions of dollars in AndroGel sales that AbbVie protected by maintaining its monopoly—money that ultimatelym nnnPage: 177age: 177h1 nyeT

ISSUES PRESENTED

1. Did the FTC's allegations that AbbVie used the TriCor agreement to induce Teva to defer competing against AndroGel state a claim of an illegal reverse payment under *Actavis*? (Argument raised at ECF Nos. 48, 110, 114; ruled upon at ECF Nos. 81, 82, 118, 119 (JA2-30).)

2. Did the district court abuse its discretion in calculating the amount of monetary relief, where it failed to consider how the reverse-payment agreement affected Teva's actions and improperly conflated the real world with the "but-for" world that would have existed absent the sham litigation? (Argument raised at ECF No. 321 at 21-24; No. 403 at 27-34; No. 405 at 121-72, 179; ruled upon at ECF No. 439 at 83-86 (JA151-54).)

3. Did the district court abuse its discretion in denying all injunctive relief despite finding an egregious antitrust violation? (Argument raised at ECF No. 321 at 20-21; No. 403 at 34-35; No. 405 at 172-73, 179; ruled upon at ECF No. 439 at 98-101 (JA166-69).)

STATEMENT OF RELATED CASES

This case has not been before this Court previously. Three actions involving the same conduct are pending in the Eastern District of Pennsylvania: *Value Drug Co. v. AbbVie Inc.*, No. 2:18-cv-2804; *Walgreen Co. v. AbbVie Inc.*, No. 2:18-cv-3494; and *CVS Phthtd tc.*

Court considered other reverse-payment agreements relating to AndroGel in *Actavis*. *See* 570 U.S. at 144-45. The FTC is unaware of any other related case or proceeding under Third Circuit Rule 28.1(a).

RELEVANT STATUTES

Statutory addendum attached.

STATEMENT OF THE CASE

A. Statutory Framework Governing Pharmaceuticals

A company seeking to market a new brand-name drug in the United States must obtain FDA approval of a new drug application ("NDA") showing that the drug is safe and effective. 21 U.S.C. § 355(a), (b)(1). Once a brand-name drug has been approved, another company may seek approval to sell a generic version of the drug. Generic drugs contain the same active ingredients as their brand-name equivalents but cost much less, so third-party payers (*e.g.*, health insurance plans) encourage (and all states permit) pharmacists to substitute generics for brand-name drugs. Once the first generic enters the market, it typically captures the vast majority of the brand's sales.

The Drug Price Competition and Patent Term Expiration Act (commonly known as the Hatch-Waxman Act) provides two ways to get approval for a generic drug. Usually, a generic company files an abbreviated new drug application ("ANDA") showing that the generic product is "bioequivalent" to the brand-name

drug. *See* 28 U.S.C. § 355(j). The FDA typically assigns drugs approved through this process an "AB" therapeutic equivalence rating, allowing pharmacists to substitute the generic for the brand.

The other pathway is known as a "505(b)(2) NDA." The FDA may require a manufacturer to use this route, rather than an ANDA, if the generic drug differs from the brand-name product in ways that could affect safety or efficacy. *See* 21 U.S.C. § 355(b)(2); 21 C.F.R. § 314.54. Drugs approved through the 505(b)(2) process rarely receive an AB rating, *see* PLX307-001 (JA1695), but those that do can be substituted for the brand just like drugs approved through the ANDA process. A 505(b)(2) drug may receive instead a "BX" rating, indicating that therapeutic equivalence has not been shown, or it may have no rating at all. Non-AB-rated generics may not be automatically substitutable for the brand, but health plans can create incentives that induce doctors to prescribe these drugs in lieu of more expensive brand-name drugs. *See* PLX032-003 (JA685).[3] Similarly,

Many brand-name drugs are protected by patents. To encourage competition

infringer is called a "reverse-payment" agreement. The Supreme Court has held that a "large and unjustified" reverse payment can "bring with it the risk of significant anticompetitive effects." *Actavis*, 570 U.S. at 158.

B. AndroGel

AndroGel is a testosterone gel approved by the FDA for treatment of hypogonadism (low testosterone) in men. Op. 7 (JA75).[4] The first forms of testosterone replacement therapy ("TRT") were injectables, which require painful shots deep into the muscle every few weeks, frequently in a doctor's office or clinic, and result in a peak of testosterone after injection followed by decreasing

C. The ’894 Patent

AbbVie and Besins jointly own U.S. Patent No. 6,503,894 (the ’894 patent), which expires August 30, 2020. PLX061 (JA1155). The patent covers the specific testosterone gel formulation used in AndroGel. In particular, it claims formulations containing isopropyl myristate (“IPM”) and other ingredients in specified amounts. IPM is a “penetration enhancer” that facilitates delivery of testosterone through the skin. Because the patent only claims formulations using IPM, it was possible for competitors to design around the patent by developing a gel using a different compound as the penetration enhancer.

Where a product does not literally satisfy all of the limitations of an asserted patent claim, it still may be found to infringe under the “doctrine of equivalents,” which extends the 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 Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 U.S. 722, 733 (2002). But that doctrine is itself limited by the rule of “prosecution history estoppel.” Where a patent application originally claimed a broad subject matter, but the applicant later narrowed the claims to meet the statutory requirements for 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.” *Id.* at 733-34. In other words, the patentee

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

In this case, the original application that resulted in the '894 patent broadly claimed transdermal pharmaceutical products using *any* penetration enhancer. PLX051-078 (JA909). The patent examiner rejected the claims as obvious.

"careful evaluation," AbbVie's predecessor Solvay "determined there was not a sufficient basis for filing patent infringement litigation" against Perrigo and publicly announced that it would not sue, citing Perrigo's different formulation. Op. 15; Tr. 5:77-79; PLX009 (JA83, 3735, 608). Besins also determined that it was "standing down" from bringing an infringement suit. Op. 15 (JA83).

Perrigo aba3 d[(Tb wAO)7.(Tr.)s

Teva's top executives did not expect to receive an AB rating for their product. PLX296-003; PLX021-001 (JA1618, 627). But Teva's analysis showed that even without the pharmacy substitution advantage conferred by an AB rating, a generic version of AndroGel could earn hundreds of millions of dollars. Teva's strategy was to employ a "brand lite" approach, working with managed care organizations to create incentives for doctors to write prescriptions for Teva's lower-priced product in lieu of brand AndroGel. Tr. 3:147-48; PLX021-001; PLX304-002; PLX295-001 (JA3638, 627, 1692, 1611). Teva already had a sales force, known as the market access group, that regularly called on insurers to negotiate for favorable formulary placement. Tr. 3:156-57 (JA3640-41). Teva

2. The Sham Lawsuit Pushes Back Teva's Launch Date

Teva's launch plans were upended in April 2011 when AbbVie and Besins filed a Paragraph IV infringement suit. The lawsuit triggered the 30-month Hatch-Waxman stay, barring the FDA from approving Teva's product until September 2013, unless the case ended earlier. Op. 18-19 (JA86-87). Teva was forced to push back its projected launch date and reduce its sales projections. Even so, it kept moving ahead with the project, beginning the costly process of selecting a trade name (which would be necessary only if Teva did not get an AB rating). PLX042-002; PLX317-001; Tr. 3:63-65 (JA796, 1740, 3617-18). Teva executive Tim Crew, who spearheaded the project, told CEO William Marth in August 2011 that "[w]e expect to launch the product in 2013," even though "[w]e do not expect a generic AB rating." PLX-021-001 (JA627). Consistent with that understanding, Teva included a non-AB-rated testosterone gel in its formal "work plan"—used by upper management and the board of directors to set the company's financial objectives—projecting launch in October 2013 and sales of $49.2 million in 2014. PLX318-004; Tr. 3:73-76 (JA1746, 3620).

But Teva also knew it was racing against the clock. In May 2011, AbbVie introduced a more concentrated version of AndroGel and began aggressively trying to switch users from the original 1% formulation to the newer 1.62% formulation. The new product was not as susceptible to lost sales from a generic version of the

"first-mover" advantage, but it was about to lose this opportunity because it had not obtained FDA approval and had no viable way of selling generic TriCor before its competitors. *Id*. ¶114 (JA4442-43). The TriCor supply deal would enable Teva to launch in November 2012, seven weeks before other generics, preserving the first-mover advantage. Teva expected to earn $175 million in TriCor sales over four years—money that it could not otherwise have earned (and actually wound up selling more than that). *Id*. ¶¶117, 120-24 (JA4443-45). In return, Teva settled the AndroGel litigation, dropping its patent challenge and agreeing not to launch generic AndroGel before December 27, 2014. *Id*. ¶¶113-17 (JA4442-43). Both agreements were executed simultaneously on December 20, 2011. *Id*. ¶¶116-17 (JA4443).

AbbVie had no standalone reason to supply Teva with generic TriCor, which would accelerate generic competition on that blockbuster product. Compl. ¶115 (JA4443). But the TriCor deal made perfect sense as a quid pro quo for Teva's agreement to forgo competing with AndroGel. AbbVie calculated that it would sacrifice about $100 million in TriCor sales, but that was a small fraction of the billions of dollars in AndroGel revenue AbbVie protected by deferring competition for three years. *Id*. ¶132 (JA4447). And the delay bought AbbVie time to protect the AndroGel franchise by continuing to shift the market to AndroGel 1.62%. *Id.*

E. Sham Litigation Against Perrigo

Perrigo filed a 505(b)(2) NDA for its generic version of AndroGel in July 2011. Op. 21-22 (JA89-90). Despite having no viable infringement claim, AbbVie and Besins sued Perrigo in October 2011, blocking FDA approval. Op. 22-23 (JA90-91). Almost immediately after filing the complaint, AbbVie contacted Perrigo to discuss settlement. *Id*. 24 (JA92). Under the terms of an FTC consent order Perrigo had signed in 2011, AbbVie and Besins could not pay Perrigo to defer entry of its generic, but they could offer Perrigo something else it highly valued: the right to launch generic AndroGel at the same time as Teva. Compl. ¶¶134-35 (JA4448). Perrigo agreed to this deal (though it did not know that AbbVie was simultaneously negotiating with Teva to push back its launch date), with AbbVie and Besins also agreeing to pay Perrigo $2 million in saved litigation expenses. *Id*. ¶136 (JA4448-49). Together, the two settlements ensured that AndroGel would not face generic competition for another three years. *Id*. ¶137 (JA4449).

F. Teva and Perrigo's Launch Decisions

The FDA approved Teva's testosterone gel product in February 2012. Op. 25 (JA93). As discussed in more detail at page 43 below, by this point the delay caused by the lawsuit and settlement had undermined the financial viability of Teva's product, and Teva abandoned the project in late 2012. Tr. 3:132 (JA3634).

The FDA later assigned Teva's product a BX rating, as Teva had expected. Op. 27 (JA95). The FDA approved Perrigo's testosterone gel in January 2013; Perrigo received an AB rating and launched on December 27, 2014. *Id*.

G. Proceedings Below

1. The Complaint

The FTC sued AbbVie and Besins for engaging in unfair methods of competition in violation of 15 U.S.C. § 45(a). Count I of the complaint alleged that AbbVie and Besins willfully maintained a monopoly through a course of anticompetitive conduct, including sham litigation. Compl. ¶¶152-53 (JA4453). Count II alleged that AbbVie restrained trade by entering into an anticompetitive reverse-payment agreement with Teva. *Id*. ¶¶154-55 (JA4453-54). The FTC sought a behavioral injunction to prevent future violations and equitable monetary relief to redress the harm to consumers. JA4454.

2. Dismissal of Reverse-Payment Claim

The district court dismissed the reverse-payment claim under Rule 12(b)(6). The court acknowledged that "something of large value passed from [AbbVie] to Teva" via the TriCor agreement, but concluded that it was not a reverse payment because Teva was "paying [AbbVie] for the supply of TriCor." MTD Op. at 15-16 (JA16-17). Rather than crediting the FTC's allegations that the TriCor agreement and the AndroGel settlement were two sides of a single anticompetitive

transaction, the court examined the two agreements separately and deemed each independently procompetitive.

3. Liability Finding on the Sham Litigation Claim

The sham litigation claim required the FTC to show (1) that the infringement lawsuits against Teva and Perrigo were objectively baseless and (2) that AbbVie and Besins subjectively intended to "interfere directly with a competitor's business relationships, through the use of the governmental *process* … as an anticompetitive weapon." *, 8U.S. at 5. The district court granted partial summary judgment for the FTC on objective baselessness, holding that the '4patent's prosecution history showed that AbbVie and Besins could not realistically have expected success on the merits of [the prosecution history estoppel] issue or have had a reasonable belief that they had a chance to prevail."MSJ Op. 34–38*

After a 6-day bench trial, the court also ruled for the FTC on the second

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lawsuits was to impose expense and delay on Teva and Perrigo so as to block their entry into the TTRT market" and "delay defendants' impending loss of

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much less expensive competitive generic products … to the detriment of consumers." *Id.* at 77 (JA145).

4. Relief and Judgment

Having found liability, the district court addressed relief. It held that the profits AbbVie and Besins earned from their illegal conduct should be deposited in a fund to be to be equitably disbursed to injured consumers. Op. 78-81 (JA146-49). The FTC's economic expert, Dr. Carl Shapiro, opined that if AbbVie and Besins had never filed sham lawsuits (1) Teva would likely have launched a non-AB-rated generic by June 2012, (2) Perrigo would have launched an AB-rated generic by June 2013, and (3) the launch of generic AndroGel 1% would have caused the market share of AndroGel 1.62% to plateau. Tr. 7:137-38 (JA3870). From those premises, Dr. Shapiro calculated that defendants' illegal profits

Despite finding a violation, the district court denied the FTC's request for injunctive relief. Op. 98-101 (JA166-69). Although the FTC presented evidence that AbbVie and Besins regularly engage in Paragraph IV patent litigation and that AbbVie had previously filed other baseless patent lawsuits, the court held that the FTC had not shown a likelihood of further sham litigation. *Id.* at 99-100 (JA167-68). It also expressed concern that an injunction would be "overbroad and punitive" and would implicate First Amendment rights. *Id.* at 100-01 (JA168-69). In reaching that conclusion, however, the court focused on an injunction far broader than what the FTC actually sought in its proposed order, and did not address whether narrower forms of relief might be appropriate.

SUMMARY OF ARGUMENT

1. The district court erred in dismissing the FTC's reverse-payment claim. The complaint alleges that Teva agreed to settle AbbVie's Paragraph IV lawsuit and defer its introduction of generic AndroGel for three years in exchange for AbbVie'sthrent to supply Teva with generic TriCor, a benefit worth $175 million. In other words, AbbVie and Teva allegedly entered into a quid-pro-quo agen with the basic pue o deferringpitioectin monopoly profits—exactly the type of anticompetitive harm at the heart of *Actavis*. The payoff to Teva was large, cannot be explained as an independent business de2, and makes sense only as a eans to protect AndroGel frommpetition.

The FTC amply met that burden with expert testimony and extensive documentary evidence showing that if Teva had not been illegally sued, it likely would have launched a non-AB-rated generic version of AndroGel by June 2012. Teva's management was fully committed to the AndroGel project and anticipated hundreds of millions of dollars in sales even without an AB rating (which Teva did not expect to receive). AbbVie likewise recognized that a non-AB-rated product would cut substantially into AndroGel saa Anch Teva AndrocuTevl

forth by this Court in *SEC v. Bonastia*, 614 F.2d 908 (3d Cir. 1980). Had it done so, it would have concluded that AbbVie and Besins are likely to engage in further sham litigation absent an injunction. AbbVie has engaged in other sham litigation involving other products and patents, and as the holder of many pharmaceutical patents it retains the means and incentives to do so again.

The district court wrongly concluded that the FTC's proposed injunction was "overbroad and punitive." That determination rested on a mischaracterization of the proposed order. Contrary to the district court's assertion, the FTC did not seek an injunction against any misuse of government processes; it sought far narrower forms of relief specifically tailored to address the kind of conduct at issue in this case. Whether or not all of this relief is warranted is a question for another day; for now, the FTC was at least entitled to a fair evaluation of the injunctive relief it actually requested under the test this Court has set forth for evaluating it. Given the egregiousness of the violations and the likelihood of recurrence, the decision not to award *any* injunctive relief was an abuse of discretion.

ARGUMENT

I. THE DISTRICT COURT ERRED IN DISMISSING THE REVERSE-PAYMENT CLAIM.

patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.*

This Court first interpreted and applied *Actavis* in *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp*., 791 F.3d 388 (3d Cir. 2015). That case involved a Paragraph IV litigation settlement in which the generic company (Teva) agreed to drop its patent challenge in exchange for the brand's agreement not to sell an authorized-generic version of the drug for 180 days after Teva's agreed-upon entry date. *Id.* at 397. The district court dismissed the complaint, but this Court reversed, holding that under *Actavis*

damages claim worth hundreds of millions of dollars in a lawsuit over a different drug, Accupril. *Lipitor*, 868 F.3d at 243-44, 253. As in *King Drug*, this Court reversed the dismissal of the complaint. It explained that an allegation that the

The complaint further alleges that an opportunity to sell generic TriCor before other generics entered that market was highly valuable to Teva. *Id.* ¶120 (JA4444). Under a prior settlement with AbbVie, Teva had the right to sell generic TriCor six months before any other generic competitor, giving it a valuable competitive advantage. But it had failed to obtain FDA approval for its product and was likely to forfeit that opportunity. *Id*. ¶¶114, 120-21 (JA4442-45). The TriCor supply agreement would allow Teva to salvage at least some of the advantage and enter the market seven et e ad3mehg

The complaint plausibly alleges that the transfer of economic value represented by the TriCor supply agreement was large. The district court effectively acknowledged that this requirement was satisfied when it stated that that "something of large value passed from AbbVie to Teva." MTD Op. 15 (JA16). In any event, the $175 million payment clearly is large enough to survive a motion to dismiss. "All that need be alleged, at this juncture, is that [the litigation] costs fail to explain" the size of the payment. *Lipitor*, 868 F.3d at 256. The alleged $175 million economic benefit to Teva far exceeded any party's saved litigation costs from settlement of the AndroGel patent litigation. Compl. ¶¶120-23 (JA4444-45). The value of the transaction to Teva is at least comparable to, if not greater than, the amount the Supreme Court deemed large when considering the allegations in the *Actavis* complaint. 570 U.S. at 145, 154; *see also Lipitor*, 868 F.3d at 254-55.

earning [AbbVie] far more than $100 million in AndroGel monopoly profits." *Id.* ¶132 (JA4447). The FTC thus "sufficiently alleged the absence of a convincing justification for the reverse payment and [was] not required to plead more than that." *Lipitor*, 868 F.3d at 257.

For purposes of assessing the sufficiency of the complaint, there is no difference between AbbVie and Teva's agreement and those in other reverse-payment cases. The parties' alleged "basic reason" for settling the AndroGel patent litigation with the lucrative TriCor deal was "a desire to maintain and to share patent-generated monopoly profits." *Actavis*, 570 U.S. at 158. The alleged agreement between them was "likely to present the same types of problems" and its effects on AndroGel consumers were likely to be "as harmful as those resulting from reverse payments of cash." *King Drug*, 791 F.3d at 404-05. Specifically, the complaint alleges that AbbVie was able to preserve its AndroGel monopoly profits by effectively using a portion of those profits to buy off its potential competitor. Nothing more was required under *Actavis* and this Court's precedents.

C. The District Court Erroneously Treated the TriCor Deal and the AndroGel Settlement as Separate Agreements.

The district court's fundamental analytical error was to treat the AndroGel settlement and the TriCor deal as unrelated agreements, rather than as the two halves of a single package deal. The complaint expressly alleges the link between them, charging that AbbVie was willing to enter into the TriCor supply agreement

"only if Teva would agree to drop its patent challenge and refrain from competing with its testosterone gel product until December 2014," and that the compensation Teva received via that agreement "was designed to, and did, induce Teva to settle the AndroGel patent litigation and agree to refrain from marketing its testosterone gel product until December 27, 2014." Compl. ¶¶115, 119 (JA4443-44). Only by ignoring these allegations could the district court have concluded that AbbVie "did not make any payment, reverse or otherwise," to Teva. MTD Op. 14-17 (JA15-18). Compounding its error, the court then analyzed the agreements separately and concluded that each was procompetitive. *Id*. Those were fundamental errors that contradict the complaint allegations and cannot be squared with core antitrust principles and the meaning of *Actavis*.

This Court has instructed that antitrust analysis must consider the "economic realities" of an alleged antitrust violation, not merely its form. *United States v. Dentsply Int'l, Inc*., 399 F.3d 181, 189 (3d Cir. 2005); *see King Drug*, 791 F.3d at 405-06 & n.24. Thus, when an alleged antitrust conspiracy consists of multiple interrelated parts, its "character and effect … are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699

(1962) (cleaned up).[6] Here, although the parties formally entered into two contracts, the alleged economic substance is a single quid-pro-quo agreement that amounts to a reverse payment under *Actavis*. The court's treatment of the parts of that transaction as unrelated matters improperly elevated form over economic substance.[7]

The district court's refusal to accept that the TriCor deal and the AndroGel settlement were inextricably linked blinded it to the economic consequences of the transaction. Scrutinizing each agreement in isolation (and thus ignoring the complaint's allegations that they were linked), the district court concluded that both were procompetitive and "clearly in the best interests of the consumer"—the TriCor agreement because it accelerated generic entry, and the settlement agreement because it allowed Teva to enter the AndroGel market before patent expiration. MTD Op. 14-16 (JA15-17). But this ignores the fact that the agreements together accelerated generic TriCor entry by just seven weeks while

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[6] *See also In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) (court could not examine in isolation three settlement agreements executed on the same day); *cf. Mannington Mills, Inc. v. Congoleum Indus., Inc.*, 610 F.2d 1059, 1066 (3d Cir. 1979) (district court erred by concluding that two agreements "negotiated and executed simultaneously as part of the settlement of a single litigation" could not be read together as a single instrument).

[7] For the same reason, the district court could not properly treat the two deals as unrelated on the ground that the AndroGel settlement and TriCor deal involved different drugs. This Court rejected that very proposition in *Lipitor*. 868 F.3d at 243-44, 253; *see also King Drug*, 791 F.3d at 410.

makes clear, Teva's payments "did not come close" to covering the $100 million in TriCor revenues that AbbVie expected to lose. Compl. ¶132 (JA4447).

The district court wrongly stated that *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*, 555 U.S. 438, 457 (2009), required it to "determine separately" whether the two sides of the AbbVie/Teva agreement independently "promote[d] competition." MTD Op. 17 (JA18). In fact, *linkLine* says nothing relevant to this case. It involved the unilateral pricing practices of a vertically integrated telecommunications company that both competed with other companies at retail and sold them an essential input for the competitive service. The issue was whether the firm could be held liable for unlawful monopolization on a "price squeeze" theory, which claimed that the firm overcharged its rivals for the essential

articulated by the Supreme Court in

explained, "[g]iven the inherent difficulty of identifying a but-for world,"

fact."

have had every incentive to keep moving toward a launch of generic AndroGel. Yet the district court never even considered the impact of the TriCor deal on Teva's incentives because it had already wrongly dismissed the reverse-payment

economically unsound. The key to reconstructing a but-for world is that illegal activity must be completely "factored out of the economic picture." *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999); *see Teo*, 746 F.3d at 107-08. In antitrust cases, this means considering "a hypothetical market free of all antitrust violations." *Nat'l Farmers Org. v. Associated Milk Producers*, 850 F.2d 1286, 1306 (8th Cir. 1989); *see also* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶392b (4th ed. 2017) ("[T]he 'but for' condition is the profit that would have been earned had the violation not occurred.").

The district court did not factor all of the consequences of the sham litigation out of the economic picture, and that was legal error. To determine what a world "free of all antitrust violations" and "untainted by illegality" would have looked like, the district court needed to evaluate the economics of the AndroGel market and Teva's financial incentives *before* the sham lawsuit was filed. The court did not conduct that inquiry. Instead, it looked at the world as it existed in late 2012—*after* the sham litigation and settlement—when Teva decided to abandon the AndroGel project. In effect, it held that the same factors that kept Teva from launching in the real world would have caused it to make the same decision in the but-for world anyway. But that analysis improperly conflates the real world and

Rather than assessing how the sham litigation altered Teva's incentives, the court held that Teva's failure to launch was due to various "intervening events." Op. 86 (JA154). But the events it pointed to were all products of the lawsuit itself, which could not properly be considered as part of the b(i)6.9 (dth)7 (e b)7 ((i)6.9 (dth)74 4]/Typ

occurred no later than the spring of 2011, when Crew was still at Teva and long before Oberman arrived. That is the relevant time frame to consider for purposes of reconstructing the but-for world. Examining Teva's actual decision in 2012 under its then-current management failed to factor out the illegality and thus was an error of law.

2. The court erred in its analysis of Teva's negotiations to expand Cipla's manufacturing facility.

The district court also found that Teva faced "serious manufacturing issues" because it "never reached an agreement with Cipla" regarding expansion of its manufacturing facilities. Op. 86 (JA154). That conclusion again improperly mixes up the real and but-for worlds. Before the sham lawsuit, Teva and Cipla were negotiating over the expansion of Cipla's manufacturing facility, which required a $10 million investment, and had worked out a schedule permitting launch by June 2012. PLX018-002-003, -006 (JA622-23, 626). The sham lawsuit and settlement threw a wrench in those plans by pushing the launch date back; there was no point in either Teva or Cipla committing to spend money for a product that could not be sold for another three years. Nonetheless, Teva kept negotiating with Cipla, and by July 2012, Cipla had agreed that if the project went forward, it would front the construction costs if Teva repaid the investment through a royalty on sales plus a promise to make up any shortfall after three years.

PLX320-003 (JA1756). But once Teva decided to abandon AndroGel later that year, it no longer needed the expanded manufacturing facilities.

Teva thus never finalized its agreement with Cipla because it abandoned the AndroGel project—not, as the district court had it, the other way round. In a but-

for world where Teva faced no legal obs (le)10.1 wh8zT47891 Td( )f zfor w3HMÄ‘ÁÀ@%d-‘

pump and resubmit it as a post-approval application. DX047-0001 (JA1988). Teva followed the FDA's advice, but (as discussed above) continued to press on with the AndroGel project.[11]

in a defendant's past conduct." *Aaron v. SEC*, 446 U.S. 680, 701 (1980). Here, AbbVie and Besins acted deliberately and with the intent to interfere in the business of their competitors by using litigation as an anticompetitive weapon. *See PRE*, 508 U.S. at 60-61. The deliberate nature of their actions "underscores the propriety of injunctive relief." *Bonastia*, 614 F.2d at 913.

Second, this is not an isolated case of misconduct. AbbVie and Besins filed two sham lawsuits against two different competitors. Although the district court held (without explanation) that two cases are not enough to establish a pattern or practice, it also overlooked evidence that AbbVie had previously filed other objectively baseless Paragraph IV lawsuits. Specifically, AbbVie filed several cases seeking to block Teva and another manufacturer from marketing generic TriCor; these cases involved two different forms of the drug and multiple patents. After the generic manufacturers won those cases, they sued AbbVie for antitrust violations, alleging that the suits were shams. *See Teva Pharm. USA, Inc. v. Abbott Labs.*, 580 F. Supp. 2d 345 (D. Del. 2008). The antitrust case settled before trial, but not before the district court held that AbbVie's patent interpretations in the underlying cases "exceeded all reasonable interpretations of the major tenets of claim construction" and that it had made "nonsensical" infringement arguments. *Id.* at 364, 365. This is strong evidence of repeated violations that "weighs heavily in favor of the imposition of an injunction." *Bonastia*, 614 F.2d at 913.

Third, defendants have not acknowledged the wrongful nature of their conduct or given any assurances against future violations; they continue to insist their sham litigation was justified. Courts recognize that "[a] defendant's persistence in claiming that (and acting as if) his conduct is blameless is an important factor in deciding whether future violations are sufficiently likely to warrant an injunction." *FEC v. Furgatch*, 869 F.2d 1256, 1262 (9th Cir. 1989); *accord SEC v. Fife*, 311 F.3d 1, 10 (1st Cir. 2002); *CFTC v. Hunt*, 591 F.2d 1211, 1220 (7th Cir. 1979). The district court did not consider this factor at all.

Finally, the district court gave no weight to the fact that AbbVie and Besins are still in the business of selling branded pharmaceutical products and regularly engage in litigation to block generic competition. *See* Tr. 5:35; Tr. 11:35 (JA3724, 4095). Since 2013, AbbVie and Besins have filed ten Paragraph IV lawsuits seeking to block generic versions of AndroGel 1.62% and AbbVie has filed at least three cases involving other drugs.[12] The district court downplayed this evidence because the FTC ha d-7. (e t)6 th n(e FT)6.3 (C h)6soeFTC hPeFT (d Bersi7.4)lC hce9-2.29 (nc

powerful evidence of the need for an injunction and of the district court's abuse of its discretion.

C. The Court Misconstrued the FTC's Request and Abused Its

reasonable and setting forth its factual basis. ECF No. 403-1, at 3. This is another form of fencing-in relief, and not especially burdensome. Moreover, it is reasonably related to the conduct at issue in this case because the district court found that no business executives at AbbVie or Besins were "in any way" involved in the decision to sue—"not even with a perfunctory sign-off." Op. 46 (JA114). Requiring a corporate executive to take responsibility for the decision to sue is important, because it is likely to deter baseless lawsuits and will provide the FTC with a means of evaluating whether future lawsuits are legitimate. The district court did not address this aspect of the FTC's request at all.

The district court's First Amendment concerns relied on the court's misconception that the FTC sought an injunction against any abuse of gove1pnt748 bictikelyc C

"well-settled" rule that "once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as to the remedy are to be resolved in its favor." *United States v. E. I. du Pont de Nemours & Co.*, 366 U.S. 316, 334 (1961). Against this background, the district court's decision to deny *any* injunctive relief was an abuse of discretion.

CONCLUSION

The dismissal of the reverse-payment claim should be reversed, and the case should be remanded for (1) further proceedings on that claim; (2) recalculation of the amount of monetary equitable relief; and (3) reconsideration of injunctive relief.

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) because it contains 12,809 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.

IDENTICAL COMPLIANCE OF BRIEFS

I certify that the text of the electronically filed brief is identical to the text of the original copies that were sent on March 28, 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 March 28, 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 March 27, 2019). No virus was detected.

SERVICE

I certify that on March 28, 2019, I filed the foregoing brief via the Court's electronic filing system. All parties will be served by the CM/ECF system.

March 28, 2019

/s/Matthew M. Hoffman
Matthew M. Hoffman

STATUTORY ADDENDUM

Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 309 *et seq.*

§ 355. New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such

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

(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is ma fothe c fothe c1.2 o7 14t toene

ii ())

determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

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

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

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

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

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

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

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

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid

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

* * *

(j) Abbreviated new drug applications

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

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

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

(ii)(I) if the listed drug referred to in clause (i) has one clthe 22.o1 (r7(i)6.6.3 ()ve /P /AMC

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

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

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

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

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

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before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

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

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

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

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

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

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination

manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been inf Tw]TJ0.002 /TT0 y (dec)11.1 (i)-1 (te)5a(s c)11.1 c8 sTJ9.726 0 Tf .0021il thug 2T

(dd) TENTATIVE APPROVAL.—

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

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from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant subm 2 (bm 967372)3.872 0139(h)--2.rtn ng it3pTjEMCfbm 2 (r0.e 1n)-1.18(bm

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