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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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 ultimately came from the pockets of consumers and other purchasers forced to pay higher drug prices.

The FTC charged AbbVie and Besins with two antitrust violations. First, it alleged that AbbVie and Besins illegally maintained a monopoly through a course of anticompetitive conduct, including sham litigation against Teva and Perrigo. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 60-61 (1993) ("*PRE*"). Second, it charged that the TriCor agreement amounted to an unlawful "reverse payment" whereby AbbVie shared some of its monopoly profits with Teva in exchange for Teva's agreement to keep generic AndroGel off the market.[2] *See FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). The FTC sought equitable monetary relief and an injunction.

[2] Teva was also a defendant on this count, but has settled with the FTC and been dismissed from this case.

The district court dismissed the reverse-payment claim under Rule 12(b)(6). Despite detailed factual allegations showing that AbbVie used the TriCor agreement to induce Teva to settle the AndroGel litigation, the court held the transaction could not be deemed a reverse payment under *Actavis*. On the sham litigation claim, the court found for the FTC following a partial summary judgment decision and bench trial, holding that the patent infringement claims were objectively baseless and intended to block generic competition and preserve AbbVie's monopoly profits. But while the FTC calculated that AbbVie and Besins earned some $1.2 billion in illegal profits, the district court awarded only $448 million in monetary relief. In addition, despite finding an egregious violation, the court declined to order any injunctive relief. The FTC now appeals the dismissal of the reverse-payment claim, the determination of the amount of monetary relief, and the denial of injunctive relief. AbbVie and Besins have cross-appealed.

JURISDICTION

The FTC sued under 15 U.S.C. §§45(a) and 53(b). The district court had jurisdiction under 28 U.S.C. §§1331, 1337(a), and 1345. Final judgment was entered on July 18, 2018. ECF No. 448 (JA171). The FTC appealed on July 20, 2018. ECF No. 450 (JA175). This Court has jurisdiction under 28 U.S.C. §1291.

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 Pharmacy, Inc. v. AbbVie Inc.*, No 2:18-cv-3495. The Supreme

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, pharmacists may earn more profit by convincing physicians to allow them to switch a patient to a lower-priced non-AB-rated substitute. *Id*. Thus, non-AB-rated 505(b)(2) generics can still pose a significant competitive threat to the brand.

[3] The term "generic" refers to both AB-rated and non-AB-rated substitutes, although a non-AB-rated product will typically be sold under its own brand name.

Many brand-name drugs are protected by patents. To encourage competition and bring generics to market as soon as possible, the Hatch-Waxman Act allows a company to seek approval to market a generic drug before patent expiration by providing a "Paragraph IV" certification stating that its product will not infringe the patent or that the patent is invalid. 21 U.S.C. § 355(b)(2)(A)(iv), (j)(2)(A)(vii)(IV). This certification is deemed a technical act of infringement that permits the patentee (typically the brand company) to sue immediately. 35 U.S.C. § 271(e)(2). A Paragraph IV infringement lawsuit blocks the FDA from approving the application for 30 months, unless the case is resolved earlier. 21 U.S.C. § 355(c)(3)(C), (j)(5)(B)(iii).

Although Hatch-Waxman was meant to promote competition, it also creates incentives for brand and generic manufacturers to enter into agreements that thwart competition. The profits the generic manufacturer stands to earn if it wins the infringement suit and launches its product are normally much less than those the brand stands to lose from generic entry. Both the brand and generic manufacturers thus may benefit, at the expense of consumers, if the parties settle the lawsuit with the brand manufacturer agreeing to pay the generic manufacturer in exchange for the generic's agreement to defer entry into the market. In effect, the brand manufacturer preserves its monopoly by sharing its monopoly profits with the generic. A patent litigation settlement where the patentee pays the alleged

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 levels over time. *Id.* at 7-8 (JA75-76). By contrast, AndroGel is a transdermal testosterone replacement therapy ("TTRT"), absorbed through the skin. Patients apply the gel painlessly once a day in the privacy of their own homes, and it delivers a steady dose of testosterone without peaks or troughs. *Id.* at 9, 11 (JA77, 79). AndroGel was launched in 2000 to great commercial success, quickly becoming one of AbbVie's flagship products with annual U.S. sales peaking at $1.15 billion in 2012. *Id.* at 9-10 (JA77-78).

[4] In this brief, "Compl." refers to the complaint. "MTD Op." refers to the district court's decision dismissing the reverse-payment claim (ECF No. 81). "MSJ Op." refers to the decision on the motions for summary judgment (ECF No. 300). "Op." refers to the district court's Findings of Fact and Conclusions of Law (ECF No. 439). Citations in the form "Tr. *a*:*b*" refer to trial day *a* and internal transcript page *b*. Citations to PLX and DLX refer to trial exhibits.

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. PLX052-006 to -008 (JA1014-16). The applicants then narrowed the number of penetration enhancers claimed, first to a specified set of 24 compounds and eventually, after discussions with the examiner, to a single enhancer, IPM, in specific amounts. PLX053-003; PLX054-008; PLX056-001; PLX057-011; PLX059-017 (JA1020, 1056, 1084, 1096, 1118). The patent issued after the examiner concluded that the narrowing amendments "all together" were sufficient to overcome obviousness. PLX060-003 (JA1152). As the district court here found, given that history, "[p]rosecution history estoppel without question prevents [AbbVie and Besins] from claiming that the doctrine of equivalents encompasses the penetration enhancers that they abandoned during the application process." MSJ Op. at 29-30 (JA61-62).

D. Sham Litigation Against Teva and Reverse-Payment Agreement

The first company to seek approval for a generic version of AndroGel using a different penetration enhancer was Perrigo, which filed an ANDA in 2008 for a product containing isostearic acid instead of IPM. Op. 13-14 (JA81-82). After

"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 abandoned its ANDA after the FDA ruled that generic versions of AndroGel using different penetration enhancers could be approved only under Section 505(b)(2). Op. 17 (JA85). In January 2011, Teva filed a 505(b)(2) NDA for a testosterone gel using isopropyl palmitate as a penetration enhancer. *Id*. That filing triggered the first sham lawsuit and ultimately led to the reverse-payment agreement between AbbVie and Teva.

1. Teva's Pre-Suit Plans: Launch By June 2012

Before it was sued, Teva planned to launch a generic version of AndroGel as quickly as possible. It invested significant resources toward that goal, spending over $1.4 million on FDA fees and studies needed to support a 505(b)(2) application. PLX296-003; Tr. 3:32 (JA1618, 3609). Teva also began planning with its manufacturing partner, Cipla, for production of the drug, which involved expansion of a manufacturing plant in India. Cipla projected "[s]hipment of the finished products" by "May/June 2012." PLX018-006 (JA626).

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 projected that with a November 2011 launch, a non-AB-rated product would yield sales of $78.7 million in 2012 and $116.5 million in both 2012 and 2013. PLX301-009 (JA1648).

AbbVie likewise understood that launch of a non-AB-rated product would pose a serious threat to its AndroGel franchise, projecting $1.3 to $1.7 billion (and possibly even more) in lost AndroGel sales through 2016. PLX026-006, PLX032-003 to -004 (JA635, 685-86). AbbVie anticipated a Teva launch by April 2012. PLX030-001 (JA682).

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

1% product. Op. 20; Tr. 1:190-91; DX296-001; PLX456-001. (JA88, 3532, 3324, 1825). For Teva, that meant the pie was shrinking: as sales of AndroGel 1.62% increased, the 1% market decreased, reducing the sales available for Teva to capture. Teva estimated that once 80% of users had switched to 1.62%, then its generic 1% product would no longer be profitable. PLX313-001 (JA1700).

3. The Reverse-Payment Agreement

In October 2011, the district court scheduled a bench trial on the dispositive prosecution history estoppel issue for the following May. Compl. ¶84 (JA4436). The early trial date posed a problem for AbbVie and Besins. A Teva victory would terminate the 30-month Hatch-Waxman stay, allowing Teva to obtain FDA approval and launch its product. *Id*. ¶107 (JA4441). To preserve their monopoly profits and buy more time to shift patients to AndroGel 1.62%, AbbVie and Besins needed another way to fend off Teva. *Id*. ¶111 (JA4442).

AbbVie decided to pay Teva to defer any launch. At Teva's request, AbbVie agreed to supply Teva with an "authorized generic" version of TriCor, a cholesterol-reducing drug with annual U.S. sales exceeding $1 billion.[5] Compl. ¶113 (JA4442). Under a prior patent litigation settlement with AbbVie, Teva had secured the right to launch generic TriCor on July 1, 2012. Because other generics could not launch until January 1, 2013, Teva had expected to enjoy a lucrative

[5] An authorized generic is the brand product marketed as a generic under the brand's NDA.

"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." *PRE*, 508 U.S. at 51. The district court granted partial summary judgment for the FTC on objective baselessness, holding that the '894 patent'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. 31 (JA63).

After a 16-day bench trial, the court also ruled for the FTC on the second *PRE* prong, finding that "[t]he only reason" AbbVie and Besins filed sham 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 hundreds of millions of dollars in AndroGel sales and profits." Op. 53 (JA121). It also found that TTRTs constitute a relevant antitrust market and that AbbVie had monopoly power within that market. *Id.* at 71, 77 (JA139, 145). The court concluded that AbbVie and Besins illegally and willfully "delayed the entry of

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 through August 2017 totaled $1.2 billion. Tr. 7:195 (JA3884).

The district court agreed with Dr. Shapiro and found in favor of the FTC on points (2) and (3), but disagreed on point (1). The court concluded that the FTC had not "established" that Teva would have launched absent the sham lawsuit and that Teva's failure to launch was due to "intervening events." Op. 86 (JA154). That reduced the illegal profits figure to $448 million, which the court apportioned between AbbVie and Besins. *Id*. at 94-98 (JA162-66).

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's agreement to supply Teva with generic TriCor, a benefit worth $175 million. In other words, AbbVie and Teva allegedly entered into a quid-pro-quo agreement with the basic purpose of deferring competition and protecting 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 deal, and makes sense only as a means to protect AndroGel from competition.

Under this Court's decisions in *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017) and *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015), which interpreted and applied the Supreme Court's teachings in *Actavis*, nothing more was required to state a claim.

When it dismissed the reverse-payment claim, the district court committed a fundamental analytical error. The district court treated the TriCor supply agreement and the AndroGel settlement agreement as though they had no connection and analyzed them separately. The complaint alleges a direct linkage, with the TriCor deal serving as the inducement for the settlement. The court could not simply ignore that allegation. Instead of considering the economic reality of the transaction as a whole, the district court improperly broke it down into its constituent parts and analyzed them independently, erroneously elevating its form over its economic substance. Accepting the complaint's factual allegations as true (as the Court must), it properly states a reverse-payment claim under *Actavis*.

2. The district court abused its discretion in determining the amount of equitable monetary relief. The FTC had the burden to show a "reasonable approximation" of AbbVie's illegal profits, *SEC v. Teo*, 746 F.3d 90, 105 (3d Cir. 2014), which required it to show what the but-for world would have looked like "as a matter of just and reasonable inference." *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 563 (1931).

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 sales. And Teva's negotiations with its manufacturing partner show it could have been ready to launch by June 2012—which was consistent with AbbVie's own expectations.

The court nonetheless held that the FTC had not "established" that Teva would have launched in a but-for world, reducing the illegal profits calculation by roughly $750 million. The court concluded in essence that the factors that eventually caused Teva to abandon the AndroGel project in the real world would have led to the same result in the but-for world. That conclusion rested upon two analytical errors of law. First, having wrongly dismissed the reverse-payment claim, the court had blinded itself to the obvious reason why Teva did not launch an AndroGel generic in the real world: AbbVie *paid* it $175 million to defer doing so for three years. During that time, AbbVie was able to shift the vast majority of the market to AndroGel 1.62%, past Teva's point of unprofitability. Had there been no lawsuit, there would have been no reverse-payment settlement and no

agreement not to compete. Teva would have retained its strong incentive to launch a profitable product as soon as possible.

Second, the district court failed to filter the consequences of defendants' unlawful conduct out of the but-for world. That faulty approach led it to wrongly deem the *effects* of the sham litigation as *intervening events* that caused Teva to abandon its AndroGel generic. For example, the court determined that new management arriving at Teva in late 2012 would have killed the project anyway. But had there been no lawsuit and no delay, Teva would have committed to the project and launched a product well before the management changes, and the economic picture facing the new leadership would have looked completely different. The district court failed to recognize that Teva's economic incentives and decisionmaking were fundamentally altered as a result of the sham litigation and settlement.

It is impossible to know for sure what would have happened had AbbVie and Besins not filed an unlawful lawsuit. That is why a but-for-world analysis requires only a reasonable inference about what would have happened, and why the risk of uncertainty is placed on the defendants. The FTC met its burden, and the district court committed reversible legal error in concluding it did not.

3. The district court abused its discretion in denying any injunctive relief. It did not apply the test for assessing the likelihood of further violations set

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.

Count II of the FTC's complaint alleges the essential elements of an unlawful reverse-payment claim under *Actavis*: a "large and unjustified" payment from the patent owner to the alleged infringer to induce it to drop a patent

challenge and refrain from competition. *Actavis*, 570 U.S. at 158. Specifically, complaint alleges in detail that Teva agreed to settle the patent lawsuit and forgo competition with AndroGel for three years in exchange for AbbVie's agreement to compensate Teva through the TriCor deal, which conferred a $175 million benefit on Teva. That money cannot be explained as saved litigation costs or compensation for services provided by Teva, and indeed exceeded what Teva expected to make selling generic AndroGel at the time it entered into the settlement agreement. This Court has explained that to survive a motion to dismiss in a reverse-payment case, a plaintiff need only "allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251-52 (3d Cir. 2017). The complaint here easily meets that standard.

The district court's contrary conclusion sprang from a fundamental analytical mistake: it treated the AndroGel settlement and the TriCor supply deal as two unrelated and independently pro-competitive agreements—even though the complaint plainly alleged that they were in fact two sides of a single anticompetitive agreement, with the TriCor deal serving as the quid pro quo for the AndroGel settlement. The court was required to accept those allegations as true, but it did not, instead contradicting the central allegations of the complaint by

holding that the TriCor deal could not amount to a reverse payment. The dismissal of Count II was erroneous and should be reversed.

A. Standard of Review

Dismissal under Rule 12(b)(6) is reviewed *de novo*. *Phillips v. County of Allegheny*, 515 F.3d 224, 230 (3d Cir. 2008). The Court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Id.* at 233 (cleaned up). A complaint states a plausible claim when it "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010) (cleaned up). Reversal is required if the complaint states a claim for relief that is "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

B. The Complaint Plausibly Alleges an Unlawful Reverse-Payment Agreement Under *Actavis*, *King Drug*, and *Lipitor*.

In *Actavis*, the Supreme Court established that reverse-payment agreements raise antitrust concerns when the patent holder makes a "large and unjustified" payment to induce the potential generic competitor to drop its patent challenge and stay out of the market. *Actavis*, 570 U.S. at 158. If "the basic reason" for settling patent litigation with a reverse payment is a "desire to maintain and to share

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* a reverse payment need not be in cash, but can be in any form "likely to present the same types of problems" and "as harmful as those resulting from reverse payments of cash." *Id*. at 404, 405. Thus, the Court determined, if a complaint plausibly alleges an "unexplained large transfer of value from the patent holder to the alleged infringer" to "induce the generic to abandon the patent fight" and forgo entry for some period, then it states an antitrust claim. *Id.* at 403, 405.

The Court provided additional guidance in *Lipitor*, making it clear that the "large transfer of value" discussed in *King Drug* could apply to valuable agreements concerning entirely unrelated products. *Lipitor* involved a Paragraph IV settlement in which the generic manufacturer agreed to defer launch of generic Lipitor for over three years in exchange for the brand manufacturer's release of a

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 damages release was the quid pro quo for the Paragraph IV settlement was sufficient to state a claim so long as the complaint plausibly alleged that the payment was large and lacked "a convincing justification." *Id*. at 254-57. The court further held that defendants have the burden of justifying the large reverse payment at the merits stage of the case; a plaintiff is not required to "come up with possible explanations … and then rebut those explanations in response to a motion to dismiss." *Id.* at 256-57; *see also King Drug*, 791 F.3d at 412 & n.37.

Under the standards set forth in *Lipitor* and *King Drug*, the FTC's reverse-payment allegations state a claim. The complaint alleges that AbbVie expected Teva to launch generic AndroGel in spring 2012, and that the generic threatened AbbVie's monopoly profits on a multibillion dollar drug. Compl. ¶¶1, 107-09, 148 (JA4416, 4441, 4452). In addition, AbbVie planned to maintain the profitability of the AndroGel franchise by shifting the market from the 1% formulation to the 1.62% formulation, and generic competition on the 1% product would interfere with that plan. *Id*. ¶¶10, 40, 112, 132, 151 (JA4419, 4426, 4442, 4447, 4453). AbbVie thus had a strong incentive to pay valuable consideration to keep Teva's generic AndroGel off the market.

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 weeks before other generics. Teva estimated this opportunity was worth $175 million in sales over four years—money that it otherwise could not have earned. *Id*. ¶¶120-21, 123 (JA4444-45). In fact, Teva ended up earning even more than that. *Id.* ¶120 (JA4444).

It therefore was to both parties' mutual advantage to settle the Paragraph IV litigation, with AbbVie compensating Teva via the TriCor supply deal in exchange for Teva's agreement to "to drop its patent challenge and refrain from competing with its testosterone gel product" for three years. *Id*. ¶115 (JA4443). AbbVie gave up about $100 million in TriCor sales, but preserved billions in AndroGel sales. *Id*. ¶¶125, 132, 148-151 (JA4445, 4447, 4452-53). Teva in return got the right to sell a valuable product before other competitors, an opportunity which by that time was worth more than Teva expected to earn from selling generic AndroGel if it won the patent litigation. *Id*. ¶¶119-124 (JA4444-45).

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.

The complaint also plausibly alleges that the payment made to Teva via the TriCor supply agreement was unjustified. The TriCor deal "cannot be explained as an independent business deal from [AbbVie's] perspective," but "made sense … only as a means to induce Teva to drop its patent challenge and refrain from competing with AndroGel." Compl. ¶125 (JA4445). AbbVie was willing to forfeit TriCor revenues "only because [doing so] achieved a significant delay in AndroGel entry, allowing [AbbVie] time to shift sales to AndroGel 1.62% and

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.

preserving AbbVie's monopoly profits on AndroGel for three years.[8] Compl. ¶¶112-151 (JA4442-53). Moreover, generic entry before patent expiration is not procompetitive if the entry date is purchased with a large and unjustified reverse payment. *Actavis*, 570 U.S. at 154.

The district court also elevated form over economic reality when it held that the TriCor deal could not be a reverse payment because Teva was "paying [AbbVie] for the supply of TriCor." MTD Op. 15 (JA16). That some money would flow from Teva to AbbVie does not mean the overall transaction was not a reverse payment. In *Lipitor*, this Court held that Teva's payment of royalties to the brand manufacturer of Effexor XR did not "undermine the plausibility of the complaint's allegations that the no-AG agreement was entered into in exchange for delayed entry of Teva" into the market. 868 F.3d at 261. *Lipitor* also recognized that Ranbaxy's payment of $1 million to the brand for release of the large Accupril damages claim did not "insulate[] review of the [Lipitor] settlement agreement." *Id*. at 258. Similarly, Teva's payment to AbbVie under the TriCor agreement does not rule out the existence of an unjustified reverse payment. As the complaint

[8] In *King Drug*, the Court reserved the legal question whether procompetitive effects in one market can justify anticompetitive harm in another. *See* 791 F.3d at 410 & n.34. But even assuming it would be proper to balance competitive effects across different markets, the complaint here alleges that any benefits to TriCor consumers are outweighed by the anticompetitive harm to AndroGel consumers resulting from deferred generic entry.

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 input while simultaneously undercutting the prices they charged to consumers. *Id.* at 442.

The Supreme Court's rejection of that theory says nothing about how a court should assess allegations that potential competitors agreed to share the rewards of avoiding competition by using two ostensibly separate deals. As this Court has recognized, *linkLine* stands for the proposition that "two antitrust theories cannot be combined to form a new theory of antitrust liability." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 280 (3d Cir. 2012). This case presents no new theory of antitrust liability; it alleges a violation under established principles of antitrust law

articulated by the Supreme Court in *Actavis* and by this Court in *Lipitor* and *King Drug*. Nothing in *linkLine* justified ignoring the allegations of the complaint that the TriCor deal and the AndroGel settlement were two parts of a single agreement.

Because the district court did not "accept all factual allegations in the complaint as true" and "construe the complaint in the light most favorable to the plaintiff," *Phillips*, 515 F.3d at 233, the dismissal of Count II must be reversed.

II. BY IMPROPERLY ANALYZING TEVA'S BUT-FOR MARKET ENTRY, THE DISTRICT COURT UNDERSTATED DEFENDANTS' ILLEGAL PROFITS.

The district court properly held that monetary equitable relief was needed to compensate consumers and that the appropriate measure of that relief was the difference between what AbbVie and Besins actually earned and what they would have earned in a hypothetical "but-for" world where no sham lawsuits had been filed. Op. 80-82 (JA148-50). But it erred in its analysis of the but-for world, and consequently understated the amount of defendants' illegal profits by roughly $750 million.

This Court set out the requirements of an equitable monetary relief analysis in *SEC v. Teo*, 746 F.3d 90 (3d Cir. 2014). Under *Teo*, the FTC had the burden to produce "evidence supporting a *reasonable approximation*" of the defendants' illegal profits under a "but-for standard." *Id.* at 105 (emphasis added). The FTC was not required to establish definitively what would have happened in the absence of the illegal conduct—that would be impossible. Rather, as the Court has

explained, "[g]iven the inherent difficulty of identifying a but-for world," monetary relief need not be "measured with certainty, but rather … demonstrated as 'a matter of just and reasonable inference.'" *Behrend v. Comcast Corp.*, 655 F.3d 182, 203 (3d Cir. 2011) (quoting *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 563 (1931), *rev'd on other grounds*, 569 U.S. 27 (2013).

Once the FTC made its initial showing, the burden shifted to defendants to produce "specific evidence" demonstrating that the FTC's approximation was unreasonable. *Teo*, 746 F.3d at 105, 108. That required AbbVie and Besins to do more than "simply … carry[]the ball back across the fifty-yard line by presenting a merely plausible alternative explanation" for their profits. *Id.* at 107-08. Rather, they had to show that "any other cause for the profits" was "untainted by illegality." *Id*. at 108. Moreover, the risk of uncertainty "should fall on the wrongdoer whose illegal conduct created the uncertainty." *Id.* at 105; *see also United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc).

Here the FTC met its initial burden under *Teo* by producing evidence—including expert testimony from Dr. Shapiro and an extensive documentary record—that a "reasonable approximation" of defendants' illegal profits through August 2017 was $1.2 billion. That figure was based on a "just and reasonable inference" that absent the sham litigation, Teva would have launched a non-AB-rated generic version of AndroGel by June 2012. Undisputed evidence showed

that in spring 2011, before it was sued, Teva was proceeding full speed ahead with its testosterone gel project—even though it did not expect an AB rating. PLX021-001; PLX296-003 (JA627, 1618). Teva's top management was committed to the project, spending millions of dollars to conduct studies, pay FDA fees, and develop a trade name (which would be necessary only if the product was not AB-rated). PLX296-003; PLX042-002; PLX317-001; Tr. 3:63-65 (JA1618, 796, 1740, 3617-18). Those investments made sense because Teva and AbbVie both understood that a non-AB-rated product would cut deeply into AndroGel's sales and generate hundreds of millions of dollars in sales for Teva. PLX301-009; PLX026-006; PLX032-004, -008 (JA1648, 635, 686, 690).[9] No economically rational company would leave this money on the table.

Even *after* AbbVie and Besins sued, forcing Teva to put its launch plans on hold and substantially reducing its sales projections, Teva initially remained committed to the testosterone gel project, predicting launch of non-AB rated testosterone gel in October 2013 in its formal work plan and underlying forecasts. Tr. 3:73-76; PLX318-004; PLX035-016-019 (JA3620, 1746, 728-731). Absent the lawsuit, Teva would have had every incentive to launch as soon as possible after it

[9] The district court stated that Teva's internal analyses showed that a non-AB generic "without a perceived advantage in the market … generally captures only 5% or less of the brand-name product's sales." Op. 84 (JA152). That was clear error—the analysis shows a figure of 10%. PLX322-008. AbbVie projected 9% to 34% loss of business from commercial high control plans. PLX032-006 (JA688).

received FDA approval in February 2012. Teva's pre-suit discussions with Cipla show that it could have had the drug ready for shipment by "May/June 2012." PLX018-006 (JA626). Thus, as Dr. Shapiro explained, entry by June 2012 is "a reasonable counterfactual" because by that time Teva would have had the "operational capabilities and a very strong incentive" to launch. Tr. 7:154 (JA3874).

Notwithstanding all of this evidence, the district court held that the FTC had not "established" that Teva would have launched its product "in June 2012 or at any time thereafter." Op. 86 (JA154). That conclusion rested on two different legal errors, each of which requires reversal. First, because it erroneously dismissed Count II and refused to recognize that the TriCor supply agreement amounted to a payment not to compete, the court never considered the effect of that payment on Teva's decisionmaking. Second, in attempting to recreate the but-for world, the court failed to factor out all of the effects of the illegal conduct, and thus wrongly treated the *effects* of the sham litigation as intervening causes. That improper economic analysis was an error of law.

A. Standard of Review

Monetary relief is reviewed for abuse of discretion, *Teo*, 746 F.3d at 101, which occurs when the district court's decision "rests upon a clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to

fact." *In re Cendant Corp. Prides Litig.*, 235 F.3d 176, 181 (3d Cir. 2000). A district court also commits "legal error subject to plenary review" where it "applies an incomplete economic analysis or an erroneous economic theory." *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 336 (3d Cir. 2016).

B. The Erroneous Dismissal of the Reverse-Payment Claim Prevented an Economically Sound Analysis of the But-For World and Mandates Reconsideration of Monetary Relief.

As shown in Argument I above, the court erred in dismissing the FTC's reverse-payment claim. That error also compels a remand for reconsideration of monetary relief. The district court held that Teva would not have launched a generic product to compete with AndroGel even if it had never been sued. That analysis is fundamentally flawed as a matter of law because it ignores the elephant in the room: Teva did not launch in the real world because AbbVie *paid it not to compete for three years*. As shown above, the TriCor deal was a $175 million inducement to Teva to refrain from launching generic AndroGel until December 2014, by which point AbbVie had converted the bulk of the market to AndroGel 1.62% and Teva's product was no longer economically viable. Teva was an active collaborator in the reverse-payment deal, which directly affected its real-world behavior.

Had there been no sham lawsuit, there would have been no payment via the TriCor deal and no agreement to defer market entry. In that situation, Teva would

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 claim. Nor did it consider that AbbVie's very willingness to pay Teva demonstrated its belief that Teva would have launched an AndroGel substitute but for the payment. The district court's blinding itself to these facts rendered its economic analysis of the but-for world fatally incomplete and therefore erroneous.

The district court's dismissal of the reverse-payment claim also unfairly precluded the FTC from fully developing the evidentiary record. The court limited discovery to the sham litigation issue. ECF No. 79 (JA1). That prevented the FTC from fully exploring the impact of the TriCor agreement on Teva's decisionmaking process. And when the FTC sought to raise issues relating to TriCor at trial during its examination of a Teva executive, the court precluded the testimony. Tr. 3:86-90 (JA3623-24). The FTC thus could not fully explore either in discovery or at trial how the TriCor deal affected Teva's decision not to launch. Further discovery and trial proceedings are necessary to rectify the error.

C. The District Court Engaged In Improper Economic Analysis By Failing To Factor All Consequences of the Sham Litigation out of the But-For World.

Independent of its erroneous failure to consider the effects of the reverse payment, the district court also erred because its analysis of the but-for world was

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

the but-for world, and ignores the ways in which the delay created by the defendants' illegal conduct fundamentally altered Teva's financial incentives.

By 2012, as a result of the sham litigation and settlement, Teva had agreed not to launch generic AndroGel before December 27, 2014. That agreement changed the economics of the project in two significant ways. First, it bought AbbVie time to convert the market from AndroGel 1% to AndroGel 1.62%, reducing Teva's profit potential. By December 2014, AndroGel 1.62% had an 83% market share—past Teva's 80% profitability threshold. PLX313-001; PLX449; Tr. 7:163-64 (JA1700, 1821, 3876). Furthermore, Teva's pre-settlement financial projections had assumed it would be the only generic on the market. PLX301-009; PLX035-020 (JA1648, 732). By December 2014, however, Perrigo was free to launch simultaneously. Tr. 7:161 (JA3876). To make matters worse, two other companies that had previously settled litigation with AbbVie's predecessor were slated to launch AB-rated generics just eight months later, on August 31, 2015. Tr. 7:162 (JA3876); *see Actavis*, 570 U.S. 145. That meant that if Teva launched in December 2014, it would be competing for a small slice of a much smaller pie. The delay caused by the sham litigation and settlement thus effectively drove a stake through the economic heart of Teva's AndroGel project, making it financially unviable.

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 but-for world. The same basic analytical error affected each step of the court's analysis.

1. The court erred in relying on Teva's 2012 post-settlement management changes.

The district court placed great weight on Teva's management changes following the settlement. In November 2012, Tim Crew, the Teva executive who had championed the AndroGel project, left Teva, and a new CEO, Alan Oberman took over. Op. 27-28 (JA95-96). Oberman "was not a proponent of a BX-rated launch," and ultimately decided to kill the project. Op. 85; Tr. 3:132 (JA153, 3634). But these events occurred *after* the sham lawsuit and settlement had pushed any launch back to December 2014 and destroyed the AndroGel project's viability. By contrast, as discussed above, the evidence shows that *before* the lawsuit, Teva was actively moving ahead with the AndroGel project and expected to launch—with or without an AB rating—by June 2012.

Meeting that schedule would have required Teva to make several decisions long before launch. In particular, it would have needed to select a brand name and to finalize its manufacturing agreement with Cipla. In a properly constructed but-for world where Teva was free to launch, those decision points would have

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 obstacle to launch and anticipated hundreds of millions of dollars in sales, both Teva and Cipla would have had strong economic incentives to finalize their agreement, and there is no reason to think they would have done otherwise.[10]

3. The court erred in its analysis of the pump dosage form.

The district court also held that Teva faced "obstacles to the profitable launch of its product" because the FDA approved only a packet and not a pump dispenser, which represented about half the market. Op. 85 (JA153). Once again, the court committed legal error by conflating the but-for world with the real world, without recognizing that Teva's behavior was altered by the sham litigation.

Teva's NDA had originally included both packet and pump dosage forms. To expedite processing, FDA recommended in June 2011 that Teva withdraw the

[10] The district court stated that Teva refused to commit to Cipla's factory expansion "unless the FDA issued an AB rating to its product." Op. 86 (JA154). No evidence in the record supports that finding. As discussed above, Teva never expected an AB rating, but was negotiating with Cipla anyway. And in a but-for world, Teva would have needed to reach agreement with Cipla long before it would have known whether it would get an AB rating.

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] Expert testimony at trial showed that Teva could have gotten pump approval within six months after approval of the packets. Tr. 2:171-72 (JA3586). But once Teva settled and agreed not to launch before December 2014, there was no point in seeking approval for a pump—the economics of the project had collapsed. In other words, the absence of approval for the pump was a consequence of the delay created by the settlement—not an intervening event that led to Teva's decision not to launch. In finding otherwise, the district court did not filter out the effects of the unlawful conduct, a reversible error of law.

* * *

The district court's conclusion that the FTC had not "established" that Teva would have launched by June 2012 in a but-for world thus rests on faulty and incomplete economic analysis, which amounts to an error of law. The court should reverse and remand for further discovery and trial proceedings on this issue and recalculation of monetary relief.

[11] Teva specifically accounted for this issue in its 2012-2014 work plan—it projected that the product would initially launch in packet form only in October 2013, and that it would not launch a pump until 2014. PLX318-004 (JA1746).

III. THE DISTRICT COURT ABUSED ITS DISCRETION IN DENYING INJUNCTIVE RELIEF.

The district court denied the FTC's request for an injunction on two grounds: first, that the FTC had not shown that defendants' illegal conduct was likely to recur, and second that the requested injunction was "overbroad and punitive" and would "implicate" First Amendment rights. Op. 99-100 (JA167-68). In reaching these conclusions, the court failed to apply the proper legal framework for assessing likelihood of recurrence, mischaracterized the specific relief requested by the FTC, and failed to assess the relief that the FTC actually requested. This Court should reverse and remand for further consideration.

A. Standard of Review

Denial of an injunction is reviewed for abuse of discretion. *SEC v. Bonastia*, 614 F.2d 908, 913 (3d Cir. 1980). "When a district court refuses to apply well-settled legal precepts to a conceded set of facts, it acts outside its allowable discretion." *Id.*

B. The District Court Failed To Apply the Proper Test for Assessing Likelihood of Recurrence.

As the district court properly recognized, an injunction based on past misconduct is proper when there is a "cognizable danger of recurrent violation." Op. 99 (JA167) (quoting *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953)); *see also FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147, 158 (3d Cir. 2019) (likelihood-of-recurrence standard "applies when a court is considering whether to

grant or deny injunctive relief"). But the court failed to apply the proper test for assessing likelihood of recurrence.

In *Bonastia*, this Court held that the determination of recurrence turns on "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." *Bonastia*, 614 F.2d at 912. The court identified five factors that a court should consider in the totality-of-the-circumstances inquiry: "[1] the degree of scienter involved on the part of the defendant, [2] the isolated or recurrent nature of the infraction, [3] the defendant's recognition of the wrongful nature of his conduct, [4] the sincerity of his assurances against future violations, and [5] the likelihood, because of defendant's professional occupation, that future violations might occur." *Id.* Although *Bonastia* involved the SEC statutes, the likelihood-of-recurrence test is the same standard that applies here, and courts have looked to similar factors when assessing likelihood of recurrence under the FTC Act. *See, e.g.*, *FTC v. Accusearch Inc.*, 570 F.3d 1187, 1201 (10th Cir. 2009).

The district court did not assess the *Bonastia* factors, or anything like them. Those factors strongly suggest that AbbVie and Besins *are* likely to engage in further sham litigation absent an injunction. First, an "important factor" in assessing likelihood of recurrence is "the degree of intentional wrongdoing evident

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 had not shown that the suits were shams. ECF No. 439, at 100 n.31 (JA168). But whether these suits are shams is beside the point; they show that defendants' business gives them many opportunities to engage in the same kind of misconduct at issue here. That fact, combined with the other *Bonastia* factors is

[12] The cases (all in the District of Delaware) are Nos. 17-cv-1199, 17-cv-47, 16-cv-810, 15-cv-1143 15-cv-1120, 15-cv-964, 15-cv-904, 14-cv-1288, 14-cv-1004, 14-cv-1003, 14-cv-985, 13-cv-496, and 13-cv-236.

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 Discretion by Failing To Grant Any Injunctive Relief.

The district court's concern that the FTC's proposed injunction was "overbroad and punitive" rested on a basic mischaracterization of the FTC's requested relief. The court stated that the FTC sought "to prohibit defendants from engaging in *any action* that misuses the government processes for anticompetitive purposes." Op. 98 (JA166) (emphasis added). But the FTC's proposed order made no such request, *see* ECF No. 403-1.[13]

In reality, the FTC's proposed injunction was narrowly tailored to protect the public by preventing AbbVie and Besins from engaging in exactly the type of misconduct they committed here. First, the FTC sought to bar defendants from suing for infringement of the '894 patent with respect to a testosterone drug product that does not contain use IPM—the precise conduct that the district court found to be a sham. ECF No. 403-1, at 2-3.[14]

[13] The FTC's pretrial brief used broader language, but the FTC later narrowed its request.

[14] The district court stated that the patent expires January 6, 2020. Op. 100 (JA168). It actually expires August 30, 2020, twenty years after the application filing. *See* 35 U.S.C. § 154(a)(2).

Second, the FTC sought to prohibit AbbVie and Besins from engaging in the same type of misconduct with respect to other patents and drugs—*i.e.*, filing other objectively baseless patent suits to interfere with or delay competition from generics. ECF No. 403-1, at 3. Such "fencing-in" relief is common in FTC cases, and is proper "so long as the injunction "bears a 'reasonable relation to the unlawful practices found to exist.'" *FTC v. Grant Connect, LLC*, 763 F.3d 1094, 1105 (9th Cir. 2014) (quoting *FTC v. Colgate-Palmolive*, 380 U.S. 374, 394-95 (1965)); *see also Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 702-10 (3d Cir. 1982) (upholding FTC order prohibiting certain deceptive advertising practices with respect to all of a drug company's non-prescription products). Here, a fencing-in order is warranted because, as discussed above, AbbVie has engaged in similar conduct in the past and it and Besins regularly engage in patent litigation as part of their business. Any overbreadth concerns can be mitigated through appropriate tailoring—*e.g.*, by including a safe harbor spelling out what AbbVie and Besins must do to avoid a finding of objective baselessness. Whether such relief is warranted is up to the district court in the first instance, but the FTC's request at least deserved fair consideration, which it did not get.

Third, the FTC sought a requirement that each time AbbVie or Besins filed a patent infringement lawsuit, it provide the FTC with a certification, signed by the company's CEO or another corporate officer, affirming that the case is objectively

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 government process and its incorrect belief that there was no evidence of sham litigation with respect to other patents. Those errors alone demonstrate an abuse of discretion.

Furthermore, the court's constitutional concerns do not pertain to the specific requests that the FTC actually made. The certification requirement, for example, implicates no First Amendment rights at all. With respect to the litigation bar, the court also failed to recognize that the First Amendment does not protect sham litigation. *See Hill v. City of Scranton*, 411 F.3d 118, 126 (3d Cir. 2005); *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 120 (3d Cir. 1999); *White v. Lee*, 227 F.3d 1214, 1231 (9th Cir. 2000). Nor did the court heed the

"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 introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b) Filing application; contents

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

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

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

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

(ii) that such patent has expired,

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

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

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

(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

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

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

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

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

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

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

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

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

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

* * *

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

* * *

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

* * *

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive

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

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

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

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

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

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

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals 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 or not infringed, the approval shall be made effective as provided in clause (i); or

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

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

* * *

(j) Abbreviated new drug applications

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

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

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

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

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

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

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

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that

the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

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

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

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

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

(II) that such patent has expired,

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

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

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

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

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

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

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

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

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

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

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

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

(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

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

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

* * *

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

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

* * *

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless,

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

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

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

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

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

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

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

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

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

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial

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

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

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

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

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

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

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

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

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

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(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision

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 date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint 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 agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 45 of title 15 to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

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