UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION, Plaintiff, v. **ABBVIE INC., ABBOTT LABORATORIES, UNIMED PHARMACEUTICALS, LLC, BESINS HEALTHCARE, INC., AND TEVA PHARMACEUTICALS USA, INC.,** Defendants.	Case No. 14-cv-5151

Plaintiff Federal Trade Commission's Memorandum
In Opposition To Defendants' Motion To Dismiss

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

INTRODUCTION

This antitrust case challenges a multifaceted anticompetitive scheme to obstruct entry of lower-priced versions of AbbVie's blockbuster testosterone replacement drug AndroGel. In 2011, AbbVie and Besins faced significant competitive threats to their AndroGel franchise from two rivals—Teva and Perrigo. Each generic firm intentionally had designed its product to avoid AndroGel's narrow formulation patent. AbbVie and Besins knew full well that Teva and Perrigo had succeeded in developing a different formulation than AndroGel's. Nonetheless, they filed sham patent infringement lawsuits to trigger a regulatory provision that would block approval of the generics' products, thereby forestalling competition for up to 30 months.

Their plan was in jeopardy, however, when the Teva litigation moved more quickly than expected. With trial fast approaching, AbbVie decided to use its monopoly profits to buy the protection from competition that its narrow patent could not provide. To secure Teva's agreement to settle the AndroGel infringement suit and refrain from launching its competing product until [redacted], AbbVie compensated Teva with a sweetheart authorized generic deal for an unrelated cholesterol drug called TriCor.

Standing alone, neither the AndroGel patent settlement agreement nor the TriCor side deal makes economic sense. Teva had no reason, absent significant compensation, to abandon a lawsuit it knew was baseless and agree to stay out of the AndroGel market for [redacted] years. AbbVie had no reason to give Teva the ability to accelerate generic TriCor entry and thereby cede seven weeks of TriCor monopoly profits, except as a way to protect its AndroGel monopoly. Together, the simultaneously executed contracts provided enormous financial benefits to defendants, but at a steep cost to consumers, who have been forced to pay hundreds of millions of dollars more for AndroGel.

The FTC's complaint alleges two violations of Section 5 of the FTC Act arising from this conduct: Count One charges that AbbVie and Besins unlawfully maintained the AndroGel monopoly through a course of conduct that included filing sham patent infringement lawsuits. Count Two alleges that AbbVie's settlement with Teva was an illegal restraint of trade. Defendants have moved to dismiss Count Two, contending that the complaint fails to plausibly allege an anticompetitive reverse-payment settlement under the standards set forth in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

Much of defendants' motion impermissibly rests on their own version of the facts, which contradicts both the well-pleaded allegations of the FTC's complaint and their own contemporaneous business documents. First, they ignore the complaint's allegations that, unlike *Actavis*, the challenged agreement in this case is a settlement of a sham patent infringement suit. The defendants' failure to account for these allegations is fatal to their motion. Long before *Actavis*, courts recognized that settlement of sham litigation raises distinct antitrust concerns. In that context, there is no longer any need to accommodate patent law concerns in the antitrust analysis. But the only argument that defendants have made for dismissal of Count Two assumes AbbVie's infringement suit against Teva was genuine. No such assumption is permissible on a motion to dismiss. Consequently, the Court should summarily deny defendants' motion and allow the case to proceed.

Second, apart from the sham litigation allegations, the complaint's restraint of trade allegations are in many respects similar to those the Supreme Court considered in *Actavis*. Just as in *Actavis*, the complaint here alleges that "in substance" the brand-name drug manufacturer paid many millions of dollars to secure a generic drug company's agreement to abandon its patent challenge and stay off the market for several years; that the sharing of monopoly profits took the

form of a lucrative business deal executed at the same time as the settlement agreement; and that the "true point" of the side deal was to compensate the generic for agreeing not to compete. Defendants' various arguments that the FTC's allegations do not plausibly state a claim under *Actavis* ignore the economic substance of the challenged agreement, contradict the well-pleaded factual allegations, and misconstrue *Actavis*. For example, their primary argument—that the complaint fails to allege a "payment"—rests on defendants' insistence that the simultaneously executed contracts on TriCor and AndroGel were entirely independent, procompetitive deals and that AbbVie was unaware of Teva's difficulties with its generic TriCor product. A host of facts in the complaint show otherwise.

With or without the sham infringement allegations, the FTC's extensive, well-pleaded factual allegations plausibly state a claim of unlawful restraint of trade. For these reasons, defendants' motion to dismiss should be denied.

THE COMPLAINT ALLEGATIONS

A. AndroGel and the Threat of Generic Competition

AndroGel is a prescription topical gel indicated for testosterone replacement therapy in men with low testosterone. (Compl. ¶ 36.) In June 2000, AbbVie's predecessor launched AndroGel 1%, the original dosage strength of the product. (*Id.* ¶ 38.) AndroGel 1.62%, a reformulated version of the product with a new dosage strength of testosterone, launched in April 2011. (*Id.* ¶ 40.) Annual U.S. sales of AndroGel products exceeded $1 billion in both 2012 and 2013. (*Id.* ¶ 41.)

The sole patent covering AndroGel 1% is a narrow formulation patent that expires in 2020. (*Id.* ¶¶ 2, 25, 59.) AbbVie's predecessor[1] and Besins originally sought a broad patent covering testosterone gel formulations with any "penetration enhancer"—an ingredient that speeds the delivery of testosterone through the skin and into the bloodstream. (*Id*. ¶¶ 2, 45-49.) But during prosecution of the patent application, they had to narrow significantly the scope of their claims to obtain U.S. Patent and Trademark Office approval. (*Id.* ¶¶ 2, 45-55.) The PTO ultimately issued U.S. Patent No. 6,503,894 (the "'894 Patent") on January 7, 2003. (*Id.* ¶¶ 2, 58.) The '894 Patent's claims are limited to one specific penetration enhancer, isopropyl myristate, along with specified amounts of testosterone and three other inactive ingredients. (*Id.* ¶¶ 45-46, 58.)

This narrow patent protection and commercial success made AndroGel an attractive target for generic drug manufacturers. The statute governing approval of generic drugs, known as the Hatch-Waxman Act, permits generic drug manufacturers to seek approval to market a generic alternative to a branded drug. (*Id.* ¶ 22); *see* 21 U.S.C. §§ 355 (b)(2), 355(j)(2). The generic applicant typically files an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration to seek approval of its product and to establish that its product is bioequivalent to the branded drug. (Compl. ¶¶ 25, 29.) If the generic is seeking to market its product before expiration of any patents listed with the FDA for the branded drug, the generic applicant must also certify that the patent in question is invalid or not infringed (known as a Paragraph IV certification). 21 U.S.C. §§ 355 (b)(2)(A)(iv), 355(j)(2)(A)(vii)(IV).

[1] Besins and Unimed Pharmaceuticals, LLC were the original co-owners of the '894 Patent. (Compl. ¶ 58.) In 1999, Solvay Pharmaceuticals bought Unimed, and in 2010, Abbott Laboratories bought Solvay. (*Id.* ¶ 39.) In 2013, Abbott split into two companies, and AbbVie now owns the rights to AndroGel. (*Id.)* Unimed is now a wholly-owned subsidiary of AbbVie. (*Id.* ¶ 19.) For purposes of this memorandum, all references to AbbVie shall mean AbbVie, its associated entities, or the predecessor entity that existed at the time.

In December 2008, Perrigo filed an ANDA and Paragraph IV certification for generic AndroGel.[2] (Compl. ¶ 64.) Perrigo's product did not contain isopropyl myristate, the only penetration enhancer specified in the '894 Patent. (*Id.* ¶¶ 62, 64.) Solvay, AbbVie's predecessor, announced in a press release that it would not sue Perrigo for patent infringement because Perrigo's product contained "a different formulation than the formulation protected by the AndroGel patent." (*Id.* ¶ 66.)

Based on this difference in Perrigo's formulation, AbbVie filed a citizen petition in April 2010 urging the FDA to reject Perrigo's ANDA because the different penetration enhancer in Perrigo's product could present distinct safety concerns. (*Id.* ¶ 69.) AbbVie asked the FDA to require any company seeking approval of a generic AndroGel product with a penetration enhancer other than isopropyl myristate to conduct additional safety studies and file a 505(b)(2) NDA application instead of an ANDA. (*Id.* ¶¶ 69-70.) Unlike an ANDA, a 505(b)(2) application must be supported by independent safety data, in addition to the information contained in the approved NDA upon which it relies. (*Id.* ¶¶ 25, 69-70.) In October 2010, the FDA largely granted AbbVie's request, meaning that companies seeking approval for generic AndroGel products using a different penetration enhancer would have to file 505(b)(2) applications. (*Id.* ¶ 70.)

By this time, Teva also had developed a generic AndroGel 1% product that did not contain isopropyl myristate. (*Id.* ¶¶ 61, 63.) Teva and Perrigo each conducted the required safety studies and filed 505(b)(2) applications in January 2011 and July 2011, respectively. (*Id.* ¶¶ 3,

[2] Two other generic drug manufacturers, Watson and Paddock, had previously filed ANDAs with Paragraph IV certifications for generic versions of AndroGel. (Compl. ¶ 73.) The FTC challenged the settlements of the patent litigations that ensued as unlawful reverse-payment agreements, and that FTC complaint was the subject of the Supreme Court's decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). The FTC's lawsuit on remand is pending in the U.S. District Court for the Northern District of Georgia.

71.) Both Teva's and Perrigo's applications contained Paragraph IV certifications asserting that their formulations did not infringe the '894 Patent. (*Id.* ¶¶ 79, 86.)

B. The Sham Infringement Suits Against Teva and Perrigo

Despite their full knowledge that Teva's and Perrigo's products contained a penetration enhancer other than isopropyl myristate, AbbVie and Besins filed a patent infringement lawsuit against each generic company. (*Id.* ¶¶ 80-81, 87-88.)

In their suit against Teva, which was before Your Honor (sitting by designation) in the District of Delaware, AbbVie and Besins conceded that Teva's product did not literally infringe the '894 Patent. (*Id.* ¶ 82.) Instead they asserted infringement under the doctrine of equivalents, claiming that Teva's penetration enhancer is equivalent to isopropyl myristate. (*Id.*) This claim of equivalence, however, directly contradicted their repeated claims before the PTO, the FDA, and another district court that different penetration enhancers are *not* equivalent. (*Id*. ¶¶ 72-77.)

In response, Teva filed antitrust counterclaims, asserting that the infringement claims were a sham because the patentees had surrendered claims covering Teva's penetration enhancer during the prosecution of the '894 Patent and were therefore precluded from arguing infringement under the doctrine of equivalents. (*Id.* ¶ 83.) Teva subsequently filed an early motion for summary judgment arguing that the doctrine of prosecution history estoppel barred the claim of infringement. (*Id.* ¶ 84.) At an October 14, 2011 hearing related to Teva's motion and the plaintiffs' request for discovery, Your Honor determined that prosecution history estoppel was a dispositive issue and by-passed summary judgment in favor of scheduling a May 2012 bench trial limited to this issue.[3] (*Id.* ¶ 84.)

[3] Transcript of Oct. 14, 2011 Oral Argument at 28-30, 66-67, *Abbott Prods., Inc. v. Teva Pharms. USA, Inc.*, No. 11-384 (D. Del.) (Dkt. No. 83).

Six days after Your Honor set the Teva trial date, AbbVie and Besins filed a patent infringement suit against Perrigo. (*Id.* ¶¶ 84, 88.) Perrigo had already advised AbbVie that any patent infringement suit against it would be a sham because its product did not contain isopropyl myristate. (*Id.* ¶ 86.) In fact, the formulation of Perrigo's product was identical in all material respects to the ANDA formulation that, two years earlier, Solvay (AbbVie's predecessor) and Besins had determined did not infringe the '894 Patent. (*Id.* ¶¶ 64-67, 71, 86-87.)

C. Teva's and Perrigo's 505(b)(2) Products Posed a Competitive Threat

Under the Hatch-Waxman Act, the lawsuits that AbbVie and Besins filed against Teva and Perrigo each triggered an automatic 30-month stay on the FDA's ability to approve the generic's product. (*Id.* ¶¶ 5, 27, 81, 88); *see also* 21 U.S.C. §§ 355 (c)(3)(C), 355(j)(5)(B)(iii). The 30-month stay would end, however, if the district court determined that the patent at issue was invalid or not infringed. (*Id.* ¶ 107); *see also* 21 U.S.C. §§ 355 (c)(3)(C), 355(j)(5)(B)(iii). With a May 2012 trial on the baseless infringement claims, Teva seemed poised to win its case and launch its product long before the expiration of its 30-month stay. (*Id.* ¶¶ 107, 110, 134.) By the fall of 2011, AbbVie, Teva, and third party analysts all projected that generic AndroGel entry would occur in 2012. (*Id.* ¶¶ 108-110.) AbbVie, however, wanted additional time to shift sales from AndroGel 1% to AndroGel 1.62% (which could not be automatically substituted with Teva's or Perrigo's products), so it approached Teva and Perrigo to discuss settlement. (*Id.* ¶¶ 112, 133.)

At the time of the settlement negotiations, the FDA had not determined the therapeutic equivalence ratings for Teva's or Perrigo's products. (*See id.* ¶¶ 85, 90.) But in October 2011, just a few months before the settlements, AbbVie projected that "[t]he most likely scenario is A-rated generic launch sometime near April 2012." (*Id.* ¶ 108.) The FDA assigns an "A" or an "AB" rating to a generic drug that is therapeutically equivalent to a branded drug, making it

automatically substitutable at the pharmacy for the brand-name product. (*Id.* ¶¶ 29-31.) A- or AB-rated generic drugs typically are priced much lower than brand-name drugs and significantly erode the sales of their branded counterparts upon entering a market. (*Id.* ¶¶ 30-31.)

The FDA can also assign a "BX" rating to a product, meaning that the data are insufficient to establish therapeutic equivalence and pharmacies cannot automatically substitute the generic product for the brand. (*Id.* ¶¶ 29-30, 33.) AbbVie's and Teva's forecasts around the time of the settlement negotiations reflect their expectations that even a BX-rated product would be priced lower than AndroGel and capture a significant amount of AndroGel sales. (*Id.* ¶¶ 34, 148, 150.) Teva's forecasts, for example, indicated that it would have priced a BX-rated product at [redacted] of AndroGel's price and captured meaningful sales. (*Id.* ¶¶ 34, 150.) AbbVie's September 2011 model predicted that it could lose up to $855 million if a BX-rated product entered the market in 2012. (*Id.* ¶ 148.)

Ultimately, the FDA approved Teva's product on February 14, 2012, and Perrigo's product on January 31, 2013. (*Id.* ¶¶ 85, 90.) On July 23, 2014, the FDA gave Perrigo's product an AB rating and Teva's product a BX rating. (*Id.*)

D. The Perrigo Settlement

AbbVie could not pay Perrigo to agree to any restriction on selling generic AndroGel without Perrigo violating the terms of a 2011 FTC consent agreement.[4] (*Id.* ¶ 134.) Thus, AbbVie proposed a settlement that would permit Perrigo to launch its generic AndroGel product on the same date as any other generic launched, without incurring any additional litigation costs. (*Id.* ¶¶ 134-35.) Given Teva's May 2012 trial date, Perrigo believed that it was unlikely to

[4] Decision and Order, *In re Perrigo Co.*, FTC Docket No. C-4329 (June 21, 2012), at 21-22, *available at* http://www.ftc.gov/sites/default/files/documents/cases/2012/06/110626perrigodo.pdf (last visited Dec. 2, 2014).

achieve earlier entry by continuing to litigate its own case. (*Id*.) Absent the settlement, Perrigo could not secure such parity with Teva because the outcome of the Teva case would have no effect on the 30-month stay blocking approval of Perrigo's product. (*Id*. ¶ 135.) Perrigo therefore accepted AbbVie's settlement offer. (*Id.* ¶ 136.) Perrigo did not know, however, that AbbVie and Besins were negotiating to pay Teva to settle and agree not to compete until [redacted]. (*Id.*)

E. The Teva Settlement

The infringement litigation was proceeding quickly toward a victory for Teva. (*Id.* ¶ 107.) To preserve its AndroGel monopoly profits for several more years, AbbVie needed a way to keep Teva off the market. (*Id.* ¶¶ 111-12.) But, Teva was not willing to settle the AndroGel litigation and agree not to compete with generic AndroGel without significant compensation from AbbVie. (*Id.* ¶¶ 9, 113, 119.) Ultimately, the parties executed a settlement agreement under which Teva agreed not to market its generic AndroGel product until [redacted], and on the same day, they executed an authorized generic distribution agreement for TriCor, which transferred significant value to Teva. (*Id.* ¶¶ 9, 116-17, 119-20.)

1. Negotiation of the TriCor side deal

In exchange for settling the AndroGel litigation and agreeing not to compete, Teva asked AbbVie for the right to sell an authorized generic version of TriCor, a blockbuster cholesterol drug with annual sales in the United States exceeding $1 billion in 2011.[5] (*Id.* ¶ 113.) Teva had been a first generic ANDA filer for TriCor. (*Id.* ¶ 114.) In 2009, Teva entered a license agreement with AbbVie that allowed Teva to launch its 145 mg generic TriCor product on July

[5] An authorized generic drug is essentially the branded drug marketed as a generic product. (Compl. ¶ 28.)

1, 2012, 180 days before other ANDA filers. (*Id.*) TriCor was a significant part of Teva's product pipeline and Teva was unwilling to lose a valuable first-filer opportunity. (*Id.*)

But, at the time of the AndroGel settlement negotiations, AbbVie knew that Teva had not secured FDA approval for its generic TriCor products over four years after filing its TriCor ANDAs. (*Id.* ¶ 127.) This meant that Teva almost certainly had forfeited its 180-day exclusivity rights. (*Id.* ¶ 114.) Because of its license agreements with other ANDA filers, AbbVie knew that if Teva were unable to launch its own generic TriCor products, branded TriCor would not face generic competition until January 1, 2013. (*Id.* ¶¶ 127-28.)

Before agreeing to supply Teva with an authorized generic version of TriCor, AbbVie calculated its loss in branded TriCor profits if generic TriCor entered the market in November 2012 as compared to January 2013. (*Id.* ¶ 132.) AbbVie performed this specific calculation even though its prior agreement with Teva permitted Teva to launch its generic TriCor product on July 1, 2012. (*Id.* ¶¶ 114, 132.) In the two-month period between November 2012 and January 2013, AbbVie projected net losses of roughly $100 million in branded profits. (*Id.* ¶ 132.) AbbVie ultimately agreed to give Teva the option to obtain supply of authorized generic 145 mg and 48 mg generic TriCor beginning November 10, 2012. (*Id.* ¶ 117.)

2. Terms of the TriCor side deal

The TriCor side deal included unusually favorable terms for Teva. (*Id.* ¶¶ 126, 130-131.) First, the TriCor side deal enabled Teva to launch generic TriCor before any other competitor and achieve a valuable first-mover advantage.[6] (*Id.* ¶ 121.) That meant Teva would likely retain a large portion of the generic TriCor market even after other generic competitors entered. (*Id.*)

[6] Teva's launch permitted the other TriCor ANDA filers to introduce their products immediately following Teva's entry. (Compl. ¶ 129.) Teva exercised its option under the TriCor deal and launched authorized generic 145 mg and 48 mg TriCor on or about November 16, 2012. (*Id.*)

Shortly before entering the TriCor side deal with AbbVie, Teva forecast that its net sales under the deal would be approximately $175 million in the first four years. (*Id.* ¶ 120.) With the first-mover advantage secured, Teva also knew it would continue to profit from the arrangement well past the initial four years, making the deal worth hundreds of millions of dollars to Teva. (*Id.* ¶¶ 120-21.)

Second, AbbVie's guaranteed supply start date of November 10, 2012, was not contingent on whether the FDA approved Teva's ANDAs or if any other generic TriCor products had launched. (*Id.* ¶¶ 117, 126.) Brand companies typically do not permit authorized generics to launch before independent generic entry. (*Id.* ¶ 126.) That is because brand companies have no incentive to give away the monopoly profits of their own brand drugs. (*Id.*)

Third, the royalty rate in the TriCor side deal is substantially lower than the royalty rate in a typical authorized generic agreement. (*Id.* ¶ 130.) Under the TriCor agreement, Teva pays AbbVie a [redacted] royalty on its authorized generic sales. (*Id.* ¶¶ 117, 130.) In contrast, under another authorized generic agreement AbbVie entered just weeks after executing the TriCor side deal, AbbVie receives a royalty rate of over [redacted]. (*Id.* ¶ 130.)

3. The role of the TriCor side deal in the AndroGel settlement

Absent the substantial value from the TriCor side deal, Teva would have been unwilling to settle the AndroGel lawsuit and refrain from marketing its generic AndroGel product until [redacted].[7] (*Id.* ¶¶ 9, 113, 119.) The TriCor side deal gave Teva the opportunity to salvage significant value from a failed first-filer opportunity. (*Id.* ¶¶ 114, 119-21.)

[7] The patent settlement prompted an angry letter from Teva's testosterone gel development partner, BioSante, challenging Teva's "incomprehensible" decision to settle "a sham infringement lawsuit," and accusing Teva of receiving a hidden reverse payment. (Compl. ¶ 118.) Teva eventually agreed to pay over $2 million to make amends with BioSante. (*Id.*)

Similarly, absent an agreement to refrain from competing with generic AndroGel until at least [redacted], AbbVie would have been unwilling to facilitate generic TriCor entry and surrender a substantial amount of TriCor profits. (*Id.* ¶¶ 9, 115, 125, 132.) By ceding nearly $100 million in branded TriCor profits, AbbVie was able to preserve hundreds of millions of dollars more in branded AndroGel sales. (*Id.* ¶ 132.) Neither agreement in isolation made business sense to both parties, but together, the AndroGel settlement and TriCor side deal allowed both the brand and generic companies to come out ahead—at the expense of consumers. (*Id.* ¶¶ 9-10, 105, 113, 115, 119, 125, 132, 144-46.)

ARGUMENT

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) "may be granted only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, a court finds that plaintiff's claims lack facial plausibility." *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 84 (3d Cir. 2011) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007)). This plausibility inquiry "does not impose a probability requirement at the pleading stage." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 556); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (explaining that the "plausibility standard is not akin to a 'probability requirement'") (quoting *Twombly*, 550 U.S. at 556). At the motion to dismiss stage, the question is "not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Twombly*, 550 U.S. at 563 n.8 (internal quotation marks omitted).

In evaluating a motion to dismiss, courts are confined to the four corners of the complaint and matters properly subject to judicial notice. *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993); *see also Stricklin v. Ferland*, No. 98-3279, 1999 WL 89694, at *1 (E.D. Pa. Jan. 19, 1999) (Bartle, J.). Courts may also consider

indisputably authentic documents that are "*integral to or explicitly relied* upon in the complaint." *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (internal citations omitted) (emphasis in original). District courts may not credit factual claims made by defendants as to matters outside the complaint. *See, e.g., In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 398 (3d Cir. 2000) (reversing 12(b)(6) dismissal where "the court impermissibly cited and relied on facts beyond the corners of the complaints").

The defendants disregard these well-established principles. As discussed below, they ignore well-pleaded factual allegations in the FTC's complaint and instead: (1) assert their own preferred "facts" as to matters that are not proper subjects of judicial notice;[8] (2) seek to have this Court draw inferences in their favor from asserted facts outside the complaint;[9] and (3) submit for the Court's consideration a document that is neither integral to nor referenced by the FTC's complaint.[10] Lest there be any doubt, the Third Circuit has made it clear that the general rules governing motions to dismiss are fully applicable in antitrust cases. *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010) ("[I]t is inappropriate to apply *Twombly's* plausibility standard with extra bite in antitrust and other complex cases.").

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[8] For example, defendants rely on a variety of facts outside the complaint to support their claim that at the time of the challenged agreement AbbVie was unaware of Teva's problems with its generic TriCor product. (*See, e.g.*, Defs.' Mem. at 13, 24 (asserting that AbbVie expected Teva to launch generic TriCor in July 2012); Defs.' Mem. at 38 (discussing investment and resources for marketing BX-rated products to physicians); Defs.' Mem. at 38-39 (suggesting that physicians would not prescribe Teva's product).)

[9] (Defs.' Mem. at 24 n.7 (referencing the FDA's approval of Lupin's TriCor product to imply that Teva's TriCor ANDAs could receive FDA approval).)

[10] Defendants attach an agreement concerning an AbbVie product known as Simcor to their motion to dismiss. They concede that this agreement is "not mentioned by the FTC's complaint," (Defs.' Mem. at 14), but claim that Simcor is part of "the basis of the FTC's allegations." (Defs.' Mem. at 9 n.2.) It manifestly is not. The Court should disregard this agreement as well as any inferences defendants seek to draw from it. *See, e.g., In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 398 (3d Cir. 2000).

Part I below explains why the defendants—having ignored the allegations that, unlike *Actavis*, the Teva-AbbVie agreement resolved sham patent claims—fail to provide any basis that would permit the Court to dismiss Count Two. Part II then explains that—with or without the sham infringement allegations—the complaint's extensive, well-pleaded factual allegations plausibly state a claim under *Actavis*. Defendants' arguments to the contrary ignore not only motion to dismiss principles, but also the economic substance of the TriCor side deal and the teachings of *Actavis*.

I. The Allegations that the Challenged Agreement Was Used to Settle Sham Patent Litigation Are Fatal to Defendants' Motion

Actavis reaffirmed that patent settlements between potential competitors are subject to antitrust scrutiny. 133 S. Ct. at 2231-33. In *Actavis*, the Supreme Court rejected a legal rule, known as the "scope of the patent test," that conferred "near-automatic antitrust immunity" on patent settlements when the alleged anticompetitive restraints do not extend beyond the patent's expiration date. *Id.* at 2237. The Court explained that reverse-payment settlements have the "potential for genuine adverse effects on competition" because they can serve as a means for the patent holder "to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." *Id.* at 2234-35. Such agreements, the Court held, are subject to antitrust scrutiny under established "rule of reason" principles. *Id.* at 2237.

The challenged settlement agreement in this case is similar in many respects to the reverse-payment agreements considered in *Actavis*. Both involve agreements to settle patent litigation accompanied by purportedly independent business transactions that are alleged to have secured a generic patent challenger's agreement not to compete. But this case differs from

Actavis in one key respect that defendants simply ignore. And their failure to account for this key difference is fatal to their motion.

The Supreme Court's analysis in *Actavis* was premised on the existence of a genuine patent dispute and thus on the need "to accommodate patent and antitrust policies." 133 S. Ct. at 2231, 2233; *see also id.* at 2239 (Roberts, J., dissenting) ("No one alleges that there was sham litigation . . . ."). Here, however, the complaint alleges facts showing that the patent infringement suits brought against Teva and Perrigo were sham. (*See, e.g.*, Compl. ¶¶ 80-83, 86-89, 91-99.) That is, they: (1) were premised on an "objectively baseless" theory of infringement, meaning "no reasonable litigant could realistically expect success on the merits;" and (2) were an attempt to use "the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 60-61 (1993) (emphasis in original). Defendants have not challenged the sham litigation allegations, and, in any event, these well-pleaded allegations must be accepted as true for purposes of this motion.

The absence of any genuine patent dispute simplifies the antitrust analysis. Where no genuine patent infringement claim exists, there is no need to undertake the balancing of patent and antitrust law policies that the Supreme Court described in *Actavis*. *See* 133 S. Ct. at 2231-33. Thus, even before *Actavis*, it was well accepted that settlements of sham patent litigation present a distinct antitrust concern.[11] Indeed, Chief Justice Robert's dissenting opinion in *Actavis*

[11] Courts adopting the "scope of the patent test" consistently acknowledged that a settlement of sham litigation may violate the antitrust laws. *See, e.g.*, *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012), *rev'd*, 133 S. Ct. 2223 (2013) ("[A]bsent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (same); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 208-09 (2d Cir. 2006) (same).

acknowledges this fundamental distinction.[12] For when a patentee brings a sham infringement claim and then enters a settlement, there is an obvious risk that the settlement, like the lawsuit itself, is a device to restrain competition. Judge Posner offered the following illustration:

> Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices—masks—for fixing prices, in violation of antitrust law.
>
> *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003)

(Posner, J., sitting by designation). Thus, a brand-name drug manufacturer is likely to face antitrust liability when it settles sham patent litigation as part of an overall scheme to restrain trade. But that does not mean that generic patent challengers who are targets of sham patent suits cannot settle such suits without risking antitrust liability. For the generic, liability requires that the settlement agreement be independently unlawful, that is, the settlement restricts competition beyond the restraint imposed by the sham litigation itself.[13]

Here, the allegations concerning the AbbVie-Teva settlement tell a straightforward story of an agreement not to compete. Knowing that AbbVie had no realistic prospect of success in the patent suit, Teva expected to enter in 2012 after receiving a court decision that would terminate the 30-month stay triggered by the sham litigation. (Compl. ¶¶ 107, 109.) Instead, Teva agreed to forgo competing with AbbVie until [redacted], well beyond this expected entry date. (*Id.* ¶¶

[12] 133 S. Ct. at 2239 (conduct "within the scope of the patent" is not subject to antitrust scrutiny, "with two exceptions concededly not applicable here: (1) when the parties *settle sham litigation* . . . .") (emphasis added).

[13] The FTC's complaint alleges that the AbbVie-Perrigo settlement was part of AbbVie's unlawful scheme to preserve its AndroGel monopoly, but it does not charge that Perrigo's agreement to that settlement was unlawful. That is because, as is discussed in more detail in Section II.A.2.d below, absent AbbVie's deal with Teva, Perrigo's agreement was likely to accelerate its entry, which was otherwise blocked by the Hatch-Waxman 30-month stay.

115-17, 119-20.) Teva did so only after AbbVie acceded to Teva's request for the TriCor side deal. (*Id.* ¶¶ 113, 115-17, 119.) Such an agreement plainly has "the potential for genuine adverse effects on competition" and requires a legitimate justification. *FTC v. Ind. Fed'n Dentists*, 476 U.S. 447, 460 (1986). As the Supreme Court explained in *Cal. Dental Ass'n. v. FTC*, "'[t]here is always something of a sliding scale in appraising reasonableness,' so 'the quality of proof required should vary with the circumstances.'" 526 U.S. 756, 780 (1999) (quoting P. AREEDA, ANTITRUST LAW ¶ 1507, p. 402 (1986)). The distinguishing circumstance here—that there was no genuine patent dispute—means that, even before *Actavis,* the FTC's allegations would have easily satisfied the *Twombly* plausibility test and withstood a motion to dismiss.

As the balance of this brief explains, defendants' tortured attempts to argue that the FTC's complaint does not plausibly state a claim under *Actavis* are wrong. But defendants have a more fundamental problem. By ignoring the sham litigation allegations, they have ignored the reason why, without the need to accommodate patent law policies, the antitrust analysis in this case can be simpler than in a case involving a non-sham patent suit. The only argument they have offered is that they would be entitled to dismissal of Count Two if this Court assumes the patent suits had been genuine. No such assumption is permissible on a motion to dismiss. Consequently, the Court can and should summarily deny defendants' motion.

II. The Complaint Plausibly Alleges a Reverse Payment under *Actavis*

In *Actavis*, the Supreme Court explained why patent settlements using "reverse payments"—payments from the patentee to the alleged infringer—can raise antitrust concerns. As the Supreme Court described, the FTC's complaint "allege[d] that in substance, the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market." 133 S. Ct. at 2231. As such, the reverse payment "in effect amounts to a purchase by the patentee of the

exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." *Id*. at 2234. The payment, the Court explained, "simply keeps prices at patentee-set levels" while "dividing that return between the challenged patentee and the patent challenger." *Id.* at 2234-35. The result is "[t]he patentee and the challenger gain; the consumer loses." *Id.* at 2235.

Reverse-payment agreements thus raise a core concern of antitrust law: that the competitive process that benefits consumers will be thwarted because a potential competitor finds it more profitable to preserve and share in the rewards of the incumbent firm's monopoly. *See id.* at 2233 ("'Collusion' is 'the supreme evil of antitrust.'"). That concern arises whether the parties share those rewards through direct cash payments to the alleged infringer or through some other form of compensation. What matters is "that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Id*. at 2236; *see also id*. (explaining that a payment "to prevent the risk of competition" is "the relevant anticompetitive harm"). A reverse payment must therefore be sufficiently large to "induce the generic challenger to abandon its claim." *Id.* at 2235. Where plaintiffs prove a large reverse payment, defendants have the opportunity to show "that legitimate justifications are present" that explain the challenged payment. *Id.* at 2236. But, if "the basic reason" for a large 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*. at 2237.

The complaint allegations in this case are similar in many respects to the allegations the Supreme Court considered in *Actavis*. Just as in *Actavis*, the complaint here alleges that "in substance" the brand-name drug manufacturer paid many millions of dollars to secure a generic drug company's agreement to abandon its patent challenge and stay off the market for a period of

years. *Id.* at 2231; (Compl. ¶¶ 9, 104, 119-20, 125). Just as in *Actavis*, the restraint on the generic's entry terminated several years before expiration of the patent that was the subject of the infringement suit. 133 S. Ct. at 2229; (Compl. ¶¶ 59, 116, 119). Just as in *Actavis*, the complaint alleges that the sharing of monopoly profits took the form of a lucrative business transaction executed at the same time as the settlement agreement.[14] *See* 133 S. Ct. at 2229; (Compl. ¶¶ 9, 117). And, just as in *Actavis*, the complaint here alleges that the "true point" of the side deal was to compensate the generic for agreeing not to compete. 133 S. Ct. at 2229; (Compl. ¶¶ 9, 119, 125). In arguing that the complaint here fails to state a claim under *Actavis*, defendants ignore the economic substance of the challenged agreement, contradict the well-pleaded allegations of the complaint, and misconstrue *Actavis*.

A. The TriCor Side Deal Functioned as a Reverse Payment to Teva

The key defining characteristic of a reverse payment under *Actavis* is that it enables parties to share monopoly profits preserved by avoiding competition. In *Actavis*, the Supreme Court contrasted the core competitive concern about settlements that share monopoly profits with those in which the opposing parties merely agree to compromise on matters at stake in the litigation. 133 S. Ct. at 2233 (noting that in traditional settlements, a party with a damages claim "receives a sum equal to or less than the value of its claim"). Such a compromise of claims, the Court noted, has not been thought to raise antitrust concerns. *Id.* This principle applies as well when the parties in Hatch-Waxman patent litigation settle with an agreement that merely sets a

[14] Commentators have noted that after the FTC began challenging cash-only reverse-payment agreements, pharmaceutical companies then turned to other more sophisticated payment arrangements. *See, e.g.*, Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 Rutgers L.J. 83, 98 (2009) ("[B]rand firms no longer are making simple payments to generics to stay off the market. Such settlements, which appear quaint in contrast to today's sophisticated version of three-drug monte, are no longer observed in today's marketplace.").

date for the generic patent challenger's market entry before patent expiration, without more. *Id.* at 2237 (describing settlement "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.") There is nothing to suggest that this familiar settlement form reflects anything other than arms-length bargaining between adverse parties.

But when the inducement to settle and defer market entry includes something that the alleged infringer could not obtain even if it prevailed in the patent litigation, "[t]hat . . . is something quite different" and may raise antitrust concerns. *Id.* at 2233.[15] Under those circumstances, it is necessary to determine whether the inducement may be a vehicle for sharing monopoly profits. *Actavis* thus reflects a two-part framework to assess whether a settlement agreement contains a reverse payment: (1) is the alleged payment something that a generic challenger could not have obtained had it won the litigation?; and (2) are the parties sharing monopoly profits by avoiding competition?

1. AbbVie Shared Monopoly AndroGel Profits with Teva Through the TriCor Side Deal

Applying the two-part framework for reverse payments reflected in *Actavis* to the TriCor side deal is straightforward. First, even by prevailing in the AndroGel infringement action, Teva could not have secured the right to sell an authorized generic version of TriCor. (Compl. ¶ 124.) A finding that Teva's testosterone gel product did not infringe the AndroGel patent would not

[15] *See also In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 391 (D. Mass. 2013) (denying motion to dismiss reverse payment claim where side deals were "entirely disconnected from" the underlying patent lawsuit at issue).

give Teva any right to sell an authorized generic of a wholly unrelated product. Thus, the TriCor side deal cannot be characterized as a mere compromise of claims raised in the litigation.[16]

Second, the complaint plausibly alleges that the TriCor side deal served as a vehicle for AbbVie to protect its AndroGel monopoly profits and to share those proceeds with Teva. As the complaint details, Teva presented the most immediate competitive threat to AndroGel. With a quickly approaching May 2012 trial of a baseless infringement claim, Teva was poised to win its case and launch its product long before the expiration of the 30-month stay. (*Id.* ¶¶ 107, 109.) Teva was only willing to abandon its patent challenge and refrain from launching its testosterone gel product until [redacted], because it received the lucrative TriCor side deal. (*Id.* ¶¶ 119-20.)

As the complaint explains, the TriCor side deal was tremendously valuable to Teva. (*Id.* ¶¶ 113-14, 116, 119-24, 127-30.) Generic TriCor was an important component of Teva's product pipeline, but by late 2011—over four years after filing its ANDA—Teva still had not secured FDA approval. As a result, it had forfeited its valuable 180-day exclusivity rights as the first ANDA filer for the 145 mg tablets.[17] (*Id.* ¶ 114.) Without a viable ANDA product to sell, Teva would squander its remaining opportunity to be the first generic seller of the billion-dollar-per-year blockbuster product and would lose all of its anticipated revenues from generic TriCor. (*Id.* ¶¶ 114, 120-21.) The TriCor side deal assuaged Teva's problems by allowing Teva to: (1) launch a generic TriCor product in November 2012, when it otherwise would have no product to sell;

[16] Defendants claim that the FTC deems any consideration beyond matters at stake in the litigation to be a reverse payment, (*see* Defs.' Mem. at 35), a claim that is simply not true. As explained, even if settlement consideration includes matters outside the specific lawsuit, further inquiry is needed to determine whether the arrangement may be a mechanism for the parties to share the rewards of prolonging the brand's monopoly.

[17] *See* 21 U.S.C. § 355 (j)(5)(D)(i)(IV) (explaining that a first filer typically forfeits its 180-day exclusivity period if its ANDA does not receive tentative approval from the FDA within 30 months after the application is filed).

(2) regain a first-mover advantage over other generic manufacturers; and (3) salvage significant value from a failed first-filer opportunity. (*Id.* ¶¶ 120-21.) The deal also included an extraordinarily favorable royalty rate that gave Teva [redacted] of the profits from distributing the authorized generic version of TriCor. (*Id.* ¶¶ 117, 130.)

AbbVie, for its part, was willing to guarantee Teva's entry into the TriCor market seven weeks before the January 1, 2013 licensed entry date of the other ANDA filers, but only because doing so prolonged its AndroGel monopoly for at least [redacted] more years. (Compl. ¶ 125.) This ensured AbbVie could charge AndroGel consumers supracompetitive prices for that extended period and bought AbbVie additional time to shift sales to its reformulated AndroGel 1.62% product. (*Id.* ¶¶ 115, 125-32.) These allegations describe the type of reverse-payment agreement that the Supreme Court held warrants antitrust scrutiny: using a purportedly independent business transaction to serve as a vehicle for the patentee to share with its potential rival some of the monopoly profits preserved by avoiding competition. *Actavis*, 133 S. Ct. at 2236. Indeed, Teva's own testosterone gel development partner characterized the TriCor side deal as a hidden reverse payment to induce Teva to settle "a sham infringement lawsuit."[18] (Compl. ¶ 118.)

In fact, the complaint's allegations are similar to claims that survived a motion to dismiss and summary judgment in the *Nexium* reverse payment settlement litigation. *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-02409, 2014 WL 4370333, at *22-24 (D. Mass. Sept. 4, 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 382, 393 (D. Mass.

[18] Defendants try to ignore these inconvenient facts, erroneously suggesting that *admissible proof* is required at the pleading stage. Even after *Twombly*, that is not so. *Phillips*, 515 F.3d at 234 (finding that the *Twombly* pleading standard "'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element") (quoting *Twombly*, 550 U.S. at 556); *see also Watts v. Fla. Int'l Univ.*, 495 F.3d 1289, 1298 (11th Cir. 2007) ("We are at the pleading stage, not the proof stage."). In any event, the complaint allegations derive from defendants' contemporaneous business documents produced during the FTC's pre-complaint investigation and likely will be supported by admissible evidence at trial.

2013). There, the alleged reverse payment from AstraZeneca to Ranbaxy included two authorized generic distribution agreements for two drugs that were unrelated to the underlying Nexium patent dispute.[19] *In re Nexium*, 2014 WL 4370333, at *22, *24. In denying defendants' motions for summary judgment, the court reasoned that:

> What the Plaintiffs have established is a reasonable inference that the Side Agreements were lucrative for Ranbaxy and that they were negotiated in conjunction with the Ranbaxy Settlement. It is notable that these agreements were formally extraneous to the Nexium patent litigation, falling into a category of non-traditional settlement forms which logically trigger heightened antitrust scrutiny . . . This evidence as a whole . . . raises enough suspicions to support a reasonable inference that the Side Agreements were improper reverse payments to induce Ranbaxy to delay its generic launch.

Id. at *24. As in *Nexium*, the complaint here alleges that the patentee provided its generic challenger with a valuable authorized generic distribution deal, which the parties entered on the same day as the patent settlement, and which induced the generic to abandon its patent challenge and agree to stay out of the market. (*See* Compl. ¶ 9.)

2. Defendants' "No Payment" Arguments Are Meritless

Defendants advance several reasons why the TriCor side deal cannot constitute a payment as a matter of law. At their core, defendants' various "no payment" arguments ask the Court to ignore the complaint's extensive factual allegations and the economic substance of the TriCor side deal.[20] (Defs.' Mem. at 17-25.)

[19] Notably, the authorized generic distribution agreements the *Nexium* court deemed plausible reverse payments allowed the generic to retain *only 20 percent* of the profits from sales of the two authorized generic drugs. *In re Nexium*, 2014 WL 437033, at *24. Here, Teva retains [redacted] of the profits under the TriCor side deal. (Compl. ¶ 130.)

[20] Defendants erroneously claim that only a "sham" side deal can operate as a payment. In support of this argument, they assert that the FTC alleged that the co-promotion side deals at issue in *Actavis* were sham. (Defs.' Mem. at 1, 21.) But in *Actavis*, the FTC did not allege that the side deals were "sham" or that they provided *no* value to the brand. Rather, as the Supreme Court summarized it, the complaint alleged facts, like here, showing that the "true point of the

a. Defendants' narrow view of the concept of "payment" makes no economic sense

Defendants contend that the TriCor side deal does not constitute an actionable reverse payment because the money Teva received came from consumers who purchased generic TriCor (not from AbbVie) and because the agreement provides "for a payment of royalties *from* Teva *to* AbbVie" and not the other way around. (Defs.' Mem. at 2, 20-21 (emphasis in original).) Defendants' narrow view of what constitutes a payment makes no economic sense and has been rejected by numerous courts.

Here, the economic realities of the TriCor side deal are the same as a direct payment from AbbVie to Teva. By enabling Teva to launch an authorized generic version of TriCor, AbbVie ceded to Teva a portion of branded TriCor sales AbbVie otherwise would have made in the last seven weeks of 2012. This arrangement effectively provided Teva hundreds of millions of dollars in profits. (*See infra* Section II.B; Compl. ¶¶ 120, 132.) The "indirect" nature of this payment—*i.e.*, that Teva receives the cash from consumers rather than straight from AbbVie—makes no difference. *See United Food and Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA*, No. 14-md-02521, 2014 WL 6465235, at *13 (N.D. Cal. Nov. 17, 2014) ("*In re Lidoderm*") (finding allegations that brand gave generic $96 million worth of brand-name Lidoderm patches to generic to sell to customers plausibly alleged reverse-payment claim); *In re Nexium*, 2014 WL 437033, at *22, *24 (finding side agreements that gave generic right to distribute two wholly unrelated authorized generic products supported a reasonable inference of illegal reverse payment). Whether the brand puts

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payments was to compensate the generics for agreeing not to compete against AndroGel until 2015." 133 S. Ct. at 2229 (citing Compl. ¶¶ 81-85).

money in the generic's pocket via a co-promotion payment like in *Actavis* or by foregoing profits from sales of another product it otherwise would get, as here, the economic result is the same.

The Supreme Court and the Third Circuit have long emphasized that antitrust analysis turns on economic substance, not mere form or labels.[21] "Economic realities rather than a formalistic approach must govern." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005). For this reason, the vast majority of courts have found that allegations of payments through purportedly independent business deals were sufficient to state a claim.[22] Antitrust scholars, including those cited by the Supreme Court in *Actavis*, concur that such in-kind forms of compensation can be a reverse payment as a matter of both economic logic and common sense.[23]

For the same reason, the direction of the royalty payment (from Teva to AbbVie) does not alter the economic reality that the TriCor side deal plausibly serves the same function as the payments that were before the Supreme Court in *Actavis*—to induce the generic to abandon its

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[21] *See, e.g., Eastman Kodak Co. v. Image Technical Servs.*, 504 U.S. 451, 466-67 (1992) (noting that "formalistic distinctions" are "generally disfavored in antitrust law"); *Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 58-59 (1977) (explaining that antitrust analysis must "be based upon demonstrable economic effect rather than . . . upon formalistic line drawing").

[22] *See, e.g., In re Niaspan Antitrust Litig.*, No. 13-md-2460, 2014 WL 4403848, at *11 (E.D. Pa. Sept. 5, 2014) (denying motion to dismiss where settlement contained payments including a no-authorized-generic commitment and co-promotion and back up manufacturing side deals for Niaspan and another unrelated drug); *King Drug Co. of Florence Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 522-24 (E.D. Pa. 2010) (finding allegations of payments made to generics under guise of licensing agreements, supply agreements, and research and development deals sufficient to support an illegal reverse payment claim); *see also In re Lidoderm*, 2014 WL 6465235, at *12-13; *In re Nexium*, 2014 WL 437033, at *22, *24. Only two cases have interpreted *Actavis* as requiring a cash payment, one of which is currently on appeal to the Third Circuit. *See In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 569 (D.N.J. 2014) (holding that *Actavis* only applies to monetary payments) (currently on appeal to the Third Circuit); *In re Loestrin 24 FE Antitrust Litig.*, No. 13-md-2472, 2014 WL 4368924, at *13 (D.R.I. Sept. 4, 2014) (holding that *Actavis* requires cash consideration to trigger the rule of reason).

[23] *See* Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, Carl Shapiro, *Activating Actavis*, 28 Antitrust 16, 18 (2013) (arguing that reverse payments "may take forms other than cash").

patent challenge in return for a share of the monopoly profits. To the contrary, the complaint alleges that unusually low royalty rate in the TriCor side deal enhanced the value of AbbVie's payment to Teva. (*Id.* ¶¶ 117, 130.) Specifically, the complaint alleges that Teva's [redacted] royalty payments are significantly lower than the royalty terms in a typical authorized generic deal. (*Id.* ¶ 130-131.) As a comparison, AbbVie had entered into another authorized generic agreement around the same time as the TriCor side deal, in which it receives an [redacted] royalty, rather than the [redacted] it receives from Teva. (*Id.* ¶ 130.) Thus, the extraordinarily favorable royalty terms make the payment—the TriCor side deal—larger and more profitable for Teva.[24] Teva's payment of some small royalty to AbbVie does not change the fact that the "true point" of the side deal was to compensate Teva for agreeing not to compete.

b. Defendants' "early-entry license" argument was squarely rejected by *Actavis*

Defendants' claim that the AndroGel settlement agreement merely gives Teva an "early-entry" license, (Defs.' Mem. at 18-19), cannot be squared with *Actavis*. The challenged agreements in *Actavis* also provided for entry before patent expiration. *See* 133 S. Ct. at 2229. Although acknowledging that settlement providing for entry before patent expiration might benefit consumers, the Supreme Court nonetheless found that, as alleged, the challenged agreements in substance amounted to the sharing of monopoly profits preserved by avoiding competition:

> [S]ettlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels,

[24] *See also* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 665 (2009) (describing as an effort to disguise a reverse payment a situation where "[t]he brand-name firm supplies the product to the generic firm at a discount, which the generic firm then resells under its own label at a profitable price. The compensation is buried in the discounted price offered by the brand-name firm.").

> potentially producing the full patent-related $500 million monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses.

Id. at 2234-35. The same is true of the FTC's allegations in this case.

Moreover, defendants' claim that an entry date prior to patent expiration amounts to "early" entry is particularly inappropriate here. Teva's entry is "early" only if the Court assumes that AbbVie was certain to win the patent litigation and thus block entry until the patent expires. *Actavis* teaches that such an assumption is improper. But more fundamentally, the complaint here alleges the exact opposite—that the patent litigation was a sham and AbbVie had no reasonable chance of success on the merits. (Compl. ¶¶ 79-85, 91-100.)

c. Defendants' claim that AbbVie was unaware of Teva's TriCor problems contradicts the complaint

According to defendants, the TriCor side deal cannot be a payment as a matter of law unless AbbVie knew with certainty when it agreed to the deal that Teva could not enter the TriCor market with its own product in July 2012. (Defs.' Mem. at 23-25.) Defendants are wrong on the facts and the law.

First, defendants contradict the complaint when they insist that, at the time of the challenged agreement, AbbVie expected Teva to launch generic TriCor in 2012 and was unaware of Teva's problems with its ANDA until the day after the TriCor side deal was signed. (*See* Defs.' Mem. at 23-24.) As alleged, at the time of the settlement negotiations, AbbVie knew that: (1) Teva had not secured FDA approval for its 48 mg and 145 mg TriCor products over four years after filing the ANDAs (Compl. ¶ 114.); (2) as a result, Teva almost certainly had forfeited its 180-day exclusivity rights under the Hatch-Waxman Act (*id.*); (3) when approached about an AndroGel settlement, Teva asked AbbVie to provide it with authorized generic TriCor (*id*. ¶ 113.); and (4) if Teva had no viable ANDA product, generic competition to TriCor would not

begin until January 2013. (*Id.* ¶ 127.) Tellingly, before agreeing to give Teva the right to sell an authorized generic version of TriCor, AbbVie calculated its loss in branded TriCor profits if generic competition began in November 2012 instead of January 2013. (*Id.* ¶ 132.) AbbVie used January 2013 as a benchmark for generic entry, even though it knew that its prior patent settlement with Teva concerning TriCor permitted Teva to launch its ANDA product on July 1, 2012. (*Id.* ¶ 114.) These factual allegations support an inference that AbbVie either knew or strongly suspected that Teva's TriCor ANDA was in trouble. Defendants contradict these well-pleaded allegations when they claim that the TriCor side deal is nothing more than "an unremarkable supply option agreement" with a company "expected to launch TriCor in July 2012." (Defs.' Mem. at 24.) Their "AbbVie was hoodwinked" argument is not merely implausible but also improper on a motion to dismiss.

Second, defendants provide no legal support for their contention that the TriCor side deal can only be a payment if AbbVie knew Teva had no other path to market. Even if AbbVie was unaware that Teva definitely could not enter in July 2012, AbbVie plainly knew that Teva's ability to enter with its own TriCor generic was highly uncertain as of December 2011, and that Teva was willing to drop its AndroGel patent challenge to obtain the TriCor side deal. (Compl. ¶¶ 113-14, 127, 132.) Thus, AbbVie knew that the TriCor side deal was sufficiently valuable to Teva to "induce the generic challenger to abandon its claim." *Actavis*, 133 S. Ct. at 2235. No greater "knowledge" is required under *Actavis*.

d. Defendants' mischaracterization of the Perrigo settlement ignores key allegations about AbbVie's anticompetitive scheme

Finally, defendants argue that the agreement with Teva cannot plausibly include a reverse payment to block Teva's entry until [redacted] because the terms of Perrigo's settlement agreement (which did not include a reverse payment) resulted in an [redacted]

entry date for Perrigo. (Defs.' Mem. at 27-28.) This argument ignores the critical differences in the circumstances of the two agreements and, in particular, the bottleneck effect that Teva's settlement had on Perrigo's entry.

As alleged in the complaint, the key settlement term from Perrigo's perspective was not the [redacted] entry date, but rather the acceleration clause that allowed Perrigo to launch generic AndroGel upon Teva's entry. (Compl. ¶ 134.) At the time Perrigo settled, Teva appeared on the verge of achieving a quick victory with an imminent trial date, while AbbVie and Besins had just sued Perrigo, blocking FDA approval of Perrigo's product for 30 months. (*Id.* ¶¶ 88, 134.) The settlement gave Perrigo the opportunity to achieve parity with Teva, which it would not have obtained by continuing to litigate its own case. (*Id.* ¶ 136.) Thus, it was plausible, and indeed likely, that the settlement agreement would accelerate Perrigo's ability to enter by terminating the 30-month stay. Perrigo, however, was unaware that AbbVie was in the process of negotiating a deal to pay Teva to defer its entry well beyond what Perrigo expected. (*Id.* ¶ 135.) As defendants concede, the Court must accept these allegations as true and draw all reasonable inferences in the FTC's favor. *See, e.g., Warren Gen. Hosp.*, 643 F.3d at 84; (Defs.' Mem. at 9 n. 2).

B. The Complaint Plausibly Alleges that AbbVie's Payment to Teva Exceeded Any Reasonable Definition of Large

Defendants argue that AbbVie's payment of hundreds of millions of dollars to Teva is not "large" because the size of the payment must be quantified based on what "AbbVie would have thought this 'payment' was worth to Teva." (Defs.' Mem. at 33-34.) Tellingly, defendants cite no case, and point to no language in *Actavis*, to support this novel standard. In fact, *Actavis*

explicitly endorses evaluating the payment's scale "in relation to the payor's anticipated future litigation costs." 133 S. Ct. at 2237.[25]

Here, the complaint plausibly and adequately alleges that AbbVie's payment to Teva in the form of the TriCor side deal far exceeded any reasonable measure of AbbVie's actual or avoided litigation costs from settling the sham lawsuit. (Compl. ¶¶ 120, 122, 132.) As described in the complaint, Teva's contemporaneous forecasts projected that its net TriCor sales under the side deal would be approximately $175 million in the first four years.[26] (*Id.* ¶ 120.) By securing the valuable first-mover advantage, Teva's profits from the deal would continue well beyond the initial four years. (*Id.* ¶ 120-21.) Given the advanced posture of the infringement litigation when the parties settled (trial on a dispositive issue was scheduled to begin five months later), (*id.* ¶¶ 107, 112), the size of AbbVie's payment is so big it bears no rational relationship to any possible estimate of the remaining litigation costs.[27] *In re Lidoderm*, 2014 WL 6465235, at *13 (denying motion to dismiss even though complaint did not provide an estimate of the avoided litigation costs because the sheer size of the alleged payment—$266 million—and the status of the underlying patent litigation was sufficient to establish the plausibility of the "large" payment allegations).

Defendants' novel standard also defies economic logic. In *Actavis*, the Supreme Court explains that the competitive concern with a reverse-payment settlement is the prospect that a

[25] Defendants' curious suggestion that "[h]ad the Supreme Court wanted to expressly define 'large' as limited to litigation costs, it could have easily (and expressly done so)," (Defs.' Mem. at 35), blatantly disregards this clear language of the *Actavis* decision.

[26] By comparison, defendants' brief characterizes BioSante's request for $10 million from Teva as a "hefty" sum. (Defs.' Mem. at 26 n.9.)

[27] In *Actavis*, the dissent indicates that the typical *total* cost of patent litigation in the paragraph IV context is about $10 million per suit. 133 S. Ct. at 2243-44 (citing Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 Colum. L. Rev. 1788, 1795 n.41 (2011)).

patent holder is "using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." 133 S. Ct. at 2236. Thus, a payment is large if it is sufficient "to induce the generic challenger to abandon its claim." *Id.* at 2235. In this case, the complaint plainly alleges that AbbVie and Teva negotiated a payment large enough to induce Teva to drop its patent challenge. (Compl. ¶¶ 9, 119.) Teva had no reason, absent significant compensation, to abandon a lawsuit it was virtually certain to win in the near future, and instead agree to stay out of the AndroGel market until [redacted]. (*Id.* ¶¶ 9, 113, 119.) Thus, when AbbVie approached Teva about settlement, Teva asked for, and ultimately received, the lucrative TriCor authorized generic deal. (*Id.* ¶¶ 112-14, 117.)

The Supreme Court also noted the possibility that in extraordinary circumstances a branded firm may "sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market." *Actavis*, 133 S. Ct. at 2235. If the payment were larger than what the generic would have earned in profits even if it won the patent litigation, then it would be profitable for the generic to accept the reverse payment and drop its patent challenge even if the generic challenger thought it was certain to win. *See In re Lidoderm*, 2014 WL 6465235, at *13. In other words, a payment of this size will always be sufficient to buy off a generic challenger. While the Supreme Court noted that this condition would be satisfied only sometimes, the complaint here alleges that the compensation from the TriCor side deal exceeded the profits Teva expected to earn by launching its testosterone gel product and competing with AndroGel. (Compl. ¶¶ 120, 123.) These factual allegations provide more than an adequate and reliable foundation to support the complaint's claim of a "large" reverse payment.

Finally, this Court should not follow Judge Sheridan's analysis in *In re Lipitor* and *In re Effexor*, requiring a precise calculation of the "unexplained" portions of the purported business deals to survive a motion to dismiss. (Defs.' Mem. at 32-33.) These decisions misconstrue the requirements for plausibly alleging a large, reverse payment under *Actavis* and err by adopting a significantly heightened pleading standard that is inconsistent with both *Twombly* and *Actavis*.[28] Indeed, the FTC's allegations in this case parallel the allegations that the Supreme Court considered and deemed sufficient to survive a motion to dismiss in *Actavis*. For example:

Actavis	**This Case**
The FTC alleged that the "compensation Solvay agreed to provide Watson was designed to, and did induce Watson to settle the AndroGel patent litigation by agreeing to refrain from marketing generic AndroGel until 2015. *FTC v. Actavis*, No. 09-cv-955, FTC's Second Amended Compl. ¶ 67 (N.D. Ga. filed May 25, 2009).	The FTC alleges that the "payment was designed to, and did, induce Teva to settle the AndroGel patent litigation and agree to refrain from marketing its testosterone gel product until [redacted]." (Compl. ¶ 119.)
The FTC alleged that the brand paid one of the generic challengers $72 million over a six-year period. *FTC v. Actavis*, No. 09-cv-955, FTC's Second Amended Compl. ¶ 74 (N.D. Ga. filed May 25, 2009).	The FTC alleges that the brand paid the generic challenger "nearly $175 million over a four-year period." (Compl. ¶ 120.)

Here, as in *Actavis*, the complaint's allegations amply support the FTC's claim that the TriCor side deal served as a "large" reverse payment that induced Teva to refrain from launching its lower-cost AndroGel alternative.

[28] Judge Sheridan held that a plaintiff must offer not only a quantification of the payment but also a "reliable foundation" showing "how the alleged non-monetary payment was calculated." *See, e.g., In re Effexor XR Antitrust Litig.*, No. 11-cv-5479, 2014 WL 4988410, at *21 (D.N.J. Oct. 6, 2014). While this may be the subject of fact and expert discovery, it is not required for a plaintiff to state a plausible reverse-payment claim. In any event, the complaint here relies on the parties' own contemporaneous business documents to quantify the value of the TriCor side deal. (Compl. ¶ 120.)

III. The Complaint Plausibly Alleges that AbbVie's Payment to Teva Is Unjustified

Defendants' claim that the FTC's complaint fails to allege that AbbVie's payment was unexplained is also flawed. (Defs.' Mem. at 31.) Defendants' various arguments all stem from the faulty premise that a plaintiff in an antitrust case is required to plead facts that exclude all possible justifications to survive a motion to dismiss. (Defs.' Mem. at 26, 29-32.)

In a reverse-payment case, however, the "FTC must prove its case as in other rule-of reason cases." *Actavis*, 133 S. Ct. at 2237. Under *Actavis* and settled antitrust law applying the rule of reason, the burden of establishing a legitimate justification for the payments lies squarely with defendants. *Actavis* refers repeatedly to "unexplained" or "unjustified" payments, but the Supreme Court identifies the defendant—the "one who makes such a payment"—as the party that must "explain" or "justify" the payment." *Id.*

The Supreme Court also recognized the possibility that a payment may reflect "litigation expenses saved through the settlement" or "compensation for other services that the generic has promised to perform," rather than the sharing of monopoly profits "to avoid the risk of patent invalidation or a finding of noninfringement." *Id.* at 2236.[29] But that mere "possibility," the Supreme Court explained, "does not justify dismissing the FTC's complaint." *Id.* Rather, defendants will have the opportunity to justify the payment as part of the rule of reason: "[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Id.* at 2236; *see also In re Lidoderm*, 2014 WL 6465235, at *13 (quoting *Actavis*, 133 S. Ct. at 2236).

[29] The Supreme Court also recognized that there "may be other justifications," although it did not identify any. *Actavis*, 133 S. Ct. at 2236.

In any event, the complaint alleges numerous facts showing that AbbVie's payment to Teva through the TriCor side deal was unjustified. (Compl. ¶¶ 125-32.) First, as discussed in Section II.B, the complaint contains facts that, if proven, would establish that AbbVie's payment to Teva far exceeded any reasonable measure of the litigation costs it avoided through settlement. (Compl. ¶¶ 122, 125-32.)

In addition, the complaint plausibly alleges that the TriCor side deal cannot be justified as a stand-alone business transaction. According to the complaint, the AndroGel patent settlement agreement and the TriCor deal were unmistakably connected. (*See, e.g.*, Compl. ¶¶ 9, 117, 119, 120, 125, 132, 146.) The two agreements were negotiated simultaneously and signed on the same day. (Compl. ¶¶ 9, 113, 117; *compare* Defs.' Ex. 1 at 14, 16, *with* Defs.' Ex. 3 at 22-23.) Teva specifically asked AbbVie for the right to sell authorized generic TriCor during the AndroGel negotiations. (Compl. ¶ 113.) Moreover, the complaint explains that, as a stand-alone agreement, the TriCor side deal makes no economic sense from AbbVie's perspective. (*Id.* at ¶¶ 125-32.) The terms of the side deal, including a guaranteed November 2012 entry date and a meager [redacted] royalty rate, were decidedly unfavorable to AbbVie and inconsistent with industry norms for authorized generic deals. (*Id.* ¶¶ 126-30.) Defendants may not "dismember" the FTC's complaint by examining the agreements in isolation. *In re Niaspan Antitrust Litig.*, No. 13-md-2460, 2014 WL 4403848, at *11 (E.D. Pa. Sept. 5, 2014) (Dubois, J.) (holding that that the patent settlement agreement at issue "must be read in conjunction with the Co-Promotion and Manufacturing Agreements executed that same day.")

Defendants also wrongly assert that the TriCor side deal was necessarily justified unless AbbVie knew with certainty that Teva could not launch its own generic product. By giving Teva a date certain for supply of TriCor, AbbVie guaranteed competition where it otherwise was only

a possibility.[30] (*Id.* ¶ 127.) According to the complaint, AbbVie faced two scenarios for generic TriCor entry: (1) if Teva could obtain approval for its own ANDA, AbbVie would face generic TriCor competition as early as July 2012; or (2) if Teva could not obtain approval for its TriCor ANDAs, generic competition would be deferred until January 2013. (Compl. ¶¶ 114, 127-28.) AbbVie's obvious economic incentive was that generic TriCor competition be deferred for as long as possible. In December 2011, when AbbVie was negotiating the AndroGel settlement with Teva, there were clear signs that Teva's independent launch of generic TriCor was improbable. (*See supra* Section II.A.1; Compl. ¶¶ 113-14.)

By entering into the TriCor agreement, however, AbbVie ensured that it would face generic competition and lose brand sales as of November 2012.[31] (Compl. ¶¶ 127-29.) In other words, AbbVie eliminated its best-case and most likely scenario (maintaining branded TriCor sales until January 2013). Based on AbbVie's own calculations at the time of the agreement, accelerating generic entry from January 2013 to November 2012 would cost AbbVie about $100 million in branded TriCor profits. (*Id.* ¶ 132.) Thus, as the complaint alleges, it made no economic sense for AbbVie to give up the very real probability that AbbVie could protect its TriCor franchise until January 2013 except as a way to protect its AndroGel monopoly. (*Id.* ¶ 127-29.)

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[30] Notably, the TriCor side deal allowed Teva to launch authorized generic versions of *both* the 145 mg and 48 mg dosage strengths of TriCor on November 10, 2012. (Compl. ¶¶ 127-29.) Teva's prior license with AbbVie allowed Teva to launch its own 145 mg generic TriCor product on July 1, 2012, if the FDA approved Teva's ANDA for that product. (*Id*. ¶ 114.) Even if the FDA approved Teva's ANDA for the 48 mg strength of TriCor, however, neither Teva nor any of the other ANDA filers for the 48 mg strength could have launched a 48 mg generic TriCor product until at least January 1, 2013, absent the TriCor side deal. (*Id*. ¶ 128.)

[31] The fact that the TriCor side deal was an option agreement has little significance. (*See* Compl. ¶ 117.) Teva had the unilateral ability to exercise the option and launch generic TriCor in November 2012, regardless of whether the FDA had approved either Teva's or any other generic's TriCor ANDA. (*Id*. ¶ 126.)

Finally, defendants pepper their brief with various assertions that the AndroGel settlement and the TriCor side deal are procompetitive.[32] But, as previously noted, the "possibility" that defendants might be able to show procompetitive justifications "does not justify dismissing the FTC's complaint," particularly where, as here, they are intrinsically factual issues. *Actavis*, 133 S. Ct. at 2236.[33]

IV. The Complaint Plausibly Alleges Anticompetitive Effects

By sharing its monopoly profits to secure Teva's agreement to defer generic entry until [redacted], AbbVie eliminated the most direct and immediate threat to its monopoly. According to the complaint, absent this compensation, Teva and/or Perrigo would have entered with a competing version of AndroGel prior to [redacted] because: (1) Teva would have entered following a district court or appellate decision; or (2) defendants would have agreed to settle their patent litigation on terms that did not compensate Teva and provided for entry earlier than [redacted]. (Compl. ¶¶ 144-45.) Entry of Teva's or Perrigo's product would give

[32] *See, e.g.*, Defs.' Mem. at 21 ("[T]he only way in which Teva could make money would be by selling a competing, lower-priced drug to consumers"); 22 ("Combining two procompetitive agreements cannot be the basis for an antitrust violation"); 25 ("Nor can the FTC base an antitrust claim on an assertion that a procompetitive agreement was not procompetitive enough."). Although not relevant to this motion to dismiss, defendants' purported justifications will fail because courts may not properly balance the procompetitive effects in one market against the anticompetitive effects in different market. *See, e.g.*, *Sullivan v. NFL*, 34 F.3d 1091, 1113 (1st Cir. 1994) ("[I]t seems improper to validate a practice that is decidedly in restraint of trade simply because the practice produces some unrelated benefits to competition in another market."); *Law v. NCAA*, 902 F. Supp. 1394, 1406 (D. Kan. 1995), *aff'd* 134 F.3d 1010 (10th Cir. 1998) ("Procompetitive justifications for price-fixing must apply to the same market in which the restraint is found, not to some other market.").

[33] *See also Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 145 (4th Cir. 1990) (explaining that for purposes of a motion to dismiss, "plaintiff's allegations of adverse effects on competition must be accepted as true, and the defendants' pro-competitive justifications considered unproven"); *Brennan v. Concord EFS, Inc.*, 369 F. Supp. 2d 1127, 1133 (N.D. Cal. 2005) (finding that "[w]hatever the merits of [defendants' procompetitive] arguments, they are intrinsically factual, contrary to plaintiffs' pleading and inappropriate for resolution at the motion to dismiss stage").

consumers the choice between AndroGel and lower-priced substitutes for AndroGel. Many consumers would choose to purchase lower-priced generic drugs instead of AbbVie's higher-priced brand-name product.

Indeed, both AbbVie and Teva independently projected that entry from even a BX-rated product would take substantial sales from AbbVie's product and provide meaningful benefits to consumers. (Compl. ¶¶ 147-49). In addition, defendants' anticompetitive agreement gave AbbVie time to shift a significant portion of the market to its reformulated AndroGel 1.62% product, further reducing the benefit from the eventual entry of either Teva's or Perrigo's 1% products. (*Id.* ¶¶ 10, 99, 132, 144-45, 151.) In short, the FTC's complaint sets forth the same theory of competitive harm endorsed by the Supreme Court in *Actavis*: "[P]ayment in return for staying out of the market—simply keeps prices at patentee-set levels, potentially producing the full patent-related . . . return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses." 133 S. Ct. at 2234-35.

Defendants' challenge to the complaint's competitive harm allegations is predicated on the fact (not known at the time of the agreement) that Teva's testosterone gel product ultimately did not receive an AB-rating from the FDA (thus not allowing for automatic substitution by pharmacists). (Defs.' Mem. at 35-39.) Specifically, defendants assert that Teva would not have launched a BX-rated product (relying on purported facts found nowhere in the complaint) and, even if it did, that competition from a BX-rated product would offer no benefits to consumers. (*Id*. at 37-39.) Defendants' argument fails for a number of reasons.

First, this argument asks the Court to draw inferences in defendants' favor from asserted facts outside the FTC's complaint and that contradict the complaint's well-pleaded allegations.

(*See, e.g.*, Defs.' Mem. at 36-38 (asserting facts about Teva's analysis of whether to launch a BX-rated product, BX-rated product marketing efforts, and doctors' prescribing decisions).) For example, defendants suggest that Teva's BX-rated testosterone product was likely to "gain few, if any, sales." (Defs.' Mem. at 38.) As the complaint alleges, however, AbbVie's and Teva's own contemporaneous documents projected that a BX-rated 505(b)(2) product would capture significant sales, be priced lower than AndroGel, and provide meaningful savings for consumers. (Compl. ¶¶ 34, 148, 150.) Specifically, AbbVie predicted that it could lose up to $855 million if a BX-rated generic AndroGel product entered the market in 2012. (*Id.* ¶¶ 34, 148.) Defendants' own contemporaneous forecasts, thus, belie any argument that the alleged competitive harm from a BX-rated product is implausible. (*Id.* ¶¶ 34, 150.) On a motion to dismiss, the Court must accept these complaint allegations as true, and may not credit defendants' preferred facts outside the complaint. *See, e.g.*, *In re Warfarin*, 214 F.3d at 398 (reversing 12(b)(6) dismissal where "the court impermissibly cited and relied on facts beyond the corners of the complaints" and stating that the district court may not take judicial notice of "facts gleaned from counsel's argument").

Second, this argument requires the Court to attach significance to the BX-rating for Teva's testosterone gel product that the FDA issued over two years *after* defendants' reverse payment settlement agreement. (*See* Defs.' Mem. at 26-39.) As defendants acknowledge elsewhere in their brief, "the reasonableness of agreements under the antitrust laws is judged at the time the agreements are entered into." (*Id.* at 31-32.) (quoting *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003).) Here, at the time the anticompetitive agreement was formed, defendants did not know which therapeutic equivalency rating either Teva's or Perrigo's products would receive. But, as described in the complaint, an internal document shows that as of late 2011, AbbVie believed the "most likely scenario" was that an A-

rated generic product would launch in April 2012. (Compl. ¶ 108.) Regardless of the therapeutic equivalency rating ultimately assigned, Teva's settlement agreement had the effect of eliminating any threat of competition until [redacted].[34]

Finally, defendants' argument overlooks the FTC's clear allegations that AbbVie's agreement with Teva also effectively blocked Perrigo's generic entry. (Compl. ¶¶ 136-37, 149.) As the complaint alleges, Perrigo had recently settled on terms that allowed it to enter as soon as Teva did. (*Id.*) Based on the relative posture of their respective patent litigations, Perrigo reasonably expected that this term would accelerate Perrigo's entry. (*Id.*) By securing Teva's agreement to forego entry until [redacted] with the TriCor side deal, AbbVie blocked competition from Perrigo as well, which as the complaint alleges, was precisely AbbVie's plan. Whether Teva was aware of this plan does not alter the anticompetitive effect of Teva's own agreement. Indeed, because the FDA ultimately assigned Perrigo's product an AB-rating, Teva and AbbVie's anticompetitive agreement had the effect of depriving consumers of a lower-priced product, which pharmacists could easily (and in many states, automatically) substitute for branded AndroGel. (*Id.* ¶ 149.) Defendants' argument requires the Court to ignore the complaint's detailed allegations describing this bottleneck theory and to draw impermissible inferences in their favor; it is inappropriate to do so on a motion to dismiss.

[34] Defendants also take one sentence in an amicus brief submitted by the FTC in *Mylan Pharms., Inc. v. Warner-Chilcott Pub. Ltd.*, No. 12-3824, 2012 WL 7649225 (E.D. Pa. Dec. 3, 2012) completely out of context and try to suggest that non-AB-rated products can never provide meaningful competition. (Defs.' Mem. at 8, 38.) To be sure, preventing competition from AB-rated generics is particularly harmful to consumers, as defendants appear to acknowledge. But this does not mean that eliminating competition from non-AB rated products has no impact on consumers as a matter of law. Here, Teva knew its product may or may not become AB-rated, but still projected substantial substitution (though not automatic) and sales with a BX rating.

CONCLUSION

For the foregoing reasons, defendants' motion to dismiss should be denied. The motion can and should be denied without oral argument.

Dated: December 12, 2014

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Certificate of Service

I hereby certify that on December 12, 2014, I filed the public version of plaintiff Federal Trade Commission's memorandum in opposition to defendants' motion to dismiss with the United States District Court for the Eastern District of Pennsylvania using the ECF system. I certify that I also served both public and unredacted versions of the memorandum in opposition on all counsel of record via electronic mail.

/s/ Patricia M. McDermott
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