

the FTC's view, the settlement involved a large, unjustified reverse payment by the patentees to the claimed infringer, Teva, in violation of the FTC Act and the dictates of the Supreme Court's decision in FTC v. Actavis, 133 S. Ct. 2223, --- U.S. --- (2013).

The FTC asserts that what occurred here amounts to unfair methods of competition under the FTC Act. In Count I of the complaint it claims monopolization against the AbbVie Defendants and Besins for initiating the alleged sham litigations against Teva. Count II presents a claim for restraint of trade against the AbbVie Defendants and Teva arising out of the settlement of their lawsuit.

Before the court is the motion of the AbbVie Defendants and Teva under Rule 12(b)(6) of the Federal Rules of Civil Procedure to dismiss Count II of the complaint, and the motion of the AbbVie Defendants and Besins to dismiss Count I to the extent it is based on the settlement of the litigation in the District of Delaware involving Abbott, Unimed, Besins, and Teva.

I.

When deciding a motion to dismiss under Rule 12(b)(6), the court must accept as true all factual allegations in the complaint and draw all inferences in the light most favorable to the plaintiff. Phillips v. Cnty. of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008); Umland v. PLANCO Fin. Servs., Inc., 542 F.3d 59, 64 (3d Cir. 2008). We must then determine whether the pleading at issue "contain[s] sufficient factual matter, accepted as true, to 'state a

claim for relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim must do more than raise a "mere possibility of misconduct." Fowler v. UPMC Shadyside, 578 F.3d 203, 211 (3d Cir. 2009) (quoting Iqbal, 556 U.S. at 679). Under this standard, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 556 U.S. at 678.

On a motion to dismiss for failure to state a claim, the court may consider "allegations contained in the complaint, exhibits attached to the complaint and matters of public record." Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993) (citing 5A Charles Allen Wright & Arthur R. Miller, Federal Practice and Procedure § 1357 (2d ed. 1990)).

II.

To put the FTC's allegations in the proper context, it is first necessary to describe the statutory background governing the approval of drugs such as AndroGel. Before a drug can be sold on the market, it must go through an approval process with the U.S. Food and Drug Administration ("FDA") pursuant to authority granted under the Food, Drug and Cosmetics Act ("FDC Act"), 21 U.S.C. § 301 et seq., to regulate the drug's manufacture and sale.² 21 U.S.C.

² For purposes of the FDC Act a "drug" means, among other things, an "article[] intended for use in the diagnosis, cure, mitigation,

§ 355(a). The FDC Act requires the sponsor of a drug to demonstrate to the agency's satisfaction that the drug is safe and effective for its intended uses. Id. § 355(b)(1).

As amended by the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act, the FDC Act also establishes procedures designed to promote competition through the approval of lower-priced generic drugs while maintaining patent-based incentives for continued investment in the development of new brand-name drugs. See id. §§ 355(b)(2), 355(j); 35 U.S.C. § 271(e). Generic drugs usually differ from their brand-name counterparts only in their inactive ingredients. According to the complaint, the retail price of a generic drug is on average 75% less costly than that of a brand-name drug.

A company seeking approval of a new brand-name drug must file with the FDA a New Drug Application ("NDA"). 21 U.S.C. § 355(b)(1). The NDA must contain: research supporting the safety and effectiveness of the drug; a list of its ingredients; an explanation of the methods used to manufacture, process, and package the drug; samples of the product; and other information. Id. An applicant seeking FDA approval for a generic drug, however, may

treatment, or prevention of disease in man or other animals; and ... [an] article[] (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1).

submit either a "505(b) (2)" application, which relies upon the data of a previously approved NDA, or an Abbreviated New Drug Application ("ANDA"). Id. §§ 355(b) (2), (j). If the generic company's application implicates a brand-name drug covered by a patent, the generic company must also certify in its 505(b) (2) application or ANDA 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." Id. §§ 355(b) (2) (A) (iv); (j) (2) (A) (vii) (IV). This is known as a "Paragraph IV certification."

The generic company must additionally notify the patentee that it is seeking generic approval so that the patentee can take any necessary steps to protect its intellectual property. Id. § 355(b) (3) (A). The filing of a Paragraph IV certification with the FDA is treated as a technical act of patent infringement which permits the patentee to bring an infringement action. See 35 U.S.C. § 271(e) (2) (A); Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1677, --- U.S. --- (2012). Importantly, if the patentee initiates a patent infringement suit within 45 days of receiving such notice, the FDA may only approve the application upon the earliest of the court's finding of no infringement, the expiration of the patent, or the expiration of a 30-month stay measured from the date the patentee received the Paragraph IV certification. Id. § 355(c) (3) (C).

III.

The following facts are taken from the complaint and construed for present purposes in the light most favorable to the FTC. AbbVie markets a brand-name prescription drug called AndroGel, a synthetic testosterone product administered in the form of a topical gel. It is indicated for testosterone replacement therapy in males for conditions associated with a deficiency or absence of testosterone, which include advancing age, certain cancers, and HIV/AIDS.

Besins had originally developed the formulation that would become AndroGel. In 1995, Besins licensed the U.S. rights to the formulation to Unimed and agreed to provide Unimed a commercial supply of the product upon its approval by the FDA. Unimed sought that approval in 1999, and it and Besins applied for patent protection for AndroGel from the U.S. Patent and Trademark Office ("PTO").³

The FDA approved AndroGel in 2000 and sales began later that year. The PTO, however, was reluctant to grant the requested patent covering certain testosterone gel formulations which contain specific amounts of testosterone, ethanol or isopropanol, sodium hydroxide, a gelling agent, and a "penetration enhancer." A penetration enhancer is an inactive ingredient that facilitates the

³ As noted above, through Solvay and Abbott, AbbVie eventually came to control Unimed's interest in AndroGel.

delivery of synthetic testosterone through a person's skin and into the bloodstream. The patent application originally disclosed a number of "non-limiting examples" of those penetration enhancers.

Patent protection for synthetic testosterone expired in the 1950s, however, and pharmaceutical gel products have been available for decades. The PTO rejected the patent application on the ground that it was obvious over prior art. Previous publications had disclosed both the use of testosterone in pharmaceuticals delivered through the skin and the use of various types of penetration enhancers.

In response, Besins and Unimed amended their claims to cover formulations that could include any one of 24 different penetration enhancers. They argued that the claims were now patentable and non-obvious because differences among penetration enhancers had previously been observed and the 24 claimed penetration enhancers were not "substitutable" with those others disclosed in the prior art. Unconvinced, the PTO rejected the application once again. Besins and Unimed therefore filed another amended application, this time claiming formulations made only with the penetration enhancer isopropyl myristate ("IPM"). They disclaimed all other penetration enhancers. The PTO thereafter approved this more limited application. The '894 Patent was issued on January 7, 2003 and is scheduled to expire in August 2020. IPM

is the only penetration enhancer identified in the patent and used in brand-name AndroGel.

After the patent was issued, Teva also advanced a testosterone gel product. It tailored its formulation to avoid the use of IPM described in the '894 Patent. Instead Teva's gel contains isopropyl palmitate ("IPP") as a penetration enhancer. The PTO, in rejecting the initial application of Besins and Unimed, had listed IPP among those penetration enhancers that were obvious in light of the prior art.

According to Abbott, topical drugs with different inactive ingredients presented "unique scientific challenges." The FDA concurred. It concluded that certain safety studies would be needed for testosterone gel products with penetration enhancers other than IPM, which it had previously approved. It required Teva to submit a full NDA for its formulation.

Teva submitted its full NDA in 2011 containing a Paragraph IV certification that its drug would not infringe the '894 Patent. In response, Abbott, through an affiliate, Unimed, and Besins filed suit against Teva for patent infringement in the District of Delaware. Abbott Prods. Inc. v. Teva Pharms. USA, Inc., Civil Action No. 11-384 (D. Del.). This step automatically triggered a 30-month stay of any FDA approval of Teva's generic testosterone gel product. The lawsuit was assigned to the undersigned, who at the time was sitting in that district by designation.

Abbott, Unimed, and Besins alleged that Teva's product infringed the '894 Patent under the "doctrine of equivalents." They maintained that infringement existed because IPP is equivalent to and therefore insubstantially different from IPM. See Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997).

Teva asserted an antitrust counterclaim that the litigation against it was a sham intended merely to extend the plaintiffs' AndroGel monopoly with the mandatory 30-month stay. Teva subsequently moved for summary judgment in its favor on the sham issue. It argued that Besins and Unimed had disclaimed penetration enhancers other than IPM during the prosecution of the '894 Patent and thus had dedicated those technologies to the public. According to Teva, the patentees were therefore barred from asserting infringement under the doctrine of equivalents. The court denied the motion for summary judgment as moot on October 25, 2011 as it was scheduling a limited bench trial on the issue to begin on May 21, 2012.

The action was settled on December 20, 2011 with two agreements signed on the same day. First, the patentees agreed to permit Teva to market a generic testosterone gel product beginning on December 27, 2014, almost six years before the '894 Patent was scheduled to expire. No payments were made by the patentees to Teva. Second, Abbott and Teva agreed to a license in which Abbott would supply Teva, at Teva's option, an authorized generic version

of a popular brand-name cholesterol drug named TriCor for a four-year term beginning November 10, 2012.⁴ The price Teva would pay for TriCor consisted of Abbott's cost, plus an additional percentage of the cost, plus a royalty on Teva's profits. The royalty in the view of the FTC was much more favorable to Teva than a patentee generally offers to a licensee for a standalone authorized generic agreement.

A previous settlement between Abbott and Teva in a separate matter had set Teva's entry in the TriCor market for July 2012, while generic competition from other companies was expected in January 2013. Teva had been seeking FDA approval for a generic version of TriCor for some time. Four years after Teva had filed its ANDA, the FDA still had not approved its application. With generic TriCor an important part of Teva's product pipeline, the FTC avers that the agreement allowing Teva to sell an authorized generic was particularly attractive and would give it a valuable hedge against continued frustration before the FDA. Under the terms of the TriCor agreement, Teva's November 2012 entry date was not contingent on the launch of any other generic TriCor product, nor was it conditioned on FDA approval of Teva's generic. The FTC maintains that the lack of any such condition was another aspect of the agreement unusually favorable to Teva when compared to common authorized generic agreements.

⁴ An authorized generic drug contains the same ingredients and is manufactured in the same way as a brand-name drug but is priced and marketed as a generic.

IV.

As noted above, the AbbVie Defendants and Teva have moved to dismiss Count II of the complaint, which concerns the settlement in the District of Delaware, and the AbbVie Defendants and Besins seek dismissal of Count I of the complaint to the extent it is based on the settlement. While the defendants contend that the settlement represents nothing more than a straightforward resolution of the lawsuit with an innocuous licensing deal, the FTC counters that it contains an impermissible "reverse payment" from the patentees to Teva, the claimed infringer, as outlined in FTC v. Actavis, Inc., 133 S. Ct. 2223, --- U.S. --- (2013).

The FTC has challenged this reverse payment in Count II as an unlawful agreement in restraint of trade under § 5 of the FTC Act, 15 U.S.C. § 45(a). Section 45(a) prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(1). It is well settled that § 45(a) contemplates a range of conduct that includes, but is not limited to, conduct that violates the Sherman Act, 15 U.S.C. §§ 1 et seq. See, e.g., FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 454 (1986). Section 1 of the Sherman Act makes unlawful "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations." 15 U.S.C. § 1.

The Actavis case, on which the FTC relies, also concerned AndroGel. The FTC alleged that Solvay Pharmaceuticals, AbbVie's corporate predecessor as co-owner of the '894 Patent, had initiated patent infringement lawsuits against Actavis, Inc. as well as two other companies after they filed ANDAs for generic versions of AndroGel. The parties to the patent litigations all settled.

Under the terms of the settlement, Actavis, the claimed infringer, agreed to delay marketing its generic for 9 years. It could enter the market beginning on August 31, 2015, over 5 years before the expiration of the '894 Patent. Actavis further agreed to promote the patentee's AndroGel to certain physicians in the interim. In exchange, Solvay paid \$19-\$30 million annually to Actavis. The other generic companies settled on similar terms. In essence, the erstwhile patent challengers contracted to help the patentee's AndroGel marketing effort, were paid substantial sums of money, and consented to stay out of the generic testosterone gel market for almost a decade.

The FTC brought lawsuits against all four companies, alleging that the settlements violated the FTC Act, 15 U.S.C. § 45(a), as unlawful agreements in restraint of trade. Specifically, the FTC alleged that Solvay's settlements with Actavis and the other companies were collectively an agreement "to share in Solvay's monopoly profits, abandon their patent challenges, and

refrain from launching their low-cost generic products to compete with AndroGel.” Actavis, 133 S. Ct. at 2230.

The Court of Appeals for the Eleventh Circuit affirmed the dismissal of the complaint. It reasoned that “absent 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.” Id. (quoting FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012)).

The Supreme Court reversed the Court of Appeals. It held that the reverse settlement payment that had occurred there, that is, a payment by a patentee to a claimed infringer, may be a restraint of trade under a rule of reason analysis when the payment is large and unjustified, even if its anticompetitive effects fall within the scope of the disputed patent. See id. at 2230, 2237-38. Noting that it is unusual for the patentee to pay a purported infringer when the latter has no pending damages claim, the Court concluded that settlement agreements limiting their breadth to the “scope of the patent” do not automatically provide a safe harbor from antitrust scrutiny. Id. at 2231.

The Court emphasized, however, that undue scrutiny of settlements between Paragraph IV litigants can endanger the amicable resolution of disputes. As courts employing the “scope of the patent” test had recognized, imposing antitrust liability for a

reverse payment settlement risks undermining the public policy favoring settlements and forcing an otherwise blameless patent challenger to litigate to the death. See id. at 2236-37. The Supreme Court explained that its decision was not meant to disturb other well-recognized forms of settlement. The Court, for example, sanctioned settlements where the patentee simply allows the claimed infringer to enter the market before the patent expires and where the patentee pays the litigation costs of its adversary. Id. at 2237. Nonetheless, a reverse payment that is large and unjustified even when analyzed with reference to traditional settlement considerations can have the potential to work anticompetitive harm. Id. at 2237.

The settlement involved here and the settlement before the Supreme Court in Actavis are materially different. In the first settlement agreement in the District of Delaware litigation, Abbott, Unimed, and Besins simply allow Teva to enter the AndroGel market almost six years prior to the expiration of the '894 Patent. The patentees here, unlike the patentee in Actavis, did not make any payment, reverse or otherwise, to the claimed infringer, that is, Teva. Actavis specifically states that such an agreement does not run afoul of the antitrust laws. Id. at 2237. Indeed, the FTC concedes that by itself this settlement agreement is legal. Since Teva is allowed to compete with the AbbVie Defendants in the

AndroGel market before the patent expires without the AbbVie Defendants making any payment, the agreement promotes competition.

We turn to the second settlement agreement signed at the same time as the first. There Abbott agreed to supply Teva with the cholesterol drug TriCor for a four-year period at a price which included Abbott's cost of production, an additional percentage of those costs, and a royalty on Teva's profits. The FTC alleges in its complaint that Abbott in this second arrangement is charging a price that is well below what is customary in such situations. The FTC pleads that this agreement is particularly suspect because Abbott had reason to believe that Teva's entry into the cholesterol drug market might be delayed due to the extended period in which Teva's application for approval of its generic cholesterol drug had been languishing before the FDA.

In essence, the FTC claims that the AbbVie Defendants, through Abbott, are making a reverse payment because Teva is to pay Abbott significantly less money for TriCor than the market calls for and Teva's access to the supply is not subject to any conditions. The FTC's position is without merit. First, the AbbVie Defendants are not making any payments to Teva. It is Teva which is paying Abbott for the supply of TriCor. Consideration or something of value invariably flows both ways as a result of any contract. However, we do not read the Supreme Court to have defined an unwarranted reverse payment so broadly as to include the opportunity

afforded Teva to buy TriCor in the supply contract before us and then sell it to the public in competition with Abbott. While the FTC correctly alleges that something of large value passed from Abbott to Teva, it was not a reverse payment under Actavis.

The FTC would have the court allow Count II to go forward on the basis of the existence of a reverse payment simply because the FTC believes Abbott signed a bad deal for itself and a good deal for Teva. What the FTC does not seem to recognize is that the benefit flowing to Teva is also a benefit flowing to consumers who will now be able to purchase the generic form of TriCor at a reduced price. This is not a situation where the FTC has alleged that Abbott agreed to sell TriCor to Teva for less than its cost or where the terms of any agreement can be considered to be anticompetitive. We see no basis in Actavis for the approach the FTC advocates.

In a word, the TriCor agreement, unlike those in Actavis, is procompetitive. It allows Teva to enter the cholesterol drug market with a generic product to compete with Abbott's product and thus advantage the purchasers of cholesterol drugs without the AbbVie Defendants making any payments to Teva. We see no basis for liability under the antitrust laws for restraint of trade.

Thus, both the first agreement simply allowing Teva to enter the testosterone gel market some six years before the expiration of the '894 Patent and the second agreement facilitating Teva's ability to compete in the cholesterol drug market are good

for the consumer. As our Court of Appeals explained in United States v. Brown University, 5 F.3d 658, 675 (3d Cir. 1993), “[e]nhancement of consumer choice is a traditional objective of the antitrust laws.” The Supreme Court has made it clear that when two agreements are involved such as we have here, the court must determine separately whether each promotes competition. See Pac. Bell Tel. Co. v. Linkline Commc’ns, Inc., 555 U.S. 438, 457 (2009). If each does, that is the end of the analysis. As the Supreme Court declared in an antitrust case of alleged price-squeezing, “[t]wo wrong claims do not make one that is right.” Id. The two agreements in issue, in contrast to the agreements in Actavis, are clearly in the best interests of the consumer.

The FTC alleges in Count I of the complaint that the AbbVie Defendants and Besins, but not Teva, initiated a sham lawsuit in the District of Delaware and thus are in violation of § 2 of the Sherman Act and § 5(a) of the FTC Act. Section 2 prohibits a person from “monopoliz[ing] or attempt[ing] to monopolize, or combin[ing] or conspir[ing] with any other person or persons, to monopolize any part of the trade or commerce among the several States.” 15 U.S.C. § 2. We are not concerned with the monopolization allegations of Count I in the pending motion to dismiss.

However, the FTC also claims in Count II that the settlement of the lawsuit was in restraint of trade because the patent infringement suit against Teva in the District of Delaware

was a sham.⁵ See 15 U.S.C. § 1. Sham litigation exists when a claim is objectively baseless, and the plaintiff has the subjective intent to interfere with the business of a competitor. See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60-61 (1993). Unlike allegations of monopolization, restraint of trade requires concerted action by at least two parties. The FTC alleges one of those parties was Teva.

However, there is no allegation in the complaint that Teva conspired with the AbbVie Defendants to bring a frivolous patent action against it for some anticompetitive purpose. Teva was merely defending itself from what it deemed a sham litigation. The FTC instead alleges that Teva settled with the knowledge that the litigation was groundless. To support its assertion of knowledge, the FTC relies on Teva's counterclaim stating that the AbbVie Defendants and Besins had filed sham litigation against it. The FTC also relies on what it says was the expectation that the court would rule in Teva's favor on the sham issue. This reasoning is flawed.

The patent action was before the undersigned. While Teva had moved for summary judgment on the basis that the litigation was a sham, the court denied that motion and scheduled a bench trial. No judicial determination of the sham issue had been made when the parties settled the case. The FTC's allegations that the court

⁵ There was no such allegation in Actavis that the patentee had filed a sham lawsuit against the claimed infringers.

would likely rule in favor of Teva is merely speculation. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). No matter what someone's crystal ball may have supposedly revealed, the undersigned had not held a trial, had not been presented with any evidence, and had not decided the matter.

Teva's allegations in its counterclaim had simply not been ruled upon by the court, and Teva did not and could not plausibly know until then whether the lawsuit was a sham. Unlike its allegations against the AbbVie Defendants and Besins, the FTC does not allege that Teva knew or even had reason to know that it was the subjective intent of the patentees to interfere with Teva's business. See Prof'l Real Estate Investors, 508 U.S. at 60-61. The FTC's claim in its complaint that Teva's agreement to settle the District of Delaware action was a restraint of trade because of Teva's unproven view of the sham nature of the suit is without merit.

If we were to accept the validity of the FTC's line of reasoning, it would mean that a party in Teva's position would risk antitrust liability by claiming the underlying action brought against it is baseless and thereafter agreeing to settle. The only way for the claimed infringer to avoid the risk would be not to raise the issue of sham litigation or to litigate the action fully with all the attendant expense and use of judicial resources. Such

a result would undermine the salutary public policy favoring settlements far beyond the holding of Actavis.

Significantly, the FTC conceded at oral argument that Teva would not be exposed to antitrust liability even if it knew the Delaware action was a sham if the parties had simply entered the first settlement agreement. This agreement provided Teva with an early entry date into the AndroGel market before the '894 Patent expired without any payment to Teva. See Actavis, 133 S. Ct. at 2237. We do not see how adding the procompetitive TriCor agreement to the mix changes the outcome. We are not persuaded that Teva, the claimed infringer, is subject to a claim of restraint of trade under the circumstances alleged in the FTC's complaint.⁶ Without Teva, Count II fails.

Accordingly, the motion of the AbbVie Defendants and Teva to dismiss Count II of the complaint and the motion of the AbbVie Defendants and Besins to dismiss Count I of the complaint to the extent it is founded on the settlement of the patent infringement litigation in the District of Delaware will be granted.

⁶ We, of course, do not decide whether the AbbVie Defendants and Besins brought a sham patent infringement action in the District of Delaware or whether they were engaged in creating a monopoly in violation of § 2 of the Sherman Act and 15 U.S.C. § 45(a). These issues are the subject of Count I of the FTC's complaint, in which count Teva is not a party. Discovery on the question of sham litigation is currently in progress.

