IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ANDROGEL ANTITRUST LITIGATION (NO. II)	MDL DOCKET NO. 2084 ALL CASES 1:09-MD-2084-TWT
FEDERAL TRADE COMMISSION, Plaintiff, v. ACTAVIS, INC., et al., Defendants.	CIVIL ACTION FILE NO. 1:09-CV-955-TWT

OPINION AND ORDER

This is an antitrust action brought by the Federal Trade Commission and private antitrust actions transferred to this Court by the Judicial Panel on Multidistrict Litigation. They are before the Court on the Defendant Solvay's Motion for Summary Judgment on the FTC's Claims [FTC Doc. 620], Solvay's Motion for Summary Judgment as to the Par/Paddock Settlement [FTC Doc. 621, MDL Doc. 1551], the Defendants Actavis and Actavis Holdco's Motion for Summary Judgment [FTC Doc. 625, MDL Doc. 1556], Solvay's Motion for Summary Judgment for Lack of Antitrust Injury Against the Private Plaintiffs [MDL Doc. 1550], Solvay's Motion for Summary Judgment as to Retailer's Damages Claims on AndroGel 1.62% Purchases [MDL Doc. 1552], the

Defendants Par and Paddock's Motion for Summary Judgment [MDL Doc. 1559], the Defendants Actavis, Inc. and Solvay's Motion to Exclude Plaintiffs' Proposed Patent Law Expert Jack C. Goldstein, Esq. [FTC Doc. 622, MDL Doc. 1553], and the Defendants Solvay, Par, and Paddock's Motion to Exclude in Part Plaintiffs' Expert James R. Bruno [FTC Doc. 630, MDL Doc. 1562].

For the reasons set forth below, Solvay's Motion for Summary Judgment on the FTC's Claims [FTC Doc. 620] is DENIED, Solvay's Motion for Summary Judgment as to the Par/Paddock Settlement [FTC Doc. 621, MDL Doc. 1551] is DENIED, Actavis and Actavis Holdco's Motion for Summary Judgment [FTC Doc. 625, MDL Doc. 1556] is DENIED, Solvay's Motion for Summary Judgment for Lack of Antitrust Injury Against the Private Plaintiffs [MDL Doc. 1550] is DENIED, Solvay's Motion for Summary Judgment as to Retailer's Damages Claims on AndroGel 1.62% Purchases [MDL Doc. 1552] is GRANTED, the Defendants Par and Paddock's Motion for Summary Judgment [MDL Doc. 1559] is DENIED, Actavis, Inc. and Solvay's Motion to Exclude Plaintiffs' Proposed Patent Law Expert Jack C. Goldstein, Esq. [FTC Doc. 622, MDL Doc. 1553] is DENIED, and Solvay, Par, and Paddock's Motion to Exclude in Part Plaintiffs' Expert James R. Bruno [FTC Doc. 630, MDL Doc. 1562] is GRANTED in part and DENIED in part.

I. Background

In the early nineties, Besins Healthcare, S.A. developed the pharmaceutical formulation for AndroGel, a prescription topical gel used to treat low

testosterone in men. In August 1995, Besins granted Solvay Pharmaceuticals, Inc., a license to sell AndroGel in the United States.[1] Besins also agreed to manufacture AndroGel and supply it to Solvay once Solvay received FDA approval to sell the drug.

At this point, it is important to understand how new drugs enter the market in the United States. In order to sell a new drug in the United States, a pharmaceutical firm must file a New Drug Application ("NDA") with the Food and Drug Administration.[2] The NDA must contain a complete report about the drug, including safety and efficacy studies, the composition of the drug, a description of how the drug is produced, and proposed labeling.[3] The process to approve new proprietary drugs – known as "brand name" drugs – is both time consuming and costly.

Although the possibility for large profits after FDA approval is often an incentive for pharmaceutical companies to pursue the NDA process for brand name drugs, the cost associated with it may also serve as a significant barrier to entry by generic formulations of the same drug. These high barriers limit competition, which in turn may hurt consumers. This concern led Congress to

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[1] Technically speaking, Unimed entered into the Agreements with Besins. Solvay, now known formally as Abbvie Products LLC, later acquired Unimed. However, in order to reduce confusion, the Court will simply use the name Solvay throughout this Opinion.

[2] 21 U.S.C. § 355(a).

[3] 21 U.S.C. § 355(b).

enact the Hatch-Waxman Act in 1984.[4] The Hatch-Waxman Act enables companies that want to market and sell a generic version of a brand-name drug to avoid filing an NDA. As long as the generic and the brand-name drug are effectively the same thing, generic manufacturers can file a substantially shorter Abbreviated New Drug Application ("ANDA"). This reduces costs for generics manufacturers, which may allow them to charge much lower prices than brand name drugs, therefore benefitting consumers.

In order to prevent generic manufacturers from completely cutting into the profitability of brand name drugs, thereby reducing the incentive for brand name manufacturers to go through the cost and risk of the NDA process, federal law provides two ways for brand name pharmaceutical manufacturers to protect their investment. First, the FDA can grant brand name manufacturers periods of "exclusivity," which means that the FDA will not approve another application to sell the same drug until the exclusivity period (usually three or five years) ends. Second, brand name manufacturers can patent their new drug. Just like any other patent, drug patents grant brand name manufacturers a legal monopoly for a limited period of time. If there are any patents that cover the brand name drug, a generic manufacturer's ANDA must contain an additional certification. The ANDA must certify that (1) the patent has not been listed with the FDA, (2) the patent has expired, (3) the patent will expire on a certain date,

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[4] Pub.L. No. 98–417, 98 Stat. 1585 (1984).

or (4) the patent is invalid or will not be infringed by the generic drug.[5] The last certification is known as a Paragraph IV certification. For any ANDA with a Paragraph IV certification, the applicant must also notify the patent holder of the ANDA.[6] If the patent holder decides to file an infringement suit after receiving notice of the Paragraph IV certification, the FDA is then prohibited from approving the generic for market entry for up to thirty months while the litigation proceeds.

In April 1999, Solvay filed an NDA for AndroGel. It was approved by the FDA in February 2000, and Solvay received three years of exclusivity. Solvay was also issued a patent on AndroGel, U.S. Patent No. 6,503,894 ('894 patent). Although AndroGel was not the only available method of testosterone replacement therapy, other methods were not as effective or as popular as AndroGel. The protection afforded Solvay by the exclusivity period and Solvay's patent helped AndroGel to quickly become the most popular form of testosterone replacement therapy. From 2000 to 2007, sales of AndroGel in the United States were over $1.8 billion.

In the meantime, other pharmaceutical companies were developing generic versions of AndroGel. Once Solvay's new drug product exclusivity expired in February 2003, the FDA was authorized to approve generic versions

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[5] *See* 21 U.S.C. § 355(j)(2)(A)(vii).

[6] 21 U.S.C. § 355(j)(2)(B).

of AndroGel. In May 2003, two companies each submitted ANDAs with Paragraph IV certifications for generic AndroGel. Actavis, Inc.[7] submitted the first ANDA, and Paddock Laboratories, Inc. submitted the second. Both companies also sent notice of their ANDAs to Solvay and Besins. In July 2003, Paddock reached an agreement with Par Pharmaceuticals. Par agreed to share any litigation costs with Paddock, and to sell Paddock's generic AndroGel. In return, Paddock agreed to share profits with Par.

Solvay responded to the ANDAs by asserting its rights under the '894 patent. In August 2003, Solvay's subsidiary, Unimed Pharmaceuticals, Inc., filed patent infringement actions against Watson and Paddock (the "Generics") in this Court.[8] Solvay alleged infringement based on the filing of the ANDAs.[9] Because Solvay filed infringement actions against the Generics within the forty-five day window of receiving notice, the FDA stayed approval of their ANDAs for thirty months.

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[7] Originally known as Watson Pharmaceuticals, the company has since split into two separate entities now known as Actavis, Inc. and Actavis Holdco US, Inc. For the purposes of this Opinion, the Court will refer to these as just Actavis. And while the Court continues to call Solvay by its original name, it will use Actavis' new name to minimize confusion in light of the Supreme Court's opinion in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

[8] *See Unimed Pharm., Inc. v. Watson Pharm., Inc.*, No. 1:03-CV-2501-TWT, 2003 WL 23824320 (N.D. Ga. Aug. 21, 2003); *Unimed Pharm., Inc. v. Paddock Labs., Inc.*, No. 1:03-CV-2503-TWT, 2003 WL 23824347 (N.D. Ga. Aug. 21, 2003).

[9] *See* 35 U.S.C. § 271(e)(2)(A)(submitting an ANDA is an act of infringement if the branded drug is covered by a patent).

For the next few years, Solvay and the Generics litigated the infringement actions. Both followed a similar schedule. From late 2003 to the middle of 2005, the parties engaged in discovery, scheduling, and other initial litigation matters. By August 2005, the parties had filed motions for claim construction. By December 2005, the Generics had filed motions for summary judgment on the validity of the '894 patent as well as claims construction briefs. All of the motions were fully briefed and ready for decision in early 2006.

While the motions were pending, Actavis and Paddock moved toward entering the market with generic AndroGel. In January 2006, the thirty month stay ended, and the FDA approved Actavis' ANDA. The FDA, however, continued to stay approval of Paddock's ANDA. The first firm to file an ANDA with a Paragraph IV certification receives generic exclusivity upon FDA approval, which is similar to brand-name exclusivity, but shorter. Generic exclusivity means that the FDA will not approve a subsequent ANDA for the same drug until 180 days after the earlier of (1) the date the first filer begins commercial marketing of its generic drug, or (2) the date a district court enters judgment that the patent is invalid or not infringed, whichever date is earlier.[10] Because Actavis was the first to file an ANDA for generic AndroGel, it received generic exclusivity over Paddock. In February 2006, Actavis prepared a report predicting that it would sell generic AndroGel by January 2007 and that the

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[10] 21 U.S.C. § 355(j)(5)(B)(iv).

price would be 75 percent less than brand name AndroGel. In the same month, Par prepared a report predicting that Actavis would sell generic AndroGel as early as March 2006 and that Par and Paddock would follow in September 2006.

But before the Court decided the pending motions in the infringement actions, and before anyone entered the market with generic AndroGel, Solvay and the Generics settled the cases. Under the September 13, 2006 settlement between Solvay and Actavis, Solvay agreed to voluntarily dismiss the infringement action, and Actavis agreed not to market generic AndroGel until the earlier of August 31, 2015 or the date another company marketed generic AndroGel.[11] And under the September 13, 2006 settlement between Solvay and Par/Paddock, Solvay agreed to a consent judgment dismissing the infringement action, and Par/Paddock agreed not to market generic AndroGel until the earliest of August 31, 2015 (but only if Actavis did not assert its 180 day generic exclusivity period), the date another company launched generic AndroGel, or February 28, 2016.[12]

On the same day as the settlements, Solvay also entered into business promotion agreements with Actavis, Par, and Paddock. Under the agreement between Solvay and Actavis, Solvay agreed to share profits of AndroGel with

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[11] FTC's Statement of Additional Material Facts ("SAMF") ¶ 174 [FTC Doc. 689].

[12] *Id.* at ¶ 186.

Actavis, and Actavis agreed to promote AndroGel to urologists.[13] Under the agreement between Solvay and Par, Solvay agreed to share profits of AndroGel with Par, and Par agreed to promote AndroGel to primary care physicians.[14] And under the agreement between Solvay and Paddock, Solvay agreed to share profits of AndroGel with Paddock, and Paddock agreed to serve as a backup supplier of AndroGel.[15]

Together, these types of settlements are called "reverse payment" settlements, and they have recently become popular in pharmaceutical litigation. Reverse payment settlements are so called because they are the reverse of traditional patent infringement settlements. In a traditional settlement, the party with the claim – in this case, the brand name manufacturer – receives a payment from the defendant – in this case the generic – either equal to or less than the value of its claim.[16] But in a reverse settlement, "a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market."[17]

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13 *Id.* at ¶¶ 180-183.

14 *Id.* at ¶ 185.

15 *Id.*

16 *Actavis*, 570 U.S. at 152.

17 *Id.*

The reverse payment settlements prompted an investigation by the Federal Trade Commission for violations of antitrust laws. That investigation was completed in 2008. In 2009, the FTC and a number of private parties filed these antitrust actions against Solvay, Actavis, Par, and Paddock. All of the actions were filed in other federal district courts and then transferred to this Court either by change of venue or by order of the United States Judicial Panel on Multidistrict Litigation. On February 22, 2010, applying settled Eleventh Circuit precedent, this Court dismissed the FTC action for failure to state a claim.[18] On appeal, the Eleventh Circuit affirmed.[19] However, the Supreme Court granted certiorari, and eventually reversed and remanded the cases in 2013.[20]

So, after five years, everything started all over.[21] The Plaintiffs are divided into three groups: the FTC, the Direct Purchaser Class Plaintiffs, and

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[18] *In re Androgel Antitrust Litig. (No. II)*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010). The Court also dismissed the Private Plaintiffs' *per se* claims, and later granted the Defendants' motion for summary judgment on the "sham litigation" claims of the Private Plaintiffs. *In re Androgel Antitrust Litig. (No. II)*, 888 F. Supp. 2d 1336 (N.D. Ga. 2012).

[19] *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *rev'd and remanded sub nom. FTC v. Actavis*, Inc., 570 U.S. 136 (2013).

[20] *See Actavis*, 570 U.S. at 160.

[21] Now, after five more years, it remains to be seen whether this case or I will first confirm Queen Gertrude's observation: "Thou know'st 'tis common; all that lives must die, passing through nature to eternity." WILLIAM SHAKESPEARE, HAMLET, act 1, sc. 2.

the Retailers.[22] The Direct Purchaser Class Plaintiffs and the Retailers constitute the Private Plaintiffs. All of the Plaintiffs allege that the Defendants violated federal antitrust law.[23] The Defendants now move for summary judgment on various grounds.

II. Legal Standards

A. Daubert Motions

Federal Rule of Evidence 702 governs the admission of expert opinion testimony. Pursuant to that rule, before admitting expert testimony a court must consider: (1) whether the expert is competent to testify regarding the matters he intends to address; (2) whether the methodology used to reach his conclusions is sufficiently reliable; and (3) whether the testimony is relevant, in that it assists the jury to understand the evidence or determine a fact in issue.[24] In ruling on the admissibility of expert testimony, "[t]he focus must be 'solely' on the expert's 'principles and methodology, not on the conclusions that they

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[22] The Direct Purchaser Plaintiffs include Rochester Drug Co-Operative, Inc., Louisiana Wholesale Drug Co., Inc., Meijer Inc., and Meijer Distribution, Inc. The Retailers include Rite Aid Corp., Rite Aid Hdqtrs. Corp., JCG (PJC) USA, LLC, Maxi Drug, Inc., Eckerd Corp., CVS Pharmacy, Inc., Caremark L.L.C., Walgreens Co., Safeway, Inc., American Sales Co., Inc., HEB Grocery Co., LP, Supervalu, Inc., and Giant Eagle, Inc.

[23] *See* Sherman Antitrust Act §§ 1–2, 15 U.S.C. §§ 1–2; Federal Trade Commission Act § 5(a), 15 U.S.C. § 45(a).

[24] Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993).

generate.'"[25] If the expert predicates his testimony on an assumption that is belied by the evidence, the expert's testimony is properly excluded.[26] The party offering the expert's testimony has the burden to prove it is admissible by a preponderance of the evidence.[27]

B. Summary Judgment

Summary judgment is appropriate only when the pleadings, depositions, and affidavits submitted by the parties show no genuine issue of material fact exists and that the movant is entitled to judgment as a matter of law.[28] The court should view the evidence and any inferences that may be drawn in the light most favorable to the nonmovant.[29] The party seeking summary judgment must first identify grounds to show the absence of a genuine issue of material fact.[30] The burden then shifts to the nonmovant, who must go beyond the pleadings and present affirmative evidence to show that a genuine issue of

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[25] *KW Plastics v. United States Can Co.*, 131 F. Supp. 2d 1289, 1292 (M.D. Ala. 2001) (quoting *Daubert*, 509 U.S. at 594-95).

[26] *Ferguson v. Bombardier Services Corp.*, 244 Fed. Appx. 944, 949 (11th Cir. 2007).

[27] *Allison v. McGhan Medical Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999).

[28] FED. R. CIV. P. 56(a).

[29] *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158-59 (1970).

[30] *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986).

material fact does exist.[31] "A mere 'scintilla' of evidence supporting the opposing party's position will not suffice; there must be a sufficient showing that the jury could reasonably find for that party."[32]

III. Discussion

The FTC and the Private Plaintiffs allege that the Defendants violated federal antitrust law by entering into the reverse settlement agreements. Section 1 of the Sherman Act states that "[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, is declared to be illegal."[33] Section 2 of the Sherman Act likewise prohibits agreements to monopolize trade.[34] And Section 5 of the Federal Trade Commission Act states that "unfair methods of competition" are illegal,[35] a prohibition which has long been held to encompass the violations of the Sherman Act.[36] Thus, the different claims can be analyzed together.

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[31] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 257 (1986).

[32] *Walker v. Darby*, 911 F.2d 1573, 1577 (11th Cir. 1990).

[33] 15 U.S.C. § 1.

[34] *Id.* at § 2.

[35] *Id.* at § 45(a).

[36] *See, e.g.*, *FTC v. Cement Institute*, 333 U.S. 683, 691-93 (1948) ("In other cases this Court has pointed out many reasons which support interpretation of the language 'unfair methods of competition' in [Section] 5 of the Federal Trade Commission Act as including violations of the Sherman Act. . . . We adhere to our former rulings.").

A. Daubert Motions

1. Jack Goldstein

Solvay and Actavis move to exclude the testimony of Jack Goldstein. The Private Plaintiffs will call Goldstein to testify at trial as to how a reasonable and competent patent attorney would have advised litigants in Solvay's or the Generics' positions at the time they settled the underlying patent litigation on (1) the likelihood of success in the litigation; (2) the likely timing of the litigation's resolution if the parties had not settled; and (3) each of the parties' likely litigation costs had they not settled.[37] The Defendants argue that Goldstein is not qualified to give these opinions, and that his methodology is unreliable. Both arguments are without merit.

The Defendants challenge Goldstein's qualifications, arguing that he does not have the requisite firsthand experience to properly assess the likely outcome, cost, or timing of the litigation. But the Defendants mistakenly argue that in order to testify about these issues, Goldstein needs to have recent, repeated, and specialized experience litigating patent cases arguing the specific legal and factual issues that were at issue in the underlying patent litigation. Goldstein does not need such specialized experience at all. "It is not necessary that the witness be recognized as a leading authority in the field in question . . . . Gaps in an expert witness's qualifications or knowledge generally go to the

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[37] Goldstein Rep. ¶ 2 [Doc. 1564-33].

weight of the witness's testimony—not its admissibility."[38] Further, Goldstein is testifying as to what a reasonable and competent patent attorney would have thought at the time of the settlements. The question, therefore, is whether Goldstein has experience as a reasonable and competent patent attorney.[39]

There can be no doubt that the answer to that question is yes. Goldstein has had a long and distinguished career in the field of patent law. He has studied, interacted with, and litigated patent issues for fifty years.[40] After earning his law and engineering degrees, Goldstein began his legal career as a clerk for a judge on the U.S. Court of Customs and Patent Appeals, one of the predecessor courts to the Federal Circuit.[41] He then went on to work for a law firm specializing in intellectual property for almost thirty years, during which time he also taught patent and copyright law as an adjunct professor at South Texas College of Law in Houston.[42] After leaving the firm in 1997, Goldstein became president of an intellectual property holding company, during which time he enforced the company's IP rights through patent litigation multiple

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[38] *Leathers v. Pfizer, Inc.*, 233 F.R.D. 687, 692 (N.D. Ga. 2006) (quoting 29 Charles Alan Wright & Victor James Gold, *Federal Practice and Procedure*; *Evidence* § 6265 (West 1997)).

[39] "Competent representation requires the legal knowledge, skill, thoroughness and preparation reasonably necessary for the representation." MODEL RULES OF PROF'L CONDUCT r. 1.1 (AM. BAR ASS'N 2018).

[40] Goldstein Rep. ¶ 4.

[41] *Id.* at ¶¶ 5, 7.

[42] *Id.* at ¶ 8.

times.[43] Goldstein now serves as a mediator, arbitrator, counsel, and expert in intellectual property matters.[44] In addition, he serves or has served in numerous national intellectual property law professional groups, including as President of the American Intellectual Property Law Association.[45] The experience the Court lists here is only a fraction of that listed on Goldstein's *curriculum vitae*. Goldstein clearly "possess[es] skill or knowledge greater than the average layman,"[46] and is qualified to testify as to what a reasonable and competent attorney would have considered the likely outcome, length, and cost of pursuing the underlying litigation to a complete and final end.

The Defendants also seek to exclude Goldstein's testimony on the grounds that his methodology is unreliable. First, the Defendants argue that Goldstein had no methodology at all for his opinion that a reasonable and competent patent attorney would have advised Solvay that it had a 20% chance of winning the litigation. This is incorrect. Goldstein began his analysis by using two studies available at the time of the settlement to assess what the average outcomes were in patent cases involving a generic defendant.[47] Using these

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[43] *Id.* at ¶ 12.

[44] *Id.*

[45] *Id.*

[46] *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998) (quoting *Aloe Coal Co. v. Clark Equip. Co.*, 816 F.2d 110, 114 (3d Cir.1987)).

[47] Goldstein Rep. ¶¶ 40-46.

studies, it is Goldstein's opinion that on average a brand manufacturer plaintiff would have about a 25-30% chance of winning a Hatch-Waxman patent infringement case.[48] Goldstein then examined the merits of the underlying patent litigation in this case to determine whether Solvay's position was stronger or weaker than the average Hatch-Waxman plaintiff.[49] Goldstein found that it was weaker than the average, although not by a lot. Goldstein estimated that a reasonable and competent patent attorney would have discounted Solvay's chances of success by about 10%, meaning that it would have had between a 15-20% chance of succeeding in the underlying litigation.[50] Goldstein clearly has a methodology, even if the Defendants believe it to be a weak one.

Similarly, Goldstein's opinions on the merits, cost, and timing of the litigation are reliable enough to be put to a jury. Although the Defendants argue that his views on the law are unreliable because they are incorrect, that is something on which reasonable and competent patent attorneys can disagree. Indeed, the only people who can say with true 100% certainty what the law is are the Justices of the United States Supreme Court. Further, while using survey data and the Court's statements to estimate cost and timing are not foolproof, they are reliable enough for reasonable jurors to consider. The

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48 *Id.* at ¶ 46.

49 *Id.* at ¶¶ 46, 53.

50 *Id.* at ¶¶ 179-181.

Defendants' arguments basically boil down to the fact that they disagree with Goldstein's opinions, not their reliability. Such arguments are better addressed through the traditional means of "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof."[51] For these reasons, the Defendants' motion to exclude Goldstein's testimony is denied.

2. James Bruno

The Defendants also seek to exclude testimony of the Plaintiffs' expert James Bruno. In particular, the Defendants seek to exclude Bruno's opinions and testimony on the valuation of the Backup Manufacturing Agreement ("BMA") between Solvay and Par/Paddock, including whether Solvay's compensation to Par/Paddock was fair value for services or constituted a large and unjustified payment. The Court agrees, and the Plaintiffs concede, that Bruno does not offer a quantitative valuation of the BMA.[52] As such, Bruno does not and cannot offer testimony as to a specific monetary value for the BMA. To the extent that other experts assign one to the BMA based on Bruno's testimony, such testimony would be inappropriate and should be excluded.

However, the Defendants are incorrect in saying that all of Bruno's testimony regarding the BMA should be excluded. Although Bruno does not offer a specific monetary value to the BMA, such testimony is not *necessary* to show

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51 *Daubert*, 509 U.S. at 596.

52 Pls.' Resp. to Defs.' Mot. to Exclude, at 13 [MDL Doc. 1616].

that a payment is "large and unjustified" under *Actavis*. As discussed later in this Opinion, the key inquiry in determining whether the reverse payment settlements violated the antitrust laws is whether they were entered into for the purpose of avoiding the risk of competition. Bruno's other testimony regarding the BMA, including his opinions that the BMA was out of step with industry practice and the Generics' regular business practices, is certainly relevant to answering that question.[53] Thus, while Bruno's testimony cannot support a specific, monetary valuation for the purpose of mathematically comparing the value of services, his testimony is relevant to answering what the "value" of the settlement was to the Defendants, whether its value was actually in the services provided, or in avoiding the risk of competition. On those grounds, Bruno's testimony would be helpful to the jury, and is allowed.

B. Antitrust Conspiracy

Turning now to the summary judgment motions, Actavis first moves for summary judgment on the theory that the Plaintiffs have failed to demonstrate that Actavis conspired to restrain trade.[54] Under the Sherman Act, Section 1 claims and Section 2 conspiracy to monopolize claims "require the same threshold showing – the existence of an agreement to restrain trade."[55] A written

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[53] FTC's SAMF at ¶¶ 278-81, 290-93 [FTC Doc. 689].

[54] *See* Actavis' Mot. for Summ. J. [FTC Doc. 625, MDL Doc. 1556].

[55] *Seagood Trading Corp. v. Jerrico, Inc.*, 924 F.2d 1555, 1576 (11th Cir. 1991).

contract satisfies this requirement "only if it embodies an agreement to unlawfully restrain trade."[56]

Actavis argues that the settlement agreements do not meet this standard because "they evince no agreement or understanding by [Actavis] to 'delay its entry' in exchange for a share of Solvay's monopoly profits . . ."[57] Actavis cites a number of cases that find that the mere existence of a contract between two parties is not sufficient to establish a conspiracy between them.[58] In those cases, however, the contracts were merely *indirect* evidence of a conspiracy from which the factfinder could infer an agreement to violate the antitrust laws. Finding a conspiracy on such indirect evidence raises the concern that "contractual partners would potentially be on the hook for any future conduct the other party engages in under color of the contract."[59]

But that concern is not present in cases with *direct* evidence, such as this one. "Direct evidence of a conspiracy 'obviates the need' for evidence that

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[56] *Procaps S.A. v. Patheon, Inc.*, 845 F.3d 1072, 1081 (11th Cir. 2016).

[57] Actavis' Mot. for Summ. J. at 13 [MDL Doc. 1556, FTC Doc. 625].

[58] *See Procaps*, 845 F.3d at 1081 (finding that an agreement which was legal at its conception could not on its own conclusively demonstrate a conspiracy related to later unlawful conduct); *Merced Irrigation District v. Barclays Bank PLC*, 165 F. Supp. 3d 122, 139-40 (S.D.N.Y. 2016) (finding that a series of contracts in furtherance of one party's monopolization efforts could support a Section 2 claim, but not a Section 1 claim because there was no evidence of an agreement on the ultimate objective).

[59] *Id.*

excludes the possibility of independent action."[60] In this case, the settlement agreements specifically address the conduct the Plaintiffs argue is unlawful. The parties negotiated and agreed that in exchange for dropping the patent litigation, providing some services, and delaying generic introduction until 2015, the Generics would receive compensation.[61] Whether that common objective – dropping the patent litigation in exchange for compensation – was an illegal restraint of trade is a separate question. But if it was, then the settlements are clear, direct evidence of an agreement to unlawfully restrain trade.[62] Not only is there enough evidence for a jury to find that there was an agreement, it is doubtful that a reasonable jury could find otherwise. Therefore, Actavis' motion for summary judgment on the issue of conspiracy is denied.

C. Anticompetitive Effect

Having disposed of Actavis' conspiracy argument, the Court now turns to what has been the central issue in this case all along: whether the reverse settlement agreements were unlawful.[63] The antitrust laws prohibit conduct

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[60] *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 770 (E.D. Pa. 2015), *aff'd*, 868 F.3d 132 (3d Cir. 2017) [hereinafter *Wellbutrin Summary Judgment*].

[61] *See, e.g.*, FTC's SAMF ¶¶ 174-82 [FTC Doc. 689].

[62] *Wellbutrin Summary Judgment*, 133 F. Supp. 3d at 770 (finding settlement agreement to be direct evidence of conspiracy where manufacturer was involved in settlement negotiations, provided sublicenses, and waived its right to launch an authorized generic).

[63] This is also why this case is different in that there is direct evidence of an agreement to restrain trade. Unlike other cases, where it is "rare.

that is "unreasonable and anticompetitive."[64] "A restraint is unreasonable if it has an adverse impact on competition and cannot be justified as a pro-competitive measure."[65] Usually this is determined by balancing the effects under the test known as the "rule of reason." "[T]he rule of reason standard hinges the ultimate legality of a restraint on whether the plaintiff has demonstrated an anticompetitive effect which is not offset by a need to achieve a procompetitive benefit or justification."[66] Sometimes, however, conduct is so blatantly anticompetitive that courts have found it to be illegal *per se*.[67]

When this case was before the Supreme Court on appeal, the FTC and the Defendants took starkly opposing views on the question of the settlements' effect on competition. The Defendants argued that the settlements were not anticompetitive because they did not delay generic entry past the life of the '894 patent. In other words, as long as the '894 patent would have independently blocked generic entry, the settlements could not possibly be anticompetitive. If

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. .that a plaintiff can establish a conspiracy by showing an explicit agreement," *Gulf States Reorganization Group, Inc. v. Nucor Corp.*, 822 F. Supp. 2d 1201, 1218 (N.D. Al. 2011), the parties here explicitly and openly agreed to the course of conduct. The real question is whether that conduct was illegal.

[64] *Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006).

[65] *Seagood*, 924 F.2d at 1569.

[66] *Id.* (citing *Kestenbaum v. Falstaff Brewing Corp.*, 575 F.2d 564, 571 (5th Cir. 1978)).

[67] *Id.* at 1567 ("Some violations of section 1, however, are illegal *per se* because of their pernicious effect on competition and lack of any redeeming virtue . . .") (quotations omitted).

anything, the settlements should be considered procompetitive by allowing entry earlier than the expiration of patented exclusivity. The FTC, by contrast, took the view that reverse payment settlements are by their very definition anticompetitive, and should be subject to the *per se* rule of illegality, because they explicitly and openly involve sharing the profits of a monopoly to buy off competitors and delay generic entry in order to restrict competition.

The Supreme Court took a middle road between these two extremes. While recognizing that a valid patent certainly would have excluded generics from the market, the Court noted that "an *invalidated* patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe."[68] Thus, the existence of a patent does not necessarily say anything about whether competition was restricted.

At the same time, the Court said abandoning the rule of reason in favor of the FTC's *per se* approach was not appropriate, because "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[69] Instead, the Court held that when

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68 *Actavis*, 570 U.S. at 147 (emphasis original).

69 *Id.* at 159.

it comes to scrutinizing reverse payment settlements, the "FTC must prove its case as in other rule-of-reason cases."

The parties disagree about what constitutes an anticompetitive harm and what the Plaintiffs must demonstrate to prove it. The Defendants argue that the relevant anticompetitive harm is an *actual* harm to consumers in the form of higher prices through the delay of generic entry into the market. Thus, the Defendants argue the Plaintiffs must show that the settlements *actually* caused a delay in the sale of generic versions of AndroGel.[70] But as the FTC points out, the Supreme Court made clear in *Actavis* that avoiding even the possibility of competition, however small, is itself an antitrust violation.[71] Rather than having to litigate the merits of any underlying patent suits or establish a theory of causation, the Supreme Court said that courts can look to the "size of the payment . . . [to] be able to assess its likely anticompetitive effects . . . ."[72] Where

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[70] *See* Defs.' Mot. for Summ. J., at 5-9. *See also* Solvay's Mot. for Summ. J. as to the Par/Paddock Settlement, at 19-27 [FTC Doc. 621, MDL Doc. 1551]; and Par/Paddock's Mot. for Summ. J., at 23-24 [MDL Doc. 1559].

[71] *Actavis*, 570 U.S. at 157 ("The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm."). Candidly, it seems unlikely that many reverse payments will survive such scrutiny. Virtually all settlements are, to some extent, designed to avoid the risk of competition. *See also id.* at 173 (Roberts, C.J. dissenting) (Under the majority's opinion, "taking away any *chance* that a patent will be invalidated is itself an antitrust problem . . . .") (emphasis in original).

[72] *Id.* at 158.

the size of a reverse payment "reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement."[73] But where a payment is "large and unjustified" by these traditional settlement concerns, it is likely directed toward avoiding the risk of competition. Thus, if the settlement payments are shown to be larger than what could reasonably be expected to cover such traditional settlement concerns as future litigation costs or the value of services rendered, the Plaintiffs will have satisfied their burden in showing that the settlements violated the antitrust laws.[74]

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[73] *Id.* at 156.

[74] *See In re Lipitor Antitrust Litigation*, 868 F.3d 231, 251-52 (3d Cir. 2017) (articulating a similar standard at the motion to dismiss stage). Solvay argues that this amounts to a "quick look" test, which the Supreme Court expressly rejected in *Actavis*, 570 U.S. at 158-59, because all the FTC has to do is show that Solvay made a reverse payment. *See* Solvay Reply in Supp. of Mot. for Summ. J., at 9 [FTC Doc. 681]. But under this standard, the FTC has to prove much more than the simple fact that a reverse payment occurred; it also has to prove that the payment was "large" relative to traditional settlement concerns. *See In re K-Dur Antitrust Litig.*, No. 01CV1652SRCCLW, 2016 WL 755623, at *12 (D.N.J. Feb. 25, 2016) ("the burden must be on Plaintiffs to show that the settlement delayed the generic company's entry onto the market, that the brand-name company paid the generic company consideration of some kind, and that the consideration exchanged in the settlement exceeded the estimated cost of litigation and the costs of other services and products, in order to establish a prima facie case.").

In this case, the Defendants entered into two separate settlement agreements.[75] The first, between Solvay and Actavis, provided that Solvay would drop its patent claims against Actavis and pay Actavis 60 to 70% of AndroGel's profits in exchange for co-promoting AndroGel and delaying generic entry until 2015.[76] The second, between Solvay, Paddock, and Par, likewise had Solvay drop its patent claims and pay $12 million to Par per year in exchange for a delay in generic entry until 2015, as well as co-promotion and manufacturing help from Paddock and Par.[77] Clearly, Solvay agreed to pay the Generics significant sums of money. The only remaining question, therefore, is whether these payments were "large" relative to the services provided or the cost of avoided litigation.

According to the Plaintiffs, Solvay determined that it would be much better off if the Generics delayed entering the market until 2015.[78] However, Solvay also figured out that the Generics would see a loss in value of generic

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[75] The two settlements actually contained multiple agreements within them. For example, the Solvay-Actavis settlement included three agreements: a Final Settlement and Release Agreement, a Patent License Agreement, and a Co-Promotion Agreement. FTC's SAMF ¶ 172 [FTC Doc. 689]. The parties do not argue that these should be considered separately, so for simplicity's sake, the Court will refer to the constituent agreements collectively, unless otherwise noted.

[76] FTC's SAMF ¶¶ 178-79, 181-82 [FTC Doc. 689]. Beginning at 60% in 2006, Actavis' share of AndroGel's profits was to increase over time to 70% by 2012. *Id.* at ¶181.

[77] *Id.* at ¶¶ 307, 308

[78] *See* FTC's Resp. to Defs.' Mot. for Summ. J., at 8 [FTC Doc. 657].

entry compared to continuing the litigation if entry was delayed that long.[79] This made it unlikely that the Generics would agree to such a settlement without added incentives.[80] Consequently, Solvay offered the Co-Promotion Agreements ("CPAs") and Backup Manufacturing Agreement ("BMA") in order to entice the Generics to settle their claims.

The Plaintiffs present significant evidence from the negotiation of the settlements to suggest that the services were merely an afterthought to the Defendants, the proverbial lipstick on the pig that was the delay in generic entry.[81] But even if taken at face value, the Plaintiffs' experts opine that Solvay vastly overpaid for the services it was receiving.[82] The Plaintiffs' experts also will testify that the side agreements did not make much business sense on their own.[83]

The Defendants respond in two ways. First, they argue that the FTC failed to show that the settlements *actually* delayed entry.[84] That may well be true, but that is not what the FTC needs to prove in order to show an antitrust

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79 *Id.*

80 *Id.*

81 *See, e.g.,* FTC's SAMF at ¶¶ 88, 100, 109, 133-34 [FTC Doc. 689].

82 *Id.* at ¶ 231.

83 *Id.* at ¶¶ 232-34.

84 Solvay's Reply in Support of its Mot. for Summ. J., at 3 [FTC Doc. 681].

harm. As discussed above, the FTC only needs to prove that the Defendants entered into the settlements in order to avoid the risk of a competitive market.

The Defendants' second argument focuses only on Solvay's settlement with Par and Paddock. The Defendants argue that the Plaintiffs have failed to show that the Par/Paddock settlement was "large and unjustified" because the Plaintiffs did not supply their own valuation of some of the services in those contracts. While the Plaintiffs' expert valued the CPA between Solvay and Par/Paddock, the Defendants point out that the Plaintiffs' expert never quantitatively valued the BMA, which the Defendants argue must be considered jointly with the CPA. Without their own valuation of the BMA, the Plaintiffs must rely on the defense expert's valuation of the CPA in order to show that the agreements were out of step with the value of the services provided. This, the Defendants argue, inappropriately shifts the burden onto them.

However, comparative valuations of services are not a necessary requirement to show that a reverse payment is "large and unjustified." Helpful, certainly, but not necessary. The size of the payment is merely the Supreme Court's proxy for reaching the ultimate question: whether the agreement was entered into for the purpose of avoiding the risk of competition. If a settlement was agreed to for that purpose, it is "large and unjustified."

As discussed above, the Plaintiffs have provided evidence to suggest that the BMA and CPA in the Par/Paddock settlement were merely vehicles to facilitate payment to the Generics for delaying entry. In addition to the size of

the settlement – $12 million per year – the Plaintiffs' experts opine that the BMA was out of step with industry practice and the Generics' regular business practices.[85] In particular, the Plaintiffs' experts criticize the loose oversight over Paddock, the lack of any assurance that Paddock could meet Solvay's manufacturing needs, Solvay's inability under the contract to cancel if Paddock did not meet its manufacturing needs, and the fact that Paddock was unable to manufacture AndroGel for the vast majority of the agreement's term.[86] In addition, there is evidence that the Defendants agreed to the reverse payment amount before negotiating the specifics of any services Par/Paddock were going to render.[87] A reasonable jury could infer from such evidence that the BMA and CPA were merely post-hoc justifications when the true purpose of the settlement was to avoid the risk of competition. This evidence is enough to shift the burden to the Defendants to justify the payments as being procompetitive.

Solvay's counsel suggested at oral argument that one way the Defendants plan to justify the settlements as procompetitive is to argue that the patents were valid and infringed; in other words, the settlements were procompetitive because they allowed generic entry earlier than the patent would have allowed. There are two ways to make this argument. One way would be to provide

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85 FTC's SAMF at ¶¶ 278-81, 290-93 [FTC Doc. 689].

86 *Id.* at ¶¶ 290-96.

87 *Id.* at ¶¶ 131-33, 135, 139.

evidence that shows what Solvay *thought* at the time about the strength of its patents. The other is to argue that Solvay would have won the underlying patent litigation.

While the former is acceptable, the latter is problematic for two reasons. First, as discussed above, the actual validity of the patent is irrelevant to the question of whether the reverse payments violated the antitrust laws. Paying the Generics to stay out of the market for the purpose of avoiding the risk of competition is an antitrust harm, *regardless* of whether or not the patent is actually valid and infringed.[88] Put another way, even if the patent was valid and infringed, the Defendants took away the opportunity to know that for sure by settling before the end of the litigation. If they did so for the purpose of avoiding the risk that a court would find otherwise, however small a risk they considered it to be, that is an antitrust violation under *Actavis*.[89]

Second, for reasons explained more fully elsewhere in this Opinion, even if the actual validity of the patent was relevant, determining the ultimate outcome of the underlying patent litigation is both fundamentally unknowable

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[88] *Actavis*, 570 U.S. at 157 ("The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.").

[89] *Id.* at 173 (Roberts, C.J. dissenting) (Under the majority's opinion, "taking away any *chance* that a patent will be invalidated is itself an antitrust problem . . . .") (emphasis in original).

and procedurally impossible. The underlying litigation was assigned to me. There is no one who can say how I would have ruled on the summary judgment motions, how I would have construed the claims, and whether I would have found infringement. There is no one who can say how the Federal Circuit would have ruled upon any unknowable judgment that may have been rendered. In Actavis, the Supreme Court said "it is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham...)."[90] I will accept the Court's invitation to "structure [this] antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences."[91] Any evidence or argument on actual outcome would be far too speculative to aid a jury in making a reasoned decision. Thus, any arguments based on the actual validity or invalidity of the patent, or about what would have happened in the underlying patent litigation, are inappropriate and will be disallowed regarding the antitrust violation question.

In sum, the Court finds that the Plaintiffs have provided enough evidence for a reasonable jury to find that, by overvaluing these side agreements in the

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90 *Id.* at 157.

91 *Id.* at 159-60.

settlement, the Defendants were able to reach agreements that left them better off than any party would have been had the Generics won the patent litigation. A reasonable jury could find that the settlements were structured so as to be more beneficial to everyone involved than a competitive market; everyone, that is, except the consumer. Settling for that purpose is an antitrust harm. Of course, the Defendants may still justify the settlements by demonstrating that the payments were for "traditional settlement considerations, such as avoided litigation costs or fair value for services,"[92] but they may not justify the payments on the grounds that the patent was valid and infringed because such an argument is irrelevant and, in any case, impossible to know without re-litigating to their conclusion the underlying patent cases. I do not plan to do that. Because the Plaintiffs have shown enough to satisfy their *prima facie* burden, the Defendants' motions for summary judgment on these issues are denied.

D. Antitrust Standing

Unlike the FTC, which only needs to prove an antitrust violation, private plaintiffs asserting a private right of action under the Clayton Act must also establish antitrust standing.[93] This is separate from Article III standing.[94]

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92 *Id.* at 156.

93 15 U.S.C. § 15(a).

94 *Associated Gen. Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 535 n.31 (1983).

"Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact, but the court must make a further determination whether the plaintiff is a proper party to bring a private antitrust action."[95]

The Eleventh Circuit employs a two-prong test for antitrust standing. "First, the plaintiff must establish that it has suffered an antitrust injury."[96] This means the plaintiff must have suffered an "injury of the type that the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful."[97] "The injury should reflect the anticompetitive effect . . . of the violation . . . ."[98] "Second, the plaintiff must be an 'efficient enforcer' of the antitrust laws."[99] The Defendants move for summary judgment only on the first prong.

In this case, the harm "that flows from that which makes the defendants' acts unlawful" – the avoidance of the risk of competition – is higher drug prices. The Private Plaintiffs must therefore prove that they suffered an injury in the

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95 *Id.*

96 *Sunbeam Television Corp. v. Nielsen Media Research, Inc.*, 711 F.3d 1264, 1271 (11th Cir. 2013).

97 *Id.* at n.16 (quoting *Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc.*, 429 U.S. 477, 489 (1977)).

98 *Brunswick*, 429 U.S. at 489.

99 *Sunbeam*, 711 F.3d at 1271.

form of higher drug prices because of the delay in generic entry caused by the reverse payment settlements. The Private Plaintiffs have offered, at various times, three alternative theories for why the Generics would have entered the market prior to 2015: (1) the Generics ultimately would have prevailed in the underlying patent litigation; (2) the Generics would have come to the market "at risk" during the patent litigation; and (3) the parties would have reached an alternative settlement with an earlier entry date than 2015.

1. Success on the Patent Merits and At-Risk Entry

During oral argument, the Private Plaintiffs disavowed the argument that they would have won the underlying patent litigation, leaving only the latter two theories to show causation. However, the Private Plaintiffs' at-risk theory of causation still ultimately depends on showing that the Generics would have won the underlying patent litigation. The *Wellbutrin* district court stated this point clearly. "The existence of a valid and uninfringed patent would interfere with the plaintiffs' chain of causation: a valid patent independently preclude[s] competition apart from any agreement and an 'at risk' launch is unlawful absent a later finding of patent invalidity or non-infringement."[100] In other words, if the patent was valid, any at-risk launch would have been unlawful if it infringed on the patent, and the law will not allow the Private

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[100] *Wellbutrin Summary Judgment*, 133 F. Supp. 3d at 764 (quotations omitted).

Plaintiffs to use illegal behavior as a link in their chain of causation.[101] At least three other courts have reached similar results.[102] In order to show that the Generics could have successfully – i.e., legally – launched at-risk, the Private Plaintiffs would therefore need to show that the patent would ultimately have been found either invalid or uninfringed in the underlying patent litigation.

This raises again the central problem raised by *Actavis*: how to determine what the outcome of the underlying patent litigation would have been in a way that is manageable. Do the parties need to accomplish what Judge Carnes called the "turducken task" of litigating "a patent case within an antitrust case about the settlement of the patent case?"[103] Alternatively, can they offer experts to testify as to what would have happened in the but-for world, neatly summarized into each party's percent chance of winning?[104] Is it even possible to do either?

It is the Court's opinion that it is not. At least in relation to this particular case, arguments which depend on determining what the ultimate

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[101] *Id.* at 765 ("Where a regulation—such as patent law—precludes competition, that regulation cuts off the chain of causation.").

[102] *See In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 63 (1st Cir. 2016) (stating that at-risk entry theories ultimately depend on the outcome of the patent litigation); *In re Wellbutrin*, 868 F.3d 132, 165 (3d Cir. 2017) [hereinafter *Wellbutrin Appeal*] (same); *Apotex, Inc. v. Cephalon, Inc.*, 2017 WL 2473148, at *8 (E.D. Pa. June 8, 2017) (same).

[103] *FTC v. Watson*, 677 F.3d at 1315.

[104] *See, e.g.*, *Wellbutrin Appeal*, 868 F.3d at 169 (finding that plaintiffs could not show generics would have won where expert testified they only had a 20% chance of winning).

outcome of the underlying patent litigation would have been are simply too procedurally burdensome and speculative to serve as valid theories of causation under *Actavis*. Consider for a moment the particularly thorny issues that would be raised were the Court to consider such a theory at trial. Would the Private Plaintiffs be allowed to make any argument that was potentially available to the Generics, or would they be limited to the arguments the Generics had actually made up to the point the parties settled? The Defendants at various points in their papers assume the latter, but the underlying litigation never came to a final, preclusive decision. It did not even reach summary judgment. Who knows what arguments may have been raised as the litigation went forward?

Further, is the outcome of the underlying litigation a question of fact or law, and who would decide what the outcome would have been – the Court or the jury? If the latter, how could a jury determine what the outcome of a bench trial would have been? Unlike the issue of an antitrust violation, a jury cannot estimate the likelihood of the Generics' success on the patent merits by simply looking to the size of the reverse payment as a proxy.[105] Instead, a jury would have to answer that question by determining how the judge – in this case, me – would have found on the merits. Thus, when combined with the standard of proof in this case, this means that to survive summary judgment, the Private

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[105] For a discussion of why the size of the reverse payment does not serve well as a proxy for what the parties thought of the merits, *see Wellbutrin Appeal*, 868 F.3d at 167-69.

Plaintiffs would have to provide enough evidence to show that a reasonable jury could find it more likely than not that a judge would have found it more likely than not that the Generics did not infringe or that the '894 patent was invalid.[106] On top of that, a jury would have to determine how the judge would have decided various legal issues, including claim construction and summary judgment. If that sounds ridiculously unwieldy, that's because it is. And even if a jury could comprehend that standard, how would the inevitable appeal be handled? Would the case be split, with the antitrust issues going to the Eleventh Circuit, but the patent issues going to the Federal Circuit? Clearly, actually litigating the underlying merits would be a procedural and administrative nightmare.

But let us assume for a moment that the procedural issues could somehow be worked out. At least with regard to this case, it is impossible to say what the court would have actually done in the underlying case. Any experts who testify otherwise, like the expert relied upon in *Wellbutrin*,[107] are coming up with probabilities out of whole cloth. Unlike the antitrust issues, where we can assume that the parties would have acted in their best economic interest, such assumptions cannot necessarily be made about courts and juries. One court is

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[106] *Id.* at 169 (using the preponderance of the evidence standard with regard to the patent merits).

[107] *Wellbutrin Appeal*, 868 F.3d at 169.

not the same as another. Much of a patent case depends on how a claim is construed, and no one can say how I would have construed the claims at issue. Nor can one simply estimate what would have happened based on other cases. Every patent case is inherently different, with numerous variable affecting the outcome. And the issue here is not what would have happened in a generic case, but what would have happened in *this* case.

By contrast, most of the cases which have considered this question and decided otherwise have differed from this case in at least one of two ways. First, at least two of those cases relied upon what this Court views was an improper causation standard, finding that the plaintiffs only needed to show that the generics *could* have won, not that they *would* have won.[108] Obviously it is much easier to provide substantive proof of what could have happened as opposed to what would have happened. Second, the experts offering testimony in those cases had at least some concrete outcome in the underlying litigation on which to base their opinions. For example, in the *Lidoderm* litigation, the defendants had actually gone to trial on the case, but settled before the judge issued his

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[108] *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. CV 14-MD-02503, 2018 WL 563144, at *14 (D. Mass. Jan. 25, 2018); *United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA, Inc. (Lidoderm)*, 296 F. Supp. 3d 1142, 2017 WL 50682533, at *5 (N.D. Cal. 2017). The Court views this standard as inappropriate because evidence that the Generics *could* have won gets us no closer than we are now to answering the question of whether the Generics *would* have been able to enter the market in a but-for world, or if a valid patent *would* have prevented them.

opinion.[109] Thus, the expert was able to rely on statements made by the judge, as well as his claim construction order.[110] And in *Wellbutrin*, where there were two underlying patent suits, the court in one of them had also entered claim construction and summary judgment orders (the plaintiffs did not argue the generic could have won the other).[111] In this case, however, the Court never entered a claim construction or summary judgment order in the underlying patent litigation in this case, let alone actually tried the issues. Any opinion that would purport to state how a particular piece of litigation would turn out without any evidence from the court in question on how it would rule can only be characterized as pure speculation. Such attenuated evidence cannot possibly serve as the basis of a reasonable decision by a jury.

Although this eliminates two of the Private Plaintiffs' theories of causation, as well as a possible procompetitive justification for the settlements, the Court feels it is justified in light of *Actavis*, the other theories available to the parties, and the desire for a logical congruency of outcome. First, as noted earlier, Justice Breyer explicitly states that:

> [a]s in other areas of law, trial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the

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[109] *Lidoderm*, 74 F. Supp. 3d 1052, 1063 (N.D. Cal. 2014).

[110] *Lidoderm*, 296 F. Supp. 3d 1142, 2017 WL 50682533, at *28-29 (N.D. Cal. 2017).

[111] *Wellbutrin Summary Judgment*, 133 F. Supp. 3d at 766-67.

> other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences.[112]

Admittedly, Justice Breyer was speaking only in the context of an antitrust violation, not causation. But his concern for the ability of trial courts to manage the cases before them extends here.

Second, not all theories of causation are now out of bounds for the Private Plaintiffs. As discussed in more detail below, they still have the ability to show that the Defendants would have reached alternative, legal settlements that would have allowed for earlier generic entry without the reverse payments. Indeed, this theory is less attenuated than any theory based on the outcome of the underlying patent litigation because a factfinder can rely on the assumption that the parties are economic actors who would have done what was in their best financial interest.

Lastly, precluding such a basis of causation avoids potentially inconsistent outcomes. As discussed above, the FTC does not need to prove causation to win its case. The Supreme Court was clear, for better or worse, that it merely needs to prove that the Defendants entered into the settlements for the purpose of avoiding the risk, however small, of competition. Consider the incongruity, then, if the FTC should win its case on those grounds, while the Private Plaintiffs lose because the Defendants are able to show the patent would have

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[112] *Actavis*, 570 U.S. at 159-60.

been declared valid and infringed. How can the Defendants both have a valid patent, and commit an antitrust violation? Such an outcome makes no sense.

The Court recognizes that this solution is not the most appetizing, but it benefits from the sheer distastefulness of the other options available. To quote Churchill, "[i]t has been said that democracy is the worst form of Government except all those other forms that have been tried from time to time."[113] The same is true here. The Court can simply see no way of entertaining arguments that purport to say what the outcome would have been in the underlying patent litigation without relying on wholly speculative evidence or untying a Gordian knot of procedural problems. With that in mind, it is the Court's opinion that such arguments are simply unworkable, and should not be considered further in this litigation.

2. Alternative Settlement Scenario

The Private Plaintiffs' remaining causation theory is that but-for the reverse payment the Defendants would have come to an alternative, legal settlement that would have allowed for generic entry earlier than 2015. In *Actavis*, the Supreme Court endorsed patent litigation settlements that do not involve reverse payments.[114] The Defendants argue that this alternative

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[113] 444 Parl Deb HC (5th ser.) (1947) col. 207.

[114] *Actavis*, 570 U.S. at 158 (Defendants "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee

settlement theory is ultimately dependent on the outcome of the patent merits because "if the '894 patent was valid and infringed, then Plaintiffs are complaining about the inability to buy an *infringing* product."[115]

This argument is unpersuasive. Unlike the at-risk theory of causation, the Private Plaintiffs are not arguing that they would have done something illegal. Instead, their theory is that Solvay, faced with the uncertain prospect of continuing the litigation and acting in its economic best interest, still would have granted the Generics a license to enter the market before the expiration of the patent. Without a payment, however, the Generics, if confident in their chances at trial and on appeal, would have required an earlier entry date than 2015, the entry date under the actual reverse settlement. Using leverage to negotiate an earlier settlement date is obviously legal. Further, focusing upon the difference between 2015 and a hypothetical earlier entry date results in the type of injury intended to be prevented by the antitrust laws as interpreted by the Supreme Court in *Actavis*. If the Private Plaintiffs can show that, but-for an illegal reverse payment intended to avoid the risk of a competitive market place, the Generics would have entered earlier, they will have shown they have suffered an antitrust injury.

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paying the challenger to stay out prior to that point.").

[115] Solvay's Mot. for Summ. J., at 8 [Doc. 1566-1].

Other courts have endorsed this approach. In *Wellbutrin*, the district court accepted the plausibility of an alternative settlement scenario, although it granted summary judgment to the defendants because the brand manufacturer had "expressly and unwaveringly refused to settle" without the allegedly anticompetitive provision of the actual settlement.[116] In *Lidoderm*, the court also found that the alternative settlement theory was cognizable, and found there to be sufficient evidence to submit the issue to a jury.[117] And in *Solodyn*, the district court also allowed the plaintiffs to proceed on an alternative settlement theory.[118]

In order to prove this theory, of course, the Private Plaintiffs must have evidence that an alternative settlement *would* have occurred in the but-for world. To do so, the Private Plaintiffs offer three expert opinions, as well as some direct evidence. The first, that of Jack Goldstein, thoroughly evaluates the merits of the underlying patent litigation, comparing it to the average patent case, and concludes that a reasonable and competent attorney would have advised Solvay and the Generics that Solvay had about a 20% chance of winning, if not less.[119]

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[116] *Wellbutrin Summary Judgment*, 133 F. Supp. 3d at 757. On appeal, the Third Circuit agreed. *Wellbutrin Appeal*, 868 F.3d at 167 & n.57.

[117] *Lidoderm*, 296 F. Supp. 3d 1142, 2017 WL 5068533, at *10-13.

[118] *Solodyn*, 2018 WL 563144, at *21-23.

[119] Goldstein Rep. ¶¶ 181, 193.

Independently of Goldstein, the Private Plaintiffs' other two experts, Dr. Leffler and Prof. Elhauge, each reach their own conclusions on what the Defendants considered their chances to be.[120] Dr. Leffler looked to the terms of the actual settlement, and concluded that Solvay likely viewed its chances of winning to be at about 33%.[121] Likewise, Prof. Elhauge looked to the actual terms of the settlement agreement and determined that it would only have been economically rational for Solvay to agree to the actual settlements at issue if it believed its chances of winning were at best 48.8%.[122] This is consistent with the "Project Tulip" evidence which shows that Solvay's executives crafted the settlement with Actavis around a 50% chance of winning the patent litigation.[123]

With these expectations in mind, Dr. Leffler and Prof. Elhauge each agree that it would have been economically rational for Solvay to settle, even without a reverse payment. Using Goldstein's estimate of Solvay's chance of winning the litigation, Dr. Leffler concludes that the Defendants would have agreed to an alternative settlement that allowed for generic entry on January 1, 2008, while Prof. Elhauge concludes the Generics would have entered on May 22, 2009.[124]

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[120] The Defendants do not move to exclude either Dr. Leffler or Prof. Elhauge.

[121] Leffler Rep. ¶ 83 [Doc. 1564-22].

[122] Elhauge Rep. ¶ 149 [Doc. 1564-31].

[123] Private Pls.' SAMF ¶ 49 [Doc. 1598].

[124] *Id.* at ¶¶ 15, 26.

And using his own estimate of Solvay's belief about the strength of the patent, based upon the actual settlement, Dr. Leffler concludes that the Generics would have entered on October 1, 2010.[125] Under all of these scenarios, the Generics would have entered the market earlier than 2015.

The Defendants argue that the Private Plaintiffs' evidence is not sufficient because they do not have actual, direct evidence that the Defendants ever negotiated a different date.[126] "Requiring such evidence, however, would be an almost impossible standard to require of Plaintiffs, given that this is a but-for scenario."[127] "Because this case is set in a but-for world, it is not surprising that no evidence shows that defendants were contemplating anything other than the actual settlement."[128] If Solvay and the Generics "were acting unlawfully to eliminate competition throughout their settlement negotiations, then it is unreasonable to expect a paper trail signifying rational, lawful business choices."[129] Any criticism the Defendants have of the experts' methodologies or conclusions are best handled through cross-examination and the production of contrary evidence.

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125 *Id.* at ¶ 14.

126 Solvay's Mot. for Summ. J., at 33-34 [MDL Doc. 1566].

127 *Solodyn*, 2018 WL 563144, at *21.

128 *Lidoderm*, 296 F. Supp. 3d 1142, 2017 WL 5068533, at *34.

129 *Solodyn*, 2018 WL 563144, at *21.

The Defendants also mistakenly argue that Dr. Leffler's and Prof. Elhauge's models assume that a reverse payment always causes delay. Their models assume nothing of the sort. Rather, both experts use their experience and knowledge in the field to conclude that reverse payments cause delay, and they confirm that conclusion in their models addressing the specific settlement at issue in this case.

Indeed, such a conclusion is economically logical, especially at the causation stage, in which the Private Plaintiffs will have already proven that the purpose of the reverse payment was to avoid the risk of competition. It would make no sense for Solvay to pay the Generics tens of millions of dollars if it could get the Generics to enter on the same date without paying them all of that money. Nor would it make sense for the Generics to agree to delay entry for free if they could receive tens of millions of dollars to do the same thing. Solvay paid the Generics a lot of money for something, and if it was not for services or saved litigation costs, it is logical to conclude it was for delay.[130]

Lastly, Par/Paddock argue that even if the Private Plaintiffs prove their case as to the Actavis settlement, they cannot show causation regarding Solvay's settlement with Par/Paddock because Par/Paddock could not have entered before

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[130] Other courts have come to the same conclusion. *See, e.g., In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) ("One can logically infer that, all else equal, with a [reverse payment], a generic would be willing to agree to a later entry date than it would otherwise agree to in order to settle a patent-infringement case.").

Actavis did.[131] But the fact that Actavis would have had to agree to a settlement before Par/Paddock could have does not vitiate causation, it merely adds another step. If the Private Plaintiffs can show that Solvay and Actavis would have settled earlier without a reverse payment, then they might also be able to show that Par/Paddock would have done so as well. And for all the reasons discussed above regarding the Actavis settlement, the Private Plaintiffs have produced evidence that indeed Par/Paddock and Solvay also would have settled earlier. For these reasons, the Court finds that the Private Plaintiffs have provided enough evidence for an alternative settlement theory of causation to survive summary judgment.

3. Lack of Injury Regarding AndroGel 1.62%

The final antitrust injury related argument involves AndroGel 1.62%. All of the Private Plaintiffs in this case are seeking damages regarding the original AndroGel formula, AndroGel 1%. However, one group of plaintiffs – the Retailers – is also seeking damages related to purchases of a newer formulation, AndroGel 1.62%.[132]

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[131] Par/Paddock's Mot. for Summ. J., at 16-18 [MDL Doc. 1559].

[132] AndroGel 1.62% was developed in order to increase the ease of application and reduce drying time, thereby increasing patient satisfaction. *See* Solvay's Mot. for Summ. J., at 5 [MDL Doc. 1552].

AndroGel 1.62% was not introduced until 2011, five years after the challenged settlements.[133] It was developed in order to improve upon AndroGel 1%, namely by increasing the ease of application and reducing drying time, thereby increasing patient satisfaction.[134] When it was introduced, AndroGel 1.62% quickly became the leading testosterone replacement therapy.[135] Even after generic versions of AndroGel 1% were introduced to the market, consumers still continued to prefer AndroGel 1.62% by a wide margin despite its significantly higher price.[136]

The Retailers argue that the settlements delayed the launch of generic AndroGel 1% long enough that Solvay could "switch the market" to AndroGel 1.62%.[137] This argument can only work under one of two theories: either Solvay engaged in an anticompetitive "product hop," or AndroGel 1.62% is essentially the same product as AndroGel 1%. The Retailers are adamant that they are not pursuing a "product hop theory," so the Court need not address it.[138] As for the

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133 Solvay's SMF ¶ 23 [MDL Doc. 1567-2].

134 *See* Solvay's Mot. for Summ. J., at 5 [MDL Doc. 1552].

135 Solvay's SMF ¶¶ 27, 29-30 [MDL Doc. 1567-2].

136 *Id.* at ¶¶ 30, 35.

137 Retailer Pls.' Resp. to Solvay's Mot. for Summ. J., at 1 [MDL Doc. 1610]. The Retailers do not allege that the introduction of AndroGel 1.62% was itself in anyway anticompetitive.

138 *Id.* at 5-6, 9.

latter theory, there can be no doubt that AndroGel 1.62% is a different product than AndroGel 1%. AndroGel 1.62% is covered by eight different patents that do not cover AndroGel 1%.[139] This is further supported by the fact that, if the products were the same, one would expect consumers in a competitive market place to choose the less expensive of two identical products. But as mentioned above, even when faced with a fully competitive market after 2015 that includes AndroGel 1.62%, and branded and generic AndroGel 1%, consumers have still chosen the significantly higher priced AndroGel 1.62% over generic AndroGel 1% by a wide margin.[140]

In essence, then, the Retailers are arguing that the alleged delay in entry of one product caused them damages by forcing them to pay higher prices for a different, better product. This is the Retailer's "shifting the market" argument, meaning that the reverse settlements gave Solvay the time to "shift the market" to AndroGel 1.62%. But courts generally presume that the introduction of new, better products is a good thing for competition. "The attempt to develop superior products is . . . an essential element of lawful competition."[141] Plus, if the '894 patent was valid, the patent itself would have given Solvay the time to "shift the market" by introducing a new product. This is further proof that "shifting the

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[139] Solvay's SMF ¶ 25 [MDL Doc. 1567-2].

[140] Solvay's Mot. for Summ. J., at 4 [MDL Doc. 1567-1].

[141] *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 286 (2d Cir. 1979).

market" is not, in and of itself, a problem.[142] Instead, the proper measure of injury is and must be the comparison between like-products. Given that AndroGel 1.62% and AndroGel 1% are different products, the Retailers cannot claim that they were injured by purchasing AndroGel 1.62% simply because that is what consumers wanted.

E. FTC's Available Remedies

Should the FTC successfully prove that the reverse payment settlements were anticompetitive and violated the antitrust laws, the FTC is seeking broad equitable relief, including preventing the Defendants from entering into any reverse payment agreements in the future, as well as compulsory generic licenses for AndroGel 1.62%.[143] The Defendants argue that these remedies are far too broad, and that they would inappropriately restrain lawful conduct.

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[142] It can potentially be a problem if brand name manufacturers tweak a drug and pull the older version off the shelf just as a generic is about to enter the market. This is the "product hopping" referenced above. It is problematic because it extends a manufacturer's monopoly at the expense of consumer choice. Again, however, the Retailers were clear that they were not pursuing this kind of theory. But even if they were, such an argument would have failed because Solvay never pulled AndroGel 1% off the shelf.

[143] The FTC abandoned any damages claims it had when it applied for *certiorari* with the Supreme Court. *See* Petition for Writ of Certiorari, *FTC v. Watson Pharmaceuticals, Inc.*, 2012 WL 4750283, at *31 (U.S.) ("here the FTC seeks only declaratory and prospective injunctive relief . . . .").

But federal courts have extensive authority to order equitable relief in antitrust cases.[144] The goal of an equitable antitrust suit is not to simply punish past behavior, "nor is it merely to end specific illegal practices."[145] The goal is to "effectively pry open to competition a market that has been closed by defendants' illegal restraints."[146] In other words, the goal is to prevent anticompetitive activity in the future, and the courts have a wide range of means at their disposal to do so.[147] "[I]t is not necessary that all of the untraveled roads to that end be left open and that only the worn one be closed."[148] Sometimes, this may even mean that otherwise legal activity may have to be enjoined.[149] "The standard against which the order must be judged is whether the relief represents a reasonable method of eliminating the consequences of the illegal

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144 *Int'l Salt Co. v. United States*, 332 U.S. 392, 400–01 (1947) *abrogated by Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006) (District Courts "are invested with large discretion to model their judgments to fit the exigencies of the particular case.").

145 *Id.* at 401.

146 *Id.*

147 *Fed. Trade Comm'n v. Nat'l Lead Co.*, 352 U.S. 419, 430 (1957) (Courts are "obliged not only to suppress the unlawful practice but to take such reasonable action as is calculated to preclude the revival of the illegal practices.").

148 *Int'l Salt Co.*, 332 U.S. at 400.

149 *Nat'l Lead Co.*, 352 U.S. at 430 ("...decrees often suppress a lawful device when it is used to carry out an unlawful purpose.").

conduct."[150] Because the appropriate remedy fundamentally depends on the nature and scope of any wrongful conduct, it is premature to determine what may or may not be an appropriate remedy at this stage in the litigation, where there has not yet been a decision on liability.

IV. Conclusion

For the reasons stated above, Solvay's Motion for Summary Judgment on the FTC's Claims [FTC Doc. 620] is DENIED, Solvay's Motion for Summary Judgment as to the Par/Paddock Settlement [FTC Doc. 621, MDL Doc. 1551] is DENIED, Actavis and Actavis Holdco's Motion for Summary Judgment [FTC Doc. 625, MDL Doc. 1556] is DENIED, Solvay's Motion for Summary Judgment for Lack of Antitrust Injury Against the Private Plaintiffs [MDL Doc. 1550] is DENIED, Solvay's Motion for Summary Judgment as to Retailer's Damages Claims on AndroGel 1.62% Purchases [MDL Doc. 1552] is GRANTED, the Defendants Par and Paddock's Motion for Summary Judgment [MDL Doc. 1559] is DENIED, Actavis, Inc. and Solvay's Motion to Exclude Plaintiffs' Proposed Patent Law Expert Jack C. Goldstein, Esq. [FTC Doc. 622, MDL Doc. 1553] is DENIED, and Solvay, Par, and Paddock's Motion to Exclude in Part Plaintiffs' Expert James R. Bruno [FTC Doc. 630, MDL Doc. 1562] is GRANTED in part and DENIED in part.

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[150] *Nat'l Soc. of Prof'l Engineers v. United States*, 435 U.S. 679, 698 (1978).

SO ORDERED, this 14 day of June, 2018.

/s/Thomas W. Thrash
THOMAS W. THRASH, JR.
United States District Judge