UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: WELLBUTRIN XL ANTITRUST LITIGATION	:	CIVIL ACTION NO. 08-2431
_____	:	NO. 08-2433
	:	
THIS DOCUMENT RELATES TO: ALL ACTIONS	:	

MEMORANDUM

McLaughlin, J. September 23, 2015

This lawsuit is one of many in the federal courts involving the application of the Supreme Court's decision in FTC v. Actavis, Inc., __ U.S. __ 133 S.Ct. 2223 (2013), to settlements between branded and generic pharmaceutical manufacturers. In this case, direct and indirect purchasers of Wellbutrin XL have brought claims under the Sherman Act and state antitrust and consumer protection statutes, alleging that the defendants SmithKline Beecham Corporation d/b/a GlaxoSmithKline and GlaxoSmithKline plc (collectively, "GSK") delayed the entry of generic versions of Wellbutrin XL to the American market by entering into illegal agreements with generic drug companies to settle patent infringement lawsuits.

In Actavis, the Supreme Court held that settlements in which the holder of a pharmaceutical patent makes a payment to an alleged patent infringer to resolve a challenge to the patent

– so-called "reverse payment settlements"[1] – "can sometimes violate the antitrust laws." Actavis, 133 S.Ct. at 2227. The Supreme Court explained that such settlements are neither presumptively unlawful nor presumptively lawful, and instructed district courts to evaluate the settlements under the long-standing rule of reason framework. Id. at 2237-38. Reverse payment settlements, the Court cautioned, could present the following anticompetitive harm: eliminating "the risk of patent invalidation or a finding of non-infringement" that the underlying patent lawsuit presented. Id. at 2236-37.

The settlements challenged in this case (collectively the "Wellbutrin Settlement") resolved patent disputes among GSK, GSK's business partner Biovail, and multiple generic manufacturers who had filed Hatch-Waxman Act Paragraph IV Certifications challenging the Wellbutrin XL patent. The Wellbutrin Settlement, reached in February 2007, allowed the

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[1] The Supreme Court illustrated its understanding of reverse payment settlements as follows:

> Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement.

Actavis, 133 S.Ct. at 2227.

underlying Hatch-Waxman litigation to continue, and provided for entry of generic Wellbutrin XL immediately upon a finding of non-infringement or patent invalidity, and in any case no later than May 30, 2008, 10 years before the expiration of the patent. The settlement also granted the generic manufacturers sublicenses to patents (which expired in 2022) at issue in a separate patent lawsuit, and provided a guaranteed generic supply of Wellbutrin XL; it also provided for enhanced review of the settlement by the Federal Trade Commission. In the settlement, GSK agreed not to launch an authorized generic Wellbutrin XL product during the generic manufacturer's period of Hatch-Waxman guaranteed exclusivity.

GSK has filed three motions for summary judgment: one motion for summary judgment as to all claims made by the plaintiffs; one motion for summary judgment addressing only the issue of causation; and one motion for summary judgment as to the indirect plaintiffs' Cartwright Act cause of action. In connection with its motions for summary judgment, GSK has filed Daubert motions to exclude the plaintiffs' experts. In addition to their oppositions to GSK's motions for summary judgment, the plaintiffs have filed Daubert motions to exclude GSK's expert Dr. Martin Adelman. The court will grant summary judgment to GSK.

The series of settlement agreements challenged here contains a provision not present in any other post-Actavis case of which the Court is aware: the generic manufacturer did not abandon its challenge to the patent held by GSK's business partner, Biovail. The settlement provided that if the generic manufacturer prevailed on its appeal in the Federal Circuit, it could immediately enter the market with generic Wellbutrin XL. GSK, therefore, argues that the Wellbutrin Settlement does not come within the purview of Actavis and should be exempt from antitrust scrutiny. The Court is reluctant to apply such a mechanical test, because it could offer blanket immunity to any reverse payment settlement in which the underlying patent litigation continues; this could create an easily exploited loophole. The Supreme Court in Actavis – and antitrust law historically – rejects such a formalistic approach to evaluating an agreement.

The fact that the Wellbutrin Settlement allowed the underlying patent litigation to continue, however, is a factor to be considered in the rule of reason analysis mandated by Actavis. The plaintiffs cannot establish the anticompetitive harm contemplated by Actavis: that the defendant in the patent infringement lawsuit would abandon its patent claim, eliminating the risk of patent invalidation or a finding of non-infringement. The plaintiffs' necessary alternate theory of

anticompetitive harm is that the Wellbutrin Settlement delayed the launch of a generic product. But the plaintiffs have not established a proper foundation for such a claim by showing either that an alternate settlement would have been reached absent a no authorized generic agreement, or that continued litigation would have resulted in earlier generic entry through an at risk launch.

As to a settlement without a no authorized generic provision, there is no evidence that such a settlement was ever contemplated, much less that it would have resulted in an earlier entry date. The summary judgment record shows that the generic manufacturers regarded the no authorized generic agreement as an essential term. As to continued litigation and the at risk launch, the plaintiffs have not made an adequate showing that a separate patent would not have been an independent bar to market entry.

Even if the plaintiffs had shown that the Wellbutrin Settlement had anticompetitive effects, the Court finds that a reasonable jury could not find that any anticompetitive effects outweigh the procompetitive benefits of the settlement. The Wellbutrin Settlement provided sublicenses to a generic patent that was the subject of separate infringement actions brought by a different pharmaceutical company, and obligated Biovail to

supply the generic manufacturer with generic Wellbutrin XL, two results not achievable through successful litigation alone.

Finally, the plaintiffs cannot prove that they suffered antitrust injury or that the Wellbutrin Settlement was the proximate cause of any injury suffered because they have not presented evidence that the Wellbutrin Settlement, as opposed to an independent patent, prevented market entry of generic Wellbutrin XL.

I. Summary Judgment Record[2]

The settlement agreement at issue in these cases – the Wellbutrin Settlement – involves the interplay between complex statutory and regulatory schemes, multiple patent infringement lawsuits, and extensive negotiations among numerous parties. The Court has addressed each factual issue individually below.

A. The Drug Approval Process and Regulatory Framework

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–92 ("FDCA"), provides that the Food and Drug Administration

[2] All facts herein are taken in the light most favorable to the plaintiffs. The plaintiffs, however, rely on a great deal of speculation in their recitation of the relevant facts; the Court will not consider the plaintiffs' speculation in deciding these motions. Summary judgment cannot be avoided by relying on speculation, and "inference based on speculation...does not create a material factual dispute." Robertson v. Allied Sig., Inc., 914 F.2d 360, 383 (3d Cir. 1990).

("FDA") must approve all drugs before they may be introduced into interstate commerce. Companies seeking to market drugs must file applications for approval under one of two procedures.

Under the first procedure, a new drug (or "brand name" drug) applicant files a New Drug Application ("NDA"), which must include examples of the proposed labeling for the drug and clinical data demonstrating the drug's safety and efficacy. The NDA must also include the patent number and expiration date of any patent that claims either the drug or a method of using the drug if "a claim of patent infringement could reasonably be asserted." Submission of an NDA involved "a long, comprehensive, and costly testing process." Actavis, 133 S.CT. at 2228. The FDA publishes the names of approved drugs and their associated patents in what is commonly known as the "Orange Book."[3] 21 U.S.C. § 355(a),(b).

Congress established the second new drug approval procedure in 1984 with the Drug Price Competition and Patent Term Restoration Act (the "Hatch–Waxman Act"). Pub.L. No. 98–417, 98 Stat. 1585 (1984). The Hatch–Waxman Act allows companies seeking to manufacture and market a generic version of a previously approved pioneer drug (known as the "listed drug") to avoid filing an NDA. Instead, generic manufacturers are

[3] The volume is officially known as the Approved Drug Products with Therapeutic Equivalents Evaluations.

permitted to file an Abbreviated New Drug Application ("ANDA"). The ANDA permits the applicant to rely on the safety and efficacy data for the listed drug if the applicant can show that the generic product is "bioequivalent" to the listed drug. 21 U.S.C. §§ 355(j)(2)(A)(iv), (j)(8)(B).

As part of the ANDA process, a generic manufacturer must make one of four certifications regarding each patent associated in the Orange Book with the listed drug: (I) that the patent information has not been filed; (II) that the patent has expired; (III) that the patent is set to expire; or (IV) that the patent is invalid or will not be infringed by the generic drug. This fourth certification is known as a "Paragraph IV Certification." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). A generic manufacturer that files a Paragraph IV Certification must give notice to the patent holder and provide a "detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B).

The Hatch–Waxman Act provides that if the patent holder files an infringement suit within 45 days after receiving notice of the Paragraph IV Certification, the patent holder benefits from a statutory stay on FDA approval of the ANDA for a period of 30 months or until the resolution of the infringement suit, whichever is shorter. 21 U.S.C. § 355(j)(5)(B)(iii). If

the generic applicant begins to market its generic product prior to a determination of the patent's validity or scope, the launch is considered to be "at risk" and the manufacturer can be forced to pay damages. See 35 U.S.C. 271(e)(4)(C).

The first generic company to file an ANDA containing a Paragraph IV Certification (the "first filer") also receives an "exclusivity" period of 180 days during which the FDA may not approve any later-filed paragraph IV ANDA based on the same NDA. *Id.* § 355(j)(5)(B)(iv). The 180–day period begins to run from either the date that the first filer begins to market its drug or the date of a final judgment that the patent is invalid or not infringed, whichever is earlier. Id. §§ 355(j)(5)(B)(iv), 355(j)(5)(D). The patent holder, however, is not barred from marketing an authorized generic product during the 180-day period. See King Drug Co. of Florence v. Smithkline Beecham Corp., 791 F.3d 388, 393 (3d Cir. 2015); Pls. Ex. 943.

B. Wellbutrin Products & Patents

The product at issue in this litigation is Wellbutrin XL, the third iteration of GSK's Wellbutrin product.

Bupropion hydrochloride, an active pharmaceutical ingredient used to treat depression, was first approved by the FDA for the treatment of major depressive disorder in 1985 in an immediate release formulation known by its branded name,

Wellbutrin IR. Wellbutrin IR provides for rapid release of the active ingredient and is taken three times a day. To reduce the degradation of bupropion hydrochloride upon contact with water, GSK added hydrochloric acid as a stabilizing agent. GSK Stmt. ¶ 1-2; Pls.' Stmt. Opp. ¶ 1-2.

The next bupropion hydrochloride product to reach the market was the sustained release Wellbutrin SR, which is taken twice a day. Wellbutrin SR was approved on the basis of its bioequivalence to Wellbutrin IR. Wellbutrin SR also used hydrochloric acid as a stabilizing agent. GSK Stmt. ¶ 1-2; Pls.' Stmt. Opp. ¶ 1-2.

Biovail acquired the rights to two U.S. patents covering extended release formulations of bupropion hydrochloride: U.S. Patent No. 6,096,341 (the "'341 patent") and U.S. Patent No. 6,143,327 (the "'327 patent"). Both patents are set to expire on October 30, 2018. GSK Stmt. ¶ 5; Pls.' Stmt. Opp. ¶ 5.

In 2001, Biovail and GSK entered into an agreement to develop, manufacture, and promote a once-a-day extended release bupropion hydrochloride (the "Co-Promotion Agreement"). The extended release formulation, brand-named Wellbutrin XL, would be taken once a day and allow for the continuous and slow release of bupropion hydrochloride into the bloodstream over time. GSK had not independently developed an extended release

version of bupropion hydrochloride. The FDA approved GSK's Wellbutrin XL NDA in August 2003. GSK Stmt. ¶ 3, 5-6; Pls.' Stmt. Opp. ¶ 3, 5-6.

C. The Underlying Patent Litigations

There are two sets of underlying patent litigations relevant to the antitrust questions presented by the Wellbutrin Settlement: the cases between Biovail and the generic manufacturers that filed Paragraph IV Certifications (the "Biovail Litigations") – specifically the Anchen litigation and the cases between Andrx Pharmaceuticals and GSK and Anchen Pharmaceuticals, respectively (the "Andrx Litigations").

1. The Biovail Litigations

Between September 2004 and May 2005, four generic manufacturers – Anchen Pharmaceuticals, Inc. ("Anchen"), Abrika Pharmaceuticals, LLP ("Abrika"), Impax Laboratories, Inc. ("Impax"), and Watson Pharmaceuticals, Inc. ("Watson") – filed Abbreviated New Drug Applications ("ANDAs") with the FDA, seeking approval for generic versions of Wellbutrin XL. Each generic manufacturer filed a Paragraph IV Certification claiming non-infringement and served GSK and Biovail with that Certification; the Certifications provided notice of the ANDA filing and declared that the generic product would not infringe Biovail's patents. The Paragraph IV Certifications triggered

the 45-day window provided by the Hatch-Waxman Act for filing a patent infringement action. GSK Stmt. ¶ 7-9; Pls.' Stmt. Opp. ¶ 7-9.

In each case, Biovail filed a lawsuit against the generic manufacturers; GSK initially joined the lawsuits against Anchen and Abrika but withdrew from both cases in April 2005.[4] Biovail and GSK's December 21, 2004 lawsuit against Anchen, the first generic ANDA filer, triggered the 30-month stay in final FDA approval provided by the Hatch-Waxman Act. GSK Stmt. ¶ 10-11; Pls.' Stmt. Opp. ¶ 10-11.

Biovail's Hatch-Waxman lawsuit against Anchen is the case particularly relevant for evaluating the Wellbutrin Settlement, because only the settlement of the Anchen litigation involved any alleged reverse payment.

Anchen's ANDA did not quantify the amount of hydrochloric acid in its product on a per unit basis. The ANDA described a product that used hydrochloric acid as a "stabilizing agent" in the manufacturing process, but stated that the acid was "evaporated during processing" and indicated a "-" under the column designated "MG PER TABLET." Similarly, the percentage of hydrochloric acid was listed as "-" and

[4] On May 11, 2012, the Court found that the patent infringement actions brought by Biovail and GSK were not sham lawsuits and could not be the basis for antitrust liability. Wellbutrin XL, 2012 WL 1657734 at *17.

ingredients other than hydrochloric acid were shown in the ANDA to add up to 100.0% of the finished product. A list in the ANDA comparing the Anchen product to Wellbutrin XL did not include hydrochloric acid as an ingredient in Anchen's product. GSK Stmt. ¶ 12-13; Pls.' Stmt. Opp. ¶ 12-13.

In the Anchen litigation[5], Anchen and Biovail disputed the proper claim construction of the term "free of stabilizer", as used in Biovail's patent '341 patent. Anchen argued that the term "free of stabilizer" means the tablet is "free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet." In contrast, Biovail argued that "free of stabilizer" meant that "the core lacks an effective stabilizing amount of an organic or inorganic acid capable of inhibiting the degradation of bupropion hydrochloride ....." GSK Stmt. ¶ 12-13; Pls.' Stmt. Opp. ¶ 12-13.

On February 8, 2006, Judge Selna issued a Claim Construction Order finding that "free of stabilizer" meant that "the core is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet." Regarding Biovail's claim construction argument, Judge Selna's order stated:

[5] The Honorable James V. Selna presided over the Anchen litigation. GSK Stmt. ¶¶ 43, 44; Pls.' Stmt. Resp. ¶¶ 43, 44.

> Biovail's proposed definition of "stabilizer" is not found anywhere in the '341 patent, and actually contradicts the summary of the invention.

GSK Stmt. ¶ 13; Pls.' Stmt. Opp. ¶ 13; Am. Order on Cl. Constr. Hr'g 9.

The parties filed cross motions for summary judgment following Judge Selna's ruling on claim construction. In addition to its claim construction argument, Biovail argued (1) that it was entitled to rely on the representations in Anchen's ANDA when initiating suit and (2) that Anchen had an obligation under FDA regulations and guidance to quantify even residual amounts of hydrochloric acid ("HCl") if the HCI tended to stabilize the final tablet, which it had not done. Biovail argued, therefore, that Anchen's ANDA controlled the infringement inquiry and suggested that Anchen's product was not "free of stabilizer" as Judge Selna had determined.[6] GSK Stmt. ¶

[6] As the Court explained in detail in its decision granting summary judgment on the plaintiffs' sham litigation claims, FDA regulations require ANDA applicants to list all components used in the manufacture of the drug product, regardless of whether they appear in the drug product, as well as a statement of the composition of the drug product. 21 C.F.R. § 314.50. ANDA applicants must also "identify and characterize the inactive ingredients in the proposed drug product." Id. § 314.94(a)(9) (ii). In 2003, the FDA issued a "Guidance for Industry" that states:

> The function (i.e., role) of each component in the formulation should be stated. Components that are used in the manufacture of the drug product and do not appear in the finished drug product except at residual

14; Pls.' Stmt. Opp. ¶ 14; In re Wellbutrin XL Antitrust Litig., 2012 WL 1657734 at *10-11 (E.D.Pa. May 11, 2012).

Judge Selna issued a tentative minute order denying Anchen's motion, finding a genuine issue of material fact regarding whether Anchen's ANDA directly addressed the infringement inquiry. GSK Stmt. ¶ 14; Pls.' Stmt. Opp. ¶ 14.

After oral argument, however, Judge Selna granted Anchen's motion for summary judgment on August 1, 2006. The court found that there were no facts to show that Anchen's product was "free of stabilizer" since Anchen's product contained the stabilizer hydrochloric acid. Judge Selna denied Biovail's motion for reconsideration, and entered judgment on August 25, 2006. Biovail appealed to the Federal Circuit, challenging both the claim construction and summary judgment

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> levels (e.g., some solvents) should be identified as processing agents.
>
> The target amount of each component by definite weight or other measure should be provided on a per unit basis.

2003 FDA Guidance at 8. Thus, in its pre-NDA submission to the FDA, the brand manufacturers of the original Wellbutrin IR had quantified a target amount per tablet of 0.5 mg of hydrochloric acid in the 50 mg formulation and 1.0 mg in the 100 mg formulation of Wellbutrin IR. Similarly, the NDA submitted for Wellbutrin SR indicated a target amount per tablet of 16.20 mg of cysteine hydrochloride, a different kind of acid stabilizer. The instruction to quantify the target amount of each component does not apply, however, to "processing agents." 2003 FDA Guidance 9. The FDA guidance does not clearly define "processing agent." See In re Wellbutrin XL Antitrust Litig., 2012 WL 1657734 at *9-11.

orders. Biovail's appeal was docketed on September 25, 2006. GSK Stmt. ¶ 14-15; Pls.' Stmt. Opp. ¶ 14-15.

Following full briefing, the Federal Circuit held oral argument on September 5, 2007. During oral argument, the Federal Circuit engaged in extensive questioning of Anchen's counsel regarding whether Anchen was required to list the amount of "stabilizing" hydrochloric acid in a tablet of generic Wellbutrin XL if the hydrochloric acid was serving a function in the tablet. As the Court recognized in granting summary judgment on the plaintiffs' sham litigation claims, the panel asked whether Anchen had complied with FDA regulation. GSK Stmt. ¶ 15, 16, 19; Pls.' Stmt. Opp. ¶ 15, 16, 19; Anchen Fed. Cir. Tr. at 16-17; In re Wellbutrin XL Antitrust Litig., 2012 WL 1657734 at *10 n10 (E.D.Pa. May 11, 2012).

The Federal Circuit granted Biovail's motion to withdraw its appeal on June 11, 2008. GSK Stmt. ¶ 15, 19; Pls.' Stmt. Opp. ¶ 15, 19; Order Granting Mot. to Withdraw.

2. The Andrx Litigations

The litigations among Biovail and the generic manufacturers were not the only patent infringement actions impacting the marketing of both branded and generic 150mg Wellbutrin XL: both GSK and Anchen faced patent infringement actions by Andrx Pharmaceuticals ("Andrx").

On December 21, 2005, Andrx filed a patent infringement lawsuit against GSK, claiming that GSK's 150mg Wellbutrin XL product infringed Anchen's '708 patent. Andrx sought treble damages and an injunction preventing the sale of the allegedly infringing products. As a defense, GSK argued that the Andrx patent was invalid and that Andrx's inequitable conduct should prevent its recovery. The parties' motions for summary judgment were pending when the case settled in February 2007. Under the settlement, GSK paid Andrx $35 million for past use of the allegedly infringing technology and an ongoing royalty for future use. GSK Stmt. ¶ 44; Pls.' Stmt. Opp. ¶ 44; Andrx Pharms. V. GlaxoSmithKine, PLC, No. 05-23264 (S.D. Fla.); GSK Exs. 5, 18, 21-22.

On November 28, 2006, Andrx filed a patent infringement lawsuit against Anchen, claiming that Anchen's generic 150mg Wellbutrin Xl product would infringe Andrx's '708 patent. Andrx sought both preliminary and permanent injunctions to prevent the sale of generic Wellbutrin XL.[7] The district court in Andrx had denied Andrx's motion for a temporary restraining order but had not ruled on Andrx's motion for a

[7] In November 2006, Andrx was acquired by Watson Pharmaceuticals; Watson had filed an ANDA to market generic 150mg Wellbutrin XL. Andrx was therefore not a "non-practicing" entity incapable of getting injunctive relief, as the plaintiffs have claimed. GSK Ex. 24.

preliminary injunction at the time the settlement was reached; the parties were still briefing the preliminary injunction issues. Andrx Pharms. v. Anchen Pharms., No. 06-7552 (C.D. Cal); GSK Ex. 23; Pls. Ex. 858; GSK Stmt. ¶ 45; Pls.' Stmt. Opp. ¶ 45.

Anchen was limited in its ability to defend the patent infringement lawsuit: Anchen's CEO, Chih-Ming Chen, was the inventor of the Andrx patent and had assigned the patent rights to Andrx. Anchen's marketing partner Teva Pharmaceuticals U.S.A., Inc. ("Teva") had therefore recognized that the doctrine of "inventor estoppel would prevent Anchen from raising an argument as to the invalidity of the '708 patent," which was the defense used by GSK. GSK Stmt. ¶ 82; Pls.' Stmt. Opp. ¶ 82; Holding Dep. Tr. 65:3-19.

The Andrx lawsuits were settled as part of the Wellbutrin Settlement, discussed below. GSK Stmt. ¶ 45; Pls.' Stmt. Opp. ¶ 45.

D. Biovail's Citizen Petition[8]

On December 20, 2005, Biovail filed a citizen petition with the FDA; GSK did not join the filing. The citizen petition

[8] The Court previously found that Biovail's citizen petition was not an independent basis for antitrust liability. In re Wellbutrin XL Antitrust Litig., 2012 WL 1657734 (E.D.Pa. May 11, 2012).

requested that the FDA require any ANDA for a generic version of Wellbutrin XL to meet four criteria: (1) all bioequivalence trials should calculate and evaluate parameters based on concentrations of the parent drug and active metabolites; (2) any generic formulation should be shown to be bioequivalent to Wellbutrin XL, sustained release and immediate release bupropion; (3) the bioequivalence studies should be conducted at steady-state evaluating the performance of the dosage form based on AUC, Cmax, Cmin; and (4) data using the FDA's approach for evaluating the effect of alcohol on the performance of the controlled-release dosage form should be required to ensure the absence of "dose dumping." The FDA granted in part and denied in part the citizen petition. GSK Stmt. ¶ 45; Pls.' Stmt. Opp. ¶ 45; In re Wellbutrin XL Antitrust Litig., 2012 WL at 1657734 *21.

E. Anchen/Teva's Production of Generic Wellbutrin

Anchen qualified for the Hatch-Waxman Act's 180-day exclusivity period for generic Wellbutrin XL because it was the first to file an ANDA with the FDA.[9] Anchen waived its

[9] Anchen was a new company and, at the time it filed its ANDA for generic Wellbutrin XL, it had never launched or received FDA approval for a product. GSK Stmt. ¶ 21; Pls.' Stmt. Opp. ¶ 21.

exclusivity for 300mg Wellbutrin XL in favor of Impax.[10] In December 2006, Anchen and Teva entered a Distribution and Supply Agreement that authorized Teva to market Anchen's 150mg version of generic Wellbutrin XL. The agreement required Teva to launch generic Wellbutrin XL no later than the later of 14 days after Anchen received final FDA approval or thirty days after Teva received the product for launch. GSK Ex. 2; Pls. Ex. 844; GSK Stmt. ¶ 20, 26; Pls.' Stmt. Opp. ¶ 20, 26.

Anchen and Teva had discussed the possible at risk launch of 150mg generic Wellbutrin XL, anticipating a launch in the first quarter of 2007. Pls. Exs. 772, 813, 846, 922, 899, 915, 770.

In December 2006, the FDA approved Anchen's ANDA for both the 300mg and 150mg versions of generic Wellbutrin XL. Anchen's ANDA listed its Goodyear facility as the intended manufacturing site for its generic Wellbutrin XL product. GSK Stmt. ¶ 22-25; Pls.' Stmt. Opp. ¶ 22-25.

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[10] In January 2006, Anchen had entered into an agreement with Teva and Impax whereby it allowed Teva to market any generic 300mg Wellbutrin XL made under Anchen's ANDA. If Anchen could not manufacture 300mg generic Wellbutrin XL, then Anchen would either relinquish its 180-day exclusivity or waive that exclusivity in favor of Impax. GSK Stmt. ¶ 23; Pls.' Stmt. Opp. ¶ 23.

Biovail had not filed an infringement action against Impax within the 45-day window provided by the Hatch-Waxman Act, so no 30-month stay of approval applied. Pls. Ex. 803; Pls. Stmt. Opp. ¶ 9, 23.

During the FDA's January 2007 inspection of Anchen's Goodyear manufacturing site, the FDA learned for the first time that Anchen was expecting to use its Jeronimo manufacturing site — rather than the Goodyear manufacturing site — to manufacture its generic Wellbutrin XL product. GSK Ex. 72.

On May 29, 2007, Anchen received the FDA's Establishment Inspection Report from the January 2007 Goodyear facility inspection. The report explained that the change involving the inspection facility "would require a prior approval supplement if the facility had never been inspected by FDA," as was the case with Anchen's Jeronimo facility.[11] The FDA told Anchen that it could provide notice of its manufacturing facility change through a "Changes Being Effected in 30 Days" supplement, known as a "CBE-30". Anchen filed a CBE-30 to add the Jeronimo facility to its ANDA on June 1, 2007; on June 9, 2007, Anchen provided the FDA with requested drug-release stability data. GSK Stmt. ¶ 31-42; Pls.' Stmt. Opp. ¶ 31-42; GSK Exs. 72, 74.

[11] The plaintiffs' assertion that there was "no regulatory block to manufacturing and selling" Anchen's generic Wellbutrin XL is contradicted by the record. Pls. Opp'n at 11. Although the plaintiffs have argued that the Goodyear and Jeronimo facilities were the "same facility" for FDA inspection purposes, and that Anchen believed such a change only needed to be reported in Anchen's annual report to the FDA, both the FDA's and Anchen's conduct suggests otherwise. It is undisputed that upon learning of the manufacturing site change, the FDA in fact required Anchen to request, and Anchen did request, prior regulatory approval. GSK Ex. 72.

The FDA orally accepted Anchen's CBE-30 on June 11, 2007. This acceptance was effective on June 12, 2007. Anchen could not market generic Wellbutrin XL until the FDA accepted Anchen's CBE-30. Choy Dep. Tr. 32:14-33:2; GSK Ex. 75.

F. The Wellbutrin Settlement

The Wellbutrin Settlement was executed on February 9, 2007 and resolved the Wellbutrin XL Hatch-Waxman litigations brought by Biovail against generic manufacturers Teva, Anchen, Impax, and Watson, as well as the patent litigation brought by Andrx against the generic manufacturers. The Wellbutrin Settlement was comprised of multiple agreements: the Omnibus Agreement (in which GSK was listed as an intended third party beneficiary); the Anchen Definitive Agreement; the Teva License Agreement; the Impax Settlement Agreement; and the Third Amendment, an agreement between GSK and Biovail by which GSK relinquished its right to launch an authorized generic during the 180-day exclusivity period provided by the Hatch-Waxman Act. GSK Stmt. ¶ 52, 54; Pls.' Stmt. Opp. ¶ 52, 54.

The following lawsuits were pending at the time of the Wellbutrin Settlement: Biovail's appeal of the summary judgement decision in the Anchen litigation; the Watson, Impax, and

Abrika[12] lawsuits brought by Biovail; the Andrx lawsuits brought against GSK and Anchen; and the action filed by Biovail against the FDA pertaining to its Citizens Petition (in which Teva, Anchen, and Impax had intervened as defendants). Biovail Labs., Inc. v. Anchen Pharms., Inc., 06-1641 (Fed. Cir.); Biovail Labs. Int'l SRL v. Watson Labs, Inc., No. 05-7799 (S.D.N.Y.); Biovail Labs. Int'l SRL v. Impax Labs. Inc., No. 05-1085 (E.D. Pa.); Biovail Labs., Inc. and SmithKline Beecham Corp. v. Abrika, LLP, et al., No. 04-61704 (S.D. Fla.); Andrx Pharms. v. GlaxoSmithKline, PLC, No. 05-23264 (S.D. Fla.); Andrx Pharms, LLC v. Anchen Pharms., Inc., No. 06-07552 (C.D. Ca.); Minute Orders, Biovail Corp. v. U.S. Food & Drug Admin., No. 06-1487 (D.D.C. Aug. 24, 2006 and Jan. 2, 2007) (granting Teva, Anchen, and Impax's unopposed motions to intervene as defendants). Biovail's appeal of the Anchen litigation remained pending following the execution of the Wellbutrin Settlement. GSK Stmt. ¶ 53; Pls.' Stmt. Opp. ¶ 53.

The Wellbutrin Settlement was initially negotiated among Biovail, Teva, Anchen, and Impax without GSK's

[12] Biovail separately settled the Abrika litigation later. The Abrika settlement allowed for entry upon the expiration of Anchen's 180-day exclusivity period and there was no payment made in exchange for the agreement. Abrika received final FDA approval to market its 150mg version of generic Wellbutrin XL on August 15, 2008. GSK Stmt. ¶ 55; Pls.' Stmt. Opp. ¶ 55.

involvement, with Teva taking the lead in negotiating for the generic manufacturers. GSK became directly involved in the settlement discussions in December 2006: at a December 20 and 21 hearing in the Impax Hatch-Waxman litigation, the Honorable Anita B. Brody, who was presiding over the Impax litigation, requested that GSK participate based on the parties' representation that GSK was necessary to resolving the litigation because of its exclusive rights to market an authorized generic of Wellbutrin XL.[13] GSK Stmt. ¶ 56-57, 59; Pls.' Stmt. Opp. ¶ 56-57, 59; Brannon Dep. Tr. 131:17-132:6 ("[T]here was a federal Judge saying 'I need you to show up, and I need you to work with these parties to make a settlement possible.").

Following Judge Brody's request, GSK joined the settlement discussions. Following settlement discussions, GSK agreed to cede licensing and manufacturing rights to its

[13] Prior to GSK's direct participation, GSK and Biovail had discussed the rights GSK may waive in a settlement and had shared draft settlement documents prior to GSK's actual involvement in settlement negotiations. For example, in early 2006 GSK informed Biovail that it was willing to "waive certain valuable rights to facilitate Biovail's desire to settle certain patent litigation," including its right to market an authorized generic. On December 16, 2006, counsel for GSK and Biovail discussed the settlement negotiations; on December 17, 2006, GSK received a draft of the settlement from Biovail for review. GSK Stmt. ¶ 56-57, 59; Pls.' Stmt. Opp. ¶ 56-57, 59.

authorized generic Wellbutrin XL. GSK also agreed to sublicense the Andrx patent license to Biovail. Initially, GSK was only willing to finalize the agreement if Judge Brody found the Wellbutrin Settlement procompetitive; GSK, ultimately acquiesced on this point, however, when Judge Brody refused to review the settlement. GSK Stmt. ¶ 60-63, 65; Pls.' Stmt. Opp. ¶ 60-63, 65; Brannon Dep. Tr. 190:17-191:4; GSK Ex. 62.

Both parties have recognized that the Wellbutrin Settlement was a complex agreement with numerous provisions.[14] The following provisions are at issue in this action:

1. The Wellbutrin Settlement Allowed the Anchen Litigation to Continue

The Wellbutrin Settlement allowed the Anchen litigation, which was on appeal in the Federal Circuit when the settlement was reached on February 9, 2007, to continue. At the time the Wellbutrin Settlement was reached, the appeal was not fully briefed oral argument on the Anchen appeal was

[14] The Wellbutrin Settlement also resolved the Watson litigation. The Watson settlement allowed for entry after Anchen's 180-day exclusivity period expired. Watson had received final FDA approval to market is 150mg version of generic Wellbutrin XL on January 31, 2007.

scheduled for September 2007.[15] GSK Stmt. ¶ 68; Pls.' Stmt. Opp. ¶ 68.

2. Regardless of the Outcome of the Anchen Litigation, the Wellbutrin Settlement Allowed Generic Entry No Later Than May 30, 2008

The Wellbutrin Settlement provided that Teva could enter the market with generic Wellbutrin XL immediately upon Anchen prevailing in its underlying patent litigation (either through a showing of patent invalidity or a showing of non-infringement, or on May 30, 2008, whichever date was earlier.[16] The Wellbutrin Settlement allowed Teva to market generic Wellbutrin XL on May 30, 2008, even if Biovail won its appeal. GSK Ex. 6 at 3.16; GSK Stmt. ¶ 68; Pls.' Stmt. Opp. ¶ 68; Cremieux Dep. Tr. 335:12-24.

Although internal GSK and Biovail documents recognized that the May 30, 2008 entry date was the most "likely" outcome, all documents simultaneously recognized that there were "defined

[15] The plaintiffs argued in their opposition to GSK's motion for summary judgment that it was inappropriate for GSK not to notify the Federal Circuit that it had reached a settlement. It is unclear, however, how this is relevant to the antitrust question currently before the Court.

[16] The Wellbutrin Settlement included seven total "triggers" for generic entry. See GSK Ex. 6 at 3.16.

exceptions" to that date, including the exception of an Anchen litigation victory.[17] Id.; Pls. Exs. 857, 589, 805, 821, 771.

3. The Wellbutrin Settlement Included a "No Authorized Generic" Promise

The Wellbutrin Settlement guaranteed Teva the exclusive right to sell 300mg generic Wellbutrin XL (which Teva had launched at risk) from December 13, 2006 through June 12, 2007, and included an agreement that GSK would not market an authorized generic 150mg Wellbutrin XL until Anchen's 180-day exclusivity period expired. Because GSK had the sole authority to decide whether to pursue an authorized generic, GSK's agreement was necessary to effectuate the no authorized generic promise in the Wellbutrin Settlement. GSK Stmt. ¶ 56, 65, 75; Pls.' Stmt. Opp. ¶ 56, 65, 75.

One constant throughout the negotiations was Teva's insistence that any settlement involve an agreement that GSK not produce an authorized generic version of Wellbutrin XL during the 180-day exclusivity period. Teva's representatives

[17] The plaintiffs also rely on GSK and Biovail's 2007 SEC 20-F filings, which described the settlement as "allowing generic entry for the 150mg form in 2008." Pls. Exs. 698, 696. The filings, however, were made in February and March of 2008, respectively, so at that point it would have been impossible for the companies to report anything other than a 2008 generic launch.

expressed the (mistaken) view that the Hatch-Waxman 180-day exclusivity period had been designed to ensure that no authorized generic would be marketed during that time period.[18]

For example, a Stipulation and [Proposed] Order that was drafted but ultimately not submitted to the court by the parties to the Impax litigation noted that the parties tried to negotiate a settlement without an exclusive license to Teva during the first 180 days but "[w]ithout this provision, there would be no settlement of this matter." All drafts of the Wellbutrin Settlement included the no authorized generic agreement. GSK Stmt. ¶ 61-63, 77-78; Pls.' Stmt. Opp. ¶ 61-63, 77-78; Brannon Dep. Tr. 129:14-130:5 ("Teva...was very adamant that there were certain issues that were deal breakers for them, and they required GSK to waive certain rights if there was going to be any settlement at all."); Brannon Dep. Tr. 96:14-16 ("Teva informed us that there could be no settlement of the litigation unless GSK waived back to Biovail the right to launch an authorized generic."); Brannon Dep. Tr. 96:20-97:8 ("Teva stated it would not settle the litigation unless GSK waived its right to launch an authorized generic during the first 180 days of generic entry.").

[18] Teva's antitrust counsel explained that it was Teva's "publicly stated" view at the time of the settlement that the Hatch-Waxman Act intended that "the first filing generic would be the only generic on the market." Holding Dep. Tr. 73:24-74:17.

4. The Wellbutrin Settlement Resolved the Andrx Litigations and Granted Anchen a Sublicense for the Andrx Patent

The Wellbutrin Settlement included sublicenses through Biovail to the license GSK obtained from Andrx with regard to the 150 mg product for each of the generic manufacturers. Teva took the position during the negotiation of the Wellbutrin Settlement that it needed "the full freedom to operate" without concern over patent infringement claim by Andrx. Additionally, because Anchen's CEO, Chih-Ming Chen, was the inventor of the Andrx patent (he had left Andrx to found Anchen), Teva had expressed concern that the theory of inventor estoppel would prevent Anchen from raising an argument as to the invalidity of the '708 patent in the Andrx v. Anchen litigation. GSK Stmt. ¶ 80-82; Pls.' Stmt. Opp. ¶ 80-82.

GSK and Andrx had settled the Andrx litigation during negotiation of the Wellbutrin Settlement. GSK agreed to pay $35 million in full satisfaction of Andrx's claims for sales of Wellbutrin XL occurring prior to February 1, 2007, and a 3.5% royalty of its net sales after February 1, 2007. Essential for Anchen, the settlement agreement also gave GSK the right to grant a sublicense of the Andrx '708 patent to Biovail, which could then sublicense the '708 patent to the generic companies which would pay a royalty to Andrx. The sublicense provisions

made it unnecessary for Anchen, Teva, and Andrx independently to settle the Andrx v. Anchen litigation and ensured that Anchen and Teva would not be prevented from launching their generic Wellbutrin XL.[19] Teva had expected that GSK's settlement with Andrx would include the sublicense provisions. GSK Stmt. ¶ 46-47; Pls.' Stmt. Opp. ¶ 46-47; GSK Ex. 5, 64.

Anchen, Teva, and Andrx communicated regarding a possible settlement to the Andrx litigation.[20] Teva was explicit in those communications that any discussions were "subject to the overall deal process" of the Wellbutrin Settlement. Pls.' Stmt. Opp. ¶ 45; Pls. Ex. 864.

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[19] The plaintiffs do not offer factual support for their allegation that "suddenly, and without explanation, the '708 patent license 'got put into'" the Wellbutrin Settlement. Rather, the generic manufacturers contemplated that the Wellbutrin Settlement would resolve the Andrx litigation. See Pls. Ex. 864; GSK Ex. 64.

Further, the plaintiffs make much of the fact that Andrx and Anchen may have possibly negotiated a settlement separate from the Wellbutrin Settlement. It is undisputed, however, that such a settlement was never memorialized or reached.

These points serve as examples of the speculation the Court cannot consider in deciding the motions for summary judgment.

[20] Anchen told Andrx that it was planning a January 12, 2007 at risk launch of its 150mg product; Anchen said it was using its potential launch to facilitate settlement discussions with Andrx. GSK Stmt. ¶ 45; Pls.' Stmt. Opp. ¶ 45.

5. Biovail Agreed to Guarantee Teva a Supply of Wellbutrin XL

The Wellbutrin Settlement also included a supply provision that required Biovail to supply Teva with Wellbutrin XL if (1) Teva faced limited supply from Anchen or (2) the FDA ruled on Biovail's citizen petition in a way that made generic Wellbutrin XL non-compliant. Biovail was obligated to provide up to 75 million pills if Anchen faced supply issues, and an unlimited amount of pills if the outcome of the citizen petition made generic Wellbutrin XL non-compliant. The supply option would provide Teva with access to immediate supply of Wellbutrin XL if Anchen prevailed on appeal and Teva was allowed to enter the market. GSK Stmt. ¶ 69, 73; Pls.' Stmt. Opp. ¶ 69, 73.

Teva requested that the backup supply provision be generous because Teva "need[ed] to be able to sell on the trigger date," which "require[d] reasonable preparations".[21] Teva's 30(b)(6) witness testified that "as a business matter" it made sense to include the supply provision because Teva would not want to have uncertainty in supply to patients. The supply provision was extensively negotiated among GSK, Biovail, and the generic manufacturers. Bauer Dep. Tr. 100:3-7, 112:18-21; Pls. Ex. 886; GSKWXLC00000808; BIOVAIL0630819; TEVA_WXL08669.

[21] In an email from Teva's General Counsel to counsel for Biovail and GSK, Teva's counsel stated that "[t]he supply commitment can't be more watered down and useless – this wasn't the intent." Pls. Ex. 886.

6. The Wellbutrin Settlement Also Contained Provisions for Enhanced FTC Review

Under the provisions of the Medicare Modernization Act Section 1112(a) of Subtitle B of Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), parties to a reverse payment patent litigation settlement are required to submit the settlement agreement and all related agreements to the FTC within 10 business days of entry of the agreement.

The Wellbutrin Settlement required the parties to submit the agreement to the Federal Trade Commission ("FTC") for review within two days of finalizing the agreement. The parties to the settlement were also required to respond to any FTC inquiries, and if the FTC raised any concerns about the settlement to either revise the settlement as directed by the FTC or terminate the agreement. GSK had equal rights to all other parties to the agreement to terminate the Wellbutrin Settlement if it faced FTC challenges. GSK Stmt. ¶ 85-86; Pls.' Stmt. Opp. ¶ 86-86.

On February 20, 2007, after submitting the Wellbutrin Settlement to the FTC, Biovail, Anchen, Teva, and Impax met with senior FTC counsel to review the terms of the agreements. Biovail and the generic companies provided the FTC with a total of twenty four documents that comprised the Wellbutrin

Settlement, as well as a list of parties to the transaction, the patents asserted, and the lawsuits involved. The parties did not provide a written summary of the agreements for the FTC. GSK Stmt. ¶ 87; Pls.' Stmt. Opp. ¶ 87.

At the meeting, the parties presented the central features of the Wellbutrin Settlement to the FTC: (i) the back-up supply provision to Teva (including the provision that allowed for supply in the event of an impediment as a result of Biovail's citizen petition); (ii) the Andrx sublicenses to Teva, Anchen, and Impax; and (iii) the early trigger date for the 150 mg product in the event the Anchen appeal was decided in Anchen's favor prior to the negotiated May 30, 2008 date. During the meeting, Teva's antitrust counsel explained to the FTC that the Wellbutrin Settlement "relieved Teva of the potential enormous liability that" launching the 300mg product at risk in December 2006 had created. Teva's counsel explained to the FTC that this feature distinguished the Wellbutrin Settlement "from a typical Hatch-Waxman settlement" and, as a result, "the FTC in particular should not want to take any action that would upset this agreement because it's procompetitive [to] launch at risk, and the FTC shouldn't take actions that might deter Teva from launching at risk, and making it harder to Teva to settle following a launch at risk could be a deterrent." GSK Stmt. ¶ 88-89; Pls.' Stmt. Opp. ¶ 88-89.

Teva's counsel also explained to the FTC that GSK had agreed to relinquish its right to launch an authorized generic during Teva's 180-day exclusivity period.[22] GSK Stmt. ¶ 88-89; Pls.' Stmt. Opp. ¶ 88-89.

On March 2, 2007, the FTC notified Biovail and the generic manufacturers that it would not investigate or take any further action regarding the Wellbutrin Settlement. GSK Stmt. ¶ 91-92; Pls.' Stmt. Opp. ¶ 91-92.

II. Procedural History

In May 2008, direct and indirect purchasers of Wellbutrin XL filed claims against defendants Biovail Corporation, Biovail Laboratories, Inc., and Biovail Laboratories International (together, "Biovail") and GSK, alleging that Biovail and GSK conspired to prevent generic versions of Wellbutrin XL from entering the American market by filing sham patent infringement lawsuits and a citizen petition

[22] The plaintiffs offer no factual support for their allegation that the parties to the Wellbutrin Settlement misled the FTC. It is undisputed that the FTC was provided with the entire Wellbutrin Settlement; the plaintiffs criticize the parties for failing to provide a "summary" of the agreements to the FTC, but it is unclear what benefit this would have had when the agency had access to the entire agreement. The parties to the settlement also met with both the head of and the deputy assistant director to the FTC's Health Care Division, which is specifically tasked with reviewing Hatch-Waxman patent settlement agreements. Holding Dep. Tr. 40:19-43:2.

with the Food and Drug Administration ("FDA"), and entering into agreements with generic manufacturers to settle the lawsuits. The Court certified the class of direct purchasers on August 11, 2011, and the class of indirect purchasers on August 15, 2011. The Court decertified the indirect purchaser class on June 30, 2015.

On May 11, 2012 the Court granted Biovail and GSK's motions for summary judgment as to the plaintiffs' sham litigation and citizen petition claims, but deferred deciding the motions as to the settlement agreements. It was not clear until the briefing on the motions for summary judgment that the plaintiffs were arguing that the settlement agreements were an independent violation of the antitrust laws as opposed to an enhancement of the anticompetitive effects of the alleged sham litigation. The complaint had not explicitly set out this theory of liability. The legality of the settlement agreements, therefore, had not been fully briefed by the parties nor had complete discovery been taken on this topic.

On August 3, 2012, the Court approved the parties'[23] stipulated scheduling order for limited fact and expert discovery pertaining to the settlement agreements in light of

[23] The Court approved Biovail's settlement with the plaintiff classes on November 7, 2012, leaving GSK as the only defendant remaining in the case.

the Third Circuit's decision in In re K-Dur Antitrust Litigation, 686 F.3d 197 (3d Cir. 2012).

On November 7, 2012, the Court stayed the case pending the Supreme Court's decision on whether to grant certiorari in In re K-Dur Antitrust Litigation, and/or FTC v. Watson Pharmaceuticals, 677 F.3d 1298 (11th Cir. 2012). On February 22, 2013, the Court continued the stay until the Supreme Court's decision in the FTC action ("Actavis") on which the Court had granted certiorari.

The Supreme Court issued its decision in Actavis on June 17, 2013. The Supreme Court rejected both the Third Circuit's "quick look" antitrust analysis (finding reverse payment settlements presumptively unlawful) and the Eleventh Circuit's "scope of the patent" test. Rather, the Supreme Court found that reverse payment settlements are to be subject to the traditional rule of reason analysis. FTC v. Actavis, 133 S.Ct. 2233 (2013).

In light of the Supreme Court's decision in Actavis, on January 16, 2014, the Court instructed the parties to report how they wanted to proceed. The parties continued discovery, and the motions for summary judgment were fully briefed on July 9, 2015 date. The Court held oral argument on the motions on July 29, 2015.

III. Analysis[24]

GSK has moved for summary judgment on the following grounds: (1) The Supreme Court's decision in Actavis does not apply to the Wellbutrin Settlement because the underlying patent litigation continued[25]; (2) there is no evidence in the summary judgment record that the Wellbutrin Settlement was anticompetitive under the rule of reason; (3) the plaintiffs have failed to make the requisite showings of antitrust injury and causation demanded in private antitrust litigation; (4) GSK

[24] Under Federal Rule of Civil Procedure 56, a party moving for summary judgment must show that there is no genuine issue as to any material fact and that judgment is appropriate as a matter of law. Fed. R. Civ. P. 56(a). The moving party bears the initial burden of demonstrating the absence of any genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once a properly supported motion for summary judgment is made, the burden shifts to the nonmoving party, who must set forth specific facts showing that there is a genuine issue for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986). The mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. Id. at 247–48.

The Court's analysis applies to both the plaintiffs' federal and state law claims except where otherwise noted.

[25] In its motion for summary judgment, GSK also argued that Actavis does not apply to non-cash payments. This argument has been foreclosed by the Third Circuit's ruling in King Drug Co. of Florence, Inc. v. Smithkline Beecham, Corp., in which the court found that a no authorized generic agreement "falls under Actavis's rule because it may well represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition." 791 F.3d 388 at 393, (3d Cir. 2015).

was not a co-conspirator to any allegedly anticompetitive scheme; and (5) the settlements in the Watson and Abrika litigations cannot be a basis for the plaintiffs' recovery[26].

A. The Applicability of Actavis to the Wellbutrin Settlement

GSK has argued that the Wellbutrin Settlement, because it allowed the underlying patent litigation to continue, should not be subject to the rule of reason analysis that the Supreme Court in Actavis held should be applied to reverse payment settlements. See Oral Arg. Tr. 173-75; GSK Br. at 20-21; GSK Reply Br. at 4-5. The Court finds some support for GSK's argument.

The Supreme Court in Actavis did outline a specific type of competitive harm that justified antitrust scrutiny for reverse payment settlements: that the defendant in the patent infringement lawsuit would abandon its patent claim, eliminating the risk of patent invalidation or a finding of invalidity. F.T.C. v. Actavis, 133 S.Ct. at 2236; King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 404 (3d Cir. 2015)(hereinafter "Lamictal"). This limited definition of

[26] Because the Court has found that the Wellbutrin Settlement as a whole is not anticompetitive, it is not necessary to address whether these settlements – which were negotiated entry date only settlements in which no payment was made – are a basis for recovery.

anticompetitive harm also appears in the Supreme Court's characterization of reverse payment patent settlements as those "in which A, the plaintiff, pays money to defendant B purely so B will give up the patent fight." Id.

In finding that Actavis applies to no authorized generic agreements, the Third Circuit in Lamictal echoed Actavis and explained that "it is the prevention of that risk of competition — eliminating 'the risk of patent invalidation or a finding of non-infringement' by 'paying the challenger to stay out' of the market (for longer than the patent's strength would otherwise allow) — that 'constitutes the relevant anticompetitive harm,' which must then be analyzed under the rule of reason." Lamictal, 791 F.3d at 404 (quoting Actavis, 133 S.Ct. at 2236-37).

Anticompetitive harm as the elimination of patent litigation reflects the careful and imperfect interplay between patent law and antitrust law. Patent law grants monopolies, and patents, therefore, act as lawful restraints of trade. See Actavis, 133 S.Ct. at 2230-31 (quoting United States v. Line Material Co., 333 U.S. 287, 308 (1948))("[A] valid patent excludes all except its owner from the use of the protected process or product."). In tension with patent law's grant of exclusivity, the antitrust laws seek to prevent restraints of trade. Actavis, 133 S.Ct. at 2230-31. Patents exist as one of

the exceptions to the antitrust laws' ban on restrains of trade. Lamictal, 791 F.3d at 394 ("A patent...is an exception to the general rule against monopolies...")(internal quotations omitted).

The Hatch-Waxman Act – under which the Biovail patent litigation was brought – also embodies this tension. The Act "balance[s] the goal of making available more low cost generic drugs...with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement." Lamictal, 791 F.3d at 394 (quoting H.R. Rep. No. 98-857). It has a "general procompetitive thrust" and implicitly encourages challenges to patents' validity. See Id. at 2232. But at the same time, the Hatch-Waxman Act also allows for stiff penalties for the launch of "at risk" generic drugs – those marketed prior to the resolution of the patent litigation; an at risk launch may subject a generic manufacturer to steep infringement damages. This reflects a recognition that a valid and infringed patent maintains its lawfully granted preclusive scope – a lawfully granted preclusive scope that is protected from the antitrust laws.

In Actavis, the Supreme Court explained that it is the joint objective of both patent law and antitrust law to eliminate "unwarranted patent grants" because the public should not be required to "pay tribute to would-be monopolists without

need or justification." Actavis, 133 S.Ct. at 2234. Patent litigation – specifically the litigation contemplated by the Hatch-Waxman Act – serves as a check against potentially "unwarranted patent grants", and settlements that end patent litigation with a payment that causes delayed generic entry may disrupt this check. Actavis, 133 S.Ct. at 2231 ("The Paragraph IV litigation in this case put the patent's validity at issue, as well as its actual preclusive scope. The parties' settlement ended that litigation."); see also Lamictal, 791 F.3d at 405 (finding that a no authorized agreement can be anticompetitive where it induces "the generic to abandon the patent fight, [and] the chance of dissolving a questionable patent vanishes (and along with it, the prospects of a more competitive market).")

There is a critical distinction between the Wellbutrin Settlement and the settlements at issue in Actavis, Lamictal, and every other reverse payment patent settlement addressed by courts in this district post-Actavis: the generic manufacturer Anchen did not "abandon its claim" and continued to litigate the patent litigation. The Wellbutrin Settlement required the underlying patent litigation to continue, maintaining the risk of a finding of patent invalidity or non-infringement and providing for immediate generic entry upon such a finding. The settlement preserved for Anchen, therefore, the possibility – and corresponding benefits – of a victory in the underlying

patent suit; the settlement preserved for Biovail the possibility – and corresponding risks – of a loss in the underlying patent lawsuit. Given this key and distinguishing provision of the settlement, the Wellbutrin Settlement does not present the same antitrust concerns that motivated the court in Actavis to subject the settlement to antitrust scrutiny.

Indeed, the Supreme Court and the Third Circuit have classified certain other types of patent lawsuit settlements as being outside the scope of antitrust scrutiny. For example, in Actavis the Supreme Court explained that parties may lawfully settle "by allowing the generic manufacturer to enter the patentee's market prior to patent expiration, without the patentee paying the challenger to stay out prior to that point.") Actavis, 133 S.Ct. 2237. The Supreme Court did not seek to make it impossible to settle Hatch-Waxman patent infringement actions. Actavis, 133 S.Ct. 2237; see also Lamictal, 791 F.3d at 408.

Such settlements, which are without question agreements in restraint of trade, are not subject to antitrust scrutiny because they allow the strength of the patent claims, not extra-litigation considerations, to control the outcome. At oral argument, the plaintiffs' counsel agreed that these settlements are not anticompetitive because the strength of the patent dictates the entry date. See Oral Arg. Tr. 178

("[W]ithout money you are negotiating back and forth over the actual strength of the patent...").

Similarly, in the Wellbutrin Settlement, the patent itself remained controlling. Unlike a typical reverse payment patent settlement, in which the settlement itself keeps the patent from playing a role in the entry date, a finding of invalidity or non-infringement – a finding on the patent's strength – dictated the entry date for generic Wellbutrin XL.[27]

The Court, however, is reluctant to apply the mechanical test suggested by GSK, whereby any reverse payment that allows the underlying patent litigation to continue is automatically exempt from the antitrust laws. Such a test could foreseeably create an easily exploited antitrust loophole for reverse payment settlements. Such "formalistic approach[s]" are unhelpful in antitrust actions. See United States v. Dentsply Int'l, Inc., 399 F.3d 181, 189 (3d Cir. 2005).

The Court, therefore, will analyze the Wellbutrin Settlement under the rule of reason, as the Supreme Court instructed in Actavis.

[27] In the event the Anchen litigation was not concluded before May 2008, or was concluded in favor of Biovail, a trigger date provided for the market entry of generic Wellbutrin XL.

B. The Rule of Reason Analysis

GSK argues that the plaintiffs have not and cannot demonstrate that the Wellbutrin Settlement was anticompetitive under the rule of reason. The rule of reason asks three progressive questions of challenged agreements: (1) does the agreement have anticompetitive effects; (2) if so, are there procompetitive justifications for the agreement; and (3) can the plaintiffs present evidence that the challenged conduct is unnecessary to achieve those justifications. Because there is no genuine issue of material fact as to the answers to these questions, and a reasonable jury could not find the Wellbutrin Settlement to be anticompetitive under the rule of reason, the Court grants GSK's motion for summary judgment.

In Actavis, the Supreme Court instructed district courts to apply the traditional rule of reason analysis when evaluating reverse payment settlements. Actavis, 133 S.Ct. 2237-38 ("We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation."); see also Lamictal, 761 F.3d at 403 ("courts should apply the traditional rule-of-reason analysis").

Under the traditional rule of reason analysis, the plaintiffs bear the initial burden of showing that the challenged agreement "produced adverse, anticompetitive effects within the relevant product and geographic market." Lamictal,

791 F.3d at 412 (quoting United States v. Brown Univ., 5 F.3d 658, 668-669 (3d Cir. 1998). If the plaintiffs succeed in showing anticompetitive effects, the burden then shifts to the defendant to show "that the challenged conduct promotes a sufficiently pro-competitive objective." Id. The plaintiffs may then rebut the defendant's procompetitive justifications as "not reasonably necessary to achieve the stated objective." Id.

In conducting the rule of reason analysis, the Court will evaluate the Wellbutrin Settlement's reasonableness at the time it was entered into. See Polk Bros., Inc. v. Forest City Enterprises, Inc., 776 F.2d 185, 189 (7th Cir. 1985); SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1207 (2d Cir. 1981). The Court will also evaluate the settlement as a whole, and not in a piecemeal, provision-by-provision approach. See In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 752 (E.D.Pa. 2014); see also In re Lipitor Antitrust Litig., 46 F. Supp. 3d 523, 548-49 (E.D.Pa. 2014). The Wellbutrin Settlement was negotiated as a whole, agreed to as a whole, and went into effect as a whole, so failing to evaluate the agreement as a whole would overlook context essential to determining any possible anticompetitive effects.

To survive summary judgment, the plaintiffs must present a "genuinely disputed issue of material fact" as to the elements of the rule of reason analysis; only then will the case

go to a jury. In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 316 & n.12 (3d Cir. 2010); see also In re Chocolate Confectionary Antitrust Litig., __ F.3d __, 2015 WL 5332604 at *6 (3d Cir Sept. 15, 2015)("[T]he summary judgment standard in antitrust cases is generally no different from the standard in other cases."); Lamictal, 791 F.3d at 413 n38 (explaining that "nothing in this opinion precludes a defendant from prevailing on a...motion for summary judgment").

1. Anticompetitive Effects

The plaintiffs bear the initial burden under the rule of reason to demonstrate that the agreement had anticompetitive effects. Nw. Wholesale Stationers, Inc. v. Pacific Stationary and Printing, Co., 472 U.S. 284, 297 n.9 (1985); United States v. Brown Univ. in Providence in State of R.I., 5 F.3d 658, 668 n.8 (3d Cir. 1993). They have failed to meet that burden.[28]

The plaintiffs, as discussed in detail above, cannot establish that the Wellbutrin Settlement presented the type of anticompetitive harm contemplated by Actavis and Lamictal because the settlement did not induce the generic manufacturer

[28] In their briefs and at oral argument, the plaintiffs made much of the fact that the no authorized generic agreement may be valued at "$200 million." GSK has not moved for summary judgment on any grounds related to the value of the no authorized agreement, however, so the plaintiffs continued reliance on it is misplaced.

"to quit its patent challenge" and thus did not eliminate the "risk of patent invalidation or a finding of non-infringement" by the court.[29] Lamictal, 791 F.3d at 411. In contrast, the Wellbutrin Settlement specifically contemplated that the generic manufacturer would continue its patent challenge and allowed the generic to enter immediately upon a finding of patent invalidity, maintaining the risk of patent invalidation or a finding of non-infringement even after the settlement.[30] This was not the type of settlement or anticompetitive harm that faced the Supreme Court in Actavis.

Because the plaintiffs cannot allege the anticompetitive harm contemplated by Actavis or addressed in Lamictal, they necessarily rely on alternate theories to satisfy their burden under the rule of reason: (1) that a showing of GSK's market power in the bupropion hydrochloride market is

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[29] The plaintiffs offer no evidence to support their speculative claim that the "only reason" the Wellbutrin Settlement allowed the underlying patent litigation to continue was that it maintained Anchen's 180-day exclusivity period. The plaintiffs' expert Dr. Blume merely restates the Hatch-Waxman statutory scheme, which specifically allows a generic manufacturer to maintain its 180-day exclusivity period without launching so long as an appeal remains pending. See 21 U.S.C. § 355j(5)(D)(i)(I)(bb)(AA).

[30] The Court is not aware of any other post-Actavis reverse payment patent settlement evaluated by courts that allowed the underlying patent litigation to continue, maintaining the risk of patent invalidity or a finding of non-infringement.

enough to satisfy their initial burden under the rule of reason; and (2) that the Wellbutrin Settlement delayed the launch of 150mg generic Wellbutrin XL.

a. Market Power

The plaintiffs have suggested that a showing of GSK's market power over the bupropion hydrochloride market satisfies their initial burden under the rule of reason. In the context of reverse payment patent settlement lawsuits, however, the Court finds that market power alone cannot be sufficient to demonstrate anticompetitive effects under the rule of reason.

Although the Lamictal court, in quoting Brown University, acknowledged that "courts typically allow proof of market power instead" of proof of actual anticompetitive effects, the court did not find that market power could supplant proof of anticompetitive effects in reverse payment patent settlement lawsuits. Lamictal, 791 F.3d at 412. In fact, the court continued to explain that "to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition." By continuing its explanation, the Lamictal court was clear that it was not enough for the plaintiffs simply to prove market power. Id.; see also In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 389-90 (D. Mass. 2013)(recognizing that

plaintiffs must demonstrate both market power and anticompetitive effects).

In explaining the application of the rule of reason to reverse payment patent settlements, the Supreme Court distinguished a showing of market power from the necessary showing of the anticompetitive harm of such payments. Actavis, 133 S.Ct. at 2236 ("[W]here a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm into practice."). Allowing market power alone to satisfy the plaintiffs' burden of showing actual anticompetitive effects in reverse payment patent lawsuits is likely to treat the settlements as presumptively unlawful because, while a patent does not create a presumption of market power, Illinois Tool Works Inc. v. Independent Ink, Inc., 547 U.S. 28, 31 (2006), by their nature pharmaceutical patents often carry with them market power, Actavis, 133 S.Ct. at 2236. Actavis rejected a framework under which reverse payment settlements were presumptively unlawful.

To allow a showing of market power to satisfy the plaintiffs' burden under the rule of reason would be in tension with the holdings of Actavis and Lamictal. The plaintiffs, therefore, must show actual anticompetitive effects of the Wellbutrin Settlement.

b. Delayed Wellbutrin XL Entry

In attempting to demonstrate the anticompetitive effects of the Wellbutrin Settlement in the form of a delayed entry, the plaintiffs first argue that they must show only a "large payment" (in the form of a no authorized generic agreement) and a "delay" of generic entry. This argument appears to be advocating that the Court use a "quick look" analysis[31] whereby every reverse payment settlement presumptively has anticompetitive effects because there is a payment and a subsequent delay of generic entry.[32] Although "pay for delay" may be a useful shorthand for discussing reverse payment settlements, it does not capture the entirety of the antitrust

[31] Although at oral argument the plaintiffs' counsel denied that he was advocating a presumption-based analysis, the plaintiffs' argument that they can demonstrate anticompetitive effects by showing a "large" payment and a delay appears to be such an analysis. See Oral Arg. Tr. at 58 ("A payment that the evidence shows is for delay that's large satisfies our first step.")

[32] The plaintiffs have relied on King Drug of Florence, Inc. v. Cephalon, Inc. to support their argument that their required showing of anticompetitive effects is satisfied by showing a large payment. 2015 WL 356913 at *10 (E.D. Pa. Jan. 28, 2015)("evidence of a large payment is required for a plaintiff to satisfy its initial burden of demonstrating anticompetitive effects under the Actavis rule of reason analysis."). The court in King Drug, however, was not faced with a settlement similar to the Wellbutrin Settlement. Rather, the court was evaluating a settlement that had ended the underlying patent litigation; the court, therefore, was faced the Wellbutrin Settlement allowed it to continue. As Actavis explained, the elimination of the risk of a patent litigation loss is the relevant harm in a rule of reason analysis.

analysis. In fact, such an analysis was explicitly rejected by the Supreme Court in Actavis. Actavis, 133 S.Ct. at 2236-37 ("The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful...We decline to do so."). Even if a reverse payment settlement agreement does end the underlying patent litigation, anticompetitive effects are not presumed: "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." Lamictal, 791 F.3d at 412 (quoting Actavis, 133 S.Ct. at 2237).

The plaintiffs also attempt to show anticompetitive effects by arguing that GSK viewed the no authorized generic promise as being made for delayed generic entry; to support this, the plaintiffs rely on both testimony by GSK officials[33]

[33] The plaintiffs cite deposition testimony from three GSK witnesses: CEO Jean-Pierre Garnier, General Counsel Rupert Brondy, and Vice President Jack Davis. Davis testified that "there was a delay that [Teva] agreed to until, I believe, it was May 30th of 2008, or some earlier date, depending on some triggers which I don't know what those are." Davis Dep. Tr. 99:8-18. The plaintiffs failed to refer, however, to Davis's subsequent testimony that he could not testify to the specific relationship between the no authorized generic agreement and the negotiated trigger dates because he "wasn't involved in any of those conversations." Id. at 100:5-14. Similarly, Bondy testified that the fact that GSK would continue marketing 150mg Wellbutrin XL for a period of time without generic competition was a "significant term of the agreements." Bondy Dep. Tr.

and internal GSK documents[34]. At most, the evidence shows recognition on the part of GSK that generic Wellbutrin XL could not enter the market until either Anchen/Teva succeeded on appeal or until the trigger date of May 30, 2008, whichever is earlier, and that a no authorized generic promise was made. The plaintiffs therefore fail to establish that the no authorized generic agreement caused the delayed entry. Even if the evidence showed a contemplated connection, however, that may not be enough to satisfy the plaintiffs' initial burden under the rule of reason where, as here, the underlying patent litigation continued after the settlement was reached and the question of patent validity remained with the court.[35]

It is in keeping with the traditional rule of reason analysis to require the plaintiffs to show that the Wellbutrin

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110:15-19. Finally, Garnier testified that GSK "[sold] its exclusivity" back to Biovail to facilitate the settlement of the underlying patent litigation. Garnier 142:16-145:3.

[34] The plaintiffs also cite a March 2007 internal GSK presentation that noted that as a result of the "deal" Teva would not market a generic Wellbutrin XL product until a "trigger date" and that GSK was barred from launching an authorized generic during the 180-day Hatch-Waxman exclusivity period. See Pls. Ex. 971. Although the document does address both elements of the deal, it does not present the "quid pro quo" that the plaintiffs suggest.

[35] Such a showing may, however, satisfy the plaintiffs' prima facie burden under the Cartwright Act. In re Cipro Cases I & II, 61 Cal. 4th 116 (2015). As discussed below, however, the Wellbutrin Settlement is not anticompetitive under the Court's full rule of reason analysis given the settlements procompetitive justifications.

Settlement actually resulted in the delayed entry of Wellbutrin XL – that absent the Wellbutrin Settlement, generic competition would have occurred earlier. The plaintiffs' own expert Dr. Leitzinger recognized that "[t]he operative question is the manner in which the agreement – inclusive of the reverse payment – altered the date at which generic entry otherwise would have occurred." Leitzinger Decl. (Oct. 6, 2014).[36] The plaintiffs' evidence, therefore, presents two but-for scenarios that could allow them to show the anticompetitive effects of the Wellbutrin Settlement: (1) that a settlement allowing earlier entry would have been reached absent a no authorized generic agreement; or (2) that continued litigation would have resulted in earlier

[36] GSK has filed a Daubert motion to exclude Dr. Leitzinger's testimony regarding a rule of reason analysis of the Wellbutrin Settlement on the grounds that Leitzinger has rested his analysis exclusively on counsel's instructions rather than an independent analysis of the summary judgment record.

The Court can decide GSK's motion for summary judgment, however, without deciding GSK's Daubert challenge of Dr. Leitzinger, because the Court relies on the undisputed facts in the summary judgment record. That said, Dr. Leitzinger's analysis of the Wellbutrin Settlement's effects are unreliable under Daubert and are excluded. Dr. Leitziner failed to analyze when and whether the generic manufacturers would have entered the market but for the Wellbutrin Settlement. Further, Dr. Leitzinger expressly failed to evaluate any procompetitive justifications of the Wellbutrin Settlement, making his already conclusory analysis fatally incomplete. Dr. Leitzinger's opinion is reciting only the plaintiffs' counsels' argument that the settlement is anticompetitive. His testimony regarding anticompetitive effects is unreliable.

entry. The plaintiffs have failed to offer any proof for either of these but-for scenarios.

i. Alternative Settlement Scenario[37]

There are no facts in the summary judgment record to support a contention that, absent the no authorized generic agreement, an alternate settlement would have been reached.

The summary judgment record, in fact, shows the opposite: Teva expressly and unwaveringly refused to settle the Biovail litigation unless the settlement contained a no authorized generic agreement. Teva had demanded a no authorized generic promise prior to GSK's involvement in the settlement process; prior to GSK's involvement, the parties had tried and failed to negotiate a settlement agreement without a no authorized generic agreement. It was Teva's insistence on the no authorized generic promise that made it necessary for Judge Brody to require GSK's involvement in the settlement process, and Teva continued to demand a no authorized generic promise

[37] Although the Lamictal court noted that it is not necessary at the motion to dismiss stage for the plaintiffs to present an alternate settlement scenario in order to establish anticompetitive effects, Lamictal, 791 F.3d at 410 (addressing the plaintiffs' burden at the motion to dismiss stage and finding that Actavis does not "require allegations that defendants could in fact have reached another, more competitive settlement."), it is one mechanism through which the plaintiffs may establish anticompetitive effects at the summary judgment stage.

after GSK was instructed by Judge Brody to participate in the settlement process. As further evidence of Teva's insistence, every draft of the Wellbutrin Settlement included a no authorized generic agreement. Brannon Dep. Tr. 129:14-130:5 ("Teva...was very adamant that certain issues were deal breakers for them, and they required GSK to waive certain rights if there was going to be any settlement at all."); Bauer Dep. Tr. 57:8-13; GSK Exs. 10, 63.

The plaintiffs' expert Dr. Leitzinger offers no testimony in support of a contention that an alternate settlement would have been reached. Dr. Leitzinger states instead that "one can fairly infer the presence of delay simply from the fact of a reverse payment that is not otherwise justified," and Dr. Leitzinger did not "[try] to answer the question of what specifically some alternative form of settlement would have looked like." Leitzinger Decl. ¶ 32; Leitzinger Dep. Tr. 46:22-24.

ii. Continued Litigation Scenario

Alternatively, the plaintiffs argue that had the Wellbutrin Settlement not been reached, the litigation would have continued, Teva would have launched generic Wellbutrin XL

"at risk" of the pending litigation, and GSK would have launched[38] its own authorized generic Wellbutrin XL product.

As discussed in detail in Section D, this argument for anticompetitive effects fails because the summary judgment record does not contain evidence that Anchen would have succeeded in both the Biovail appeal and the Andrx litigation.

Although he Court is not convinced that the plaintiffs have met their preliminary burden of demonstrating anticompetitive effects of the Wellbutrin Settlement, the Court, nevertheless, will continue the rule of reason analysis and evaluate the procompetitive justifications for the Wellbutrin Settlement.

2. The Wellbutrin Settlement's Procompetitive Justifications

If plaintiffs meet their initial burden of presenting sufficient evidence of anticompetitive effects, the defendant must then show that the "challenged conduct promotes a

[38] GSK's contention that there is no evidence in the summary judgment record that it would have independently launched an authorized generic is not persuasive as to the lack of anticompetitive effects at the summary judgment stage. It was the promise of the no authorized generic, not only the failure of GSK to actually launch an authorized generic, that the plaintiffs claim caused the alleged anticompetitive effects in the form of delayed market entry for generic Wellbutrin XL. Even if the Court found that GSK had not planned to launch an authorized generic Wellbutrin XL product, there is no dispute that GSK made the promise that it would not do so.

sufficiently procompetitive objective." U.S. v. Brown University in Providence in State of R.I., 5 F.3d 658, 669 (3d Cir. 1993); see also Race Tires, Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 74-75 (3d Cir. 2010). Procompetitive benefits are those that "enhance consumer welfare and competition in the marketplace" and are "consistent with the procompetitive aspirations of antitrust law." Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 309 (3d Cir. 2007). Summary judgment is appropriate if there is no dispute of material fact and no reasonable jury could find that the anticompetitive effects outweigh the proffered procompetitive justifications.

In the context of reverse payment settlements, the Supreme Court in Actavis found that the settlements would only sometimes "prove unjustified" and could be justified as a reflection of litigation expenses, the cost of services performed by the generic manufacturers, or other justifications. Actavis, 133 S.Ct. at 2235-36 ("[O]ffsetting or redeeming virtues are sometimes present."); see also In re Cipro Cases I & II, 61 Cal. 4th 116, 158 (2015)(recognizing that procompetitive justifications must be considered).

GSK has presented the following procompetitive justifications for the Wellbutrin Settlement: (1) the Andrx License that allowed Anchen/Teva to enter the generic Wellbutrin Market without the risk of losing the Andrx case; (2) a

provision obligating Biovail to supply Teva with generic Wellbutrin if Anchen faced manufacturing or regulatory hurdles; and (3) a provision guaranteeing Anchen/Teva immediate entry if Anchen prevailed in the Biovail appeal, or no later than May 30, 2008 even if Biovail prevailed. There are no genuine issues of material fact as to the procompetitive nature of GSK's justifications; both the Andrx sublicenses and the supply provision offered the generic manufacturers — and thus the consumers — something they could not have received through successful litigation alone. Even if the plaintiffs had demonstrated anticompetitive effects of the Wellbutrin Settlement, therefore, GSK has successfully presented sufficiently procompetitive justifications. The plaintiffs have not presented an actual factual dispute as to GSK's procompetitive justifications.

a. The Andrx Sublicense

The Wellbutrin Settlement included a provision through which GSK — through Biovail — sublicensed Andrx's product to Anchen/Teva, eliminating an independent and substantial hurdle to generic entry. Andrx had sought injunctive relief to keep Anchen/Teva off the market; Andrx's patent was set to expire in 2022. At the time of the Wellbutrin Settlement, GSK entered into a settlement agreement with Andrx, whereby GSK paid Andrx

$35 million in satisfaction of Andrx's infringement claims for sales prior to February 1, 2007, and a 3.5% royalty of its net sales for sales following February 1, 2007. GSK Ex. 5. The settlement agreement also allowed GSK to sublicense its rights to Biovail, which could in turn sublicense those rights to the generic manufacturers. Anchen/Teva received that sublicense as a provision of the Wellbutrin Settlement.

Anchen had been severely limited in its defense of the Andrx lawsuit in which Andrx had sought damages and injunctive relief to prevent the sale of generic Wellbutrin XL; Andrx's lawsuit against Anchen was not brought under the Hatch-Waxman Act. Anchen's CEO at the time of the lawsuit was the inventor of the Andrx patent, and therefore the doctrine of inventor estoppel prevented Anchen from arguing that the Andrx patent was invalid (GSK had asserted patent invalidity in defense of Andrx's lawsuit). Teva, leading the settlement negotiations for the generics, expressed concern about this limitation. Holding Dep. Tr. 64:18-65:20.

The summary judgment record demonstrates that Teva demanded that the Wellbutrin Settlement to provide a sublicense to the Andrx patents. Contemporaneous documents show that Teva wanted the "full freedom to operate" without the risk of either the Biovail or Andrx patent infringement claim and anticipated that GSK's negotiations with Andrx would include address generic

license for Anchen/Teva. GSK Ex. 64. The Wellbutrin Settlement guaranteed Teva that freedom, and eliminated the possibility that Andrx could prevent generic Wellbutrin XL from being marketed for the 15 years remaining on its patent. Absent a license for the Andrx patent or success in the underlying litigation, it would have been impossible for Anchen/Teva lawfully to market generic Wellbutrin XL.

b. The Biovail/Teva Supply Provision

The Wellbutrin Settlement also included a supply provision that required Biovail to supply Teva with Wellbutrin XL if (1) Teva faced limited supply from Anchen or (2) the FDA ruled on Biovail's citizen petition in a way that made generic Wellbutrin XL non-compliant. Biovail was obligated to provide up to 75 million pills if Anchen faced supply issues, and an unlimited amount of pills if the outcome of the citizen petition made generic Wellbutrin XL non-compliant. GSK Ex. 6.

The parties to the Wellbutrin Settlement extensively negotiated the settlements' supply provisions. Nine versions of the supply terms were exchanged between the December 16, 2006 draft and the final February 9, 2007 Wellbutrin Settlement. See GSK Exs. 6, 10-17.

The summary judgment record is clear that Teva was concerned about its ability to market generic Wellbutrin XL on

the trigger date, and was therefore highly motivated to negotiate a robust supply option. In an email from Teva's General Counsel to counsel for Biovail and GSK, Teva's counsel stated that "[t]he supply commitment can't be more watered down and useless – this wasn't the intent." Pls. Ex. 886 ("We [Teva] need to be able to sell on the trigger date. This requires reasonable preparations."; Brannon Dep. Tr. 163:12-164:3; Holding Dep. Tr. 96:24-97:3; Bauer Dep. Tr. 112:6-13 ("there's concern if there was an earlier trigger date that Anchen might not be able to have a continuous supply without a backorder situation"); GSK Ex. 67 (A February 2007 email from Teva explaining that Teva was concerned about supply if a launch would occur in October 2007).

Supply contracts can assure steady supply, limit risk, and allow for long-term planning on the part of the recipient. Standard Oil Co. v. United States, 337 U.S. 293, 306 (1949). In this case, the The Wellbutrin Settlement supply provision "ensure[d] that the generic will be able to be on the market if there's a regulatory reason why it otherwise could not be." Holding Dep. Tr. 52:7-16. The provision was designed to achieve the seamless facilitation of a risk-free generic Wellbutrin XL launch by ensuring consistent supply of product to Teva, and thus to consumers.

c. Continued Litigation

Finally, the Wellbutrin Settlement preserved for consumers the benefits of Anchen/Teva's immediate entry should Anchen prevail in the Biovail appeal. Under the Wellbutrin Settlement, once Anchen succeeded on appeal, Anchen/Teva were in a position to lawfully enter the market with generic Wellbutrin XL, not at risk of infringing the Biovail patent. The Wellbutrin Settlement also allowed Anchen/Teva to market generic Wellbutrin XL on May 30, 2008 at the latest – ten years prior to patent expiration – even if Biovail prevailed on appeal. Finally, the Wellbutrin Settlement eliminated the liability Anchen faced for its at risk launch of 300mg generic Wellbutrin XL. GSK Exs. 6, 46; Holding Dep. Tr. 55:16-20.

3. Balancing Anticompetitive Elements with the Procompetitive Benefits

An allegedly anticompetitive restraint survives a rule of reason analysis if it achieves legitimate, procompetitive justifications and is reasonably necessary to achieve those justifications. Brown Univ., 5 F.3d at 678-79. "To determine if a restraint is reasonably necessary, courts must examine first whether the restrain furthers the legitimate objectives, and then whether comparable benefits could be achieved through a substantially less restrictive alternative." Id. To survive

summary judgment, the plaintiffs have the burden of presenting evidence that raises a material dispute of fact regarding the procompetitive justifications offered by the defendants. Id. The plaintiffs have not met that burden.

The plaintiffs have not presented evidence to challenge GSK's procompetitive justifications on the grounds that the allegedly anticompetitive conduct was unnecessary to achieve the justifications. In fact, as discussed above, there would have been no settlement agreement — and thus no supply provision or sublicense — had GSK not agreed to abstain from marketing an authorized generic product.

Rather, the plaintiffs challenge GSK's procompetitive justifications on the grounds that the justifications themselves are "unnecessary", "illusory", and "pretextual".

The summary judgment record, however, does not contain any evidence that would allow a reasonable jury to find that GSK's procompetitive justifications were "unnecessary", "illusory", or "pretextual".

First, the plaintiffs argue that Anchen did not need GSK's "help" to negotiate the Andrx settlement because the parties had been engaging in bilateral settlement discussions. Although it is undisputed that Anchen and Andrx were directly communicating regarding the Andrx litigation, it is further undisputed that no bilateral settlement agreement was ever

reached. The plaintiffs' contention that bilateral discussions were taking place mere weeks before the final Wellbutrin Settlement was reached misrepresents the documentary evidence: in fact, Teva and Anchen were having discussions with Andrx subject to the Wellbutrin Settlement, not apart from it. Pls. Ex. 864; Bauer Dep. Tr. 233:11-15; 240:7-12.

The plaintiffs challenge the Teva supply provision on similar grounds. It is undisputed, however, that Teva aggressively negotiated for the provision and that the provision remedied the possible supply hurdles perceived by Teva. Further, although the plaintiffs focus on the fact that no final supply agreement was actually reached, there is a clear explanation: neither of the supply-triggering events (a successful citizen's petition or an appellate victory) ever occurred. See Bauer Dep. Tr. 100:3-7 ("I think, as a business matter, it would make sense that we would...want to have that kind of backup supply option under these circumstances.").

4. Submission of the Wellbutrin Settlement to the FTC

The parties to the Wellbutrin Settlement presented all elements of the Wellbutrin Settlement – including the allegedly anticompetitive elements and the procompetitive justifications – to the FTC. The summary judgement record demonstrates that the

Wellbutrin Settlement provided for FTC review beyond what is required by the MMA. The Wellbutrin Settlement required the parties to present the entirety of the settlement to the FTC on an abbreviated time frame, resolve any questions or concerns raised by the FTC in response to the settlement, and terminate the settlement in the event the FTC's questions or concerns could not be addressed. A note of concern from the agency was sufficient to alter or terminate the settlement; no formal agency action was necessary.

The parties presented the Wellbutrin Settlement to the following individuals at the FTC: Markus Meier, the head of the FTC's Health Care Division; Bradley Albert, the Deputy Assistant Director of the FTC's Health Care Division; and FTC staffer Meredyth Smith Andrus. After meeting with the parties and reviewing the settlement, the FTC raised no concerns regarding the Wellbutrin Settlement.[39]

GSK argues that the FTC's decision not to challenge the Wellbutrin Settlement underscores its procompetitive character. GSK urges the court to follow the decision of

[39] There is no support in the summary judgment record for the plaintiffs' contention that the parties to the Wellbutrin Settlement concealed the nature of the settlement from the FTC. Rather, there is undisputed evidence in the summary judgment record that the parties to the settlement presented the entire settlement agreement to the FTC and met with the agency to explain the settlement.

another district court that held that any "antitrust intent" on the part of the defendants was negated by the defendants' submissions to the FTC beyond what was required by the MMA and the FTC's subsequent decision not to pursue any action. In re Effexor Antitrust Litig., 2014 WL 4988410 at *24 (D.N.J. October 6, 2014). The Court does not find the FTC's decision not to challenge the Wellbutrin Settlement determinative on any issue presented in the motions, but the provisions for enhanced FTC review do tend to negate any anticompetitive aim of the parties, in particular GSK.[40]

The provisions for enhanced FTC review may also be described as procompetitive, at least in an indirect way. If the FTC objected to the settlement, the parties agreed that they would either resolve the objection or have the right to terminate the entire settlement. The FTC was given, in effect, veto power over the Wellbutrin Settlement. The FTC, therefore, did not have to use their limited resources to file a lawsuit to force changes to the agreement or even abrogation of it; the FTC

[40] Another reason why the Court has not considered the FTC's decisions to the Wellbutrin Settlement as evidence of either the lack of anticompetitive effects or the procompetitive nature of the settlement is that it is unlikely that the FTC's decision itself would be admissible on these topics. The circumstances surrounding the inclusion of the review provisions in the Wellbutrin Settlement and the submission of the settlement to the FTC, however, would be admissible at trial on a number of bases, including intent and the fact that enhanced FTC review had at least indirect procompetitive benefits.

only had to raise concerns to have the agreement changed in a way that would be more beneficial to consumers.

C. Antitrust Injury/Causation

GSK argues that the plaintiffs cannot establish antitrust injury or causation, two essential elements in any private antitrust action. GSK's argument takes two forms: (1) the plaintiffs cannot show antitrust injury or causation because they cannot show that it was the Wellbutrin Settlement, rather than the underlying patent(s), that prevented generic entry; and (2) in the alternative, the plaintiffs cannot establish causation because they cannot show that Anchen/Teva could have and would have entered at risk.

Although the plaintiffs concede that they must show antitrust injury and causation, they argue that both elements are made out by their showing of a large payment and a delay. In essence, the plaintiffs argue that once they have shown a large payment and a delay, they have established not only anticompetitive conduct but also antitrust injury or causation. The Court concludes that the principle propounded by the plaintiffs would not only eviscerate the rule of reason analysis, as discussed above, but also ignores the long-standing and strict principles of antitrust injury and causation.

To succeed in an action under Section 4 of the Clayton Act, private plaintiffs must show that they suffered an antitrust injury and that the defendant's allegedly anticompetitive conduct was the actual and proximate cause of that antitrust injury. 15 U.S.C. § 15. In many cases, and in this case, the questions of antitrust injury and causation are closely linked and most effectively analyzed together.[41] See, e.g., West Penn Power Co., 147 F.3d at 266.

Antitrust injury is "an injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful."[42] Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977). To be an antitrust injury, the injury must "reflect the anticompetitive effect either of the violation or of the anticompetitive acts

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[41] Antitrust injury and causation are two essential elements of the doctrine of antitrust standing; the lack of antitrust standing prevents a plaintiff from recovering from the antitrust laws. Assoc. Gen. Contractors of Calif., Inc., v. California State Council of Carpenters, 459 U.S. 519; Ethypharm S.A. France v. Abbot Labs., 707 F.3d 223, 232-33 (3d Cir. 2013). If antitrust injury and causation are lacking, the Court does not need to address the remaining factors of antirust standing.

[42] The Third Circuit in Lamictal did not address the issue of antitrust injury. Lamictal, 791 F.3d at 410 n.35 ("we do not decide the question of antitrust injury in private actions such as this litigation...nor do we preclude the parties from raising the issue on remand.")(citing Ian Simmons et al., Viewing Actavis Through The Lens of Clayton Act Section 4, Antitrust, Fall 2013, at 24). No other federal court of appeals has addressed the issue of antitrust injury in the context of reverse payment settlements.

made possible by the violation" and represent "the type of loss that claimed violations...would be likely to cause." Id.; see also Race Tires Am. Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 76 (3d Cir. 2010); City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 266 (3d Cir. 1998).

Antitrust injury cannot be presumed simply because there is an agreement that results in harm. J. Truett Payne, Inc. v. Chrysler Motors Corp., 451 U.S. 557, 562 (1981); see also City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 266. The ban on presumption of antitrust injury is supported by the Clayton Act's strict causation requirement.

To establish causation, the Clayton Act requires antitrust plaintiffs to demonstrate that their injuries were caused "by reason of" allegedly anticompetitive conduct. 15 U.S.C. § 15(a). The "by reason of" language requires both a showing that defendant's actions were the but-for and the proximate cause of the injury. Assoc. Gen. Contractors of Calif. v. California State Council of Carpenters, 103 S.Ct. 897, 905. Private plaintiffs bear the burden of establishing causation. See Out Front Prods., Inc., v. Magid, 748 F.2d 166, 169 (3d Cir. 1984)(citing Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 114 n.9 (1969)).

Given the Clayton Act's "by reason of" language, an independent regulatory scheme can cut off the necessary chain of

causation.[43] As the Third Circuit explained in City of Pittsburgh v. West Penn Power Co.:

> the interposition of the regulatory scheme and actions of the parties – both defendants and plaintiff – interferes with the chain of causation. The statutory scheme precluded competition without the requisite regulatory permission. As Professors Areeda & Hovencamp describe, 'a plaintiff cannot be injured in fact by private conduct excluding him from the market when a statute prevents him from entering the market in any event.'

West Penn Power Co., 147 F.3d at 267-68 (emphasis added); see also In re Nexium (Esomeprazole Antitrust Litig., 42 F. Supp. 3d 231, 265-75 (D. Mass. 2014)(finding the chain of causation broken because there was no evidence that the generic manufacturer could have received the necessary regulatory approvals).

Other circuits have likewise found that an independent regulatory limitation can cut off the chain of causation under

[43] The plaintiffs have mistakenly characterized GSK's argument that the patent cuts off the chain of causation as an "illegality defense" to antitrust claims. Courts have rejected such a defense. See Consolidated Exp., Inc. v. New York Shipping Ass'n, 602 F.2d 494, 525-26 (3d Cir., 1979) (citing Perma Life Mufflers, Inc. v. Int'l Parts Corp., 392 U.S. 134 (1968) (finding that the unclean hands defense was not applicable to antitrust violations)). GSK, however, is arguing that an independent regulation cut off the chain of causation that the plaintiffs are attempting to establish. The court in Consolidated Exp., Inc. did not address the issue of causation. It found only that the plaintiffs' violation of an unrelated law or regulation could not serve as a complete bar to antitrust liability. Notably, this case predates the Third Circuit's decision in City of Pittsburgh v. West Penn. Power.

the Clayton Act. In In re Canadian Import Antitrust Litigation, the plaintiffs claimed that the defendants unlawfully conspired to prevent the import of Canadian prescription drugs for personal use. 470 F.3d 785 (8th Cir. 2006). The Eighth Circuit found that the plaintiffs could not establish antitrust injury because the importation of drugs from Canada was banned under federal law, and therefore the absence of Canadian drugs in the American market was caused by "the federal statutory and regulatory scheme adopted by the United States government, not by the conduct of the defendants." Id. at 791. Therefore, "the alleged conduct of the defendants did not cause an injury of the type that the antitrust laws were designed to remedy." Id.

Similarly, in RSA Media, Inc. v. AK Media Group, the First Circuit did not allow plaintiffs to recover for the defendants' allegedly anticompetitive refusal to sell the plaintiffs' billboard access, because the plaintiffs' desired entrance into the billboard market was blocked by a Massachusetts regulatory scheme that operated independent of the the defendants' conduct. 260 F.3d 10 (1st Cir. 2001). The court found that because market exclusion was a byproduct of a government scheme, the plaintiffs could not demonstrate the "by reason of" causation necessary under the Clayton Act. Id. at 14-15.

In discussing its application of the rule of reason to reverse payment settlements, the Supreme Court in Actavis explained that it is "normally not necessary to litigate patent validity to answer the antitrust question" because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." Actavis, 133 S.Ct. at 2236. Actavis, however, was brought by the FTC. The FTC faces a different standard of causation in bringing agency antitrust actions such as Actavis: the FTC must establish only that the defendant's action is "likely to cause injury." 15 U.S.C. § 45.[44] Because the FTC Act's causation requirement is broader and more relaxed than the Clayton Act's, no showing of proximate cause is required. Compare 15 U.S.C. 45(n) with 15 U.S.C. § 15(a). The hurdle, therefore, that independent regulation poses for causation under the Clayton Act is not necessarily present in FTC Actions.

The Supreme Court's language in Actavis directly tracks the FTC Act's "likely to" causation standard. Because the FTC must show only that the agreement at issue was "likely to" cause harm, and the payment itself "normally suggest[s]" a low likelihood of success on the patent suit, it is

[44] Private plaintiffs cannot bring actions under the FTC Act.

understandable that an analysis of patent validity may normally be unnecessary in actions brought under the FTC Act.

But the Clayton Act does demand such an analysis, and nothing in Actavis altered the Clayton Act's causation requirement. Unlike the FTC Act, the Clayton Act's "by reason of" causation requirement cannot be satisfied by using the size of the payment as a proxy for patent strength and the success of the underlying patent litigation. The "heart of a [patent monopoly] is the right to invoke the state's power" to prevent others from marketing the patented product. Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 135 (1969). 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. [45] See West Penn Power Co., 147

[45] The Court is not persuaded by the district court and California Supreme Court decisions that found that causation is satisfied by showing that the defendants' actions ended the patent litigation, making it unnecessary to consider the patent's validity. In re Cipro Cases I&II, 61 Cal. 4th 116, 159 (2015)("nothing in the United States Supreme Court's discussion of the legal rules at the boundary between antitrust and patent law hinged on the happenstance that the case under review involved a public prosecutor."); In re Aggrenox Antitrust Litig., No. 14-2516 2015 WL 4459607 at *9 (D. Conn. July 21, 2015). It appears to the Court that these decisions relax Section 4's causation requirement for the specific circumstance of challenges to reverse payment settlements. Additionally, even in Actavis, a case brought under the FTC Act, the Supreme

F.3d at 269. Where a regulation – such as patent law – precludes competition, that regulation cuts off the chain of causation. In other words, if an agreement only replicates the effect of the underlying patent litigation, any exclusion resulting from that agreement must be caused by the underling patent. See id.

To succeed under the plaintiffs' theory of anticompetitive harm – that the Wellbutrin Settlement prevented an at risk launch of generic Wellbutrin XL – the plaintiffs must show first that it was the Wellbutrin Settlement, and not the underlying patents, that prevented market entry of generic Wellbutrin XL, and second, that Anchen/Teva had the ability and the intent to launch at risk.

Court said only that it is normally not necessary to litigate patent validity, not that such litigation would never be necessary.

The Court, however, is bound by the In re Cipro Cases decision in evaluating the indirect purchaser plaintiffs' claims under the California's Cartwright Act. Because the Court, however, has found that the Wellbutrin Settlement is not anticompetitive under the rule of reason, this does not alter the outcome of the summary judgment motion.

1. Success on the Underlying Patent Lawsuits[46]

Anchen/Teva had not one but two patent litigations to overcome in order lawfully to launch Wellbutrin XL: The Biovail Litigation and the Andrx Litigation. Failure in either action would have served as an independent bar to the marketing of generic Wellbutrin XL. The Court cannot conclude that no reasonable juror could find that Anchen would have prevailed in the Biovail litigation, but the Court does conclude that no reasonable juror could find that Anchen would have succeeded in the Andrx patent litigation.

GSK has presented the expert opinion of Dr. Martin J. Adelman on both the Biovail and the Andrx litigations. The plaintiffs have filed a Daubert motion to exclude the testimony of GSK's patent litigation expert Dr. Adelman. In their motion, the plaintiffs have taken the position that Dr. Adelman is not qualified to offer expert opinion and has used unreliable methodologies.

[46] The plaintiffs have relied on Andrx Pharmaceuticals, Inc. v. Biovail Corp. Intl., 256 F.3d 799 (D.C. Cir. 2001) and In re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003), to support their argument that an at risk launch can support antitrust injury without evidence of success on the underlying patent claim. But neither case is persuasive in this context. Both cases were evaluating complaints at the motion to dismiss stage under a per se analysis. Both cases also predate – and are in conflict with – the Supreme Court's decision in Actavis (and the Third Circuit's decision in Lamictal) which control this decision.

Dr. Adelman, however, is a qualified expert offering appropriate expert testimony. The Court, therefore, denies the plaintiffs Daubert motion.

Federal Rule of Evidence 702 allow a "witness who is qualified as an expert by knowledge, skill, experience, training, or education" to offer opinion testimony. Fed. R. Evid. 702. To offer opinion testimony, the expert must offer "scientific, technical, or other specialized knowledge" to "help the trier of fact understand the evidence or to determine a fact in issue." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589-91 (1993). Courts in this Circuit must evaluate the expert's qualifications, methodologies, and "fit" of the proposed testimony to the case to determine admissibility. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741-43 (3d Cir. 1994).

In his Second Expert Report (Dr. Adelman's first report addressed whether Biovail's patent claims against Anchen were shams), Dr. Adelman opines that (1) Biovail had a greater than 50 percent chance of prevailing in the Biovail litigation and (2) Andrx had an 80 percent chance of prevailing in its infringement suits against GSK and Anchen. Adelman Second Rep. ¶¶ 16, 18, 22, 64.

Dr. Adelman is a patent law professor who has taught at George Washington University Law School, University of

Michigan Law School, and Wayne State University Law School. In forming his opinions, Adelman relied on the ANDA interpretations made by FDA experts; the plaintiffs did the same in addressing the since-dismissed sham litigation claims. Dr. Adelman also relied on the opinion of GSK's chemistry expert, Dr. Burgess. Dr. Adelman, an expert in patent litigation, appropriately relies on the conclusions of other experts in reaching his opinion, and is qualified to give that opinion. Adelman Second Rep. ¶¶ 1-3, 14, 44-47.

The Court, therefore, will consider Dr. Adelman's opinion in evaluating both the Biovail and Andrx litigations.[47]

a. Biovail Litigation

Biovail appealed the district court's grant of summary judgment to Anchen in the Biovail litigation on two grounds: (1) the district court's claim construction regarding the claim "free of stabilizer" and (2) the district court's summary judgment decision regarding the ANDA indicating that "there was no HCl in the final formulation." Had Biovail prevailed on

[47] The plaintiffs also challenge the reliability of Dr. Adelman's methodologies with respect to his opinions on the Biovail litigation. These challenges go to the weight of Dr. Adelman's testimony, not its admissibility. Because the Court finds in the plaintiffs' favor on the Biovail litigation, the plaintiffs' objections on this basis are moot.

either argument, the case would have been remanded to the district court for reconsideration.

GSK has offered the expert opinion of Dr. Adelman that: (1) "there is a strong likelihood that Biovail would have prevailed" on either – or both – claim construction or infringement and (2) had the "Federal Circuit reversed on one or both issues, it almost certainly would have remanded the case to the district court for further proceedings consistent with its opinion." Given those considerations, Adelman concluded that Biovail had a more-than-50 percent chance of success on appeal. Adelman Second Rep. ¶¶ 22-24, 123-25, 127.

On appeal of the claim construction order, Biovail had argued that "free of stabilizer" may have meant free of any functionally stabilizing amount, rather than any stabilizing amount. The district court in the Biovail litigation had found otherwise in its grant of summary judgment. Other district courts evaluating the same patent and ANDA and relying on each other's reasoning had found similarly at the summary judgment stage. Biovail Labs. Int'l SRL v. Impax Labs., Inc., 433 F. Supp. 2d 501, 505 (E.D.Pa. 2006); Biovail Labs. Int'l SRL v. Abrika, LLP, No., 04-61704 2006 WL 6111777 at *13 (S.D. Fla. Aug. 24, 2006).

The plaintiffs have not offered their own expert to rebut Dr. Adelman's testimony. Instead, the plaintiffs rely on

the grant of summary judgment by the district court, and their own counsel's analysis of Biovail's chances of success on appeal. See Oral Arg. Tr. 74-76. The latter undoubtedly would not be admissible at trial. Having said that, and acknowledging that GSK did an excellent job of making the case for Biovail prevailing in the litigation, the Court cannot conclude that no reasonable juror could find that Anchen would have succeeded in the Biovail litigation. The grant of summary judgment by the district court would be powerful evidence to overcome and Dr. Adelman would have no doubt been vigorously cross examined by plaintiffs' counsel.

b. Andrx Litigation

There is no question of fact, however, as to Anchen's likelihood of success in the Andrx Litigation: The summary judgment record contains no evidence that Anchen would have succeeded in defending Andrx's patent infringement claim, and the plaintiffs do not even argue that the generic manufacturers could have succeeded in the Andrx litigation.[48]

[48] Instead, they argue that Anchen/Teva would have reached a license agreement with Andrx. As discussed above, however, no license agreement exists between the parties and there is no evidence in the summary judgment record that an agreement would have been reached absent the Wellbutrin Settlement.

Upon a review of the briefs, pleadings, ANDA, and underlying patent at issue in the Andrx litigation, GSK's expert Dr. Adelman concluded that Andrx had an 80 percent chance of prevailing on the patent litigation; Anchen's success was unlikely. There is no dispute of fact as to Dr. Adelman's conclusions, and no countervailing facts in the summary judgment record. No reasonable juror could find, based on this record, that Anchen could have succeeded in the Andrx litigation.

Further, in the Andrx Litigation, Anchen would have been prevented from arguing that the patent is invalid or unenforceable under the doctrine of inventor estoppel, which prevents an inventor of a patent from later arguing that the same patent is invalid or unenforceable. Shamrock Tech., Inc. v. Med. Sterilization, Inc., 903 F.2d 789, 793 (Fed. Cir. 1990). In this case, Anchen's founder and Chief Executive Offer invented and then assigned to Andrx the rights to the '708 patent, the patent at issue in the Andrx suit. There is no dispute of material fact, therefore, that Andrx would have succeeded in the underlying patent claim.

Because there is no question of material fact as to whether Andrx would have succeeded in its underlying patent claim, the Andrx patent served as an independent regulatory bar to Anchen's launch; an at risk launch would have been unlawful and subject to damages and injunctive relief. It was the patent

itself, therefore, and not the Wellbutrin Settlement, that caused generic Wellbutrin XL's lack of market presence.

2. Anchen/Teva's Possible At Risk Launch

To succeed on their theory that Anchen/Teva would have launched at risk absent the Wellbutrin Settlement, the plaintiffs must establish that Anchen/Teva could have and would have done so. GSK has argued that (1) FDA regulations barred Anchen/Teva's planned March 2007 at risk launch; and (2) there is no evidence in the summary judgment record that Anchen/Teva contemplated a June 2007 at risk launch given the regulatory hurdles faced in May. GSK is correct that Anchen/Teva was prevented under FDA regulations from a launch before June 2007; but there is a question of fact as to whether Anchen/Teva would have launched at risk following June 2007.

The ANDA submitted by Anchen for production of its generic Wellbutrin XL product listed only the Goodyear Facility as a manufacturing site, although Anchen ultimately produced its generic Wellbutrin XL at its Jeronimo Facility. The FDA first learned of the production site change in January 2007 during its inspection. On May 29, 2007, Anchen received the report from FDA's inspection: the report stated that the Jeronimo Facility required final approval. The FDA allowed Anchen to get its approval by submitting a supplement to its ANDA; the FDA

accepted Anchen's ANDA supplement on June 11, 2007, making production permitted at the Jeronimo Facility on June 12, 2007. Under FDA regulations, Anchen was not permitted to launch its generic Wellbutrin XL before this date. 21 C.F.R. § 314.70.[49]

Similar to the regulatory ban in West Penn Power Co., the FDA's regulations "precluded competition without the requisite regulatory permission." West Penn Power Co., 147 F.3d at 268. It was the FDA regulations, not the Wellbutrin Settlement, that delayed possible generic entry until June 2007; the FDA's independent action cuts of the plaintiffs' requisite chain of causation. Accordingly, even assuming that the plaintiffs could have shown success on the underlying patent lawsuits, they could not recover for damages prior to June 2007.

There is a question of fact, however, as to whether Anchen/Teva would have launched an authorized generic in June 2007. The plaintiffs have pointed to evidence in the summary judgment record that in late 2006 and early 2007 Anchen/Teva had planned to launch generic Wellbutrin XL "at risk" of the ongoing patent litigation. Internal emails between Anchen and Teva addressed the possibility of an at risk launch, and meeting minutes and presentations anticipated a "1Q07" launch for

[49] The plaintiffs' assertion that no law prohibited its production is counter to both FDA regulations and Anchen's conduct in response to FDA action.

generic Wellbutrin XL. See Pls. Exs. 772, 813, 846, 922, 899, 915, and 770.

The plaintiffs have also relied on the following circumstances to support their contention that Anchen/Teva would have launched at risk following June 2007: (1) Teva and Impax launched 300mg Wellbutrin XL at risk; (2) Teva and Anchen had the financial incentive to launch at risk "as soon as possible" to take advantage of its 180-day exclusivity period; (3) Anchen had manufactured product for an at risk launch; and (4) Teva frequently launches its products at risk. Finally, the Distribution and Supply Agreement between Teva and Anchen required Teva to launch at risk absent an "adverse occurrence." Pls Ex. 844; Bauer Dep. Tr. 209:7-210:6.

The plaintiffs, however, have not presented any evidence through documents or testimony that an at risk launch would have occurred in June 2007 in view of the regulatory hurdles faced by Anchen/Teva.[50] Rather, the plaintiffs take the position that nothing had changed "in the 'but-for' world between February and June of 2007." Pls. Opp'n at 18.

GSK is correct that the summary judgment record does not establish a certainty of a post-June 2007 at risk launch.

[50] Despite being given the opportunity, the plaintiffs declined to ask any witness from Anchen/Teva whether an at risk launch after June 2007 was planned. Instead, the plaintiffs chose to rely only on the documents that do not address the issue one way or another. See Oral Arg. Tr. at 68-69.

Notably, the circumstances surrounding Teva/Impax's launch of 300mg generic Wellbutrin XL were different than those of Anchen/Teva's possible 150mg launch. Impax did not face the regulatory and production hurdles faced by Anchen, and Impax did not face a patent infringement suit by Andrx. The plaintiffs have not offered support for their contention that it was "commonplace" for Teva to launch at risk.

The Court cannot conclude, however, that no reasonable juror could find that Anchen would have launched at risk after June 2007 given the Anchen/Teva documents that explicitly contemplate an at risk launch. Although the Anchen/Teva documents discussing a planned at risk launch may have been prepared prior to Anchen's regulatory hurdles, those regulatory hurdles were resoved in June 2007 and a reasonable juror could conclude that the earlier analysis as to at risk entry would apply after June 2007.

Finally, GSK does not address Anchen and Teva's agreement to launch at risk. The existence of such an agreement may allow a reasonable jury to find that Anchen/Teva would have launched at risk after June 2007.

D. Participation in Conspiracy

GSK has also moved for summary judgment on the ground that it was not a co-conspirator to any allegedly

anticompetitive arrangement.[51] GSK has put forward two arguments to support this contention: (1) it was not a co-conspirator because the "common scheme" to which it committed was not "designed to achieve an unlawful objective" as required by the Supreme Court's decision in Monsanto Co. v. Spray-Rite Service Corp., 465 U.S. 752 (1984); and (2) there is no evidence that GSK's conduct was inconsistent with its independent interests and thus it cannot be liable under Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574 (1986). The Court does not find either of these arguments persuasive.

To prove conspiracy under the antitrust laws, the plaintiffs must point to direct or circumstantial evidence in the summary judgement record that "reasonably tends to prove that [the parties] had a conscious commitment to a common scheme designed to achieve an unlawful objective." Monsanto, 465 U.S. at 768; see also Edward J. Sweeny & Sons, Inc. v. Texaco, Inc., 637 F.2d 105, 111 (3d Cir. 1980).

GSK's first argument – that it did not have an "unlawful objective" as required by Monsanto because (1) Judge Brody ordered that it participate in the settlement discussions; (2) GSK requested that Judge Brody approve the settlement; and

[51] Because the Court will grant summary judgment on other grounds, there is no need for the Court also to decide this issue. But in an effort to be complete, the Court has considered all bases for summary judgment.

(3) GSK required that the Wellbutrin Settlement be subject to stronger FTC oversight – is not persuasive, because an intent to avoid liability does not protect conduct that has otherwise been found anticompetitive.

To withstand a summary judgment motion, the plaintiffs do not need to demonstrate that the defendants had the specific intent to restrain trade in reaching an agreement. See Times-Picayune Pub. Co. v. United States, 345 U.S. 594, 614-15 (1953); see also National Collegiate Athletic Ass'n v. Board of Regents of Univ. of Oklahoma, 468 U.S. 85, 100-01 n.23 (1984)("it is...well settled that good motives will not validate an otherwise anticompetitive practice"); Geneva Pharma. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 507 (2d Cir. 2004). The relevant intent is whether the defendants intended to enter the agreement itself, knowing of its unlawful objective. See Petruzzi's IGA Supermarkets, Inc. v. Darling-Delaware Co., Inc., 998 F.2d 1224, 1242-43 (3d Cir. 1993)(evaluating a conspiracy based on alleged conscious parallelism).

The summary judgment record contains sufficient evidence for a reasonable jury to find that GSK intended to enter into the Wellbutrin Settlement, was in fact a party to the Wellbutrin Settlement, and understood its objective. GSK acknowledges that it (1) was involved in the settlement negotiations; (2) provided the Andrx sublicenses to Biovail; and

(3) waived its rights to launch an authorized generic, an essential element of the Wellbutrin Settlement.[52] GSK was also a signatory to the Third Amendment to the Wellbutrin Settlement. The summary judgment record also shows that GSK understood the terms of the Wellbutrin Agreement.

GSK's argument that it participated in the Wellbutrin Settlement only to the extent that it was instructed to do so by Judge Brody appears to be a "reluctant conspirator" defense. Even reluctant participants, however, can be held liable for conspiracy. See Fineman v. Armstrong World Indus., Inc., 980 F.2d 171, 212 (3d Cir. 1992); see also In re Processed Egg Prod. Antitrust Litig., 902 F. Supp. 2d 704, 710 (E.D.Pa. 2012). "Acquiescence to an illegal scheme is as much a violation of the Sherman Act as the creation and promotion of one." United States v. Paramount Pictures, 334 U.S. 131, 161 (1948).

Second, GSK's argument regarding its independent motivation misconstrues the holdings of Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp. and its progeny. The Supreme Court's decision in Matsushita limits the range of permissible inferences from ambiguous indirect evidence of a conspiracy. 475 U.S. 574 (1986). In Matsushita, the Court found that to

[52] Although the defendants can argue — and have successfully argued — that the Wellbutrin Settlement is not anticompetitive, there is no question that GSK intended to participate in the settlement negotiations.

withstand summary judgment on an antitrust conspiracy claim, a plaintiff must present evidence that tends to exclude the possibility that an alleged conspirator acted independently. Id. at 588. This requirement, however, applies only to claims supported by indirect evidence. In re Baby Food Antitrust Litig., 166 F.3d 112, 118 (3d Cir. 1999); see also In re Flat Glass Antitrust Litig., 385 F.3d 350, 357 n.7 (3d Cir. 2004)("The strictures of Matsushita do not apply when a plaintiff provides direct evidence...").

Direct evidence of a conspiracy "obviates the need" for evidence that excludes the possibility of independent action. See In re Insurance Brokerage Antitrust Litig., 618 F.3d 300, 324 n.23 (3d Cir. 1999)("[D]irect evidence of a conspiracy, if credited, removes any ambiguities that might otherwise exist with respect to whether the parallel conduct in question is the result of independent or concerted action."). A signed agreement is direct evidence of a conspiracy. See Id. at 324.

GSK appears to be arguing that it was in its independent interest to join the agreement, not that it acted independent of any agreement. Because direct evidence of an agreement exists in the form of the Wellbutrin Settlement, however, an analysis under Matsushita is inappropriate. The existence of the Wellbutrin Settlement – an agreement – is

sufficient evidence for a reasonable jury to find that GSK participated in the alleged conspiracy.

Although the summary judgment record does not contain evidence that GSK was a "calculating conspirator," and the Court recognizes that GSK went to great lengths to "safeguard against antitrust liability," given its desire to have Judge Brody approve the settlement and its insistence on enhanced FTC review, a reasonable jury could find that as a party to the agreement GSK was a co-conspirator and was not engaging in independent action. The Court, therefore, denies GSK's motion for summary judgement on the ground that it was not a co-conspirator.

An appropriate order shall issue.